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The Clean Air Act's National Ambient Air Quality Standards: A Case Study of Durability and Flexibility in Program Design and Implementation

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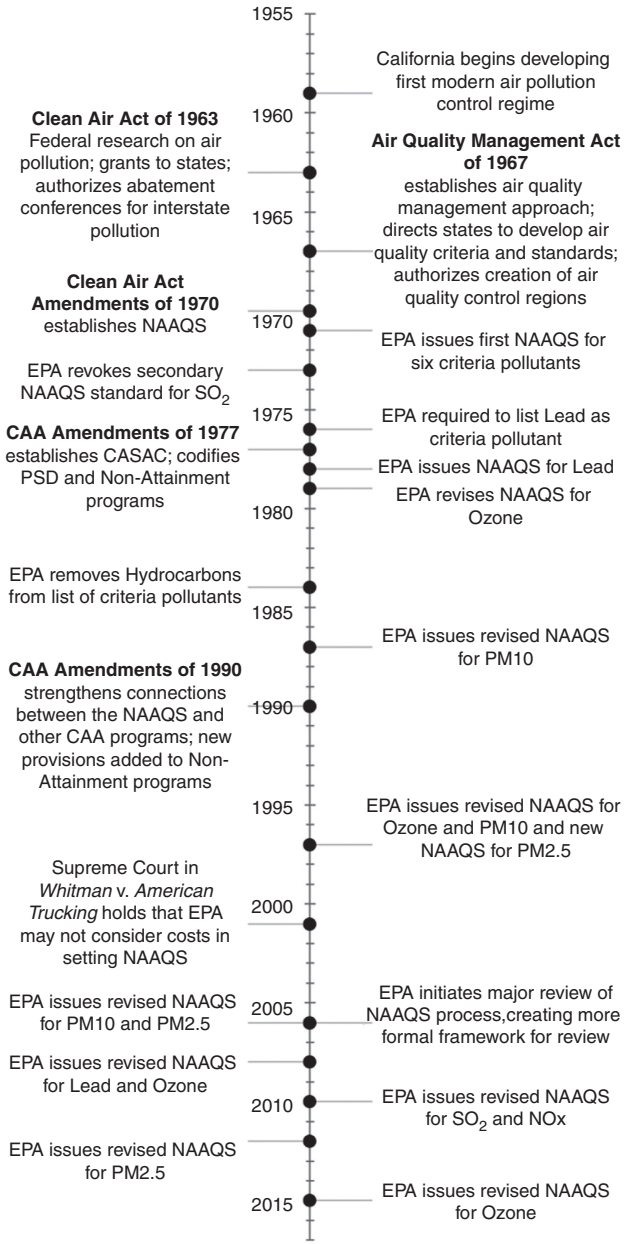

2

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A Case Study of Durability and Flexibility in Program Design and Implementation

William Boyd

2.1 INTRODUCTION

The Clean Air Act's National Ambient Air Quality Standards (NAAQS) can make a strong claim to being the most ambitious and successful major program in US environmental law. It is the "engine" that drives much of the Clean Air Act (CAA), the nation's flagship environmental statute, touching most of the other major provisions of the Act.[1] It embodies the very notion of cooperative federalism and mobilizes substantial resources from the states in the fight against air pollution. And since 1970, it has, in the aggregate, delivered huge benefits for environmental quality and public health. Put simply, air quality in the United States today is far better than it was in 1970, largely because of the NAAQS, with cumulative public health benefits measured in the trillions of dollars, despite significant growth in population and economic activity.[2]

And the program is still going strong, with continued growth and elaboration even as it enters middle age. Since establishing the NAAQS as the centerpiece of the CAA in 1970, for example, Congress has stepped in on two major occasions (1977 and 1990) to strengthen the program and its connections to other parts of the Act. The Environmental Protection Agency (EPA) has likewise developed elaborate internal policies and procedures for managing the NAAQS program and continues to devote substantial resources to major rulemakings under the NAAQS. Ongoing independent scientific reviews have come to provide an integral part of the continuous review and revision of the NAAQS. And, of course, the federal courts have played a fundamental role in shaping the program – often in response to citizen suits

[1] *See*, e.g., Whitman v. American Trucking, 531 U.S. 457, 468 (2001) (observing that "§109(b)(1) and the NAAQS for which it provides are the engine that drives nearly all of Title I of the [Clean Air Act]").

[2] *See*, e.g., U.S. EPA, The Benefits and Costs of the Clean Air Act from 1990 to 2020, (2011); U.S. EPA, The Benefits and Costs of the Clean Air Act, 1970 to 1990 (1997). *See also* J. Bachmann, *Will the Circle Be Unbroken: A History of the U.S. National Ambient Air Quality Standards*, 57 J. Air & Waste Mgm't Assoc. 652, 692 (2007).

and petitions making use of important procedural opportunities embedded in the statute.[3] The result is a strong science-based program that is durable, adaptive and flexible and one that depends on extensive cooperation with the states.

But the story of the NAAQS is not one of unalloyed success. Despite significant improvements in air quality since 1970, air pollution continues to kill large numbers of people in the United States. Although estimates vary, recent studies have put the number of premature deaths resulting from air pollution in the United States at over 100,000 per year – roughly three times the number of people who die from handguns or automobile accidents.[4] Most of these deaths result from so-called criteria pollutants – that is, pollutants that are widespread and produced by numerous and diverse sources and are the targets of the NAAQS program.[5] In particular, despite substantial progress in reducing pollution and meeting the NAAQS for several criteria pollutants across most of the country, a number of areas around the United States continue under serious and even severe nonattainment for ozone and fine particulates ($PM_{2.5}$), the two major sources of premature death, in part because of the ongoing difficulties of dealing with mobile source emissions as well as the challenges created by interstate transport of these pollutants and their precursors.[6] This problem of interstate "downwind" pollution, in fact, has arguably been made worse by certain features of the NAAQS program, and it stands as a stark reminder that the program, despite its successes, needs to be revised and adapted yet again to deal effectively with the nation's air pollution problems.[7]

[3] *See* Elizabeth Fisher et al., *Rethinking Judicial Review of Expert Agencies*, 93 Tex L. Rev. 1681, 1689 (2015) (noting that "[j]udicial review of the EPA's ambient air quality standards offers one of the longest histories of judicial review of agency science, dating to the 1970s").

[4] *See*, e.g., Neal Fann et al., *Estimating the National Public Health Burden Associated with Exposure to PM 2.5 and Ozone*, 32 Risk Analysis 81, 92 (2013) (finding that between 130,000 and 340,000 premature deaths are attributable to $PM_{2.5}$ and ozone using ambient measurements (2005) and nonanthropogenic background $PM_{2.5}$ and ozone concentrations simulated by atmospheric chemistry models and a health impact function); Christopher J. L. Murray et al., *The State of U.S. Health, 1990–2010: Burden of Diseases, Injuries and Risk Factors*, 310 JAMA 591, web appendix table 8 (2013) (reporting 110,000 premature deaths in 2010 [all ages] from PM and ozone pollution); Fabio Caiazzo, *Air Pollution and Early Deaths in the United States, Part I: Quantifying the Impact of Major Sectors in 2005*, 79 Atmos. Env't 198 (2013) (reviewing studies).

[5] The 1970 Act defined these criteria pollutants as pollutants that have "adverse effects on public health and welfare" and "result from numerous or diverse mobile or stationary sources." Section 108, 84 Stat. 1676, 1678.

[6] These two pollutants ($PM_{2.5}$ and tropospheric ozone) are responsible for the vast majority of premature deaths and illnesses attributed to air pollution in the United States.

[7] *See*, e.g., Richard L. Revesz, *Federalism and Interstate Environmental Externalities*, 144 U. Pa. L. Rev. 2341, 2349 (1996) (arguing "that the ambient and emissions standards . . . which form the core of the Clean Air Act, are an ineffective and poorly targeted means for dealing with the problem of interstate externalities . . . [and that] these provisions may have exacerbated the interstate spillover problem"). EPA's recent efforts to use its FIP authority combined with the good neighbor provisions to deal with this problem through its Cross State Air Pollution Rule (also known as the Transport Rule) are obviously an important step, but such efforts are constrained by the statutory text and, more importantly, have taken decades of work. See Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 Fed. Reg. 48,208 (Aug. 8, 2011)

In terms of instrument choice, the NAAQS program operates as a hybrid. Health-based ambient environmental standards make up the core of the program; they apply uniformly across the country and are intended to limit the concentrations of criteria pollutants to levels that are determined by the EPA administrator as necessary to protect public health with an adequate margin of safety. The Act mandates an ongoing five-year review of the science pertaining to each of the criteria pollutants and requires the administrator to revise the NAAQS as appropriate. These ambient environmental standards are then supplemented with source- and area-specific technology and performance standards that are tied to the attainment or nonattainment status of particular regions. Mobile source standards and various boutique fuels programs provide additional measures for controlling criteria pollutants.[8]

States are responsible for implementation and are required to submit *state implementation plans* (SIPs) that demonstrate how the NAAQS will be achieved in their jurisdictions. Once approved by EPA, these SIPs become federally enforceable. If a state fails to submit a SIP or EPA deems a SIP to be inadequate, EPA can impose its own Federal Implementation Plan or FIP for the state. EPA also has authority to withhold highway funds as a sanction for inadequate or incomplete SIPs. Needless to say, the exercise of establishing the NAAQS and the effort to implement the reductions necessary to achieve them can be quite challenging, requiring large scientific and technical investments at both federal and state levels.[9]

Taken as a whole, the NAAQS program embodies all the design principles identified in Chapter 1 as essential to durability and flexibility. The strong health-based standard for ambient air quality provides a *clear signal* to the states and to sources of air pollution. The statutory requirement of an ongoing five-year review of the science provides a mechanism for *continuous revision* based on new information. The NAAQS program has been subjected to *systematic evaluation* by Congress, EPA and various independent scientific bodies over the years, which has led to a number of revisions and improvements in the program. And the program's environmental and public health *outcomes are greatly valued* and perceived as such. Indeed, few, if any, programs in US environmental law have delivered more in terms of public health benefits.

This chapter provides an overview of the NAAQS, with particular attention to the provisions and features of the program that contribute to flexibility and durability. Section 2.2 briefly discusses the problem of ambient air pollution. Section 2.3 describes the complex NAAQS regulatory regime, including the basic

[hereinafter Cross-State Air Pollution Rule (CSAPR)]; EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584 (2014) (reversing the DC Circuit and upholding EPA's Cross-State Air Pollution Rule).

8 Chapters 4 (mobile sources) and 5 (fuels) address the regulation of mobile sources.

9 *See*, e.g., Bachmann, *Will the Circle Be Unbroken*, *supra* note 2 at 652–53 (noting the "extraordinary level of technical and scientific information needed to establish effect-based ambient targets, measure key pollutants, inventory sources and emissions, develop and estimate costs for alternative control scenarios, and forecast and assess results").

statutory framework, EPA's core responsibilities, the important role of independent scientific review, citizen suits and public participation and the monitoring and modeling infrastructure that supports the program. Section 2.4 discusses the goals of the program and the features that allow for signaling to the states and affected sources. Section 2.5 describes the structure of cooperative federalism and the critical role of the states in implementation. Section 2.6 provides a more detailed look at flexible implementation, with particular attention to statutory provisions, agency procedures and practices and the SIP process. Sections 2.7 and 2.8 look briefly at environmental performance and economic impacts, respectively. Finally, Section 2.9 discusses broader issues of political economy, durability and flexibility.

Several key lessons emerge from the case study. First, history matters. The NAAQS program was able to mature and benefit from two decades of robust functional interactions between Congress, EPA and the federal courts. Many of the key provisions of the program that contribute to its durability and flexibility were added, revised and strengthened in subsequent rounds of amendments by Congress. Without this, the program would not be nearly as effective as it is today. Second, the structure and design of the program have contributed to its overall durability in part by building in provisions for flexibility and adaptation at multiple levels – all in the context of a long-term commitment to continuous review and revision of existing standards. By design, the NAAQS program is always in motion, but the goals and overall direction of the program are clear, and there are procedural mechanisms in place that continue to push the program forward. Third, process has been fundamental in bolstering the credibility of the program and strengthening its results – from EPA's internal NAAQS review process, to the formal and informal roles of independent scientific review, to the multiple opportunities for public participation. Taken together these process features have facilitated important signaling to regulated entities and the states. They have served to ventilate, vet and strengthen proposed revisions to the NAAQS. And they have proven to be more than sufficient to satisfy judicial review in most cases. In sum, the success of the NAAQS program has derived in large part from a combination of history, structure and process. There are important lessons for energy and climate policy here, but perhaps one of the most important lessons is that the task of building a durable, adaptive and flexible policy cannot be reduced to a set of simple design choices. Complicated programs such as the NAAQS are more than the sum of their parts. Deriving lessons from them for future policies thus requires understanding them as a whole and how they have evolved over time.

2.2 THE PROBLEM OF AMBIENT AIR POLLUTION

Decades of research across multiple disciplines have revealed significant associations between exposure to ambient air pollution and negative human health effects,

including respiratory ailments, cardiovascular disease and premature death.[10] Although ambient air pollution is typically a complex mixture, consisting most often of particulates, ground-level ozone, oxides of nitrogen and sulfur dioxide (among others), most health effects studies have focused on individual pollutants. While the majority of this research has been conducted in Europe and North America, the associations between health effects and ambient air pollution are consistent around the world. Put simply, ambient air pollution is a major cause of disease and premature death all over the world. One recent study, for example, estimated that exposure to fine particulates ($PM_{2.5}$) resulted in 4.1 million premature deaths globally in 2016 and found that 95 percent of the world's population lived in areas that exceed World Health Organization (WHO) guidelines for fine particulates ($PM_{2.5}$).[11]

As part of its responsibility to establish national ambient air quality standards, EPA conducts extensive reviews of the scientific literature on the health effects of the various criteria pollutants regulated under the NAAQS program. These integrated science assessments have revealed a host of specific health effects associated with exposure to individual criteria pollutants and provide the scientific basis for establishing health-protective standards. In its most recent integrated science assessment for particulates (2009), for example, EPA concluded that long-term exposure to $PM_{2.5}$ is associated with premature death, heart attacks, irregular heart beat, and respiratory problems such as aggravated asthma and decreased lung function.[12] Likewise, in its most recent assessment for ozone (2013), EPA concluded that short- and long-term exposure to ozone is associated with respiratory effects, cardiovascular effects and premature death.[13]

New evidence of the health effects of ambient air pollution is also accumulating on a near-continuous basis. This includes advances in our understanding of known

[10] *See*, e.g., J. Lepeule et al., *Chronic Exposure to Fine Particles and Mortality: An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009*, 120 Env. Health Persp. 965 (2012); M. Turner et al., *Long-Term Ozone Exposure and Mortality in a Large Prospective Study*, 193 Am J. Resp. Crit. Care Med 1134 (2016); M. Jarrett et al., *Long-Term Ozone Exposure and Mortality*, 360 N. Engl. J. Med. 1085 (2009); M. L. Bell et al., *Ozone and Short-Term Mortality in 95 US Urban Communities, 1987–2000*, 292 JAMA 2372 (2004).

[11] *See* Health Effects Institute, State of Global Air 2018: A Special Report on Global Exposure to Air Pollution and its Disease Burden 1-3 (2018). Another recent study from the World Health Organization (WHO) estimated that exposure to ambient $PM_{2.5}$ pollution resulted in more than 3 million premature deaths globally in 2012. *See* WHO, Ambient Air Pollution: A Global Assessment of Exposure and Burden of Disease 40 (2016). This is an estimate that does not include the even larger number of deaths from indoor air pollution (estimated at more than 4 million per year). According to the WHO report, "[a]ir pollution represents the biggest environmental risk to health" in the world, with one out of every nine deaths globally the result of "air pollution related conditions." *Id.* at 15.

[12] U.S. EPA, Final Report: Integrated Science Assessment for Particulate Matter, EPA/600/R-08/139F (2009).

[13] U.S. EPA, Final Report: Integrated Science Assessment of Ozone and Related Photochemical Oxidants, EPA/600/R-10/076F (2013).

human health effects of air pollution such as respiratory and cardiovascular effects, as well as research on possible new effects. One recent study, for example, suggests that exposure to particulate matter in older women may contribute to the acceleration of brain aging and Alzheimer's disease.[14] Evidence is also mounting regarding other adverse neurological effects, including neurodevelopmental disorders in children, as a result of chronic exposure to ambient air pollution.[15] And there is a nascent body of research on the confluence of health risks resulting from exposure to multiple pollutants, raising important questions regarding the additional health gains that might come from a multipollutant approach to air quality management.[16] While the scientific understanding of the human health effects of ambient air pollution is considerable (and growing all the time), there is still much more to know about the links between air pollution and public health, including both existing and well-understood health endpoints as well as more subtle ones. As we learn more about these various health impacts, moreover, it raises the bar for regulation.

Regulating ambient air pollution, either on a single- or multipollutant basis, thus poses a host of challenges. Health-based approaches must confront a constantly expanding body of scientific information on health effects, some of them novel. Any effective approach to pollution control must contend with the fact that ambient air pollution is widespread, affecting very large populations, and is produced by a wide range of sources and activities. Most of the major pollutants are also subject to complicated regional and even international transport dynamics that create additional challenges of upwind contributions to diminished air quality in downwind regions. Put simply, controlling these common pollutants and protecting ambient air quality require regulation of millions of mobile and stationary sources across vast areas combined with careful attention to regional transport – all in the context of constantly evolving scientific literature on health impacts.

[14] *See* M. Cacciottolo, *Particulate Air Pollutants, APOE Alleles and Their Contributions to Cognitive Impairment in Older Women and to Amyloidogensis in Experimental Models*, 7 TRANSL. PSYCH. 1 (2017).

[15] *See*, e.g., X. Xu et al., *A Review of Epidemiological Research on Adverse Neurological Effects of Exposure to Ambient Air Pollution*, 4 FRONT. PUB. HLTH. 1, 1 (2016) (concluding based on a review of existing epidemiological research that there is "mounting evidence implicating adverse effects of air pollution on neurobehavioral function in both adults and children"); L. Calderon-Garciduenas et al., *Air Pollution and Detrimental Effects on Children's Brains*, 8 FRONT. HUM. NUEROSCI. 1, 1 (2014) (concluding that "there is enough evidence supporting the perspective that the effects of air pollution on brains of children and teens ought to be key public health targets").

[16] *See*, e.g., N. Fann et al., *Characterizing the Confluence of Air Pollution Risks in the United States*, 9 AIR QUAL. ATMOS. HLTH. 293, 296–99 (2016) (noting the potential for criteria pollutants and air toxics in air pollution mixtures to behave synergistically and identifying counties in the United States with elevated levels of criteria pollutants and air toxics); K. Wesson et al., *A Multi-Pollutant, Risk-Based Approach to Air Quality Management: Case Study for Detroit*, 1 ATMOS. POLLUTION RES. 296, 303 (2010) (finding that a multipollutant approach focused on PM, ozone and hazardous air pollutants in the Detroit urban core resulted in greater net health benefits and was more cost-effective than the standard single pollutant approach).

Given these characteristics, any successful regulatory approach to the problem of ambient air pollution must be both durable and flexible. Because ambient air pollution is a long-term, persistent problem that affects vast areas of the country and implicates multiple economic sectors, it is not the kind of problem that will one day be "solved." Rather, it requires a constant, ongoing effort. A successful program thus needs to send clear signals regarding reduction goals, commitments of resources and affected sources of emissions in order to channel pollution control investments in a manner that will allow for long-term maintenance and improvement of air quality. But such a program also needs to have sufficient flexibility to adjust to new science, to tailor emissions-reduction requirements to local and regional circumstances and to adapt to a changing political-economic context. The NAAQS program has, for the most part, performed well on these fronts, combining durability and flexibility in a manner that has led to major improvements in ambient air quality. But there is still significant work to be done if the program is going to achieve its original goal of attaining the NAAQS for all criteria pollutants for all areas of the country.

2.3 THE NAAQS REGULATORY REGIME

The NAAQS program has evolved considerably since it was established in 1970. This section reviews the history and basic elements of the program. It emphasizes specific features of the NAAQS program that contribute to its durability and flexibility, as well as some of the persistent challenges facing efforts to attain some of the NAAQS. The overall conclusion is that the NAAQS program – though hardly perfect – has successfully combined durability and flexibility as part of an effective science-based approach to controlling ambient air pollution. As discussed in more detail later, this combination of durability and flexibility is a product of several specific design features, creative use of administrative process and the fact that the program was able to develop and mature based on two decades of active engagement and adjustment by Congress, EPA and the courts.

2.3.1 *The Statutory Framework*

The basic statutory framework for the NAAQS was established in the 1970 Clean Air Amendments.[17] As noted, Congress modified the program in 1977 and again in 1990 on the basis of strong bipartisan majorities.[18] In both cases, Congress was more

[17] Clean Air Amendments of 1970, P.L. 91–604, 84 Stat. 1676 (1970).

[18] The Conference Report containing the 1977 amendments was adopted by voice vote in both chambers. The Conference Report containing the 1990 amendments passed the Senate by a vote of 89 to 10 and the House by a vote of 401 to 25. *See Policy Tracker: Clean Air Act and Air Pollution*, Congressional Quarterly, https://library.cqpress.com/cqalmanac/document.php?id=cqal90-1112490.

prescriptive than it had been in 1970, creating additional programs and requirements for both EPA and the states in their respective efforts to achieve the NAAQS and cabining some of the flexibility of the original program.

During its first twenty years (1970–90), the NAAQS program was subject to robust interactions between Congress, EPA and the federal courts, with the states playing a fundamental role in implementation. Since 1990, however, other than some efforts with respect to fuels (as discussed in Chapter 5), Congress has been largely absent from review, evaluation and revision of the program. This has left EPA and the courts to adapt the program within the constraints of the existing statutory framework to deal with ongoing challenges such as interstate transport of criteria pollutants and their precursors. As discussed in more detail later, not all of these efforts have been successful, and it is unclear whether the program can respond effectively to persistent challenges such as interstate pollution in the absence of new legislation.

2.3.1.1 Establishing the NAAQS Program

Although the idea of ambient air quality standards as a tool for controlling air pollution has been around since the 1930s, the first regulatory approaches that made use of such standards took shape in California during the 1950s.[19] In 1955, Los Angeles developed a set of regulations based on ambient air quality standards in an effort to combat the region's growing smog problem.[20] Four years later, the state of California expanded the approach to the whole state and began to develop the first modern air pollution control regime.[21] California, however, was an outlier. Air pollution control efforts in other states during the 1950s and 1960s were, for the most part, woefully inadequate.[22]

During this time, the federal government played a convening role and took some modest steps to support nascent state pollution control efforts. The 1963 Clean Air Act, for example, established a grants program for state air pollution control agencies and provided for abatement conferences to address interstate air pollution

[19] *See* Bachmann, *Will the Circle Be Unbroken*, *supra* note 2 at 661; Harold W. Kennedy, *The Legal Aspects of Air Pollution Control with Particular Reference to the County of Los Angeles*, 27 S. CAL. L. REV. 374 (1954).

[20] SCOTT HAMILTON DEWEY, DON'T BREATHE THE AIR: AIR POLLUTION AND U.S. ENVIRONMENTAL POLITICS, 1945–1970 (2000) chap. 3.

[21] Bachmann, *Will the Circle Be Unbroken*, *supra* note 2 at 661.

[22] According to a 1962 report from the US Public Health Service, some 60 percent of the nation's population (approximately 107 million people) lived in areas with air pollution problems, 43 million in areas with "major" problems. Although the number of people living in such problem areas had increased by some 23 million people since 1950, only seventeen states had air pollution programs with expenditures of $5,000 or more per year. Depending on how one interpreted *enforcement*, only four to six states actually enforced pollution regulations. *See* Jean J. Schuenenman, *Air Pollution Problems and Control Programs in the United States*, paper no. 62-84, U.S. Dept of Health Education and Welfare Public Health Service, Cincinnati, OH, 1 April 1962).

problems.[23] The 1963 Act also directed the Secretary of Health, Education and Welfare to compile "criteria" summarizing current scientific knowledge on pollutants present in the air at harmful concentrations.[24]

Congress took further action in 1965, calling for the first federal air pollution standards for mobile sources, and again in 1967, with the Air Quality Act of 1967.[25] Among other things, the 1967 Act provided a more explicit endorsement of the air quality management approach underway in California, calling for the designation of Air Quality Control Regions across the country and directing the states to develop tailored, regionally specific air quality standards based on criteria documents being prepared by the Department of Health, Education and Welfare.[26]

By all accounts, the 1967 Air Quality Act achieved very little.[27] Without any ability to force the states to act, little progress was made in establishing (much less enforcing) air quality standards. Moreover, as growing public interest in the environment spilled over into electoral politics, the 1967 Act was soon overtaken by events. With Senator Muskie and President Nixon competing to prove their environmental bona fides, support grew for strong federal legislation on air pollution.[28] The result was the Clean Air Amendments of 1970, passed by a unanimous Senate and only a single "No" vote in the House and signed into law by President Nixon on December 31, 1970.[29] The 1970 legislation provided for a much stronger federal role in air pollution control and established the basic framework of what we now know as the Clean Air Act – the centerpiece of which was the National Ambient Air Quality Standards (NAAQS).[30]

In contrast to the 1967 Act's preference for standards that would vary by region, the new NAAQS program would be based, as the name suggested, on a set of nationally uniform standards established by the EPA administrator and subject to ongoing federal supervision and enforcement. Concentrations of criteria

[23] *See* section 4–5, 77 Stat. 392, 393–99.

[24] *See* section 3(c)(2), 77 Stat. 392, 395. This provided the basis for what later came to be identified as the *criteria documents* (and the *criteria pollutants*) under the NAAQS program.

[25] *See* Motor Vehicle Air Pollution Control Act, P.L. 89-272, 79 Stat. 992 (1965). *See* Air Quality Act of 1967, P.L. 90-148, 81 Stat. 485 (1967).

[26] *See* section 107, 81 Stat. 485, 490–91 (air quality control regions and air quality criteria); section 108, 81 Stat. 485, 491–97 (air quality standards and abatement of air pollution). These original criteria documents prepared by HEW provided the basis for the first NAAQS established in 1971.

[27] By 1970, fewer than three dozen air quality regions had been designated, as compared with an anticipated number in excess of 100, and not a single state had developed a full pollution control program.

[28] Bachmann, *Will the Circle Be Unbroken*, *supra* note 2 (recounting history). During this time (the late 1960s), there was a vigorous debate over the relative merits of ambient air quality standards versus uniform technology standards. The 1970 amendments adopted both approaches.

[29] The Senate bill passed by a 73–0 roll-call vote. A weaker House version of the bill passed by a 374–1 roll-call vote. In conference, the Senate version was adopted. *See Policy Tracker: Clean Air Act and Air Pollution*, Congressional Quarterly, https://library.cqpress.com/cqalmanac/document.php?id=cqal70-1293712.

[30] Clean Air Amendments of 1970, P.L. 91-604, 84 Stat. 1676 (1970).

pollutants would be established at levels necessary to protect the public health and welfare. The statute called for two types of standards: *primary standards* necessary to protect the public health with an adequate margin of safety and *secondary standards* to protect public welfare from known or anticipated adverse air pollution effects.[31]

EPA had a number of new duties under the program, including listing of criteria pollutants and preparation of criteria documents under section 108, establishing NAAQS for criteria pollutants under section 109, periodic review and revision of the NAAQS and review and approval of SIPs.[32] The whole program was based on a model of cooperative federalism, and the states were given significant flexibility under section 110 to determine how the NAAQS would be attained in their Air Quality Control Regions.[33] Among the most important and innovative provisions included in the 1970 amendments were those pertaining to citizens' suits and public participation.[34] These have provided an important additional check on agency behavior and created ample opportunities for judicial review.[35] Congress also established specific statutory deadlines for attainment of the NAAQS. All states were expected to be in attainment with the NAAQS within five years, a deadline that would prove to be wildly optimistic and would have to be extended in future legislation.[36]

2.3.1.2 1977 Amendments

Congress amended the CAA in 1977, providing a number of substantial revisions to the NAAQS program. Specifically, Congress extended the attainment deadlines.[37] It changed the previous open-ended requirement of "periodic review" of the NAAQS to a mandatory five-year review process.[38] The 1977 amendments also required EPA to establish a new independent Clean Air Science Advisory Committee (CASAC) that would play a formal role in the NAAQS review process going forward – an institutional innovation that would prove to be very important in reinforcing the credibility and legitimacy of the NAAQS program in the years ahead.[39]

[31] Section 109, 84 Stat. 1676, 1679-80.
[32] Sections 108, 109, 110, 84 Stat. 1676, 1678–83.
[33] Section 110, 84 Stat. 1676, 1680–83.
[34] Section 304 (citizen suits), 84 Stat. 1676, 1706–7; Section 307 (judicial review), 84 Stat. 1676, 1707–8.
[35] These were the first such provisions in US federal environmental law, but they drew on past experience in the states.
[36] *See* Sections 110(a)(2)(A) (calling for SIPs that provide for attainment within three years) and 110(e)(1) (allowing for a two-year extension of attainment deadline in specific cases), 84 Stat. 1676, 1680 and 1682.
[37] Deadlines for attainment were extended by the 1977 amendments to 1982 in most cases and 1987 for areas in severe nonattainment for certain pollutants. *See* Section 172(a), 91 Stat. 685, 746–47.
[38] Section 109(d)(1), 91 Stat. 685, 691.
[39] Section 109(d)(2), 91 Stat. 685, 691.

The 1977 amendments also enhanced the SIP process, providing for a bifurcated state planning process depending on whether particular Air Quality Control Regions were in attainment or not. States were now required to classify their Air Quality Control Regions as "attainment," "nonattainment" or "unclassifiable" for each of the NAAQS, and various controls and requirements applied depending on that status.

Perhaps most significantly, the 1977 amendments codified and expanded EPA's Prevention of Significant Deterioration (PSD) program and created a new nonattainment program.[40] Among other things, the PSD and nonattainment programs provided for preconstruction review and permitting for new and modified sources that imposed technology controls on these sources depending on their attainment status. Together these became known as the *New Source Review* (NSR) program.

Going forward, states with nonattainment areas would be required to adopt measures (reflected in their SIPs) for both existing and new and modified sources (see Chapter 3).[41] Similarly, under the PSD program, state plans were required to include a preconstruction review and permitting program that imposed best available control technology (BACT) on new and modified sources in "attainment" and "unclassifiable" areas. The PSD program also established "increments" of allowable air quality deterioration over a baseline concentration based on classifications of Air Quality Control Regions.[42]

Congress also took aim in the 1977 amendments at the problem of interstate air pollution – a reaction in part to EPA's almost complete lack of attention to the problem under the original 1970 provisions.[43] First, Congress strengthened the so-called good neighbor provision in section 110, requiring that SIPs contain provisions

[40] *See* Title I, Part C: Prevention of Significant Deterioration of Air Quality, 91 Stat. 685, 731–45; Title I, Part D: Plan Requirements for Nonattainment Areas, 91 Stat. 685, 746–51.

[41] Existing sources were subject to "reasonably available control technologies" (RACTs). New and modified sources were subject to "lowest achievable emissions reductions" (LAERs) plus a requirement to "offset" any additional increments of pollution. *See* Title I, Part D: Plan Requirements for Non-Attainment Areas, 91 Stat. 685, 746–51.

[42] *See* Title I Part C: Prevention of Significant Deterioration of Air Quality, 91 Stat. 685, 731–42. The PSD program has an interesting history that illustrates the role of the federal courts in driving certain developments under the Act. The program was initially created out of whole cloth by DC District Court Judge John Pratt in 1972 – a decision widely viewed as having no defensible basis in the operative provisions of the statute but one that was upheld on appeal. *See* Sierra Club v. Ruckelshaus, 34 F. Supp. 253 (D.C. Dist. 1972), aff'd per curiam 4 ERC 1815 (D.C. Cir. 1972), aff'd by an equally divided court, sub nom. Fri v. Sierra Club, 412 U.S. 541 (1973); *see also* A. Stanley Meiburg, Protect and Enhance: "Judicial Democracy" and the Prevention of Significant Deterioration of Air Quality (1991) (tracing history); R. Shep Melnick, Regulation and the Courts: The Case of the Clean Air Act (1983) 71–112 (discussing evolution of the PSD program); Richard Stewart, *Judicial Review of EPA Decisions*, 62 Iowa L. Rev. 713, 741–50 (1977) (criticizing decision on various grounds). Pursuant to Judge Pratt's injunction, EPA issued final regulations in 1974 and 1975 that were upheld in 1976 by the DC Circuit. *See* Sierra Club v. EPA, 540 F. 2d 1114 (D.C. Cir., 1976). Congress then stepped in to codify and expand the program in the 1977 amendments.

[43] See Vickie Patton, *The New Air Quality Standards, Regional Haze, and Interstate Air Pollution Transport*, 28 *ELR* 10155 (1998); Revesz, *Federalism and Interstate Environmental Externalities*, *supra* note 7.

prohibiting any stationary source in the state from preventing attainment or maintenance of the NAAQS in downwind states and from interfering with PSD and visibility requirements.[44] Congress also expressly prohibited states' reliance on dispersion techniques to meet the NAAQS, disallowing emissions-reduction credit for intermittent control measures that relied on meteorological conditions and tall stacks instead of good engineering practices.[45] It also added a new section 126, which allowed downwind states to petition EPA to force upwind states to modify their SIPs and abate pollution from sources that were "significantly contribut[ing]" to nonattainment with the NAAQS in downwind states.[46] These provisions have proved to be important statutory hooks for some of EPA's recent efforts to deal with cross-state transfers of criteria pollutants and their precursors.[47]

2.3.1.3 1990 Amendments

Congress amended the CAA again in 1990.[48] Among other things, the 1990 amendments overhauled section 112 dealing with hazardous air pollutants, created a cap-and-trade program for SO_2 and NO_x to deal with acid rain, enhanced provisions for interstate cooperation on regional air pollution problems (notably ozone in the Northeast and haze in the western United States), added extensive new mobile source provisions, adopted implementing legislation to meet US commitments under the Montreal Protocol and created the Title V permitting program. All together, the 1990 amendments ran to almost ten times the number of pages as the original 1970 amendments and almost three times that of the 1977 amendments – a reflection of the growing complexity of the problems to be addressed, the use of new policy instruments such as cap and trade and a congressional desire to constrain agency discretion through more prescriptive and precise statutory language.[49]

The most important provisions related to the NAAQS included revised nonattainment provisions for ozone and carbon monoxide, new initiatives focused specifically

[44] *See* Section 110(a)(2)(E), 91 Stat. 685, 693.
[45] *See* Section 123; 91 Stat. at 721–22
[46] *See* Section 126, 91 Stat. 685, 724–25.
[47] *See* Cross-State Air Pollution Rule (CSAPR), *supra* note 7. As noted, the cross-state rule was upheld by the Supreme Court in EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584 (2014).
[48] P.L. 101-549, 104 Stat. 2399 (1990).
[49] To be sure, Congress's general lack of faith in the executive branch and its corresponding preference for increasingly prescriptive and complex provisions were readily apparent (and remarked on) in the CAA amendments of 1970 and 1977. *See*, e.g., William D. Ruckelshaus, *Environmental Protection: A Brief History of the Environmental Movement in America and the Implications Abroad*, 15 ENVT'L L. 455, 460 (1985) ("If you have ever tried to read the Clean Air Act, and I would not wish that on anybody who did not have to administer it, and if you are puzzled by what some of the language in the Act means, try thinking about it as an expression of Congress's lack of confidence in the executive branch. A lot of provisions that are otherwise baffling become clear.").

on controlling regional air pollution, particularly ozone and haze, and extensive new provisions for mobile sources. Interestingly, although the widely celebrated SO_2 trading program (Title IV) was not directly related to the NAAQS program, it was in some ways a response to the problems created by EPA's earlier decision to allow states to use dispersion techniques (tall stacks) to demonstrate compliance with the NAAQS. It also ended up generating significant NAAQS "co-benefits" by reducing $PM_{2.5}$ in a number of "downwind states" (largely through the reductions in SO_2 as a PM precursor). And it was ultimately rendered obsolete by the NAAQS program as new research on the health and mortality effects of $PM_{2.5}$ drove more stringent reductions than those required under the cap.[50]

In looking back at the evolution of the NAAQS statutory framework, several developments stand out, all of which reflect an effort by Congress to reduce some of the flexibility contained in the original 1970 version of the program. First, Congress sought to strengthen and enhance the NAAQS program by providing more prescriptive source-specific requirements through the PSD and nonattainment provisions. This cabined some of the flexibility that states enjoyed previously under the SIP process. Second, Congress required more elaborate and formal scientific review, constraining EPA's discretion and flexibility over the NAAQS process. This bolstered the overall credibility and legitimacy of the program, thereby enhancing its political durability. Third, Congress took a more aggressive approach to regional/interstate problems, in part because of EPA's inability or unwillingness to use its full authority to mitigate interstate air pollution. Fourth, Congress strengthened the connections between the NAAQS and other CAA programs, designing some of these programs (fuels and mobile sources, for example) with an eye toward assisting with NAAQS attainment. The overall result is a hybrid program that combines ambient air quality standards with specific emissions control requirements built on a foundation of state implementation (see Figure 2.1).

2.3.2 *EPA Responsibilities*

EPA's major responsibilities under the NAAQS program can be divided into two main categories: (1) establishment, review and revision of the NAAQS and (2) review and approval of SIPs. In addition, EPA has developed extensive regulations and informal guidance under the PSD and nonattainment programs.[51] And more recently, it has used its authority under the NAAQS program in new and creative ways, particularly in its efforts to deal with interstate pollution problems.[52] Not

[50] Richard Schmalensee & Robert N. Stavins, *The SO_2 Allowance Trading System: The Ironic History of a Grand Policy Experiment*, 27 J. Econ. Persp. 103 (2013).

[51] *See* Chapter 3.

[52] *See*, e.g., Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone, 63 Fed. Reg. 57, 356 (Oct. 27, 1998) (the NO_x SIP call), upheld in Michigan v. EPA, 213 F.3d 663 (D.C.

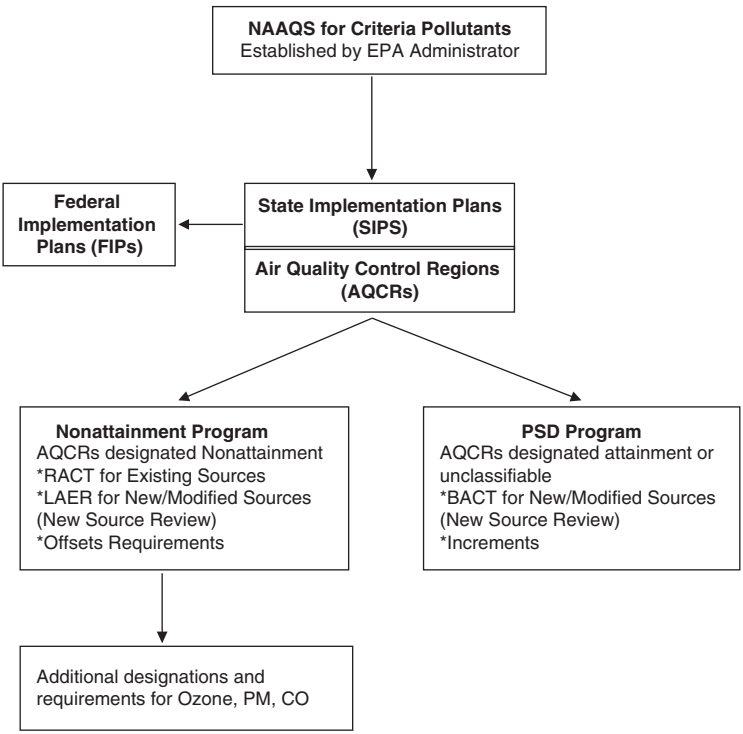

FIGURE 2.1 NAAQS framework

surprisingly, much of EPA's regulatory effort under the NAAQS program has been the subject of litigation, resulting in court-imposed deadlines for many rulemakings.

2.3.2.1 Establishment, Review and Revision of the NAAQS

Since the moment it was created, EPA has devoted a considerable amount of time and resources to discharging its basic responsibilities under the NAAQS program. Establishing the NAAQS is its most fundamental responsibility in this respect. But before it can do that, EPA must first create a list of so-called criteria pollutants and develop a criteria document for each listed pollutant. As defined in the statute, *criteria pollutants* are pollutants which the EPA administrator determines have an adverse effect on public health or welfare and that are present in the ambient air as a result of "numerous or diverse mobile or stationary sources."[53] Criteria documents, which are a holdover from pre-1970 air pollution

Cir. 2000); and Cross-State Air Pollution Rule (CSAPR), *supra* note 7, upheld by the Supreme Court in EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584 (2014).

[53] Section 108(a)(1), 84 Stat. 1678.

legislation, are intended to capture the latest scientific information on the air pollutant in question and its impacts on public health and welfare.[54]

After establishing the list of criteria pollutants and preparing criteria documents, EPA is required by section 109 to establish two types of NAAQS for each criteria pollutant. Primary standards are set to protect public health with an adequate margin of safety, including the health of "sensitive" populations such as asthmatics, children and the elderly.[55] Secondary standards are set to protect public welfare, including protection against visibility impairment and damage to animals, crops, vegetation and buildings. For all the criteria pollutants except $PM_{2.5}$ and SO_2, EPA has allowed the primary standard to serve as the secondary standard, raising concerns that these secondary standards may not be adequately protecting welfare.[56]

EPA's efforts under the NAAQS program began in early 1971, when the months-old agency issued the first NAAQS for six criteria pollutants, sulfur dioxide (SO_2), particulate matter (PM), carbon monoxide (CO), photochemical oxidants, hydrocarbons (HC) and nitrogen oxides (NO_x), based on criteria documents that had been prepared by the Public Health Service pursuant to pre-1970 air pollution legislation. The entire rule establishing the NAAQS for all six of these pollutants covered a mere fifteen pages in the *Federal Register*.[57] In response to litigation, EPA listed lead as a new criteria pollutant in 1976 (the only new criteria pollutant it has ever listed under the program) and prepared its first criteria document as a basis for the first lead NAAQS in 1978.[58] Photochemical oxidants were replaced with ozone in 1979.[59] The HC standard was revoked in 1983.[60] PM was revised in 1987 to include only PM_{10} and further revised in 1997 to include $PM_{2.5}$.[61]

54 Section 108(a)(2), 84 Stat. 1678–79.

55 Section 109, 84 Stat. 1679–80. *See also* Lead Industries Assoc. v. EPA, 647 F.2d 1130, 1152–54 (D.C. Cir. 1980) (confirming that EPA must set the primary NAAQS at levels that will protect the health of sensitive populations).

56 National Research Council, Air Quality Management Report 87 (2004) (noting that the "current practice of letting the primary standard serve as the secondary standard for most criteria pollutants does not appear to be sufficiently protective of sensitive crops and unmanaged ecosystems").

57 *See* National Primary and Secondary Ambient Air Quality Standards, 36 Fed. Reg. 8186 (April 30, 1971). The only criteria pollutant for which a separate secondary standard was issued was sulfur dioxide. This standard turned out to be based on an error, which EPA fixed on remand after a challenge from Kennecott Copper. *See* Kennecott Copper Corp. v. EPA, 462 F.2d 846 (D.C. Cir. 1972).

58 *See* Natural Resources Defense Council v. Train, 545 F.2d 320, 328 (2d Cir. 1976) (holding that once EPA found that lead met the requirements of section 108(a)(1), it was required to list the pollutant and develop a NAAQS for it).

59 *See* Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202 (Feb. 8, 1979) (revising photochemical oxidant standard to be expressed as ozone standard). This was the only time that a NAAQS was revised upward, in this case from 0.8 to 1.2 ppm. *Id.*

60 *See* National Primary and Secondary Ambient Air Quality Standards, 48 Fed. Reg. 628 (Jan. 5, 1983) (revoking NAAQS for hydrocarbons on grounds that there were no demonstrated direct health effects).

61 *See* Revisions to National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24,634 (Jul 1, 1987) (revising existing particulate matter standard to reflect a new PM_{10} standard); National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652 (July 18, 1997) (establishing separate standards for PM_{10} and $PM_{2.5}$).

Pollutant [links to historical tables of NAAQS reviews]		Primary/ Secondary	Averaging Time	Level	Form
Carbon Monoxide (CO)		primary	8 hours	9 ppm	Not to be exceeded more than once per year
			1 hour	35 ppm	
Lead (Pb)		primary and secondary	Rolling 3-month average	0.15 µg/m^3[(1)]	Not to be exceeded
Nitrogen Dioxide (NO_2)		primary	1 hour	100 ppb	98th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		primary and secondary	1 year	53 ppb[(1)]	Annual Mean
Ozone (O_3)		primary and secondary	8 hours	0.070 ppm[(3)]	Annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years
Particle Pollution (PM)	$PM_{2.5}$	primary	1 year	12.0 µg/m^3	annual mean, averaged over 3 years
		secondary	1 year	15.0 µg/m^3	annual mean, averaged over 3 years
		primary and secondary	24 hours	35 µg/m^3	98th percentile, averaged over 3 years
	PM_{10}	primary and secondary	24 hours	150 µg/m^3	Not to be exceeded more than once per year on average over 3 years
Sulfur Dioxide (SO_2)		primary	1 hour	75 ppb[(4)]	99th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		secondary	3 hours	0.5 ppm	Not to be exceeded more than once per year

FIGURE 2.2 Current NAAQS

Starting in the late 1970s, EPA also issued revised NAAQS for the criteria pollutants on eleven separate occasions, most recently in 2015 when it issued a revised NAAQS for ozone (Figure 2.2 shows a table of the current NAAQS). As might be expected, EPA has struggled to meet the five-year NAAQS review requirement on a consistent basis, leading to litigation and court-mandated review schedules. Moreover, as the science of air pollution has grown in volume and sophistication, EPA's review processes and the resulting criteria documents have become larger and more complex ("encyclopedic" in the words of one observer), raising questions about the relative merits of health-based ambient environmental standards compared with other approaches.[62]

[62] *See* WENDY WAGNER, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES 30 (2013) ("The scientific analyses in these [NAAQS] reviews have grown from short, relatively simple assessments to encyclopedic assessments that even experts sometimes labeled as impenetrable."). *See*

In an effort to improve the NAAQS process, EPA has engaged in periodic reviews over the years and has made a number of adjustments.[63] Specifically, EPA's Clean Air Science Advisory Committee conducted formal evaluations of the NAAQS process in 1981 and 1985 – both of which resulted in changes to the process.[64] The National Academy of Sciences has also produced several important reports on various aspects of the NAAQS and the CAA more generally, often in response to specific requests from Congress or EPA, which have informed efforts to revise the NAAQS process.[65] EPA initiated a major review of the NAAQS process in 2006, leading to substantial revisions that separated analytically distinct components and created a more formal framework for NAAQS review and revision.[66] In 2009, EPA Administrator Lisa Jackson issued a memorandum on the NAAQS review process that further elaborated the basic components, including an initial planning document and literature review, an integrated science assessment (previously known as the *criteria document*), a risk and exposure assessment, a policy assessment and the formal rulemaking[67] (see Figure 2.3).

In each of these steps, EPA has been "procedurally generous," allowing for various forms of public participation that go well beyond the requirements of the Administrative Procedures Act.[68] Several commentators have argued that these new procedures adopted by EPA in the mid-2000s have resulted not only in greater transparency and accountability but also in a more productive "partnership" with the courts in their effort to review agency science underlying the NAAQS.[69]

also Michael L. Livermore & Richard L. Revesz, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U L. Rev. 1184, 1258–64 (2014) (questioning the health-based approach of the NAAQS).

63 *See also* Morton Lippmann, *Role of Science Advisory Groups in Establishing Standards for Ambient Air Pollutants*, 6 Aerosol Sci. Tech. 93, 108–13 (1987) (summarizing 1981 and 1985 CASAC assessments of and recommendations regarding the NAAQS review process).

64 *See* U.S. EPA, Clean Air Science Advisory Committee, Setting National Ambient Air Quality Standards: Improving the Process (1981); U.S. EPA, Science Advisory Board, Report of the Clean Air Science Advisory Committee (CASAC) on Improving the Process for Setting National Ambient Air Quality Standards: An Update (1985).

65 *See*, e.g., National Research Council, Air Quality Management in the United States (2004); National Research Council, Rethinking the Ozone Problem in Urban and Regional Air Pollution (1991).

66 *See* U.S. EPA, NAAQS Process Workgroup, Review of the Process for Setting the National Ambient Air Quality Standards (2006). *See also* Sidney Shapiro et al., *The Enlightenment of Administrative Law: Looking Inside the Agency for Legitimacy*, 47 Wake Forest L. Rev. 463, 493–96 (2012) (describing the separate steps of the new NAAQS review process and characterizing them as a "deliberative-constitutive" process that enhances legitimacy and accountability).

67 Lisa Jackson, Memorandum on Process for Reviewing National Ambient Air Quality Standards, May 21, 2009.

68 *See* Steven P. Croley, Regulation and the Public Interests: The Possibility of Good Regulatory Government 258 (2008) (observing that EPA was "procedurally generous" in the 1997 ozone/$PM_{2.5}$ rulemaking, soliciting comments and input from a wide variety of stakeholders and experts that went well beyond the minimum requirements of the APA).

69 *See* Fisher et al., *Rethinking Judicial Review of Expert Agencies*, *supra* note 3; Shapiro et al., *The Enlightenment of Administrative Law*, supra note 66. *See also* Croley, Regulation and the Public Interests, *supra* note 68 at chap. 9.

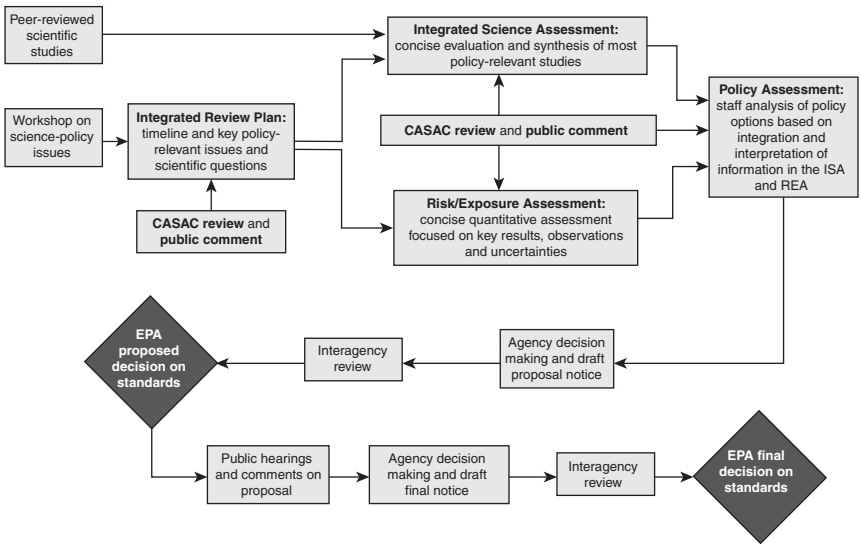

FIGURE 2.3 NAAQS review process

In particular, they point to the development of internal agency "yardsticks" and a coherent "epistemic framework" for managing the complex process of NAAQS review and revision and weighing scientific evidence as key elements of EPA's new process that have facilitated a more hospitable climate for public participation and judicial review.[70] As discussed in more detail later, the development of robust internal procedures at EPA has been an important contributor to the overall legitimacy of the program. Administrative process, in this respect, has been a key component of the success and durability of the NAAQS.

2.3.2.2 Review, Approval and Enforcement of SIPs

EPA's other major responsibility under the NAAQS program is to review, approve (or disapprove) and enforce the SIPs. Under the statute, once a state submits a SIP or SIP revision to EPA, the agency can approve or disapprove the SIP in whole or in part.[71] EPA *must* approve a SIP if it finds that it meets all applicable requirements, and the courts have expressly held that EPA cannot impose particular emissions controls or requirements other than those called for in the statute on the states

[70] Fisher et al., *Rethinking Judicial Review of Expert Agencies*, *supra* note 3. *See also* Wagner, SCIENCE IN REGULATION, *supra* note 62 (" Although it has not been easy, EPA appears to have finally developed a transparent process that produces analyses that are accessible to expert onlookers and that manages successfully to bridge science and policy in ways that appear worthy of replication.").

[71] Before reviewing, however, EPA must determine whether the submission is complete. *See* section 7410(k)(1). EPA's criteria for whether a submission is complete are set out at 40 C.F.R. pt. 51, App. V; 40 C.F.R. pt. 51, App. V.

through its SIP authority.[72] If EPA finds that a SIP does not meet the requirements of the CAA, it may disapprove the SIP. EPA can also partially or conditionally approve a SIP or SIP revision.[73] Conditional approvals require states to agree to adopt enforceable measures by a definite date no more than one year from the conditional approval.[74] If the state later fails to adopt those measures, the SIP is treated as disapproved.[75] Finally, EPA can also ask states to revise SIPs that have been previously approved if it later finds that these SIPs are inadequate. This process, known as a *SIP call*, has been used by EPA in a variety of contexts, most notably in its efforts since the late 1990s to force "upwind" states to consider and deal with their contributions to attainment problems in "downwind" states.[76]

If a state fails to submit a satisfactory SIP, EPA must develop its own compliance plan within two years. This plan is known as a *federal implementation plan* (FIP).[77] In the past, EPA has generally used FIPs in situations where states have failed to correct some previously identified deficiency. Recently, however, EPA has taken a more proactive approach in using its FIP authority. In its 2011 Cross-State Air Pollution Rule (also known as the Transport Rule), for example, EPA simultaneously announced a regulatory emissions budget that quantified states' obligations for curbing interstate NO_x and SO_2 air pollution and promulgated FIPs to implement the budget and associated controls in noncomplying states.[78] Significantly, EPA did not first give states an opportunity to meet the newly quantified obligations in their SIPs, based on the theory that the states' existing SIPs were inadequate to satisfy the good neighbor provision and that immediate federal intervention was therefore authorized. This approach was

[72] 40 C.F.R. pt. 51. See Train v. NRDC, 421 U.S. 57, 79 (1975) ("Under § 110(a)(2), the Agency is *required* to approve a state plan which provides for the timely attainment and subsequent maintenance of ambient air standards and which also satisfies the section's other general requirements. The Act gives the Agency no authority to question the wisdom of a State's choices of emission limitations if they are part of a plan which satisfies the standards of §110(a)(2), and the agency may devise and promulgate a plan of its own only if a State fails to submit an implementation plan which satisfies those standards" (emphasis in original); Virginia v. EPA, 108 F.3d 1397, 1407–9 (D.C. Cir. 1997) (holding that EPA had exceeded its authority under section 110 by requiring certain states to adopt California's vehicle emission program as the principal means of reducing ozone precursors).

[73] 42 U.S.C. § 7410(k)(3). A partial approval is not complete until EPA approves the entire plan.

[74] *Id.* § 7410(k)(4).

[75] *Id.*

[76] *Id.* § 7410(c)(1). EPA used its SIP call authority in 1998 when it issued the NO_x SIP call to twenty-two states and the District of Columbia, mandating that they revise their SIPs to mitigate interstate transport of ozone and its precursors (NO_x). *See* Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone, 63 Fed. Reg. 57,356 (1998). The major provisions of this rule were upheld by the DC Circuit in Michigan v. EPA, 213 F.3d 663 (D.C. Cir. 2000).

[77] 42 U.S.C. § 7410(c)(1).

[78] 76 Fed. Reg. 48,208 (Aug. 8, 2011). As noted earlier, the good neighbor provision requires SIPs to control emissions contributing significantly to nonattainment or that interfere with NAAQS maintenance in another state. *See* 42 U.S.C. § 7410(a)(2)(D)(i)(I). A closely related provision requires states to consider the impacts of their air pollution on foreign countries. *See id.* §§ 7410(a)(2)(D)(ii), 4215.

recently upheld by the Supreme Court in *EPA* v. *EME Homer City Generation, L.P.*[79]

Four brief observations are worth making regarding EPA's major responsibilities under the NAAQS program. First, the NAAQS review process has become much more complex and science intensive, requiring mobilization of significant internal and external resources. Second, EPA's efforts to establish more formal and transparent procedures for the NAAQS review process, including its reliance on independent scientific review, has been a critical component of the overall durability of the program. Third, the SIP review and approval process has not received the same level of attention as the NAAQS review process, leading to criticisms that it is overly bureaucratic and ineffective. Fourth, EPA has made more creative use of its SIP/FIP authorities and the CAA's good neighbor provisions in recent years to deal with persistent problems of interstate transport of criteria pollutants and their precursors.

2.3.3 *Independent Scientific Review*

Independent scientific review has played a fundamental role in the NAAQS program, bolstering EPA's own scientific efforts and helping to maintain the credibility of the program. This has contributed significantly to the political durability of the NAAQS. As noted earlier, Congress was an important early driver in this respect, instructing EPA in the 1977 amendments to create an independent Clean Air Science Advisory Committee (CASAC) that would play a formal role in the NAAQS review and revision process.[80] As amended, section 109 required EPA to appoint an independent seven-member CASAC that includes at least one member of the National Academy of Sciences and one representative from state air pollution control agencies. The CASAC reviews the air quality criteria and NAAQS at five-year intervals and makes recommendations to the EPA administrator regarding new criteria pollutants and revisions of existing air quality criteria and NAAQS as appropriate.[81] Section 307 also requires that EPA explain in its rulemakings the reasons for any differences between the proposed or final NAAQS and CASAC recommendations.[82]

[79] EME Homer City, 134 S.Ct. at 1595–96 (2014).

[80] The CASAC has been subject to the Federal Advisory Committees Act (FACA) since it was established. For an illuminating discussion of CASAC's role and relationship with EPA management during its early years, *see* Shelia Jasanoff, The Fifth Branch: Science Advisers as Policymakers 101–22 (1990).

[81] The Environmental Research, Development, and Demonstration Authorization Act of 1978 established EPA's Science Advisory Board (SAB) and also calls for review of the NAAQS. EPA has historically relied on the CASAC review process to satisfy these ERDDAA provisions. In conducting its reviews, the CASAC is supplemented with additional subject-matter experts forming a CASAC Review Panel.

[82] In its 2008 revision of the ozone NAAQS, for example, EPA chose a standard (0.075 ppm) above the range recommended by the CASAC (0.060–0.070 ppm). *See* National Ambient Air Quality Standards

Since its creation, the CASAC has played an active role in the NAAQS review process. In addition to reviewing and providing feedback on the various formal documents prepared by EPA as part of the process, the CASAC also convenes various meetings and workshops with the broader scientific community.[83] At the end of the process, the CASAC provides a formal assessment (known as a *closure letter*) to the EPA administrator containing its views on the state of the science and suggesting a range for a revised standard if it concludes that the existing standard needs to be changed. The CASAC also provides advice to EPA on a variety of other issues, including air quality modeling and monitoring, research needs and reform of the NAAQS review process itself.[84]

In addition to these formal efforts to ensure that independent scientific review is well integrated into the NAAQS process, there have been multiple outside scientific reviews by the National Research Council (NRC) and other bodies looking at the NAAQS program as a whole as well as at specific challenges associated with particular pollutants.[85] In some cases, these various reviews and reports were called for by Congress, demonstrating again a congressional commitment to ensuring ongoing independent assessment of the NAAQS program and its challenges. The 2004 NRC report, *Air Quality Management in the United States*, for example, was prepared in response to a congressional request for an independent evaluation of the effectiveness of the NAAQS and the CAA more generally.[86] Likewise, the 1992 NRC report, *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, was developed in part as a response to a congressional request for a National Academy of Sciences study on ozone precursors and their role in ozone formation and control.[87] In these cases and others, the resulting reports have provided important additional input to EPA as it has worked to strengthen the scientific foundations of the NAAQS and to improve the overall process.

for Ozone, 73 Fed. Reg. 16,436, 16,482 (March 27, 2008). EPA's decision was upheld by the DC Circuit in Mississippi v. EPA, 723 F.3d 246–9 (D.C. Cir. 2013).

83 The key documents here are now known as the *Integrated Science Assessment*, previously known as the *Criteria Document*, a *Risk/Exposure Assessment* and a *Policy Assessment*, previously known as the *Staff Paper*. The CASAC typically reviews and comments on multiple drafts of these documents before they are finalized.

84 On CASAC reports on the NAAQS review process, *see* CASAC, Setting National Ambient Air Quality Standards: Improving the Process (1981); CASAC, Improving the Process for Setting National Ambient Air Quality Standards: An Update (1985).

85 *See*, e.g., National Research Council, Global Sources of Local Pollution: An Assessment of Long-Range Transport of Key Air Pollutants to and from the United States (2009); National Research Council, Air Quality Management in the United States (2004); National Research Council, Rethinking the Ozone Problem in Urban and Regional Air Pollution (1992).

86 *See* National Research Council, Air Quality Management in the United States (2004). The report contains a number of important recommendations for improving the NAAQS process and adapting the program to deal with difficult challenges such as regional transport issues.

87 *See* National Research Council, Rethinking the Ozone Problem in Urban and Regional Air Pollution (1992).

The NAAQS program thus draws on a broad and robust network of independent scientific review. The integrated science assessments are based on a thorough review (internal and external) of literally thousands of scientific studies.[88] These documents are designed to reflect the current state of the science and now often stretch well beyond 1,000 pages (not including appendices). During each individual NAAQS review, moreover, EPA's science assessment, its risk and exposure assessments and its policy assessment are all subject to multiple rounds of review and input from the CASAC as well as more informal review and input from the broader scientific community and from the public at large. At a more general level, the NRC and others provide yet another layer of independent review of various aspects of the NAAQS program (and other aspects of the CAA), as well as particular challenges confronting the program (e.g., ozone chemistry, long-range transport of pollutants, etc.).

To a considerable extent, the evolution of the NAAQS program and the increasingly formal role that independent scientific review has come to play in the NAAQS review process reflect a broader trend in regulatory science toward increased reliance on external peer review as a means of insulating agency decision making from claims of bias and excess discretion. This "*renegotiation of expertise*" has often translated into a focus on process rather than the substance of specific decisions as a means to bolster the credibility of EPA's decision making.[89] Without question, difficult and inescapable policy judgments remain at the heart of NAAQS standard setting, and a preoccupation with process can create its own problems (including a loss of flexibility). On the whole, though, it is clear that the efforts by Congress and EPA to create a robust process of independent scientific review as a fundamental part of the NAAQS process has contributed significantly to the overall success of the NAAQS in withstanding challenges (legal and political) and in maintaining public trust and credibility.

2.3.4 *Public Participation*

Like other environmental statutes, the CAA contains multiple avenues for public participation. Most prominently, the "citizen suit" provisions under section 304 and the petition process under section 307 have allowed various citizens groups, advocacy organizations, state and local governments and industry groups (among others) to challenge EPA action (or inaction) on many fronts and to force the agency to

[88] Wagner, Science in Regulation, *supra* note 62 at 30 ("A single NAAQS review can involve the analysis of thousands of studies.").

[89] *See*, e.g., Shelia Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 Osiris 194, 197 (1992) ("[I]n the arena of environmental decision making public representation of science has shifted away from an emphasis on testable knowledge claims to a preoccupation with the processes of knowledge production. Under continual assault from political adversaries, EPA's environmental science has more and more justified itself in terms of its legal, institutional, and procedural underpinnings rather than the truth-value of the facts it alleges.").

discharge its responsibilities under the CAA. Section 304 allows "any person" to commence a civil action against any other person (including the United States) alleged to be in violation of an emission standard or limitation under the Act or an order issued by EPA or a state with respect to such a standard or limitation.[90] It also allows such persons to commence an action against the EPA administrator for failure to discharge any nondiscretionary duty.[91] Section 307 contains procedural and venue provisions regarding petitions for review of specific actions taken by EPA, including various procedural steps that EPA takes in discharging its duties.[92] Taken together, these provisions have allowed for robust participation (manifest in a large amount of litigation) by citizens groups, industry representatives and others, resulting in major judicial decisions, court-imposed deadlines and a more general check on regulated entities and EPA that have profoundly shaped the NAAQS program.

Indeed, since 1970, scores of lawsuits have been filed on various aspects of the NAAQS program, resulting in dozens of appellate decisions. Among other things, citizen suits and section 307 petitions have resulted in new listings of criteria pollutants (lead), court-imposed deadlines for the NAAQS review process, challenges to the NAAQS as promulgated, challenges to PSD and NSR regulations, challenges to individual SIPs and the SIP process, challenges to attainment and nonattainment designations and challenges to EPA's efforts to use various authorities to deal with interstate transport issues. In sum, hardly any aspect of the NAAQS program has escaped judicial review, and it is fair to say that the NAAQS program would not look anything like it does today in the absence of these provisions for public participation.

These important procedural features of the statute have contributed to both durability and flexibility. Robust citizen participation and judicial review have worked to reinforce the overall quality (and the legitimacy) of EPA's efforts under the NAAQS program, although there are surely cases where EPA has focused too much on surviving judicial review rather than on substantive outcomes. The constant threat of litigation from interest groups on all sides has likely protected the program from various forms of capture and has arguably allowed it to respond to evolving social priorities. Court-imposed deadlines have also given EPA much-needed political cover, allowing it to move forward with expensive and controversial rulemakings. In effect, these provisions have kept the pressure on EPA, providing an

[90] Section 304(a)(1), 84 Stat. 1676, 1706.

[91] Section 304(a)(2), 84 Stat. 1676, 1706. This provision also waives the traditional requirements of amount in controversy. A third set of activities subject to the citizen suits provision was added in the 1977 amendments pertaining to persons who construct any new major emitting facility without a permit under either the PSD or nonattainment program. *See* new Section 304(a)(1)(3), 91 Stat. 685, 771.

[92] Section 307(b), 84 Stat. 1676, 1708. This provision would be elaborated further in the 1977 amendments with a long list of specific EPA actions to which it applied. *See* new Section 307(d), 91 Stat. 685, 772–76.

additional check on agency behavior and allowing the program to move forward even in the face of politically challenging circumstances. But, of course, lawsuits are cumbersome and time-consuming and do not always result in progress toward the overall objectives of the NAAQS program.

Other, less formal (and less litigious) opportunities for public participation have also enhanced the durability of the program. In particular, over the last decade or so, EPA has created multiple opportunities for public review and input as part of the NAAQS review process, often in the form of workshops and solicitations of feedback on draft assessments. None of these are required as part of any rulemaking; they are in addition to formal notice and comment provisions. But they serve the important function of allowing EPA to vet revised standards before any formal proposal is made. This, in turn, allows the Agency to receive valuable feedback on possible revisions and, at the same time, to signal to the regulated community and other stakeholders the Agency's thinking about future NAAQS revisions.[93] By the time EPA releases its formal proposal for a revised NAAQS, no one can really claim surprise. Given prior vetting of the proposed revision, moreover, the rulemaking is almost certainly stronger and less vulnerable to attack (from whatever side) than it would have been. As a result, these informal means of public participation contribute further to the overall political legitimacy and durability of the program.

2.3.5 *Monitoring and Modeling Infrastructure*

In contrast to some traditional end-of-pipe pollution control standards, ambient environmental quality standards require an elaborate technical and analytical infrastructure. As noted earlier, EPA's efforts to establish the NAAQS (and to review and revise the NAAQS over time) are extremely science-intensive, requiring review of thousands of studies from multiple disciplines.[94] The entire enterprise, moreover, depends on a range of tools for monitoring and modeling air quality, assessing risk and exposure and developing scenarios to evaluate future controls.

The nation's air quality monitoring network provides the empirical foundation for the NAAQS.[95] As such, it has evolved considerably over the years as EPA has worked to make it more responsive to the needs of the program. Similarly, air quality

[93] *See* Croley, Regulation and the Public Interests. *supra* note 68; Fisher et al., *Rethinking Judicial Review of Expert Agencies*, *supra* note 3; Wagner, Science in Regulation, *supra* note 62.

[94] Wagner, Science in Regulation, *supra* note 62.

[95] The 1977 Amendments to the Clean Air Act directed EPA to establish an air quality monitoring system in the United States. *See* section 309, 91 Stat. 781–82 (directing the EPA administrator to promulgate regulations establishing an air quality monitoring network throughout the United States that would, among other things, use uniform criteria and methodology, provide for air quality monitoring in major urban areas in a manner that supplemented state monitoring programs, provide for daily analysis and reporting of air quality and compile air monitoring data to inform the administrator's actions). *See also* National Research Council, Air Quality Management in the United States 219 (2004) ("Since the 1980s, the United States has had an extensive air quality monitoring network that routinely measures the concentrations of selected air pollutants in some locations."); *id* (noting that the network

modeling has been central to the entire NAAQS enterprise since its inception, and the courts have generally been deferential to EPA in reviewing how it uses models.[96] Modeling has been particularly important regarding EPA's efforts on interstate regional pollution issues and not always to good effect. In the late 1970s and early 1980s, for example, EPA repeatedly used the *limits* of regional air quality models to avoid taking strong action on interstate air pollution – a course of action that the courts largely upheld.[97]

The SIP process has also long relied on emissions inventories and air quality models to determine control strategies and demonstrate compliance. Emissions inventories, for example, have been critical in developing estimates of current air pollution and in identifying sources. Air quality models, in turn, have provided the basis for developing scenarios for future controls in order to demonstrate attainment with the various NAAQS.

All these tools have limits and shortcomings, some of which can have important consequences for the effectiveness of the NAAQS program.[98] Efforts to control ozone offer a cautionary tale in this respect. Until the early 1990s, efforts to comply with the ozone NAAQS focused primarily on controlling volatile organic compounds (VOCs) rather than NO_x, both of which are ozone precursors. This control strategy, however, was based on erroneous emissions inventories that had been systematically underestimating VOC emissions. At relatively low VOC to NO_x ratios, controlling VOCs is the best way to reduce ozone. At higher ratios, however, the preferred mitigation strategy shifts to NO_x control. When field data from the 1980s and 1990s revealed much higher emissions of VOCs (from mobile and

was "largely designed to monitor urban pollution levels and compliance with the National Ambient Air Quality Standards (NAAQS)"). The CAA requires states to establish air monitoring stations for the criteria pollutants. There are around 4,000 of these state and local air monitoring stations (SLAMS) distributed across the country based largely on the needs of state and local air pollution agencies to meet their SIP obligations. A subset of the SLAMS network (about 1,800 stations) is designated as national air monitoring stations (NAMS), which are typically located in urban and multisource areas. The 1990 amendments also required EPA, in partnership with state and local agencies, to carry out more extensive monitoring of ozone and its precursors in areas of persistent nonattainment. EPA responded by establishing a network of photochemical assessment monitoring stations (PAMS) in twenty-four urban areas. *See id* at 221–26 (discussing SLAMS, NAMS and PAMS).

96 *See* Thomas O. McGarity and Wendy E. Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, 33 ELR 10751 (2003) (reviewing thirty years of judicial challenges to EPA's use of models to support various regulations); National Research Council, Models in Regulatory Decision Making 76–79 (2007) (discussing legal challenges to EPA's use of models to support environmental regulations).

97 *See* Patton, *supra* note 43, at 10168 (discussing cases).

98 *See* National Research Council, Air Quality Management in the United States 113 (2004) ("Literature estimates for individual components of an air quality model – emissions, chemistry, transport, vertical exchange, deposition – typically indicate uncertainties of 15–30%, but when the supporting data sets are weak, the uncertainties can be significantly higher . . . Relying solely on the output of an air quality model to resolve emission-control issues or to demonstrate attainment of an air quality standard or objective is problematic."); *id.* at 99 ("The consequences of errors in emission inventories can be profound.").

biogenic sources) than was apparent from previous emissions inventories, it became clear that ozone mitigation needed to focus more on NO_x controls than on VOC controls.[99] It would take the better part of a decade for EPA to shift its overall approach, resulting in the NO_x SIP call in 1998, the Clean Air Interstate Rule (CAIR) and, finally, the Cross-State Air Pollution Rule (CSAPR), which was recently upheld by the Supreme Court in the *EME Homer Generation* case.[100]

This episode provides another reason why flexibility is so important to the NAAQS program. As tools for monitoring and modeling air quality improve, new problems and new aspects of old problems come into view. These new ways of seeing condition not only how such problems are understood but also how EPA and others think about the possibilities for response.[101] At the same time, when our ways of seeing particular problems are uneven, incomplete or faulty, large misallocations of resources can sometimes result.[102] Ongoing review, assessment and, where necessary, revision of the underlying monitoring and modeling infrastructure that supports the NAAQS are thus a critical part of the success of the program. Here again, the flexibility to make adjustments as tools improve and as the underlying science evolves is critical to the long-term success and durability of the program.

2.4 GOALS, DEADLINES AND LONG-TERM SIGNALING

The goal of the NAAQS program is deceptively simple: to reduce concentrations of criteria pollutants in the ambient air to levels that will protect public health and welfare. EPA sets the standards and regulates mobile sources, while the states are charged with implementing controls on stationary sources necessary to meet the federal standards. The Supreme Court held in 2001, as the DC Circuit previously held in 1978, that EPA may not consider costs in setting the NAAQS.[103] The statute

[99] *See* NATIONAL RESEARCH COUNCIL, AIR QUALITY MANAGEMENT IN THE UNITED STATES 107–8 (2004); NATIONAL RESEARCH COUNCIL, RETHINKING THE OZONE PROBLEM IN URBAN AND REGIONAL AIR POLLUTION (1991).

[100] *See* EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584 (2014) (discussing the various EPA rulemakings on interstate air pollution and upholding the Cross-State Air Pollution Rule).

[101] *See* William Boyd, *Ways of Seeing in Environmental Law: How Deforestation Became an Object of Climate Governance*, 37 ECOLOGY L.Q. 843, 898–915 (2010); William Boyd *Genealogies of Risk: Searching for Safety, 1930s–1970s*, 39 ECOLOGY L.Q. 895, 944–47 (2012).

[102] These issues can also emerge as important sources of conflict. Although often hidden from public view, the choices made about how and what to monitor, as well as the assumptions and protocols used in air quality modeling, can elicit intense scrutiny and opposition from the regulated community and other stakeholders. *See*, e.g., Art Fraas, John D. Graham & Jeff Holmstead, *EPA's New Source Review Program: Time for Reform?*, 47 ENVT'L L. REP. 10026 (2017) (criticizing EPA's current modeling assumptions and guidance as a component of NSR permitting and arguing for adoption of a probabilistic modeling approach).

[103] *See* Whitman v. American Trucking, 531 U.S. 457, 465 (2001) ("Section 109(b)(1) instructs the EPA to set primary ambient air quality standards 'the attainment and maintenance of which . . . are requisite to protect the public health' with 'an adequate margin of safety.' Were it not for the hundreds of pages of briefing respondents have submitted on the issue, one would have thought it fairly clear that this

thus requires that the EPA administrator make a policy judgment based on the scientific case contained in the criteria document and supporting analyses in determining the level at which the NAAQS for a particular criteria pollutant will protect public health "with an adequate margin of safety."[104] This is an ambitious, precautionary standard. Critics have argued that it puts EPA in a difficult (if not impossible) situation with respect to nonthreshold pollutants, requiring the Agency to set the NAAQS at zero if, in fact, it is going to protect public health with an adequate margin of safety. But there is no evidence in the legislative history that Congress intended for the "margin of safety" language to mean "zero risk," and EPA and the federal courts have consistently interpreted safety as "acceptable risk" in order to allow for more flexibility in determining the level at which to set the NAAQS.[105]

The NAAQS program thus provides a clear signal to the states and affected sources that the standards will be set at levels necessary to protect public health and welfare without consideration of technological or economic feasibility. To be sure, considerations of cost and feasibility do come into play in the implementation of the NAAQS (see below), and they are clearly visible in the Regulatory Impact Analyses (RIA) and Office of Information and Regulatory Affairs (OIRA) reviews of NAAQS rulemakings. At times, these cost considerations (and the associated politics) have intruded into the NAAQS process (e.g., 2011 OIRA letter to Lisa Jackson directing EPA to pull the revised ozone NAAQS[106]). But as a formal legal matter, EPA is barred from considering costs in setting the NAAQS.

The ambitious health-protective goals of the NAAQS have been tempered in some respects by adjusting attainment deadlines and by various provisions that allow for flexible implementation. As noted earlier, the initial 1970 version of the NAAQS program proved to be quite unrealistic with respect to the time it would take for states to comply with the NAAQS, leading to frustration on the part of some state agencies

text does not permit EPA to consider costs in setting the standards. The language, as one scholar has noted, 'is absolute'", (citations omitted.)) *See also* Lead Industries v. EPA, supra note 55. *But see* Livermore & Revesz, *Rethinking Health-Based Environmental Standards*, *supra* note 62 (arguing for a reinterpretation of *American Trucking* to allow for cost–benefit analysis to serve as a regulatory floor for setting the NAAQS, especially for nonthreshold criteria pollutants). For a brief response to Livermore and Revesz, *see* Gary Guzy, *Rethinking Rethinking Health-Based Environmental Standards and Cost-Benefit Analysis: A Solution in Search of a Problem?*, 46 ENVT'L L. REP. NEWS & ANAL. 10,681 (2016).

[104] Section 109.

[105] *See* Bachmann, *Will the Circle Be Unbroken*, *supra* note 2 at 667 (noting that there is no evidence that "margin of safety" meant zero risk for nonthreshold pollutants). *But see* NATIONAL RESEARCH COUNCIL, AIR QUALITY MANAGEMENT IN THE UNTED STATES 77–78, 87 (2004) (noting challenges to setting NAAQS based on "adequate margin of safety" language for nonthreshold pollutants). For a broader discussion of how safety was redefined as acceptable risk across multiple domains of US health, safety and environmental law in the 1970s and early 1980s, *see* William Boyd, *Genealogies of Risk*: *supra* note 101, 964–83.

[106] *See* Letter from Cass R. Sunstein, Administrator of OIRA, to Lisa Jackson, Administrator of EPA, dated September 2, 2011.

and gaming of the SIP process.[107] In response, Congress adjusted the attainment deadlines in the 1977 amendments. Moreover, in order to deal with the persistent and widespread nonattainment with the NAAQS for ozone, Congress established in the 1990 amendments a sequence of attainment dates based on an area's particular nonattainment classification, thereby providing a more flexible timetable for state and local agencies to deal with the problem.[108]

Notwithstanding the relaxation of attainment deadlines, the ongoing five-year review of the NAAQS combined with the requirement that EPA revise the standards as necessary have together established a set of general expectations about the overall direction of the program. In this context, EPA's NAAQS review process allows the Agency to start signaling to the states and affected sources well in advance of any final rule establishing a new standard. States and affected sources then have additional time to comply with the NAAQS after the new standard is finalized. This kind of long-term signaling combined with flexibility on timing has likely been an important source of the program's overall political durability, but it also begs the question about the overall efficacy of the program. How long will it take, in other words, to bring persistent areas of ozone nonattainment into attainment, and what does this say about the success of the program?

SIPs can also perform an important signaling function with respect to affected sources. By laying out an implementation framework and schedule that includes specific controls, the SIP process provides a forum for affected sources to develop their own compliance plans and to negotiate with state regulators. The courts have also held that SIPs can include emissions control requirements that are not technologically feasible under current conditions – that they can be "technology-forcing," which also sends a powerful signal to affected sources.[109]

2.5 COOPERATIVE FEDERALISM: THE SIP PROCESS

The NAAQS SIP process is one of the oldest and best examples of cooperative federalism in US environmental law. States are the primary implementers of the NAAQS and, historically, have enjoyed considerable flexibility in allocating emissions reductions across various sectors and sources.[110] In effect, the SIPs provide the

[107] National Research Council, Air Quality Management in the United States 129 (2004).

[108] *Id.* at 132.

[109] *See*, e.g., Union Electric Co. v. EPA, 427 U.S. 246, 265 (1976) (concluding that claims of economic and technological infeasibility cannot be considered by EPA in deciding whether to approve a SIP); *see also id.*, at 269 ("Technology forcing is a concept somewhat new to our national experience and it necessarily entails certain risks. But Congress considered those risks in passing the 1970 Amendments and decided that the dangers posed by uncontrolled air pollution made them worth taking.").

[110] As is the case in various other environmental statutes, the states can impose more stringent standards and controls than those required under the NAAQS (Train v. NRDC, 421 U.S. 60 (1975); Union Electric, *supra* note 108).

basic implementation framework for the NAAQS, linking the substantive standards established by EPA with state regulations and federal oversight and enforcement.

Under section 110 of the CAA, states are required to submit SIPs within three years of the establishment of a new NAAQS for one of the criteria pollutants. Tribes submit tribal implementation plans (TIPs). Each SIP (or TIP) must demonstrate (largely on the basis of modeling) how the various Air Quality Control Regions within the state (or reservation) will attain the NAAQS. The statute sets forth the general requirements for SIPs, including (1) an emissions inventory, (2) attainment demonstrations based on air quality models and other analyses, and (3) a description of emission control strategies and enforcement measures that will allow achievement of the required reductions.[111] SIPs are also required to include provisions that will prohibit emissions that will interfere with other "downwind" states' attainment or maintenance of the NAAQS.[112]

While states are charged with developing SIPs, the CAA establishes planning procedures regarding who should be involved in the process.[113] SIP planning must include state, regional and local government officials.[114] Preparation of the SIP is done by an organization certified by the state and must include state air pollution regulators, state transportation planning officials, metropolitan transportation planning officials and local elected officials.[115]

Once approved by EPA, SIPs are federally enforceable. As noted earlier, if EPA finds that a SIP is inadequate or that a state is delinquent in implementing its SIP, it can develop a FIP. The agency can also impose sanctions (loss of highway funds) on states that fail to carry out their responsibilities under the SIP process.

The SIP process was designed to be one of the most important sources of flexibility under the NAAQS program. Individual states and tribes would be allowed to determine in large part which sources they would control (and how) in order to attain and maintain the NAAQS within their respective Air Quality Control Regions. This flexibility, which derived from the CAA's commitment to cooperative federalism, was intended to contribute to the overall political durability of the program. Efforts by EPA to force the states to adopt specific measures in their SIPs have repeatedly been rejected by the courts.[116]

Starting with the 1977 amendments, however, Congress constrained some of the flexibility that states had historically enjoyed in the SIP process. The PSD and nonattainment programs, for example, required certain technology controls for

[111] 42 U.S.C § 7410(a)(2).

[112] This is known as the *good neighbor provision*. See 42 U.S.C. § 7410(a)(2)(D)(i). *See also* EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584, 1587 (2014).

[113] 42 U.S.C. § 7504(a).

[114] *Id.*

[115] *Id.*

[116] *See* Train v. NRDC, 421 U.S. 60 (1975); Virginia v. EPA, 108 F.3d 1397 (D.C. Cir. 1997). *See also* Michigan v. EPA, 213 F.3d 663, 686–87 (D.C. Cir. 2000) (discussing Train-Virginia federalism bar to EPA efforts to condition SIP approval on adoption of particular control measures).

specific sources depending on the attainment status of the various Air Quality Control Regions in the state. Likewise, the 1990 amendments provided for specific requirements and schedules depending on the severity of nonattainment for ozone, carbon monoxide and particulate matter.[117]

State flexibility in the SIP process has also been subject to additional requirements and controls to deal with the persistent and difficult issue of interstate air pollution. To be sure, some of this stemmed from EPA's inability or unwillingness to force meaningful consideration of interstate issues for many years. Although section 110(a)(2)(E) of the 1970 Act required SIPs to contain "adequate measures for intergovernmental cooperation, including measures necessary to ensure that emissions of air pollutants [inside the state] will not interfere with the attainment or maintenance" of the NAAQS in another state, EPA's implementing regulations minimized this requirement by calling for information exchange only. A pair of court challenges by the Natural Resources Defense Council (NRDC) arguing that these regulations were inadequate were rejected.[118] This created an opening for states to adopt policies allowing tall stacks and other dispersion techniques that would move air pollution out of their states in order to achieve compliance, creating more downwind pollution in the process.[119] By the time Congress stepped in to deal with this in 1977, more than a dozen states and hundreds of sources had taken advantage of the "tall stacks" loophole.[120]

And despite this effort by Congress to force more consideration of interstate pollution, EPA continued throughout the 1980s (and much of the 1990s) to avoid using the full extent of its SIP authority to force more attention by states to downwind pollution impacts. Congress thus stepped in again in the 1990 amendments with several provisions intended to further strengthen the SIP process and promote regional air planning and coordination, particularly with respect to ozone. The Ozone Transport Commission and the voluntary Ozone Transport Assessment Group both established important multistate and multistakeholder processes to fashion regional solutions to the ozone problem in the Northeast.[121] Among other things, these efforts directly influenced EPA's 1998 NO_x SIP call and laid the groundwork for the subsequent CAIR and CSAPR rulemakings. Here again,

[117] *See* 42 U.S.C. Ch. 85, subch. I, pt. D, subpts. 2–4. These provisions distinguish areas by their level of nonattainment and impose stricter measures with tailored deadlines for areas depending on the severity of nonattainment. Five categories apply for ozone: "marginal," "moderate," "serious," "severe," and "extreme." The CO and PM provisions include two categories: "moderate" and "serious."

[118] *See* NRDC v EPA, 483 F2d 690 (8th Cir. 1973); NRDC v. EPA, 494 F.2d 519 (2d Cir. 1974); *see also* Patton *supra* note 43.

[119] Revesz, *Federalism and Interstate Environmental Externalities*, *supra* note 7. *See also* Richard L. Revesz & Jack Lienke, Struggling for Air: Power Plants and the War on Coal 82–99 (2016) (discussing problem of tall stacks and downwind pollution).

[120] *See* Patton, *supra* note 43 at 10162.

[121] *See* Ann Carlson, *Iterative Federalism and Climate Change*, 103 N.W. Univ. L. Rev. 1097 (2009) (discussing OTC and OTAG).

though, the SIP process (and the statutory language of the good neighbor provision) has limited the effort to create robust multistate trading programs as a means for dealing with interstate pollution.

Needless to say, developing and revising SIPs takes considerable time and resources. The process has been criticized on various grounds, including charges that it is overly bureaucratic, focuses too heavily on attainment demonstrations, is limited to single pollutants and does not adequately consider interstate transport issues.[122] The SIP process has also long been a source of litigation between EPA and the states – something that will surely continue as states struggle with attainment of increasingly stringent NAAQS for pollutants such as ozone.[123] Despite these shortcomings and challenges, however, the SIP process, at least in its better moments, continues to provide an important space for states to tailor their air pollution control efforts based on their own priorities and to experiment with new ideas and approaches. As such, it is a good example of how flexible implementation can contribute to political durability.

2.6 FLEXIBLE IMPLEMENTATION

As discussed earlier, the NAAQS program was designed to combine ambitious health-based standards that would apply uniformly across the country with flexible state-led implementation. In the original 1970 version of the program, Congress intended that the SIP process would give states maximum flexibility in deciding how to allocate the emissions reductions necessary to achieve the NAAQS. While Congress came back in 1977 and again in 1990 with new provisions that constrained some of that flexibility, the basic model of cooperative federalism at the heart of the NAAQS program continues to provide the most important example of flexible implementation under the program. In effect, the SIP process gives states significant flexibility in determining *how* implementation will proceed and provides a forum for affected sources to seek flexibility with respect to their own compliance obligations.

Complementing the flexibility inherent in the SIP process, several other statutory provisions provide for flexibility with respect to the *timing* of implementation. These include, most obviously, the decisions by Congress to modify and relax compliance deadlines and to create specific compliance schedules that are tied to the current level of nonattainment for ozone, CO and PM. But they also include statutory provisions allowing for postponements of deadlines and variances from the normal

[122] *See* National Research Council, Air Quality Management in the United States, 128–32 (2004).

[123] *See*, e.g., Mississippi v. EPA, 744 F.3d 1334 (D.C. Cir., 2013) (addressing challenges to the 2008 ozone NAAQS); Findings of Failure to Submit State Implementation Plan Submittals for the 2008 Ozone National Ambient Air Quality Standards (NAAQS), 82 Fed. Reg. 58,118 at 58,120 (Dec. 11, 2017) (finding that New Jersey, Illinois and California had failed to meet various requirements in their SIPs for the 2008 ozone NAAQS). Various petitions have also been filed challenging the 2015 NAAQS for ozone.

SIP process as well as EPA's authority to waive compliance deadlines for certain stationary sources if sufficient control measures are unavailable and "the continued operation of such sources is essential . . . to the public health or welfare."[124]

EPA also enjoys some limited flexibility in discharging its responsibilities to establish and revise the NAAQS. The policy judgment at the heart of section 109, for example, provides for some discretion on the part of the EPA administrator in determining the precise concentration that will protect public health "with an adequate margin of safety." More recently, EPA efforts to use its authority under the SIP and good neighbor provisions to deal more effectively with interstate pollution can be seen as examples of flexible implementation. The 1997 joint rulemaking for ozone and $PM_{2.5}$, the NO_x SIP call, and the CAIR and CSAPR all demonstrate an effort on EPA's part to use its authority under the statute in more creative and flexible ways than it has in the past.

Finally, the White House has played an important, though limited, role in flexible implementation of the NAAQS program. The 1997 Presidential Implementation Memorandum on Ozone and PM NAAQS, for example, stressed the need for flexibility in implementation, the importance of regional approaches and the attractiveness of market-based approaches.[125] The memorandum provided guidelines for EPA to follow in implementing the new standards and strongly endorsed regional approaches "to respond to the fact that pollution travels hundreds of miles and crosses many State lines."[126] This provided important political support to EPA as it sought to use its existing authorities in more creative and flexible ways to fashion regional market-based approaches to controlling ozone and PM pollution, first with the NO_x SIP call and then with the CAIR and CSAPR rulemakings.

The 2011 letter from OIRA Director Cass Sunstein to EPA Administrator Lisa Jackson provides a different example of White House involvement in the NAAQS process – one directed at slowing down EPA in the context of the controversial revision of the 2008 ozone NAAQS.[127] In returning the rule to EPA and stating emphatically that the President "does not support finalizing the rule at this time," the White House flexed its political muscle to force EPA to adjust the timing of the ozone revision.[128] Regardless of one's views on the merits of this action, it does represent a rather dramatic example of the use of Presidential authority to inject additional flexibility into the NAAQS process. That said, it is not at all clear whether this contributed to the long-term political durability of the program, and it raises important questions about whether this sets any sort of precedent for the future.

[124] *See* section 110(f)(1), 84 Stat. 1683.
[125] *See* 62 Fed. Reg. 38,421 (1997).
[126] *Id.* at 38,421.
[127] *See* Letter from Cass R. Sunstein, Administrator of OIRA, to Lisa Jackson, Administrator of EPA, dated September 2, 2011.
[128] *Id.*

2.7 ENVIRONMENTAL PERFORMANCE

By any measure, the environmental performance of the NAAQS program has been impressive. From 1970 to 2015, aggregate national emissions of the six criteria pollutants declined by an average of 71 percent while the US population grew by 57 percent, gross domestic product (GDP) by 246 percent, vehicle miles traveled by 184 percent and energy consumption by 44 percent.[129] These emissions reductions have led to dramatic improvements in air quality. Between 1980 and 2015, national ambient concentrations declined by 99 percent for lead, 84 percent for carbon monoxide, 84 percent for sulfur dioxide, 60 percent for nitrogen dioxide and 32 percent for ozone. Fine-particle concentrations declined by 37 percent and coarse-particle concentrations by 36 percent between 2000, when trends data began for fine particles, and 2015[130] (see Figure 2.4).

With substantial improvements in air quality have come very significant public health benefits. As a result of reductions in $PM_{2.5}$ and ozone, for example, a 2011 EPA study on the benefits and costs of the CAA estimated that close to 240,000 premature deaths will have been avoided by 2020.[131] Unhealthy air days – a broad measure that combines PM and ozone concentrations into an air quality index – have declined continuously across the country since the index was first used in the early 2000s.[132] These improvements in air quality have resulted in the avoidance of hundreds of thousands of hospitalizations for asthma and other respiratory and cardiovascular ailments, as well as avoidance of millions of lost work and school days.[133] Likewise, as a result of the massive reduction in ambient concentrations of lead due to the phase-out of leaded gasoline under the CAA's fuels provisions and the NAAQS program, blood lead levels in the US population, notably children, have declined dramatically, leading to substantial reductions in cognitive impairment that comes from lead exposure.[134] Taken together, one estimate puts the public health benefits from improvements in air quality to 2020 as a result of the CAA at more than $2 trillion.[135]

[129] These figures come from the EPA Air Trends site, https://www.epa.gov/air-trends.

[130] *Id.*

[131] *See* U.S. EPA, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020 (2011). The vast majority of this comes from reductions in $PM_{2.5}$.

[132] EPA Air Trends, https://www.epa.gov/air-trends.

[133] U.S. EPA, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020 (2011).

[134] See Herbert L. Needham, *The Removal of Lead from Gasoline: Historical and Personal Reflections*, 84 ENVIRONMENTAL RESEARCH 20 (2000) (discussing removal of lead from gasoline in the United States and substantial reductions in children's blood lead levels that followed); Phillipe Grandjean & Philip J. Landrigan, *Developmental Neurotoxicity of Industrial Chemicals*, 368 LANCET 2167, 2169–70 (2006) ("A 90% reduction in blood-lead concentrations followed the termination of lead additives in gasoline."); Philippe Grandjean & Philip J. Landrigan, *Neurobehavioral Effects of Developmental Toxicity*, 13 LANCET NEUROL. 330, 335 (2014) (citing studies showing that the prevention of neurodevelopmental toxicity resulting from phaseout of lead in gasoline in the United States has generated economic benefits of $200 billion in each annual birth cohort since 1980, leading to "an aggregate benefit in the past 30 years of over $3 trillion").

[135] U.S. EPA, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020 (2011).

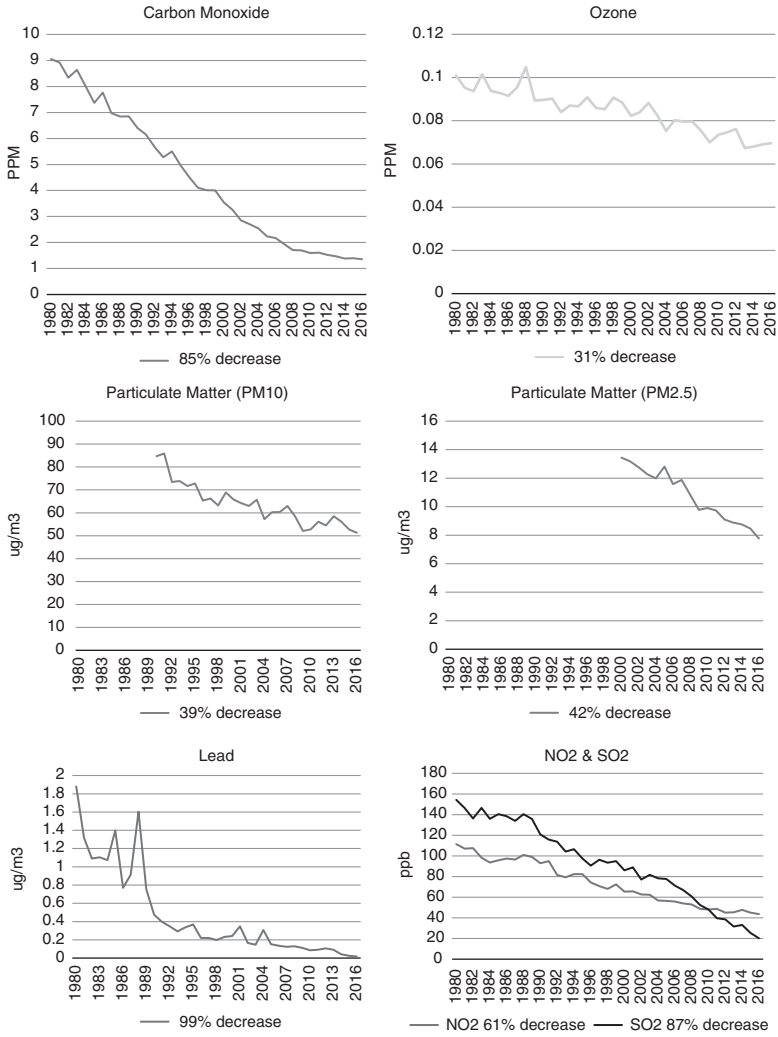

FIGURE 2.4 Progress in reducing criteria pollutants

Despite such remarkable success, however, there are still a number of areas around the country that continue to struggle with stubborn and persistent nonattainment issues, particularly for ozone.[136] Los Angeles, for example, may never be able to achieve attainment with the ozone NAAQS, raising important questions about the success of the program in delivering clean air to all Americans.

[136] Information on NAAQS nonattainment status across the United States by criteria pollutant is compiled by EPA in the so-called Green Book, available at https://www.epa.gov/green-book. For a map of areas in the United States that are in nonattainment for one or more of the NAAQS, *see* https://www3.epa.gov/airquality/greenbook/mapnpoll.html.

More generally, it is important to recognize that aggregate trends showing substantial progress in reducing ambient concentrations of criteria pollutants do not reveal the unevenness across and even within Air Quality Control Regions and the associated distributional impacts of poor air quality on specific populations. The techniques of measuring and monitoring air pollution, as well as the form of the standard itself (average concentrations over particular time periods), can also hide peak air pollution episodes over the course of a day, a month or even a season. And the existing air quality monitoring network often does not reveal local hot spots of high ambient air pollution.[137] Put simply, a nontrivial portion of the population of the United States continues to breathe unhealthy air, and far too many people continue to die or get sick as a result.

With new, more stringent standards for ozone and $PM_{2.5}$, moreover, the burdens on nonattainment areas will increase. This is particularly true for ozone, given that the most recent revision to the standard in 2015 is pushing up against background levels in some areas. All of which makes the distributional issues associated with the NAAQS program's impressive overall record of environmental performance increasingly important. Without question, the NAAQS program can rightly claim to be among the most (if not the most) successful major programs in US environmental law. But its work is still not finished, and the remaining improvements in air quality needed to meet the original 1970 goal that all areas of the country would be in attainment with all the NAAQS will likely be even harder to achieve than the progress already made. In the meantime, millions of Americans will continue to live in areas of the country with air quality that still does not protect public health with an adequate margin of safety.

2.8 ECONOMIC IMPACTS

Although the benefits of the NAAQS program far outweigh the costs, the program is expensive with widespread impacts across multiple economic sectors.[138] To take one recent example, the 2015 revision of the ozone NAAQS, which reduced the allowable concentration of ozone in the ambient air by 0.05 ppm (from 0.075 to 0.070 ppm) was projected to result in compliance costs ranging from $12 billion to $20 billion.[139] Every time a NAAQS is revised, each state must submit a new SIP

[137] *See* JOHN WARGO, GREEN INTELLIGENCE: CREATING ENVIRONMENTS THAT PROTECT HUMAN HEALTH 207–40 (2009) (discussing problems of existing air quality monitoring and averaging). *See also* Ann Carlson, *The Clean Air Act's Blind Spot: Microclimates and Hotspot Pollution*, 65 UCLA L. REV. 1036 (2018).

[138] Various cost-benefit analyses of the program confirm very large net benefits. U.S. EPA, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020 (2011) (finding that central benefits estimate exceeds costs by a factor of more than 30:1; high benefits estimate exceeds costs by 90:1; low benefits estimate exceeds costs by 3:1).

[139] *See* SUMMARY OF THE UPDATED REGULATORY IMPACT ANALYSIS (RIA) FOR THE RECONSIDERATION OF THE 2008 OZONE NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS) at S1–4 (indicating annual costs ranging from $12 billion to $20 billion as a result of change in ozone standard from 0.075 to 0.070 ppm).

that includes provisions relating to the many and varied sources of the pollutant in question. More stringent standards can also push air quality control regions into nonattainment (or a more serious category of nonattainment), which, in turn, triggers additional controls and requirements for sources of emissions. All of this can be costly. The new 2015 ozone standard, for example, is expected to push some Air Quality Control Regions from attainment into nonattainment while raising the severity of nonattainment for a number areas already out of attainment.[140] Given that the new ozone standards are starting to push up against background levels in some areas (e.g., the Colorado Front Range), the costs imposed on these areas in terms of foregone economic activity and jobs will likely increase.

Congress, of course, has long been aware that a program built around health-based ambient environmental standards has significant economic impacts. The 1967 Air Quality Act, for example, called for a study on economic impacts,[141] and the 1977 and 1990 amendments both mandated studies looking at the costs and benefits of the CAA as a whole.[142] As noted earlier, the general conclusion that results from these studies (and others) is that the benefits of the CAA, and the NAAQS program in particular, have far outweighed the costs.

In contrast to other major regulatory efforts under the CAA, which can impose large costs on a specific sector or even specific facilities within a sector (see, e.g., the Mercury Air Toxics Standards or the Clean Power Plan), the costs associated with the NAAQS program (and with revisions to individual NAAQS) are often more diffuse, are filtered through many different SIPs and kick in over an extended time frame. This likely has an important impact on the political economy of the program that may contribute to its durability. Opposition is less focused and less intense but potentially more widespread.

2.9 POLITICAL ECONOMY, DURABILITY AND FLEXIBILITY

The NAAQS program has proven to be highly durable since it was established in 1970. From a public choice perspective, this may seem odd given a diffuse class of regulatory beneficiaries (the public at large), the fact that the most important beneficiaries (children and future generations) are not exactly top of mind for elected officials and the large number of affected sources. Although the NAAQS program would almost certainly not enjoy the widespread bipartisan support today

[140] EPA completed the designations for attainment and nonattainment for the 2015 ozone NAAQS in the spring and summer of 2018. See EPA, Air Quality Designations for Ozone, available at https://www.epa.gov/ozone-designations.

[141] The Air Quality Act of 1967 called for "a detailed estimate of the cost of carrying out the provisions of this Act; a comprehensive study of the cost of program implementation by affected units of government; and a comprehensive study of the economic impact of air quality standards on the Nation's industries, communities, and other contributing sources of pollution." Section 2, 81 Stat. 505.

[142] *See*, e.g., U.S. EPA, The Benefits and Costs of the Clean Air Act from 1990 to 2020 (2011); U.S. EPA, The Benefits and Costs of the Clean Air Act, 1970 to 1990 (1997).

that it benefited from in 1970 and again in 1977 and 1990, the program has worked well enough and long enough to give it a certain amount of staying power that makes it hard to undo even if it has outlived the bipartisan support that produced it. Put another way, the continued success of the program, imperfect as it is, may be one of the most important components of its overall political durability. The real and tangible nature of the benefits of the NAAQS program – improved air quality and avoided premature deaths – make it hard to attack; few politicians want to run against clean air. And because the costs are often spread across many different entities, accrue over extended time frames and are buried in many different SIPs, they are in some ways less likely to provide a basis for focused opposition.

The program has also benefited from the fact that it was able to mature over a two-decade period (1970–90) marked by active engagement from Congress, EPA and the federal courts. This allowed for important statutory adjustments to the program as it evolved and confronted new problems, creating a set of expectations with respect to its day-to-day workings. In the process, the NAAQS reached deep into the organizational and administrative capacities of the states, mobilizing substantial state resources in the fight against air pollution. And all the while, citizen suits and public participation kept the pressure on and forced agency action – even and especially in cases that were politically fraught.

As this chapter has demonstrated, specific design features of the program have also contributed to its durability. Credible goal setting combined with a clear signal that the NAAQS will be reviewed every five years and revised as appropriate has created a clear set of expectations about the NAAQS among the states and affected sources. Everyone knows that the wheels are turning – that the program is subject to a continuous ratchet. Moreover, EPA's efforts to develop a robust and transparent set of internal procedures for the NAAQS review process, combined with independent scientific review and layers of public comment and participation, have allowed for long-term signaling and vetting of proposed changes well before any final rules are issued.[143] Finally, the provisions allowing for citizen suits and public participation have created an additional check on the program, leading to court-imposed deadlines and schedules for EPA action and providing important political cover for the agency to move forward on controversial rulemakings.

A large part of the success of the program also derives from the fact that it was designed to be flexible. This is perhaps most apparent in the requirement that the

[143] *See* Fisher et al., *Rethinking Judicial Review of Expert Agencies*, *supra* note 3 at 1689–90 ("Because the air quality of the entire nation is riding on the [NAAQS] (as well as the compliance requirements for the millions of sources of pollution), a diverse set of interest groups closely follows EPA's NAAQS process and participates vigorously in it."). *See also* Croley, Regulation and the Public Interests, *supra* note 68 at chap. 9 (describing the robust administrative process followed by EPA, marked by extensive external peer review and layers of public comment, combined with a commitment to flexibility on the timing of implementation, as critical in allowing the controversial 1997 ozone and $PM_{2.5}$ rules to survive in the face of strong opposition from industry, state and local governments and Congress).

NAAQS be reviewed every five years and revised as appropriate to take account of new scientific information. But flexibility is also built into the program at multiple levels. The policy judgments at the heart of section 109's standard-setting exercise, the SIP process, adjustments to deadlines and compliance schedules, creative use of existing authorities as a basis for EPA rulemakings and targeted White House interventions are all important examples of flexibility.

To be sure, there are limits to this flexibility, and the program continues to struggle with the original goal of attaining all the NAAQS across the entire country. Substantial numbers of people continue to live in areas that are out of attainment for at least one of the NAAQS. EPA's long-standing difficulties in creating a robust trading program under the NAAQS program to deal with regional air pollution problems have stemmed in large part from the limits of the existing statutory language and Congress's inability or unwillingness to further revise the program. Similarly, the traditional single-pollutant approach of the NAAQS and the single-state approach of the SIP process have further blocked the development of regional multipollutant approaches that might be more effective and efficient.[144]

Going forward, it seems unlikely that the NAAQS program will be dismantled any time soon, much less that it will somehow complete its work in protecting public health. It is like a machine that continues on under its own power, and it will surely continue to deliver major public health benefits for years to come. But whether it will be able to fully live up to its purpose and potential – to fully achieve the ambitious goals of the program as established almost a half century ago – will likely depend on new statutory adjustments and modifications. To state the obvious, this seems highly unlikely in the current political environment, and of course, there is always a risk that Congress could do long-term damage to the program if it were ever to reengage. Thus, while the NAAQS program has struggled over the last twenty-five years in the absence of robust engagement and support from Congress, it seems that EPA and the courts (and the public at large) will have to continue to find ways, at least for the foreseeable future, to work with the program we have and to continue adapting it to deal with new and persistent problems.

2.10 CONCLUSIONS: LESSONS FOR ENERGY AND CLIMATE POLICY

No policy is perfect, and few work as intended. Major government programs such as the NAAQS are always works in progress – complicated political undertakings crafted under a particular set of circumstances and legal constraints, informed by particular understandings of problems and based on a particular coalition of supporters. If they are to survive beyond the conditions of their making, such programs must be able to evolve and adapt to new circumstances, new understandings and

[144] *See* National Research Council, Air Quality Management in the United States 271 (2004) (discussing the importance of regional multipollutant approaches to deal with ozone, PM and regional haze).

new political landscapes. Doing that while holding onto their core principles and continuing to deliver on their original objectives is a sure sign of durability.[145] Viewed in this light, the NAAQS program has performed admirably over the last half century. In the process, it has generated a set of experiences that hold important lessons for future efforts to craft policies that successfully combine durability and flexibility in an effort to deal with long-lived problems such as global climate change.

As this chapter and others have demonstrated, there are specific design choices tied to particular mechanisms, instruments and authorities that can help to strike the right balance between flexibility and durability and allow a program to survive over extended time periods.[146] Core structural features of the NAAQS program that would seem to be relevant considerations in an effort to craft energy and climate policy include the five-year NAAQS review, the role of independent scientific evaluation as part of the NAAQS process, the model of cooperative federalism and the flexibility of the SIP process and citizen suits. In addition, EPA's efforts to use its authority under the SIP process and the good neighbor provisions to deal with regional transport issues are an example of the ways in which broad, even if long-dormant, statutory provisions can be mobilized to fashion responses to new and persistent problems.

Administrative process has also been a critical part of the success of the NAAQS program. EPA's efforts to develop and refine its own internal process for NAAQS review and revision – an exercise that played out over many years – has resulted in a robust science-based approach to the NAAQS that allows for multiple layers of scientific review (formal and informal), extensive public participation and careful vetting of proposed revisions well before any formal proposals are made. This has not only strengthened the proposed revisions once they are made but also has provided an important signal to states and the regulated community regarding the content of any proposed revisions. And it has given comfort to the federal courts in their review of EPA's efforts, providing strong evidence that the Agency has more than satisfied the requirements of reasoned decision making. These commitments to and elaborations of process are not outcomes or features of the program that can be reduced to a simple set of design choices. Rather, they look more like organic, emergent properties of the program that took considerable time to develop based on years of trial and error.

To that end, it is important to recognize that durability and flexibility are about more than a set of design choices. They cannot be reduced to a recipe that will guide future policy designs. There is no single portfolio of instruments and authorities that

[145] *See* Chapter 6. Obviously, some policies are politically durable, even while they fail to deliver on their initial objectives.

[146] *See* Ann Carlson & Robert W. Fri, *Designing a Durable Energy Policy*, 142 DAEDALUS 119 (2013). *See also* Richard J. Lazarus, *Super Wicked Problems and Climate Change: Restraining the Present to Liberate the Future*, 94 CORNELL L. REV. 1153 (2009).

can be plugged in and optimized for the next set of challenges. Put another way, policy instruments and mechanisms are not widgets, even though it is sometimes helpful to think of them as such. They don't always work as intended when we transplant them from one context to another, something we need to recognize as we set forth on the truly daunting task of trying to design energy and climate policy for the next half century.

It is a mistake, therefore, to see a complex program such as the NAAQS as simply a collection of rules, instruments, actors and authorities from which we can draw lessons regarding the elements of flexibility and durability. The program is more than the sum of its parts, and any effort to summarize the key features of the NAAQS program that have allowed it to be flexible and durable needs to be complemented with an effort to understand the program as a whole and over time – how it has evolved and taken on new features, how it has developed new and thicker connections (internal and external) across various domains and constituencies and how it has responded to political and legal challenges.

On this broader register, one of the most important reasons why the NAAQS program has been able to survive (and even thrive) over the last half century is that it was able to mature over its first two decades with active involvement by all three branches of government, particularly Congress. Many of the most important features of the NAAQS program were added and subsequently revised and strengthened by Congress in the 1977 and 1990 amendments, including the five-year mandatory review, the Clean Air Science Advisory Committee, the PSD and nonattainment programs and new and stronger provisions to deal with regional transport issues, among others. Had Congress not stepped back in to revise the program, we can say with some confidence that it would not be nearly as effective as it is today. In the absence of future statutory updates, moreover, the NAAQS program will likely continue to struggle with persistent problems such as regional, interstate air pollution.

It may be that federal climate and energy policy, assuming that it is even possible to get comprehensive legislation in the future, will not have the luxury of ongoing constructive engagement by Congress. If true, this may lead to different design choices at the outset. That is, if we assume that Congress will likely not be available to come back and make important adjustments as it did with the NAAQS program, the initial choices in designing the program may need to be different. This might argue, for example, for more administrative discretion and flexibility in adjusting the program. But there are obvious limits to how far this approach can go.

History matters in at least one other respect as well. With the original NAAQS program, Congress was not writing on a completely blank slate, but it did not face major constraints in terms of preexisting regulatory regimes (at the state or federal level), and it was drafting the new legislation in the midst of an expansive bipartisan lawmaking moment. With the exception of California and a few other nascent state efforts, there was no extensive record of air pollution regulation on which to draw.

Prior federal efforts had been largely limited to trying to assist and nudge the states to act, and almost everyone recognized that strong federal action was needed.

With greenhouse gases, the context will surely be quite different. Bipartisan majorities seem to be a thing of the increasingly distant past. If and when federal legislation starts to take shape, moreover, it will have to confront a much more complicated landscape of preexisting efforts and regulatory models given ongoing efforts by states to move forward with all manner of energy and climate policies. With much of the focus on the electricity sector, any such effort will also have to contend with the complex regulatory framework for electricity – one that involves a different structure of federalism, a different set of state regulatory agencies and a more diverse set of regulatory models across the country. Long-standing preferences for market-based approaches will also likely exert an important influence on instrument choice and program design.

None of this is intended to suggest that the experience of the NAAQS program does not hold important lessons for future efforts to craft energy and climate policy. As this chapter has demonstrated, there are many valuable lessons in the NAAQS experience – for climate policy and beyond. But perhaps one of the most important lessons is that we need to be careful about drawing too many firm lessons about individual design choices and mechanisms; that we need to recognize that it is the interactions between history, structure and process that ultimately shape these programs and provide the conditions for their success.

"Solution-Focused Risk Assessment": A Proposal for The Fusion of Environmental Analysis and Action

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Abstract:

Rethinking risk assessment as a method for helping to solve environmental problems, rather than (merely) understanding environmental hazards, may provide three major classes of benefits over the status quo. First, it can help break the endless cycle of analysis: when the goal is to know enough to decide, rather than to know everything, natural stopping points emerge. Secondly, it can lead to more true decisions about how to achieve risk reduction, rather than mere pronouncements about how much risk reduction would be optimal. As much as agencies rightly value performance-oriented interventions, setting a permissible exposure limit or a national ambient air quality standard is often more a conclusion about what level of risk would be acceptable than any kind of guarantee that such a level will be achieved, let alone a decision about which actual behaviors will change and how. Third, it can promote expansive thought about optimal decisions, ones that resolve multiple risks simultaneously, avoid needless and tragic risk-risk tradeoffs, and involve affected stakeholders in debating what should be done. Arguably, the longer the disembodied analysis of risk information is allowed to proceed before solutions are proposed and evaluated, the more likely it is that the "problem" will be defined in a way that constrains the free-wheeling discussion of solutions, to the detriment of human health, the environment, and the economy. Therefore, I propose a new "solution-focused risk assessment" paradigm, in which the tentative arraying of control decisions would *precede* and guide the assessment of exposures, potencies, and risks.

Keywords: risk management, standard-setting, decision theory, public involvement, technology options

1. Introduction:

We have steadily allowed the analysis of risks to health, safety, and the environment to drift apart—conceptually, bureaucratically, functionally—from the actions we take (or fail to take) to reduce these risks. It is time, this ambitious proposal asserts, to repudiate both of the extremes—headstrong actions uninformed by careful analysis, or endless analysis leading only to more understanding rather than to any tangible benefits—in favor of a new paradigm, one in which scientific and economic knowledge is harnessed in service of identifying reliable, creative, and equitable solutions to health, safety, and environmental problems.

To assert that we need to balance the resources devoted to dissecting problems and the resources devoted to implementing beneficial policies may seem trite, but I will argue that the steady rise of quantitative risk assessment (QRA) and cost-benefit analysis (CBA) – two developments I otherwise enthusiastically welcome– has crowded out improvements in how we solve problems, and has even begun to lull us into a false sense that we are doing *anything* to improve health and the environment. This was not an inevitable consequence of more rigorous analysis, and it therefore can be reversed without compromising that rigor by one iota.

In organized attempts to protect public health and the environment, the relationship between analysis and action is the interplay of risk assessment and risk management, and hence the interactions among risk assessors and decision-makers, who jockey both on behalf of their disciplines (science and economics, law and politics, respectively) and as individuals seeking influence. In addition to the amount of effort devoted to either assessment or management, however, the sequencing and content of the interactions is of paramount importance. This proposal seeks not only to focus relatively more attention on risk management (by making risk assessment directly relevant to identifying sound decisions), *but to change the nature of the questions risk assessors are directed to answer.* In a sense (see Section 2 below), this reverses the process first

codified in the 1983 "Red Book"[1], in which assessors study problems and managers may then use this information to develop and choose among alternative control strategies, into one in which a tentative set of alternatives come first and the analyses explore how these alternative decisions would impel changes in risk (and cost).[1]

This reversal would place risk assessors into the same common-sense relationship that experts and other purveyors of information have always had with those who seek their counsel in everyday life. The mundane utterance that "I've got a problem..." is commonly an overture to "... and I don't know what to do about it." Only in the psychiatrist's office, and perhaps in the environmental, health, and safety regulatory agencies, is it instead an overture to "... and I don't know how to think about it." As a risk assessor, I know that the expertise my colleagues bring can help decision-makers think, but as a citizen, I wonder if instead that expertise should help them decide what to do. Somehow, our environmental protection apparatus has evolved to the point where our best minds are occupied helping society think about risks, not helping society reduce risks expeditiously and efficiently.

This proposal is both, and equally, aimed at improving risk management and risk assessment – but rather than adding any major ideas to the litany of admirable technical improvements to risk assessment offered by many others [2-5], I aspire to increase the usefulness of the analyses and, perhaps selfishly, even to make the assessors' jobs more interesting. *We assessors can answer narrow, obscure, and deflating questions well, but we can also answer broad, momentous, even lofty questions well, if we are empowered*

[1] Much has been written (see especially the entire special issue in August 2003 of *Human and Ecological Risk Assessment*) about whether the current conception of the desired risk assessment/risk management relationship actually originated with the Red Book committee, or arose through extrapolation beyond what the "mis-read" book actually said. Through discussions with many of the original committee members (and through service on the two NAS panels convened circa 1994 and 2006 to re-examine these issues), I have come to believe that the Red Book committee did not oppose the notion of a symbiotic and iterative relationship between risk managers and risk assessors, so long as the functions were kept "conceptually separate." However, by concentrating on the landmark four-step process map for how risk assessment could best be carried out – and by omitting any detail about what kinds of questions assessors should be pursuing – the Red Book did contribute greatly to the impression that risk assessment should "hand off the ball" to risk management, rather than vice versa. In any event, when I refer to the "Red Book paradigm," I intend this to mean how the recommendations were generally heard, not necessarily what they authors may have meant.

(or assert the power) to consider them. With respect to improving risk management, I start from the view, firmly rooted in consequentialist ethics, that streams of harms (to health, safety, the environment, or to wealth and economic growth) and benefits (to the same) constantly flow from our actions and from our failures to act. Therefore, every act we fail to take that would increase benefits net of harms[2] – or every act we take that fails to do as well on this score as a feasible alternative would – may be a defeat. This proposal aspires not merely to help us declare more missions accomplished, but to accomplish them.

2. Summary of Proposal:

Solution-focused risk assessment (SFRA), as I define it, *must* change the timing of when risk assessors consider risk management solutions, and *may* change the nature of the solutions considered. Without the "mandatory" process change, there is no SFRA, but it is possible to reject the "optional" rethinking of the kinds of risk management options we contemplate and still transform the paradigm. Therefore, I will occaisionally refer to the more ambitious "SFRA 2.0" when discussing the pros and cons of changing both the "when" and the "what" to a solution-focused approach.

The most basic definition of any form of SFRA is that it occurs when alternative risk management pathways are arrayed before detailed scientific analyses of exposures, potencies and risks begin – in order that these analyses can focus on the risks (and costs) of specific actions. Figure 1 shows simplified process maps both for the current (traditional) paradigm and for SFRA. I acknowledge that various agencies have added all manner of "bells and whistles" to the 1983 Red Book diagram in which the four steps of risk assessment precede risk management, but Figure 1 remains faithful to much of present-day decision-making. In particular, EPA has come to rely more and more of late on a "damage function approach"—which maps "emissions to concentrations to exposure to effects to benefits." This, however, only adds detail to the same basic logic: risk

[2] By this I do not necessarily mean the simple measure of [total benefit minus total cost], but preferably estimates of social benefit and cost that give special weight to individuals disproportionately harmed either by the prevailing risks or by the costs of actions to reduce them.

assessment culminates when it provides a way to convert changes in emissions (or concentrations) to changes in benefit.

Neither in traditional nor solution-focused assessment should (or do) detailed risk assessments snowball on their own absent a "signal of harm" (generally, adverse findings from one or more bioassays or epidemiologic investigations). In either case, reliable conclusions that there is no problem – for example, that human exposures are non-existent or negligible, and/or that the signal of harm was a false positive – can and should end the exercise. Risk management is not about fine-tuning solutions to trivial problems, and nothing about SFRA encourages such wasted effort. There may also be situations in which the problems are clearly non-trivial but no conceivable risk-reduction options exist (this may tend to occur, for example, with naturally-occurring contaminants ubiquitous in soil or other environmental media); here too further efforts to analyze would be wasteful.

However, in all other kinds of cases—where we analyze risks under the reasonable expectation that there exist various optimal, sensible (but sub-optimal), ineffectual, and perverse (net-risk-increasing) ways to reduce them—I assert that there can be enormous differences between the outcomes of an assessment-first process and a solution-focused process.

Consider the likely results of a traditional versus a solution-focused approach applied to the very basic task of controlling a particular substance present in ambient or workplace air. At EPA, both the National Ambient Air Quality Standards (NAAQS) process for criteria air pollutants and the residual risk process for toxic/carcinogenic air pollutants[3] embody the assessment-first approach: risk assessors work to establish an ambient concentration that either (in the former case) is "requisite to protect the public health... allowing an ample margin of safety," or (in the latter case) would assure that "the individual most exposed to emissions from a source [of a given substance]" does not

[3] I will return to the toxic air pollutants example in Section 4 below, as I recognize that Congress in the Clean Air Act Amendments of 1990 also established a technology-based process to precede the residual risk phase that EPA is now undertaking.

face a lifetime excess cancer risk greater than 10^{-6}. At OSHA, risk assessors work to establish an occupational exposure concentration (the Permissible Exposure Limit, or PEL) that comports with the 1980 Supreme Court decision in the *Benzene* case [(6)] (i.e., does not reduce lifetime excess fatality risk beyond the boundary of "insignificance," which the Court helpfully said falls somewhere between 10^{-3} and 10^{-9}), although here an assessment of economic and technological feasibility must accompany the risk assessment and is often the limiting factor in constraining the PEL[4] [(7)].

These exercises can yield extremely precise results, a precision that is not necessarily false or overconfident. As long as risk assessors realize that any statement about the relationship between concentration (or exposure) and risk can only be properly interpreted as correct in "three dimensions" [5], the NAAQS or the residual-risk concentration or the PEL can encapsulate all the scientific and economic (if applicable) information needed to serve its purpose of demarcating acceptable risk (or a risk level that justifies the costs of attainment)[(8)].

But doing the assessment is not at all the same as reducing the risk. Sometimes we *pretend* that the assessment sets the table for the management of risk, when in fact we do little or nothing to turn what is *per se* nothing more than a pronouncement – "*if* the concentration of substance X in ambient air falls below the NAAQS, the ample margin of safety will have been provided," or "*if* workers breathe substance Y at less than the PEL, their risk will be acceptably small" – into actions that can move us to, or closer to, the desired state of affairs.

This grim verdict is not merely a pessimistic appraisal of the vagaries of separating regulatory enforcement from goal-setting. I appreciate that (for example) Congress intended the NAAQS process to bifurcate, with a pronouncement about what concentration is desirable at the national level totally separate from the subsequent

[4] Note that because OSHA generally sets one limit for a substance across all industries, there is no attempt to consider whether the PEL requires "best available technology" to achieve—only that in one or more sub-sectors the PEL could be no lower without going beyond what is economically feasible.

[5] That is, the risk at a given exposure is a particular estimator from a probability distribution of uncertainty in risk, and it applies to a person at a particular point on a distribution of interindividual variability.

approval of State Implementation Plans that specify how each state will strive to attain the desired concentration. I also appreciate that failure to enforce (which can involve insufficient efforts to find violators, inefficient targeting of those inspection resources that are deployed, insufficient penalties to deter repeated or similar conduct, insufficient follow-through to verify abatement, and other lapses) is distinct from the failure to choose a sensible course of action. I simply observe that there are some fundamental, though remediable, deficiencies with the very idea of setting risk-based goals:

- We may forget to ever move beyond articulating the goal, towards furthering the goal! I worry that even the use of the term "decision" to announce the culmination of the limit-setting step of processes like the NAAQS and PELs (for example, EPA [9] explained in 2008 that "the Administrator has *decided* to revised the level of the primary 8-hour O3 standard to 0.075 ppm") (emphasis added) puts us on a slope towards believing that intoning a number is in any way tantamount to "deciding" something.

- *Most "risk-based" goals are in fact exposure-based goals*, with an implicit but perhaps grossly flawed equation made between exposure reduction and risk reduction. Even if every establishment that had a workplace concentration above a new OSHA PEL immediately ended all excursions above that concentration, worker risk might rise rather than fall, if the compliance behavior entailed substituting a more toxic substance for the regulated one. The growing literature on "risk-risk trade-offs" [10-14] attests to the complexity of risk management and to the ease with which good intentions can produce untoward results.[6]

- Most fundamentally, the ways we ultimately manage risk will likely differ depending on whether we set the goal first and subsequently think about the best way(s) to achieve it, or instead set our sights immediately upon trying to

[6] In a forthcoming paper expanding on an SRA presentation [15], I attempt to make the case that many of the most publicized "trade-offs" were in fact either concocted by the regulated industry to deter agency action (and were never plausible responses to the regulation), or were more properly interpreted as "wake-up calls" to find cost-effective ways to control both the primary and the offsetting risk. Nevertheless, I believe many legitimate trade-offs do exist and should be accounted for in policy.

find the best way(s) to maximize net benefit (or achieve "acceptable risk," or any other endpoint dictated by law or policy). *A major aim of this article will be to argue that not only will a "solution focus" produce different results, but superior results to the traditional paradigm.*

For all three reasons – the traditional process can end with no risk-reduction actions at all, with actions that increase net risk, or actions that are less efficient than otherwise attainable – a decision process that thinks its way from solutions to problems, rather than from problems to solutions, may be well worth adopting. Consider two stylized examples of a "solution-focused" process, one from outside and one from inside the environmental, health, and safety realm:

2.1 A lonely 20-year-old college student wants to find a compatible girlfriend for a long-term relationship. Along each of several dimensions that vary greatly among women his age (e.g., physical beauty, intelligence), his preferences are for more rather than less—but he also believes that the odds he will be able to strike up a conversation and ultimately sustain a relationship are less favorable the more desirable the potential companion is. He can certainly try to "solve" this "risk/benefit" problem by estimating the point where the properly-weighted utility function crosses the probability-of-success function; such an exercise would provide him with the goal and an *abstract* guide to what to do (don't approach women substantially more or less desirable than the "best estimate" of the most desirable person with whom he stands a chance). He could instead tackle the situation by clearing his mind of the abstract ideal and focusing on the attributes of women he actually knows and could approach. Although the former process has the virtue of keeping an infinite number of possible outcomes in play, the latter strategy is of course much more practical, and I would argue is how we intuitively approach personal decision problems – by evaluating choices, not by dissecting the problem in a vacuum and then trying to map reality onto the abstract conclusion.

2.2 After 15 years of drafting and redrafting, a federal agency synthesizes all the toxicologic and epidemiologic evidence about the cancer and non-cancer effects of

> 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), and recommends an Acceptable Daily Intake (ADI) in pg/kg/day. A National Academy of Sciences committee then rank-orders various broad anthropogenic sources of TCDD (e.g., coal combustion, pulp and paper effluent) by the fraction of total environmental loading they contribute, and various agencies set priorities among the sources within their purview. Together, their goal is to steadily reduce entry of TCDD into the environment until everyone's uptake falls below the ADI. But suppose instead that early into the scientific assessment phase, EPA and FDA collaborated to examine the various products available to filter coffee (similarly, to brew hot tea) in residential and commercial use – the most common of which rely on chlorine-bleached paper and add trace amounts of TCDD to the diets of tens of millions of Americans. Other means exist to bleach coffee filters white, unbleached paper filters or metal mesh filters could be produced, and some methods do not rely on mechanical filtration at all. Each alternative has implications for the price, taste, and risk level of the finished beverage, and these factors can be evaluated comparatively in a multi-attribute decision-making framework; the results could drive policies ranging from information disclosure to tax incentives to subsidized R&D to outright bans on products deemed needlessly risky. The steps taken would not "solve the TCDD problem," but might solve the portion of it attributable to these particular sources.

So with reference to Figure 1, the key step that makes a decision process "solution-focused" is the second one, which is really the first step in the process where risk assessment and/or risk management begins. *SFRA requires an initial brief moratorium on conducting free-form exposure and dose-response assessment until the risk managers and assessors discuss the following sorts of questions:* What are the sources of this potential harm? How can the social purposes that the sources serve be fulfilled with less risk to human health or the environment? And how can we quantify the implications of each possible risk-reducing intervention on risk, cost, equity, offsetting risk, and any other factor we should consider before choosing whether and how to intervene? The same dose-response, exposure, cost, and other information will likely be needed to reach the decision point under both paradigms, but in the solution-focused process, that

information will help discriminate among feasible alternatives, rather than be packaged first and only later re-opened in the (vain?) hope that it will help guide action.

As I will emphasize later, the first key step of the alternative process is not "problem formulation," but "solution formulation." I will argue that while it is certainly smarter to think creatively about what the real problem is (the sources of exposure, not the substance per se), the highest use of risk-based decision-making is to manage opportunities, not simply to manage risks.

The two examples above also place into sharp relief the major differences between problem-centered and solution-centered processes:

- The former sets up an expanding "work increases to exhaust the allotted time" dynamic, whereas the latter already starts from an expansive view and narrows the analysts' sights to converge upon a conclusion. When the goal is to understand the problem, the finish line can recede faster than the movement toward it, whereas when the goal is to identify the best available solution, the analysis has a natural and hard-to-miss stopping point – when further analytic refinement would not change the decision.[7]

- A series of solutions to components of a problem can provide incremental benefits, and perhaps can ameliorate the entire problem, without having to wait for full understanding. This is an especially dramatic contrast between the two approaches when we misconstrue the problem as a single issue when in fact is an agglomeration of issues (arguably, we don't face a "dioxin problem," but a series of dioxin exposures that each form part of an industrial policy problem or an environmental design problem).

- Most importantly, real choices are all about navigating a sea of constraints and opportunities, and the two-step process (assessors opine about a desirable abstract goal, leaving managers to puzzle out a way to achieve

[7] More precisely, value of information theory (see Section 5 below) specifies that when the cost (in resources and/or delay) of obtaining additional information exceeds the expected reduction in the [probability times consequence] of making a sub-optimal decision in the absence of that information, the additional analysis should not be pursued.

> it—or to not achieve it) neither exploits real opportunities nor is tethered to real constraints. This applies to environmental risk management in part because we can measure and model both risks and costs as continuous variables, but the real-world interventions we might undertake tend overwhelmingly to be discrete and granular. We apply a mental model of pollution control (or food safety, or natural hazard management) that posits a "visible hand" controlling a dial to reduce exposures until the remaining risk reaches a level of acceptability or cost-effectiveness, but in reality there is no "dial" but rather a series of switches that provide only particularized increments of exposure reduction. It may be interesting to know where we would cease "turning the dial" if we had one, but our first priority should be to assess the performance (benefits conferred and costs associated) of the switches we actually could choose to flip, in order to decide which one(s) to engage. Note that considering real solutions is not the same as the practice (common at OSHA, and not uncommon at EPA) of analyzing multiple abstract goals, such as "the desired exposure concentration along with half and twice that concentration."[8] The optimal solution may turn out to be closer to one of these permutations than it is to the initial pronouncement, but that will only occur by coincidence, not because getting to "twice the original proposed limit" is a well-specified means to an end.

None of this enthusiasm for analyzing solutions rather than problems will strike anyone trained in decision theory as novel – but perhaps that says something about how although we tend to think of risk assessment and decision theory as emerging from the same intellectual ferment, the two fields have drifted apart.

The other important attribute of real decisions involves the interplay between the timing of when solutions are first raised and the breadth of solutions considered. In addition to the lack of grounding in opportunities and constraints, the other major flaw in

[8] For example, the 2006 NAAQS for fine particles proposed three "decisions"—the current baseline, a new limit of 15 $\mu g/m^3$, and a stricter limit of 14 $\mu g/m^3$ that EPA eventually rejected. I hope it goes without saying that this is *not* "evaluating solutions."

a problem-centered approach is that as soon as the mind begins to formulate in terms of a problem, *it closes the book on some solutions that can and will never even be considered, because they appear to fall outside the boundaries of acceptable deliberation.* The adage that "when all you have is a hammer, everything starts to look like a nail" may be more instructive when turned on its head: once you call what you've tripped over a "nail," you immediately stop thinking about looking for any tool other than a hammer. The most basic innovation of "SFRA 2.0" is that it starts by looking not at substances or hazards or risks as problems, but as *opportunities for change*. Risks arise because sources of risk exist, and arguably the job of the risk manager is to "see things that never were and ask 'why not'?" – to go back to the source and ask how changing it can create a future with substantial and varied increases in net social benefit.

Therefore, the new risk management paradigm presented here challenges decision-makers to take the first step—to envision possible interventions that might achieve an array of social goals – and then to turn risk scientists and economists loose to amass information on the pros and cons of each possible intervention. The process does not stop there, and it contains many elements that will strike critics as familiar and uncontroversial, but this basic insistence that (tentative) solutions should precede conceptually the detailed dissection of problems questions the wisdom of much of the effort, time, expense, and accomplishments of risk assessors and managers in the 25 years since the "Red Book" launched the era of risk-based governance.

3. Objections that Do Not Apply to this Proposal:

Before discussing (in Section 7 below) various thoughtful and sobering criticisms I have heard raised about these ideas, it may help to clarify several of the possible objections that do not apply, because they presuppose a vision for SFRA that I agree would be unworkable or unwise. There are enough obstacles to creating a solution-first mindset, where appropriate, without adding concerns based on a misperception of the concept:

- *SFRA is not intended to displace the traditional problem-centered approach, but to complement it in some settings and defer to it in others.* There will always the need for untethered risk assessments designed to increase our understanding of potencies, exposures, and risks, and there will always exist agencies such as NIEHS whose missions do not include implementing solutions (agencies whose names do not include words like "protection" and "safety," suggesting a mission that ought to go beyond "problem formulation"). Even in the regulatory agencies, some activities are better suited to (or currently constrained by statute to follow) problem-focused thinking. And even if an agency embraces SFRA for a particular activity, thinking about solutions should occur in parallel with thinking about problems: doing the latter should help refine or expand the range of solutions contemplated, and doing the former should help refine the areas of uncertainty that need to be resolved in the risk or cost analyses. I think it is a useful metaphor to consider the two approaches in terms of a "gestalt diagram" like the one in Figure 2: it takes mental discipline (especially if you've been looking only at one part of the picture for too long) to be able to switch between perspectives at will and recognize that the risks we study are both problems and opportunities.

- *Identifying an optimal solution does not imply that the risk manager should or can require anyone to implement the solution.* Many critics of government regulation reserve special ire for rules that specify the means of compliance (although as I will discuss below, there is an element of strategic behavior in this objection). However, government certainly can determine which solution would maximize net benefit and yet not have the authority to force its adoption, or choose not to exercise such authority. This would not at all make solution-focused analysis a waste of effort, but might reflect a reasoned belief that more good could be done via a voluntary regime or through market forces acting with new information on risks and costs. But if merely *discussing* a preferred solution can be attacked as coercive, then both SFRA and the

traditional process will draw fire; both decision-making paradigms are intended for societies that have evolved beyond anarchy.

- *SFRA does not presuppose a single "right answer."* The term "options-focused" might be more palatable as a way to convey that the management interventions are being contrasted relative to each other rather than to some absolute standard, but to many risk assessors, "options" implies modeling options (defaults and model uncertainty). There is admittedly some arrogance even in striving for the relatively best approach to a dilemma, but "solution" is meant here in the sense of many ways to ameliorate a situation, not *the* conclusion that must supplant all others (as in the usage of that word in submarine warfare, where the task is to plot *a* "solution" to guide weapons fire). Moreover, even the relatively best idea at one point in time may need to be reevaluated and refined, both during the analysis phase and after implementation. A well-designed SFRA process should admit proposed solutions into the mix during the analysis (informed by an improved understanding of risk) and should "look back" to ensure that the intervention chosen is delivering the benefits expected, and that new ways of doing even better have not sprung up in the meantime.

- *SFRA only makes sense in situations where risks and/or costs matter.* If a given decision must be made by random chance, by an uninformed power struggle, or by Congressional earmark, then SFRA will be a waste of time—but then so would any form of risk assessment.

- *SFRA explicitly allows for "leaving well enough alone."* The word "solution" is intended to encompass situations where doing nothing is the best alternative. However, there is a world of difference between doing nothing out of procrastination or denial, versus doing nothing because any other alternative was found to have smaller net benefit or larger net cost.

- *Regulatory agencies can (and do) promote solutions other than regulatory ones.* Emphasizing risk reduction over risk understanding does not imply any

> particular method of risk reduction – and if tax incentives, or right-to-know campaigns, or voluntary programs recognizing excellence, or the like make more sense than regulation, SFRA can and should be able to accommodate this.

There are also some objections to SFRA that would be fatal to it, could they not be anticipated and corrected. Foremost among these is the concern that putting decisions first in a sequential process is tantamount to putting *decision-makers* in charge of the analysis, which of course is the well-founded fear that drove the Red Book's committee's deliberations 25 years ago. There is no question that a corrupt SFRA process could yield corrupt results: it would be farcical or worse if risk managers were allowed to instruct assessors to "evaluate the pros and cons of options A, B, and C, but you had better make sure C comes out on top." *But there is nothing about asking the question this way that increases the risk of corruption over the current process,* in which managers could instruct (and certainly have instructed) assessors to "assess the risk of substance X, but you had better make sure to conclude the risk is trivial (or failing that, at least to 'lowball' it as much as possible)." The "conceptual separation" of analysis and management, and the safeguards needed to keep managers from polluting the analysis, are crucial whether the managers request objective information about risks or about risk-reduction alternatives. On the other hand, while managers should keep a hands-off posture during the analysis itself, they should never have been encouraged (as the Red Book or its misinterpretation may have done) to absent themselves when the reasons for the analysis are articulated.

Some may also object to putting the brakes on risk assessment when uncertainty has been reduced enough to confidently make a control decision. I respond that "settling" for less than exhaustive knowledge about risk in no way "dumbs down" the assessment. To the contrary, when the goal is to know enough about risk-reduction benefits to choose wisely, it will no longer be acceptable to exhaustively pinpoint a non-risk measure such as the RfD or the margin of exposure—risk assessment will have to grow "smarter" in order to express the science in metrics that relate to expected improvements in human health or

the environment [16, Chapter 5]. But it will be important to make sure that assessors are not thwarted from continuing to refine their understanding of risk just because they may have reached a point in an immediate decision problem where they know enough to present the results of a risk-based comparison of decision alternatives.

4. Echoes of SFRA in Familiar Places:

In the spirit of acknowledging that SFRA borrows nearly all of its features from processes that others have already invented, and of trying to engender an "I've seen this before" reaction among audiences who may be comfortable with solution-focused thinking in other settings, the following are some parallels that have strongly influenced my own thinking:

Within the risk management domain, SFRA can be thought of as assembling together the main thrusts of both lifecycle analysis (LCA) and cumulative risk assessment (CRA). SFRA merely extends LCA to social interventions that government can require or set in motion, as opposed to choices individual producers or consumers can make on their own; it applies CRA to evaluating *changes* in risk (and cost) rather than to improving our understanding of the status quo of risk or cost. So, for example, while LCA might compare the panoply of health and environmental effects of paper grocery bags versus plastic ones [17], concern about a signal of harm from a substance found in plastic bags might spur an SFRA exercise that would evaluate various ways to minimize exposure to that substance, *including* policies that would discourage the use of plastic bags. In all of the comparisons, CRA could improve the risk assessment by considering incremental exposure to the substance in terms of the concomitant exposures to that substance from other sources (or exposures to other substances believed to act via the same biochemical pathway(s) to increase the risk of a particular health endpoint). Unlike the typical CRA, however, SFRA would also explore the risk implications of policies that would increase the use of substitutes for plastic bags, and consider the incremental risks from *those* substances in terms of their own baseline CRA. To the extent that more and more experts in our field agree that ignoring life-cycle impacts of a substance or product

is suboptimal, as is focusing on marginal increments of exposure without considering the cumulative burden, SFRA should comfortably fit along with those related ideas for increasing the complexity and usefulness of risk assessments.

Aficionados of the regulatory design literature and observers of regulatory policies should also recognize SFRA as continuing the long-standing tug-of-war between performance-based standards versus design- or technology-based ones (with "technology" here intended to cover the various means of effecting risk reduction, including substitution, personal protective equipment, lifestyle changes, etc., not necessarily end-of-pipe hardware). *But it is crucial to understanding SFRA to recognize that while it does view pure performance standards with suspicion, it also aspires to reform technology-based standards as they have come to be developed*.

To conclude as I have above that "a NAAQS or a PEL is not a true decision at all" certainly displays a mistrust of performance standards expressed as single-substance exposure limits. Industry has typically advocated for performance standards over design standards, on the grounds that central planners (implicitly or explicitly, they mean planners who likely have no first-hand knowledge of the industrial sectors they have power to regulate) cannot possibly design methods of compliance to achieve a given level of risk reduction at the lowest cost, and should therefore satisfy themselves with setting the bar and letting companies reach the performance goal in the efficient ways only they can devise [18-20]. But the most vociferous (and successful) industry condemnation of a federal regulation in my experience was directed at OSHA's ergonomics role in 2001, and although that rule had many procedural and substantive flaws along with its many strengths, the lion's share of opposition centered on its near *absence* of specific design requirements![9] [21,22]. Small business, in particular, convincingly expressed dismay that OSHA had set performance goals without providing any blueprint(s) for how companies

[9] For a representative argument along these lines, consider the floor statement of then-Senator Tim Hutchinson (R-AR), urging his colleagues to vote to strike down the ergonomics regulation: "The rule is replete with vague and subjective requirements where employers must have an ergonomics plan in place to deal with such hazards. OSHA said it is being flexible by allowing employers to design a plan that caters to their own workplace, but that same 'flexibility' also requires the employer to be an expert on ergonomic injuries."

could meet them. So the spectrum from the vaguest performance goals to the most detailed specifications does not necessarily correspond to the range from least to most intrusive and unwelcome to industry.

By its very nature, SFRA develops and compares design outcomes. In that sense, SFRA would definitely shift the balance toward specifying the means of compliance. However, I personally endorse the idea of crafting hybrid regulations whenever practical: the SFRA could identify the optimal design, which would then have a risk reduction level (a performance goal) associated with it, and the rule could give the regulated parties the option of either following the specified design (the "safe harbor" option) *or* changing products, processes, or uses to yield equivalent or greater net risk reduction.

I also recommend a different and even more important synthesis of performance and design orientation, for which the Clean Air Act Amendments of 1990 provides an instructive motivation. Over the past 35 years, Congress has lurched between requiring EPA to impose performance-based and technology-based standards for toxic air pollutants. When the initial risk-based regime only yielded seven emission standards in 20 years, Congress shifted gears in the 1990 Amendments to a technology-based regime (the MACT standards), but also foreshadowed a subsequent risk-based round that EPA is now beginning to put into place. In the first round after 1990, EPA assessed the relative efficiency of different technologies without regard to how much absolute risk reduction they offered; so far in the opening initiatives of the subsequent round, EPA has tended to set additional exposure reduction goals without assessing how they will be achieved (and at what cost and with what effects on other risks). For example, the 2005 residual risk rule for coke ovens [(23)] emphasizes a performance goal to limit "allowable visible emissions" to a small specified percentage of the time the units are operating. So the best-available-technology exercise divorced from risk assessment is the how without the why, and (unless the stars align fortuitously) can result in "too much technology" (the "best" is very costly and reduces risk well below *de minimus* levels) or in "too little technology" (the best at present is simply not good enough when viewed through the lens of risk). The other extreme of a risk-based approach not grounded in technology results,

as I have argued above, in "why without the how" aspirational statements. *What is missing here is the logical marriage of the risk-based and technology-based ways of thinking—namely, a risk-based technology options analysis* [(24)]. SFRA asks the regulatory agency to probe into the risk-reducing capacity of various specific control options, and to produce a rule that answers both the why and the how (but again, possibly allowing case-specific innovations that meet the risk goal in different ways than the "safe harbor" can). If the best available technology is simply insufficient to reduce risks to acceptable levels, SFRA reveals this in one step rather than the Clean Air Act model of a decade's worth of BAT followed eventually by residual risk analysis. If a less expensive control is ample to eliminate or minimize risk, SFRA can stop here, avoiding technology "overkill."

Because some of the pioneering advocates of technology options analysis have expressed disdain or contempt for risk assessment [(25)], I hasten to emphasize that SFRA does not presuppose that a zero-risk control option is desirable or even exists. This is not an idle observation, because when viewed through the (proper) lens of cumulative risk, even a total ban on a substance or product might increase net risk despite its superficial appeal. But the central parable of O'Brien's book – that you should not be advised to wade across an icy river, even if the risks are trivial, when there is a footbridge nearby – tells an important *half* of the story SFRA seeks to tell. Yes, look at the alternatives, but look through the lens of risk assessment, not the lens of "natural is better" or any other dogma. SFRA demands we open our eyes to win/win options that some may hope we ignore, but it doesn't expect to find (or to concoct) such escapes when they are not truly available.

A regulatory paradigm that harnesses risk assessment in the service of evaluating solutions challenges the conventional wisdom in the same way that critics of risk-based priority-setting have tried to focus planners' attention on allocating limited resources to specific actions rather than to disembodied problem areas. Soon after EPA embarked upon risk-based priority-setting with its "Unfinished Business"[(26)] and "Reducing Risk"[(27)] reports, several scholars proposed wholly different ways to set a broad

environmental agenda that did not treat comparative risk ranking as an end in itself [28]. The advice that EPA could instead identify promising pollution prevention opportunities[29], or focus on localities where residents faced multiple threats from overlapping "hot spots" of pollution [30], or develop technology-forcing regulations for industrial sectors that had resisted innovation away from toxic and energy-inefficient processes [31], all derived from the basic orientation that agencies should see the task as how to take the best actions first, which is not at all the same as tackling the "worst risks first." Although EPA has never undertaken a solution-ranking initiative comparable to its major risk-ranking exercises, U.S. experts have participated in global priority-setting exercises organized by Bjorn Lomborg, in which they ranked defined solutions to disparate environmental problems that together could be achieved with an arbitrary amount of expenditure [32,33]. The results of these exercises have sometimes been misinterpreted to denigrate the importance of problems such as global climate change, when in fact the rankings reflect a set of views about the net benefits of particular policy and other interventions, some of which effectively eliminate "smaller" problems and others of which chip away in cost-effective ways at much larger problems. Lomborg called some of his expert elicitations "Ranking the Opportunities," which is exactly the spirit of SFRA.

The solution-focused alternative to traditional environmental decision-making may be least surprising to practitioners trained in decision theory [34-37], which at its core counsels individual and social actors to structure their thinking so as to compare alternatives ("decision nodes") in light of information about probabilities and consequences ("chance nodes" following each possible decision, whose consequences can be assigned values along single-or multi-attribute scales).[10]

[10] One of the modern pioneers in decision theory, Ralph Keeney, argues that the standard way of thinking about choices is backwards, because it encourages people to identify alternatives first before they articulate and reconcile their underlying values. While SFRA might seem to push us further into this trap, I believe its emphasis on early brainstorming about solutions actually promotes the kind of "value-focused thinking" Keeney advocates. While traditional risk management relegates valuation (the conversion of consequences to commensurable units of good and harm) to the latter stages of the process, SFRA encourages decision-makers to widen the range of solutions they accept as worth evaluating, precisely by encouraging them to think about values early and broadly. Keeney famously wrote that an unexpected phone call from a rival company offering you a job does not create a "should I stay or move to the rival?" problem, but a "what do I want to do with my career?" problem—there are more than two options here. In the same way, I argue

SFRA also aspires to be part of a tradition, dating back at least as far as Bernard Goldstein's 1993 essay,[38] urging less hand-wringing about the uncertainties in risk assessment and more attention to decision-making as a craft whose improvement would provide tangible benefits to society and also spur improvements in analysis.

Disparate fields outside the area of environmental risk management also have traditions of encouraging solution-focused thinking to complement or supplant the problem-focused mindset:

- Clinical medicine and public health have often emphasized prevention over treatment when possible, and looking to alter root causes of disease rather than alleviating or masking symptoms. With analogy to the concentration of some pollutant in some environmental medium, the complaint to a physician that "my pants are too tight" would probably not elicit a measurement and a recommendation to buy larger pants, but a discussion about opportunities for change, perhaps including a comparative analysis of the pros and cons of diet/exercise versus liposuction versus diuretics.

- In psychology, "solution-focused therapy" (SFT) arose in the 1980s as an alternative to the kind of counseling that emphasizes finding roots in the patient's past to explain his current problem(s) [39]. Instead, SFT seeks to help the patient identify things she wishes would change in her life and to nurture those aspects of her current life that are positive. One technique the therapist often uses to forge connections between goals and concrete behavioral change is the so-called "miracle question," which typically asks the patient to imagine that he is awakened one morning to find all his problems solved as if by a miracle. The key to this technique is asking the patient how she would *know* that the miracle had happened; by articulating the signs of miraculous change, the patient may recognize concrete steps she can take to make some of those

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that a worrisome signal of harm does not reveal a "how much should we reduce exposure to Substance X?" problem, but a "(how) can we fulfill the social purposes that products containing X provide, at reduced risk?" problem – and of course both of the broader questions require you to think creatively about future states of nature and how you might value them.

changes happen. SFT also tries to help patients recall small successes they have had that could be replicated, and which show that they don't have to wait passively for the miracle to occur. The parallels to environmental decision-making should be obvious – thinking about a better future can point towards attainable ways to get there, and small improvements beget larger ones (whereas waiting until the omnibus solution has been pinpointed invites paralysis).

- Among the various business management and quality control theories that have sprung up over the past half-century, one that originated in the former Soviet Union points the way to a very different approach to environmental risk management, much as SFRA aspires to do. "TRIZ," which is the acronym for the Russian "Theory of Inventive Problem-Solving" (*Teoriya Resheniya Izobretatelskikh Zadatch*), is described by its current popularizers as a "science of creativity that relies on the study of the patterns of problems and solutions, not on the spontaneous and intuitive creativity of individuals or groups." TRIZ emphasizes looking for solutions have already been applied to similar problems, and adapting them to the current situation. With particular resonance to the growing problem of risk-risk trade-offs in environmental protection, TRIZ recognizes that many problems pose inherent conundrums ("I want to know everything my teenager is doing, but I don't want to know"), as do some conventional solutions ("the product needs to be stronger, but should not weigh any more"). So TRIZ stresses the notion of the "ideal final result" as a way to open the mind to new solutions that may sidestep the trade-offs entirely: the ideal final result seeks to fulfill the function, not to fine-tune the existing means of minimizing externalities. For example, Domb [(40)] describes the lawnmower as a noisy, polluting, potentially unsafe, and maintenance-heavy solution to the problem of unruly lawns. Rather than continuing to optimize the chosen means, she suggests one ideal final result

might be the development of "smart grass seed" – grass that is genetically engineered to grow only to the desired length.[11]

- The ecological tradition also has currents within it that emphasize moving conceptually from solutions to problems rather than exclusively in the opposite direction. Agrarian Wendell Berry calls this "solving for pattern (41): "To define an agricultural problem as if it were solely a problem of agriculture—or solely a problem of production or technology or economics—is simply to misunderstand the problem, either inadvertently or deliberately… The whole problem must be solved, not just some handily identifiable and simplifiable aspect of it."

5. Expected Benefits of SFRA:

A focus on solutions should yield some obvious classes of benefits, chief among them a portfolio of actions that are more timely and concerted than what we have become used to. But an improved decision process actually offers more than the promise of better outcomes:

5.1. It should give stakeholders opportunities to do what they most want and are best at doing – to contribute their special knowledge and preferences about decisions, rather than about science and risk. Recommendations from many quarters have emphasized that broadly inclusive decision processes are superior to narrow ones, but have concentrated more on stakeholder access than on the content of their intended influence. And when content is discussed in the planning of public involvement, it sometimes tends to emphasize either "special local knowledge" of exposure (e.g., the possibility that groups such as subsistence fishers have unique exposures) or special preferences in the abstract (e.g., subgroups who might be particularly concerned

[11] I thank Michael Callahan of EPA for calling attention to this example in an excellent presentation he made to the National Research Council's *Science and Decisions* committee in February 2007.

about cultural landmarks). Highlighting these sorts of issues in a public meeting is certainly more likely to yield useful information, and less likely to frustrate the participants and smack of bias, than the practice of inviting public comment on arcane controversies around the underlying science, but more sensible still would be the open discussion of the pros and cons of contrasting solutions to the problem at hand. Although the particular solution that many of the participants were coming to favor was made moot by other forces, one model for a solution-focused exercise in "civic discovery"[42] was already pioneered at EPA, in the form of the "Tacoma process" championed by administrator William Ruckelshaus in 1984. In the future, EPA and other agencies could also involve the affected public in the initial arraying of possible solutions, as well as the subsequent discussion of how information on risks and costs distinguishes the solutions from each other, which is what Ruckelshaus tried to do around the Asarco smelter in Washington. The 1996 National Academy of Sciences "Orange Book" [43] emphasized interactions among public officials, technical experts, and the populace to help reach a common understanding of how to "describe a potential hazardous situation in as accurate, thorough, and decision-relevant a manner as possible" (p. 2); SFRA simply suggests that rather than only trying to reach a common understanding of the problem, we should be making the decision relevant to the analysis and to the affected population.

5.2. It will demand more complete and rigorous analyses, in three fundamental and long-overdue respects, giving scientists and economists more license to incorporate information hitherto marginalized:

- moving the endpoint from "acceptable levels of exposure" to "best-performing decisions" will highlight the deficiencies of arbitrary single measures of exposure, in favor of continuous relationships between exposure and consequence. The growing dissatisfaction some risk assessors, and many economists, stress about the RfD/RfC and the "margin of exposure" metrics stems from concern that these measures do not relate to harm or benefit – they merely demarcate a possible "bright line" separating desirable from undesirable, with no quantitative relationship between the two. Various

expert groups (see, e.g., Chapter 5 of **Science and Decisions**) have recommended strongly that EPA and other agencies develop parallel (or "unified") dose-response assessment processes for carcinogenic and non-carcinogenic hazards, in part so that decision makers and the public can evaluate the benefits of exposure reductions that move some individuals from above the RfC (or below an MOE of 1) to the other side of those lines. More importantly, the current approach leaves us powerless to gauge all those exposure reductions that do not "cross the line" (i.e., the benefits of moving from an exposure well above the RfC to an exposure closer to but not below it, and of moving from below the RfC to a level further still below it). Any risk management process that relies on comparing the benefits of available control options will drive demand for these more useful, and arguably more scientifically appropriate, methods of assessing toxicologic potency.

- SFRA puts risk trade-offs front-and-center, forcing decision makers to confront offsetting risks before they create them, rather than having to backpedal after the fact. The contrast between substance-focused risk assessment and SFRA is particularly stark when regulating the substance turns out to encourage substitution to a more toxic material—*a quintessentially perverse outcome to which the traditional PEL/NAAQS process is oblivious*. If, as I and others argue is not infrequently the case [15, 44], multiple interventions could readily reduce both the primary and the offsetting risks, then surely it is far more sensible to analyze these trade-offs up front and design an optimal approach taking net risk into account, rather than chasing after new risks created by clumsy interventions.

- SFRA makes more visible what we often consider covertly—the costs of control. Even when agencies are forbidden from making the costs of control a determining factor in decision-making, it is clear that the solution set simply excludes options that would break the proverbial bank[45]. To logically compare those options that remain, SFRA will demand more rigor in how we estimate costs, thereby helping fix the weakest link in all of quantitative

environmental analysis. Defined actions to reduce risks have costs, as do promises that risk-based goals will be met through some undetermined future actions – but it is much easier to gauge whether the actions will yield risk reductions worth their cost if they are chosen through the kind of process of comparing alternatives that SFRA impels. Inattention to cost can lead either to over-regulation or to under-regulation, with the latter occurring both across-the-board (through the well-documented tendency to exaggerate costs) and in important aspects of regulatory scope (where tacit consideration of costs results in exemptions, variances, and lax treatment for sectors of industry that sometimes impose high risks whose reductions would be costly to them). In an ongoing series of projects, colleagues and I are documenting the lack of attention in regulatory analysis to uncertainty and interindividual variability (in the sense of the share of total cost borne by individuals and subpopulations of consumers and producers) in cost, especially as compared to the increasing rigor with which risk scientists now routinely estimate uncertainty and variability in risk[46,47]. Even if SFRA does not add back into the solution set various options excluded before their large costs were ever compared to their huge benefits, the act of starting the cost estimation process earlier should improve it, to the extent that the lack of rigor is due to the "11th hour" nature of this activity at present.

5.3 *It structures the decision-making process to embrace uncertainty and make the best of it.* SFRA can break the vicious circle of mishandling uncertainty leading to poor decisions, and help us confront uncertainty as the ally it should be to effective policy rather than its adversary. For the important special case when *model uncertainty* makes it impossible to know which of two or more dramatically different estimates of risk is correct, there are logically only three basic ways to proceed: (1) put the model uncertainty to the side, giving one "default" model at each inference point primacy over all alternatives, until an alternative becomes compelling enough to supplant the default; (2) construct a hybrid risk estimate (or hybrid uncertainty distribution) by averaging together the various point estimates or distributions, weighted by the degree of belief assigned to each: or (3) do it the way decision theory instructs—namely, *assess the pros*

and cons of different decisions, in full light of the multiple possible risk estimates. Because the second option is so wrong-headed compared to the third, I have favored the first option, assuming that EPA could somehow finally develop a common-sense and transparent system for evaluating default assumptions versus alternative ones out of the current morass of confusion it has created around this issue[16, Chapter 6, esp. footnote 2]. But risk estimates that place zero weight on all inferences other than the default are by definition overconfident, and SFRA simply handles model uncertainty correctly rather than incorrectly. When the risk is either of magnitude A (with probability *p*) or B (with probability (1-*p*)), it is simply incorrect for the risk assessor to cause the decision maker to act as if the risk was known with certainty to equal [*p*A+(1-*p*)B], but this is exactly what most proposals for model averaging do [48,49]. With reference to the "hurricane parable" I developed during the regulatory "reform" years[50], the Red Book process (assessors do their work shielded from knowledge of the alternative solutions) would tempt participants into discussing (non-existent) landfall sites between New Orleans and Tampa, and perhaps to construe the decision problem as "how best to warn or evacuate Mobile?" Instead, they need only ask this simple question rather than that fatuous one: if the risk is either A or B, how does solution X perform against a risk of size A or size B, as compared to how solution Y would perform? To turn the parable into a real analogy, consider a risk that is either "huge" (under the default assumption) or zero (under a plausible alternative assumption). The "risk-first" process misleads the decision maker into thinking about the acceptable exposure to a risk of size "*p* times huge," whereas SFRA asks whether ignoring a huge risk (with probability *p* of making that mistake) is better or worse than the cost of eliminating a non-existent risk (with probability (1-*p*) of erring in that way). Sure, it might sometimes be best of all to reduce the risk by a factor of (1/*p*) ("evacuating Mobile"), because that action has a smaller expected loss than either of the two strategies that might actually be correct, but that kind of compromise should arise out of a thoughtful weighing of consequences rather than as the inevitable result of a process guaranteed to mislead.

SFRA also may be the only way to correctly open the door to an enormously useful category of real decisions – those in which *gathering more information* emerges as preferable to deciding now. While there are ways to think about the value of information

other than by formal VOI methods [51,52], those methods do absolutely require that the decision options be specified. Indeed, the crux of VOI theory is that information has value *only* insofar as armed with it, one can reduce the probability or consequence of choosing a decision that is inferior to another available choice. This is very different from putting research money into "interesting" questions, or into the largest uncertainties, which is the thought process that often passes for systematic these days. VOI theory insists that seeking information that could potentially change the rank ordering of solutions is the most valuable—indeed, the only valuable—way of spending one's time short of deciding. And of course, one can't even begin to think about how much money and time should be spent on research rather than on control, and which research projects might be the most valuable, unless one is willing to monetize by how much the choice among solutions suffers due to the existing uncertainty.

6. Advances in Decision-Making Processes that Do Not Constitute SFRA.

Although observers have raised various serious concerns about the wisdom of SFRA (see Section 7 below), it may actually face more obstacles to ever being tried out from assertions that is already being done or that it has already been proposed elsewhere. Several recent sets of recommendations for changing risk-based decision-making are creative, visionary, and responsible for opening doors to solution-focused ideas – and each may well be superior to SFRA in some or all respects – but they do *not* propose SFRA as I describe it here, and some cases may in fact be its antithesis:

- The 1996 National Academy of Sciences "Orange Book"[43] expanded upon the Red Book paradigm that risk assessment should remain conceptually separate from risk management, by redefining risk assessment as a "decision-relevant" exercise. In the context of the entire report, I believe this Committee meant "decision-relevant" in the sense of "the importance and scope of the decision should determine (respectively) the level of resources and rigor the corresponding risk assessment should have, and the array of stakeholders who should be brought into the process." While this is doubtless

true, it is not tantamount to recommending that decision options be arrayed before risk assessment begins in earnest, as I am proposing here. There are many connotations of the statement, made in the Orange Book and in many other influential documents, that "risk assessment should serve the needs of decision makers"; SFRA asserts that what need they most of all are assessments that compare the risks and costs of different decisions, whereas these and other reports seem to leave it up to decision makers to determine their own needs.

- Soon thereafter, the Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRAM) released its two-volume report[53], a centerpiece of which was its "Framework for Environmental Health Risk Management." This framework sought to greatly improve the usefulness and relevance of risk assessment by emphasizing the need to consider multiple sources of exposure, multimedia transfers, risk-risk tradeoffs, and cumulative exposures to hazards affecting common biological pathways, and it did carve out a place in its six-phase "hexagon" for the risk-based evaluation of decision options. All these advances reflected cutting-edge thinking, but the Commission clearly did not envision anything like SFRA. Indeed, the Framework takes pains to mention (p. 11) that "it is very important to consider the full context of the problem before proceeding with the other stages of the risk management process." The sequence is clear: the work of examining options "does not have to wait until the risk assessment is *completed*" (emphasis added) (whereas SFRA's foundation is doing so before the risk assessment really begins), and only "in some cases may examining the options help refine a risk analysis" (p. 23). If I am correct that the very act of "defining the problem" can foreclose consideration of some options, then not identifying the solutions until the third of six steps in the PCCRAM framework saps the solution focus entirely.

  I also infer a very different ambition than mine in PCCRAM's emphasis on "putting risks in context." SFRA urges decision makers and the public to look

for opportunities to *broaden* their sights and reduce multiple risks. The recurring example in the explanation of the Framework, in contrast, is that of a refinery that exposes nearby residents to toxic air pollutants; every additional reference in the example to other sources of the same or different toxicants reinforces and leads up to the suggestion (p. 13) that "if the residual leukemia risk from refinery emissions... proves insignificant [compared to the leukemia risk from other sources], risk reduction might better be directed at other sources." SFRA would never insist that the optimal solution must necessarily involve a reduction in refinery emissions, but neither would it prejudge that such a solution *couldn't be optimal* simply because the affected population also faced other voluntary or involuntary risks.

- A 2005 NAS report(54) to the U.S. Department of Energy (DOE) did put forward a decision-making framework that contains many of the elements of SFRA: "A coherent and efficient risk assessment requires … that a sufficient number of options from which to choose be considered in the decision to avoid excluding potentially superior options. Therefore, the first step is that a decision be defined; and second that a list of decision alternatives from which to choose be considered." But this committee, I assume, did not intend to propose a general framework, but one specific to the structured binary choice facing DOE of whether or not to exempt a particular kind of waste from a default requirement that the waste be stored permanently in a deep geologic repository. When the decision options are this cut-and-dried, a comparative risk assessment seems the natural way to proceed, although this NAS committee certainly made a compelling case for a solution-focused mindset.

- Most recently, the 2009 NAS study on "Science and Decisions" devoted substantial effort to proposing a new "Framework for Risk-Based Decision-Making" that endorses some of the principles of SFRA as discussed in this article.[12] On one hand, the 2009 Framework explicitly contrasts the

[12] I was a member of this NAS Committee, and advocated in that forum for essentially all of the concepts described in this article – so the differences reflect the reasoned objections of many distinguished scholars of risk assessment and policy. Elements in this article's version of SFRA not contained in **Science and**

traditional approach with one that asks "what options are there to reduce the hazards or exposures that have been identified?" before the risk assessment begins (p. 242), and it concludes that "risk assessment is of little usefulness… if it is not oriented to help discriminate among risk-management options." This represents a giant step towards insisting that solutions need to be arrayed early in the process, and the report reinforces this with an upbeat tone about the *increased* importance of risk assessment in the new paradigm and about the readiness of risk assessors to deliver on the "raise[d] expectations for what risk assessments can provide." But on the other hand, the key Figure describing the Framework (Fig. 8-1 in the report) does not fully track this narrative description, in that the activities prior to the risk assessment phase are called "problem formulation and scoping," and start with the question "what problems are associated with existing environmental conditions?" before moving on to considering options to address these problems.

To the extent that this initial phase is meant to endorse and subsume the concepts of "Problem Formulation" (PF) and "Planning and Scoping" (P&S) in EPA's Guidelines for Ecological Risk Assessment, Air Toxics Library, and elsewhere, the Framework ends up being "decision-driven" (as in the Orange Book 13 years prior) but not truly solution-focused. P&S makes the important advance of grounding the size and rigor of the technical analysis to meet the demands of the particular decision for timeliness and fidelity to statutory dictates, and of focusing it on questions within the boundaries of the problem (neither straying outside the boundary nor leaving important issues unaddressed). A properly-planned risk assessment will surely be more useful and cost-efficient than a free-form "fill up your blue book until we say your time is up" analysis, but *it may never analyze the benefits and costs of any particular solution, and will likely fail to contemplate certain solutions*

Decisions probably should be interpreted as the Committee having found them undesirable or poorly-explained. In particular, at least one of the other Committee members explained in the trade press[55] that "we were 'very careful' to write the section on increasing utility in risk assessment such that it did not recommend beginning risk assessment with solutions"—which is exactly what SFRA *does* recommend (assuming that the reporter's quote should have read "beginning risk management with solutions").

altogether. Likewise, PF aims to shape the risk assessment so as to shed light on specific effects on defined populations or receptors—sharpening the analysis to clarify the "real problem" in all its facets rather than the pieces of it that lie in the light of the proverbial lamppost—but this too is not the same as SFRA. In the case of PF, the name really gives it away; thinking hard about the problem is valuable, but it is actually the *opposite* of seeing the situation as an opportunity to explore solutions.

The Committee's description (p. 247) of Phase I reveals how the new Framework stops far short of endorsing SFRA. The goal of Phase I is clearly to shape the risk assessment to the "problem," because in the example used of premarket approval of new pesticides, "there are well-established guidelines for risk assessments… [which already] constitute Phase I planning in this type of decision." In other words, if you know what analysis is needed to provide the decision-maker with ample information *of the type s/he believes is needed,* the problem is properly "formulated" and the assessment properly "scoped." *But that is exactly the mold SFRA seeks to break.* Even a narrow "solution formulation" exercise would look beyond the simple yes/no question of whether or not the new pesticide is safe and effective for specific crops (and further beyond the quantitative exercise of setting an acceptable application rate or field re-entry interval), and would consider supplementing the "well-established guidelines" to consider different acceptable exposures depending on cumulative and aggregate risk and other factors. To truly open the door to opportunities would further require all participants to consider the decision the way Keeney urges we think of the proverbial unexpected job offer: not "should we add one more pesticide to the arsenal?", but "how can we encourage the safer and more efficient production of the foodstuffs this pesticide might be used on?" That is a different decision than the one EPA normally contemplates, which is precisely the point and precisely the door the **Science and Decisions** report apparently did not wish to open.[13]

[13] Interestingly, another unit of the National Research Council has reportedly begun to plan a new study, "A Framework for Alternatives Assessment to Inform Government and Business Decisions Concerning Safer

7. Serious Concerns, and Partial Counter-Arguments.

The steps that **Science and Decisions** made towards earlier consideration of risk management options have already aroused criticism[55], and the more expansive concepts of SFRA have prompted these and other objections in several public forums over the past year. I offer here a partial catalog of the more portentous concerns that have been raised, including some others that were raised during the **Science and Decisions** Committee's deliberations, along with the beginnings of some attempts at rebuttal and synthesis. The breath and intensity of these concerns has convinced me that SFRA should not be implemented on other than a demonstration basis without much more discussion of its possible flaws, but also that pilot projects are well worth undertaking in order to see which of these objections are truly clear-headed.

7.1 *SFRA will exacerbate the existing "inappropriate over-involvement on the part of political risk managers"* (Peter Preuss, quoted in [55])*, perhaps leading to the kind of corruption the Red Book committee worked so hard to identify and minimize.* As I discussed above, I agree that this could be a fatal flaw of SFRA, but I do not agree that a discussion of solutions could be "hijacked" any more readily than could any discussion of hazards and risks. One also needs to weigh both worst-cases – the effecting of risk management decisions that reflect the political will of elected or appointed officials, against the other extreme, which would be the (eventual) completion of pristine assessments that may lead to no risk reduction activities at all.

7.2 *Agencies are forbidden by statute from analyzing the risks (and costs) of defined options, but must study risks in isolation before contemplating solutions.* The universe of situations where an agency does not conduct a particular analysis is much broader than situations where laws or court decisions actually have forbidden it from doing so[45], and in still other cases, the agency does not publish the analysis but nevertheless conducts one for internal use or to satisfy the Office of Information and Regulatory Affairs. Even

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Chemical Policies and Practices," that may consider marrying LCA and comparative risk assessment in an alternative assessment process that may look very much like SFRA—so it is possible that **Science and Decisions** may represent the needed partial step towards SFRA that paves the way for a real evaluation by the NRC of whether it has promise.

where an agency is required to produce a free-form risk estimate, as in the NAAQS process, it could still do so after thinking expansively about solutions, in effect conducting both a solution-focused exercise and a generic (risk per unit exposure) analysis in parallel, and shunting the former into a public-information exercise. Ultimately, some statutes may need to be amended for SFRA to make major inroads, but some of us see that as a bridge that may need to be built for other reasons,[56] not as a chasm that must necessarily remain uncrossed.

7.3 *Because "he who controls the options controls the outcome," SFRA (further) skews the power structure away from the affected citizens and their public-interest guardians, and towards the regulated industries.* This criticism has significant merit, as some of the crucial information about solutions (their very existence, as well as their costs and efficacies) may be closely held by the regulated community, and injected into the process strategically (and perhaps not in a verifiable way). Some of the same concerns have always applied to risk information, but in theory independent replication of toxicology testing or exposure monitoring could be undertaken. In the spirit of a win/win response, a sensible reaction to this problem might be for the agencies to subsidize participation in solution-generating exercises by representatives of the public. I also note that some of the "unequal distribution of power" argument is reminiscent of similar concerns environmental groups have raised about risk assessment itself, and that it is possible some of this asymmetry is deliberate and self-fulfilling on their part[57,58].

7.4 *The explicit choice of a solution (and the rejection of others) in a regulatory proceeding is fodder for litigation challenging the decision.* Here the (more) perfect is the enemy of the good, assuming reasonably than a vague performance-oriented standard that survives judicial and Congressional challenge is better than nothing. On balance in my experience, the risk-aversion of agency lawyers has stymied sensible attempts to make regulations more stringent, participatory, and transparent, but despite a general tendency towards judicial deference, the lawyers' job does remain that of reducing the risk of ending up with no standard at all. The same sorts of objections, though, have been raised about the efforts by risk analysts to be more honest about uncertainty, and courts increasingly now seem to appreciate that acknowledging uncertainty is not a sign of

weakness in the analysis—so showing more of the logic behind a choice among solutions may create a "virtuous circle" that increases judicial and public tolerance for ambiguity and for optimization in the face of it.

7.5 *SFRA makes risk assessment harder to do.* Former EPA Assistant Administrator George Gray made this point at the SRA annual meeting session on SFRA in December 2008[55], suggesting that once decisions are compared, deficiencies in how uncertainty (especially model uncertainty) is quantified become more apparent and more debilitating. I agree, but see this as a strength of SFRA, both *per se* and for how it might help lessen the long-standing mismatch between the enormous financial and human stakes of making sound risk management decisions relative to the meager resources we devote to conducting and improving analysis[59].

7.6 *Assessments performed for an SFRA may be useless for other purposes, leading to widespread and wasteful duplication of efforts.* According to risk reporter Steve Gibb[60], "when risk assessments are tailored to specific problem sets and circumstances, the immediate decision may be served extremely well, but there may be a tradeoff that erodes the common applications of these types of assessments elsewhere." I agree, and urge that the "science agencies" (NIEHS, NIOSH, etc.) be expanded to provide more raw materials (dose-response assessments for substances and mixtures, exposure assessments for industrial processes and products) that can be adapted to jump-start solution-focused assessments the regulatory agencies will undertake. Duplicate risk assessments are already a growing problem in the current environment, of course, in which disparate agencies (and even programs within a single agency) seem reluctant to take advantage of work performed elsewhere.

7.7 *It makes no sense to array any solutions before you know what the problem is.* Because I believe the balance is currently tipped so much in favor of dissecting problems and considering solutions too late in the game or not at all, I have emphasized the inverse of this process. I do not agree that it is nonsensical to begin by mapping the "signal of harm" back onto the products and process from which it emerges, and considering tentative ways to improve these processes in risk-reducing ways. But the initial step (after you have thought carefully about what the signal of harm represents) of expansive

thinking about solutions should promptly return to re-grounding the endeavor in traditional problem-focused thinking—and thence to a recursive process in which more information about risk refines the solution set, and more information about solutions directs the analysis towards specific knowledge gaps and uncertainties. If either strain of thinking proceeds for too long without the other, the process will suffer, but while "too much" thinking about solutions may turn into idle daydreaming, "too much" fixation on problems, I warn, may foreclose opportunities to design the interventions that will in fact yield the greatest net benefit, a more unfortunate outcome.

7.8 *Specifying the means of compliance freezes technology, leading to less risk reduction in the long run.* In theory, this drawback of SFRA concerns me more any of the others mentioned so far; the literature contains many criticisms of technology-based standards for inherently deciding that "the best we can do now" is more important than continuous improvement [(61)]. One could, of course, argue with that very calculus, as the President's chief of staff prominently did recently in the health-care debate ("there are a lot of people...who will tell you what the ideal plan is. Great, fascinating. You have the art of the possible measured against the ideal.") [(62)]. I think there are also two more objective reasons to be less enamored of risk-based performance goals in light of the new potential of SFRA: (1) in the past, technology-based standards have not generally had the risk-based check and balance I advocate here – so if current technology is ample to reduce net risk to acceptably low levels (as indicated by a thorough risk assessment), there should be no concern about "locking in" that level of pollution; and (2) do performance goals *really* "unfreeze" technological innovation? Many risk-based limits could be tightened over time to spur further control technologies, but in practice the limits themselves are "frozen" by lack of agency attention and political will (OSHA, for example, has only tightened three PELs in its 39-year history). EPA has tightened some of the NAAQS limits for criteria pollutants, but it is not clear how often the periodic moving of the bar has spurred innovation, as opposed to cases where innovation emerged independently and *allowed* EPA to move the bar. Continuous improvement requires continuous vigilance, and I think that is more a function of resources and will than the type of regulatory instrument.

7.9 *Government should be doing less "central planning," not (much) more.* Now is surely an inopportune time, perhaps even a tone-deaf time, to be proposing something that could be dismissed as "socialism." In addition to the ideological battle lines SFRA may draw, less visceral concerns have long been expressed about the appropriateness of government meddling in technological choices and the inefficiency of interventions that do not encourage "flexibility" among means of compliance by firms and sectors with very different economic characteristics[(63)]. I agree with the latter objection, and support a brand of SFRA that considers marketable permits, hybrid performance-specification standards (see Section 4 above), and other "many sizes fit all" approaches among solutions that should be evaluated. As to the ineptness or effrontery of government assessing technologies, I can only point out (without implying any preference for the status quo or for radical change) that society picks "winners and losers" all the time in other arenas of social policy. Among the substances that can produce mild euphoria, we allow (and subsidize some of the ingredients of) beverage alcohol, but we criminalize marijuana. Among the products of the firearms industry, we draw a line with handguns and hunting rifles on one side, and machine guns on the other. We do all this *without* conducting any cost-benefit analyses (considering neither the consumer and producer surplus if banned products were decriminalized, nor the health risks of legal products)—so what would be so odd about promoting (or regulating) one type of lightbulb over another, with the *help* of risk and cost information? SFRA may be rejected on the grounds it is too intrusive, but my own opinion is that would be reasonable but naive considering the degree of intrusion, for good or ill, in today's marketplace.

7.10 *We're doing well enough without a new decision-making paradigm.* Although this is even more subjective than the previous criticism (is your environmental glass half-empty or half-full?), the question must be asked: is SFRA (pun intended) a solution in search of a problem? If our progress towards reducing environmental, health, and safety risks, at reasonable costs to the economy, is laudable, then any meddling with the current system is a risky attempt to fix what isn't broken. There is ample support for this proposition, especially when one looks at the variety of key environmental indicators that have moved steadily in the right direction since 1970, such as the 92 percent drop in airborne lead, the controlling of 96 percent of the roughly 2,000 contaminated sites in the

RCRA program between 2000 and 2008, and the increase since 1990 from roughly 80 percent to roughly 90 of the population served by community drinking water systems that had no reported violations of any health-based drinking water standards.

Although a full analysis of these trends and the many countervailing ones is far beyond the scope of this article, I think there is room for serious debate whether sufficient progress has indeed been made, notwithstanding the obvious retort that no matter how noble the track record, we might always be able to do better still. Here are some areas where lack of progress suggests a role for a new decision-making paradigm:

- Other trends in environmental concentration are not so favorable: some of the other criteria pollutants have fallen slightly on average, but less so at the upper ends of the distribution (the 90^{th} percentile of PM_{10} concentrations fell only from 113 $\mu g/m^3$ to 88 $\mu g/m^3$ between 1997 and 2008, and the same measure for ozone only fell from 97 to 87 (ppb), while NO_x levels continue to rise across-the-board. Some of the air toxics concentrations have not declined all (1,3-butadiene levels were stable from 1994 to 1998). More importantly, the atmospheric CO_2 level has risen from 326 ppm in 1972 to 386 ppm in 2008.

- Indicators of progress in other areas of risk management have reached an asymptote (as in the number of fatal occupational injuries) or are increasing (as in the number of foodborne illnesses, and the concentrations of many workplace pollutants).

- Trends in disease incidence and mortality reveal a mixed record, with decreases in many cancers among adults offset by increases in childhood cancers, and rates of asthma, autism, and other conditions increasing beyond what improved detection or reporting can likely explain.

But all of these metrics evaluate only half of the evolution in environmental management. Since SFRA is about opportunities, it is fair to ask also whether the *sources* of environmental stress are evolving relative to reasonable expectations. The gold standard for rapid technological innovation since 1970 has been the breakneck pace of improvements in computer technology: today's $400 desktop has 20 million times the

storage capacity, 2 million times the RAM, and 2000 times faster processing speed than the computer that guided Apollo 11 to the moon in 1969. And yet,

- 210 of the 1045 make/model combinations of cars sold in 2003 achieved lower mpg than the 1979 Cadillac Eldorado;
- 65 percent of U.S. homes are poorly insulated, wasting billions of gallons of fossil fuels annually;
- we still dry-clean clothes using chlorinated solvents, that create significant risks even in homes far from laundries, just from the exhaled breath of workers when they return home at night [(64)] (and the EPA "phaseout" of perchloroethylene by the end of 2020 applies only to cleaners co-located in residential buildings, not those which emit into adjacent workplaces or free-standing establishments);
- in 1970, the major source of drinking water was the kitchen sink and the water fountain: today, we in the U.S. purchase roughly 35 billion plastic bottles of water each year, with implications for energy use and human health.

We may end up satisfied with the pace of innovation in products and processes that impact on the environment, but surely a decision-making paradigm that dares to ask the question "can it be done better?" is not outlandish how uneven the rise of new and better ideas has been across the various sectors of the economy.

8. Organizational Change to Implement Solution-Focused Assessment

The final chapter of **Science and Decisions** offered various "infrastructure" recommendations to increase the ability of federal and state agencies to manage risks according to the "Framework" the Committee endorsed, and emphasized the value of crafting new guidance documents, creating organization-wide teams to pick targets for innovative decision-making, and developing the technical skills necessary for managers and assessors to collaborate more productively. In addition to these improvements,

however, more fundamental change may be necessary. One current proposal for the creation of a "Department of Environmental and Consumer Protection"[65], incorporating six existing agencies and adding bureaus to conduct environmental and health surveillance, emphasized the ability of such an organization to regulate products (as opposed to substances *per se*, which may make less and less sense as new nanomaterials emerge whose risks depend completely on how they are incorporated into finished products) and to produce "social impact statements" of the impacts of technologies.

In addition to bold ideas such as those Davies has put forward, I urge serious thought be given to a somewhat less sweeping organizational change: the creation of a true interagency risk management collaboration mechanism, either under the auspices of OMB/OIRA or (preferably, in my view) under an expanded White House Office of Science and Technology Policy. So many of the solutions one agency impels can affect risks in other agencies' purview – and/or can put society on a path that makes opportunities for future risk reduction in another area more expensive or impossible – that it seems bizarre for the environmental, occupational, transportation, energy, housing, agriculture, and other functions of government to pursue separate regulatory and informational agendas. Past OIRA administrators have claimed interagency collaboration among their priorities and achievements[66], but in my limited experience (as OSHA's representative to several of these groups between 1995 and 2000), while there was extensive collaboration around legislative issues (notably the regulatory "reform" proposals), issues that involved risk transfers, duplication of effort, or inconsistent requirements across two or more agencies were rarely an opportunity for true collaboration; rather, they prompted OIRA to orchestrate one agency's aquiescence to the plans of another (for example, to write letters attesting that alleged risk-risk transfers were not significant). In contrast, brainstorming about solutions and opportunities could flourish if OIRA was willing (perhaps by reallocating its sights and resources somewhat away from intense rule-by-rule oversight, a development some would welcome on its own merits) to "prompt" agencies to work together on interventions whose ideal solutions depend on multiple perspectives, and to develop their own plans to solve problems revealed by, or exacerbated by, the actions of another agency. The notion of a "forest group" looking broadly at options to minimize contradictory interventions and increase

win/win coordination is reminiscent of the proposal then-Judge Stephen Breyer made 15 years ago [67] for a "coherent risk regulatory system" that would involve far more meaningful interagency collaboration than harmonizing allometric scaling[68] or agreeing not to comment on another agency's rule, although Breyer did not envision a solution-focused approach to risk management or a central role for the public in technology options analysis [69].

9. A Specific Example

Although they were not included in the main body of the report, the **Science and Decisions** Committee published three short case studies of how risk-based decision-making could involve, as Appendix F of its report. In addition to a hypothetical discussion of the siting of a new power plant in a low-income neighborhood (in which the government, the community, and the utility company might discuss the risks and benefits of the proposal as well as alternative designs and locations) Appendix F contained a brief discussion of continuous improvement in maintaining a community drinking water system.[14] The third case study also brings in issues of risk-risk transfer and life-cycle solutions, and I will briefly expand upon it here.

Suppose that EPA and OSHA were each considering how to reduce human exposures to methylene chloride (MC), and were considering (on their own accord or by prompting from OIRA) working jointly on one important source of MC exposure: the stripping of paint from aircraft.

Table I depicts four different kinds of risk management questions the agencies could ask, moving from the least to the most solution-focused and from the narrowest to the broadest range of solutions. The first two rows depict the traditional substance-

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[14] A recent op-ed [70] tackled the safe drinking water problem from a novel solution-focused perspective: the author suggested that drinking water could be made even safer via the installation of point-of-use filters on household taps used for drinking and cooking water, while taps used for laundry and toilet water could instead meet a slightly relaxed set of toxic contaminant levels. This idea sprang from the question "how can we provide water safe enough for its intended use?", not from "what is the acceptably safe concentration of each substance in household water?"

specific (and bureaucratically compartmentalized) approach: each agency separately sets an exposure (or emissions) limit for this operation. The only technical analysis required for this decision is a dose-response assessment, although at OSHA, if this sector (aircraft repainting) was the one that had the most difficulty meeting the one-size-fits-all PEL for MC, the agency might have to ensure that the technology to achieve the PEL was economically feasible for this sector. The imposition of the exposure-limit solution could result in adequate compliance (which would have to be verified by chemical sampling and analysis), or in non-compliance, or in any of at least three kinds of unfortunate risk-risk trade-offs: (1) the repainters could substitute a more toxic material for MC[15]; (2) depending on the vagaries of economics and enforcement, they could comply with the EPA requirement by decreasing ventilation in hangars or spray booths, or with the OSHA requirement by increasing it—either way, transferring exposure to or from the workplace rather than reducing it[(73)]; or (3) they could repaint less often, which conceivably could result in mechanical defects underneath the paint going unnoticed.

The third row is a highly simplified summary of technology-based thinking uninformed by risk analysis: the controls already used elsewhere in this sector are presumed to be affordable, and compliance is presumably more likely and is easier to verify, but the degree of risk reduction (with or without considering offsetting risks) is not gauged.

The fourth row asks the most basic solution-focused question: what are the risks and costs of methods to fulfill the function? (defined for the moment as "freshly-painted aircraft"). It is possible that mechanical removal of old paint, using more or less abrasive materials, could emerge as the method providing the greatest net benefit, and not incidentally one that defuses the potential zero-sum risk transfers (assuming there are no significant ergonomic risks to the workers handling the new spray guns).

The fifth row supposes that the agencies (perhaps joined here by DOE and DOT, who have a vested interest in fuel economy) choose to ask a more fundamental solution-

[15] This is a highly plausible scenario—for example, after OSHA's MC regulation was promulgated in 1997, manufacturers began aggressively touting an unregulated substitute (1-bromopropane), despite its known neurotoxic properties and close structural relationship to several animal carcinogens[(71)]. The brominated material is now also being used as a substitute for perchloroethylene in dry cleaning.[(72)].

focused question: could the function be fulfilled without the cycle of painting, stripping, inspecting, and repainting aircraft? American Airlines implemented its own "ideal final result"(40) on its own accord some years ago, and now saves 7 million gallons of jet fuel per year by coating the bare metal rather than painting it.

There is no reason that government, industry, and the affected public couldn't convene and ask even more probing questions about the function of air travel: to the extent that some portion of it serves to bring people together for face-to-face meetings, aiding innovation in the sector that provides virtual substitutes for in-person meetings might derive still more net benefit by reducing energy use and the other externalities of air travel.

The "solution focused" question can be as ambitious as the participants desire: the point of this example, regardless of where the reader balks at the breadth of the solution, is that *no innovation beyond "less MC exposure to some or all of the affected persons" would be part of a decision process that defined the problem before considering the opportunities.*[16] Viewed this way, I hope it is clear that the traditional paradigm can do no better than to provide an optimal answer to a sub-optimal question.

10. Conclusions

Risk assessment for its own sake is an inherently valuable activity, but at best, a risk assessment can illuminate what we should *fear* – whereas a good solution-focused analysis can illuminate what we should do. In the same vein, the search for an acceptable level of risk is motivated by the noble desire to do less harm, but there is a different goal possible—to do more good. This latter orientation requires us to see opportunities where we are tempted to see only hazards to abate. Again, I have never believed that risk assessment is or must be that which "keeps the death camp trains running on time"(74), so I think we need to be aware that there are alternative visions that take risk assessment out

[16] Similarly, defining the medical problem in Section 4 above as "uncomfortable pants" would foreclose thinking about diet and exercise (bigger pants being a cheap and effective solution to this problem).

of the equation in the vain hope that precaution or "best available technology" alone can make the choices facing us less tragic [75, 76].

The notion that analysts and decision makers must interact is no longer controversial. And in a steady manner, others have moved the center of gravity of our field gradually towards the conclusion that decision options ("solutions") should be arrayed earlier and earlier in the process than the Red (or the "Mis-read"[77]) book originally intended. **Science and Decisions** is to date the culmination of this forward motion to turn risk assessors loose to evaluate solutions rather than hazards, and so this proposal for SFRA is incremental in that it moves the initial enumeration of possible solutions to the very beginning (after the signal of harm is deemed significant) rather than "closer to the beginning" as in **Science and Decisions**. It is much more than incremental, though, if I am correct that it is much more difficult to see the situations we confront in risk management as both problems and opportunities unless we "formulate and scope" in a way that initially keeps all opportunities open, until such time as analysis finds them to be impermissible or clearly dominated by other available responses.

I offer this proposal out of concern for human health and the environment, but also out of concern, misplaced or legitimate, for our shared profession of risk analysis. I look around at our unfinished risk-reduction business and believe that bolder solutions are worth contemplating, and that government – in the sense of officials acting in concert with the regulated and the affected—must play a greater role in envisioning specific technologies and lifestyle changes than it has in the past. But I also look around and see others who share the sense of urgency about goals but who are contemptuous of risk analysis as a means. The marriage of technology options analysis and risk analysis is especially compelling, I believe, when viewed with eyes open as an alternative to technology-based interventions *without* risk analysis, or precaution without assessment, or exposure limits without considering whether too much or too little cost accompanies them. Perhaps a train is coming down the track wherein some new ways will be promoted for protecting human health and the environment—some wise, others less so, and still others counter-productive or worse. If so, we risk assessors should be on board that train, preferably (in my view) in the lead car along with the conductor and the

engineer, not watching it go by while we display our erudition and understanding of hazards. And if that train is not already on the track, perhaps we risk assessors should put it there.

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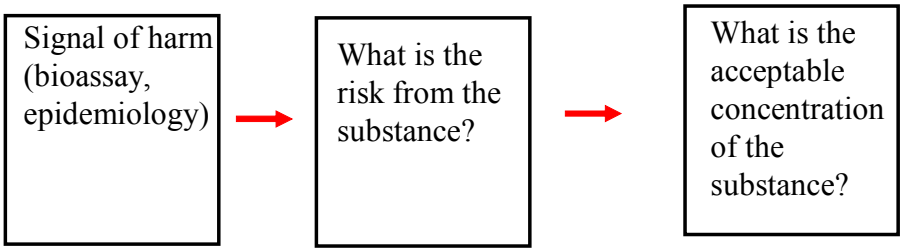
FIGURE 1

[the "old" (current) way]



[a possible new way]

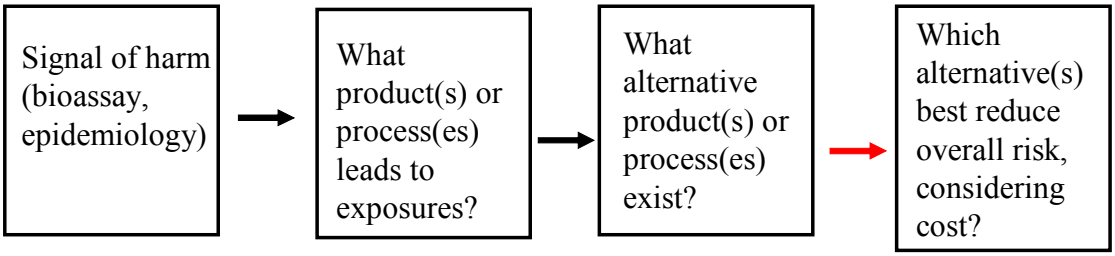


FIGURE 2

A Gestalt Diagram

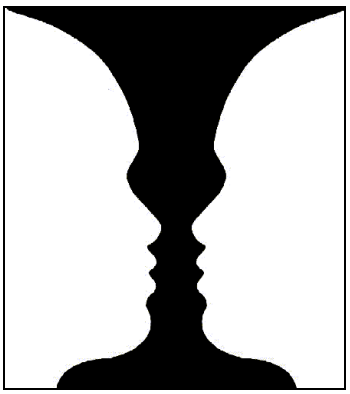


Table I: An Example of "SFRA 2.0"

Question	Analytic Exercise(s)	Pronouncement		Response by Airplane Painters
(EPA) What is the RSD(10^{-6})?	Potency	No more than X ppb in outdoor air (or Y g/L VOC)		• nothing? More toxic substitute? • Close windows? • Still dispose of paint/MC slop
(OSHA) What is the RSD(10^{-3})?	Potency, Technical feasibility	No more than Z ppm in indoor air		• nothing? More toxic substitute? • "Open windows" • Strip less often (accidents)?
What is BAT for this operation?	Efficiency	Spray booths, respirators, carbon adsorption		• comply (accidents?) • move overseas?
How can we **repaint planes** at min [risk plus cost]?	Risk, Efficiency, Cost, Distribution	Require steel shot, walnut shells, or starch pellets		• comply? • not? • dispose of paint
How can we provide **air travel** at min [risk plus cost]?	Risk, Efficiency, Cost, Distribution	Ban (tax) painted planes		• Coated metal with artwork • Less fuel used*

* An unpainted 747 weighs 500 lbs. less than a painted one; American Airlines saves 7 million gallons of jet fuel per year by eliminating paint (about 0.5% of its total fuel consumption)

There's No Place Like Home: Reshaping Community Interventions and Policies to Eliminate Environmental Hazards and Improve Population Health for Low-Income and Minority Communities

*Emily A. Benfer and Allyson E. Gold**

Introduction

Substandard housing and environmental conditions threaten the health and well-being of individuals residing throughout the United States. Empirical evidence on the relationship between housing and health has increased exponentially.[1] However, despite the growth in research, residents continue to be exposed to environmental health hazards. Minorities and people in poverty are exposed to environmental health hazards at a disproportionately high rate. Hazards, such as lead, mold, pest infestation, radon, and carbon monoxide, among others, threaten individual safety and health and limit one's ability to access opportunity in society. Moreover, the effects of exposure can be far-reaching.[2]

Common approaches to healthy communities and homes fail to protect residents from exposure to environmental health hazards. Federal, state, and local jurisdictions often rely on education and research, regulation of real estate transactions, heightened standards for special populations, enactment of minimum habitability standards, hazard mitigation, and community-level interventions. Taken together, these approaches are fragmented, reactive

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[1] *See* World Health Org., International Workshop on Housing, Health and Climate Change: Developing Guidance For Health Protection in the Built Environment—Mitigation and Adaptation Responses (Oct. 13, 2010), http://www.who.int/hia/house_report.pdf [https://perma.cc/RK8X-NNYR].

[2] *See generally* Emily A. Benfer, *Contaminated Childhood: The Chronic Lead Poisoning of Low-Income Children and Communities of Color in Federally Assisted Housing*, 41 Harv. Envtl. L. Rev. (forthcoming 2017); U.S. Gov't Accountability Office, GAO-73-577, Lead and Children's Health 11 (2007) [hereinafter Lead and Children's Health].

rather than preventive, and under-resourced. As a result, they are inadequate to prevent negative health consequences that accrue to residents.

This article analyzes the relationship between policies governing healthy communities and housing and health outcomes for residents. Part I discusses how environmental and housing conditions affect community and individual health, with a particular focus on conditions that cause lead poisoning, asthma and respiratory distress, and cancer. Part II examines current federal, state, and local approaches to healthy housing policy, including interventions directed at individual housing units as well as the community at-large. This part also analyzes the limitations of these policies that prevent residents from attaining good health. Part III offers recommendations to improve health outcomes for individuals and communities.

I. Overview of the Environmental and Housing Conditions Affecting Individual & Community Health

It is widely accepted that there is more to health than health care.[3] Only ten to twenty percent of health is related to access to care and quality of health care services.[4] The remaining determinants of health include social, economic, and environmental factors.[5] "We literally embody, biologically, the societal and ecological conditions in which we grow up and develop and live."[6] The environmental factors affecting individual and community health include conditions of the home, hazards in the community, and lack of affordable decent housing. These factors disproportionately affect minorities and people with low socioeconomic and minority status.

A. The Home as a Predictor of Individual Health

The home can have a significant impact on individual health. On average, the majority of Americans spend "90 percent of their time indoors, and two-thirds of that time is spent in the home."[7] Children spend even more time in the home and are more vulnerable to household hazards.[8] Especially in light of the extensive time spent in the home, good health outcomes de-

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[3] Sandra Braunstein & Risa Lavizzo-Mourey, *How the Health and Community Development Sectors Are Combining Forces to Improve Health and Well-Being,* Health Aff. 30, No. 11 at 2042.

[4] *See* Tyler Norris & Ted Howard, Can Hospitals Heal America's Communities? "All in for Mission" is the Emerging Model for Impact 3, Democracy Collaborative (2015); *see also* J. M. McGinnis et al., *The Case for More Active Policy Attention to Health Promotion*, 21 Health Aff., 78, 83 (2002).

[5] *See* McGinnis, *supra* note 4, at 79–80.

[6] Harvard T.H. Chan School of Public Health, *Racism-Induced Stress Linked with High Black Infant Mortality Rates* (2017), https://www.hsph.harvard.edu/news/hsph-in-the-news/racism-induced-stress-black-infant-mortality/ [https://perma.cc/DPA5-DMAH].

[7] *See* Robert Wood Johnson Found., Issue Brief 7, Exploring the Social Determinants of Health: Housing and Health 1 (2011).

[8] *See id.*

pend on the safety and physical conditions of a home.[9] According to former Surgeon General Steven K. Galson, "A healthy home is sited, designed, built, renovated, and maintained in ways that support the health of residents."[10] In contrast, substandard and inadequate housing can result in health problems, including infectious and chronic disease, injuries, and permanent disability.[11]

Thirty-five million, or forty percent of, metropolitan homes in the United States have one or more health and safety hazards.[12] Two million people in the United States live in severely inadequate homes that lack heat, hot water, electricity or maintenance of structural defects and problems.[13] Health hazards in the home may include indoor air quality, water quality, the presence of chemicals, structural safety, infestations, water leaks, roofing problems, damaged interior walls, and other factors that affect health outcomes.[14] Indoor environmental health hazards, which include a variety of health-harming agents including dust (lead, mold, pet and pest allergens, particulate matter, and insects), gas (smoke, radon, carbon monoxide), and water (moisture and polluted water sources), pose particular risks to the health of residents. Frequently, multiple health and safety hazards exist in residences and substandard homes and neighborhoods tend to cluster together,[15] compounding the risk of adverse health outcomes for occupants.[16]

On average, poor conditions affect low-income renters more than other populations. "[One] in ten poor households nationally live in inadequate housing. . . . Low-income households may be unable to afford expensive improvements, and renters may fear retaliation from their landlords if they report problems or seek to have them addressed."[17] Rental properties have a greater prevalence of health harming conditions than owner-occupied homes.[18] Homes in the inner city tend to have a greater negative impact on health than those located outside the city.[19]

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[9] *See* Lindsay Rosenfeld et al., *Are Neighborhood-Level Characteristics Associated with Indoor Allergens in the Household?*, 47 J. ASTHMA 66, 67 (2010) ("Neighborhood-level characteristics, specifically housing code violations, appear to be related to indoor allergens, which may have implications for future research explorations and policy decisions.").

[10] U.S. DEP'T OF HEALTH AND HUMAN SERVS., OFFICE OF THE SURGEON GENERAL, THE SURGEON GENERAL'S CALL TO ACTION TO PROMOTE HEALTHY HOMES, at vii (2009) [hereinafter THE SURGEON GENERAL'S CALL TO ACTION].

[11] *See* ROBERT WOOD JOHNSON FOUND., *supra* note 7, at 2.

[12] *See* NAT'L CTR. FOR HEALTHY HOUS., STATE OF HEALTHY HOUSING: EXECUTIVE SUMMARY (2013), http://www.nchh.org/Policy/2013StateofHealthyHousing/ExecutiveSummary.aspx [https://perma.cc/NP9P-T37Q].

[13] *See* THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 10, at 14.

[14] *See id.* at 5.

[15] *See* Wilhelmine D. Miller et al., *Healthy Homes and Communities: Putting the Pieces Together*, 40 AM. J. PREVENTIVE MED. 48, 49 (2011) [hereinafter Miller et al., *Healthy Homes and Communities*].

[16] *See id.*

[17] *Id.* at 51.

[18] *See* NAT'L CTR. FOR HEALTHY HOUS., *supra* note 12.

[19] Office of Healthy Homes and Lead Hazard Control, *Healthy Homes Issues: Mold*, U.S. DEPT. OF HOUS. AND URB. DEV. (Nov. 2011), http://healthyhousingsolutions.com/wp-content/uploads/2014/12/HUD_Mold_Paper_Final_11-20-12.pdf [https://perma.cc/Z5TS-FH46].

The negative health effects related to poor housing conditions include injuries,[20] mental health impairments,[21] respiratory distress, carbon monoxide poisoning,[22] gastrointestinal illness,[23] lead poisoning, and cancer, among other disabling conditions. Nearly a third of asthma cases result from substandard housing conditions, about 21,000 lung cancer deaths result from radon in homes, and over 24 million homes have lead-based paint hazards that put children at risk of lead poisoning and irreversible neurological damage.[24] The following discussion provides an overview of health effects caused by exposure to lead hazards, infestations, and radon found in the home. It is by no means exhaustive of the most relevant home health hazards, but rather illustrates the serious health consequences of common substandard housing conditions.

1. Lead Poisoning

Lead poisoning is an entirely preventable public health crisis that has resulted in permanent brain damage for millions of children throughout the twenty-first century.[25] Children, who are especially vulnerable to the effects of lead, are most often exposed to lead hazards in the home "in the form of chipping and peeling lead paint, lead dust, lead soil, and water contaminated by lead pipes, solder, or leaded sealant in wells."[26] Homes built before 1978 often contain lead-based paint and lead hazards.[27] Lead is present in approximately eighty-seven percent of homes built before 1940, sixty-nine percent of homes built between 1940 and 1959, and twenty-four percent of homes

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[20] *See* THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 10, at 10. There are 18,000 residential injury deaths annually. *Id.*

[21] *See id.* at 14 (2009) ("Poor housing conditions . . . are associated with risk for poor mental health [including] aggression and withdrawal, lower general health status, and psychological distress, particularly among women and children.").

[22] *See id.* at 6 ("Carbon monoxide exposure is responsible for approximately 450 deaths and more than 15,000 emergency department visits annually; 64% of these exposures occurred in the home. Acute exposure to high levels can cause unconsciousness, long-term neurological disabilities, coma, cardiorespiratory failure, and death.") (internal citations omitted).

[23] Patrick Drayna et al., *Association Between Rainfall and Pediatric Emergency Department Visits for Acute Gastrointestinal Illness*, 118 ENVTL. HEALTH PERSP. 1439, 1439 (2010). During periods of heavy rainfall, flooding, groundwater saturation, sewer overflows, and cross-contamination in water pipes can all lead to an increased risk for acute gastrointestinal illnesses due to water quality issues. *Id.*

[24] CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 5 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/SM5Y-9GZ6].

[25] *See generally* Emily A. Benfer, *Contaminated Childhood: How Federal Law and Policy Failed to Prevent the Chronic Lead Poisoning of Low-Income Children and Communities of Color in the United States*, HARVARD ENVTL. L. REV. (forthcoming 2017) [hereinafter *Contaminated Childhood*].

[26] Benfer, *supra* note 2.

[27] Lead-based paint was banned from residential use in 1978. *See* CONSUMER PROD. SAFETY COMM'N, CPSC ANNOUNCES FINAL BAN ON LEAD-CONTAINING PAINT (1977), https://www.cpsc.gov/Recalls/1977/cpsc-announces-final-ban-on-lead-containing-paint [https://perma.cc/MMC3-9GNH] (discussing regulations banning the use of lead in residential paint).

built between 1960 and 1978.[28] Approximately twenty-three million homes have one or more lead-based paint hazards, and an additional thirty-eight million homes have lead-based paint that will eventually become a hazard if not maintained.[29] "Lead in the environment does not dissipate, making it likely that a developing child will inhale or ingest it and become lead poisoned."[30]

Lead poisoning has an adverse effect on most major organ systems, including the cardiovascular, reproductive, immune, nervous, digestive, kidney, and renal systems.[31] As a result, lead poisoning causes severe and permanent biological and neurological damage that affects cognition, behavior, bodily functions, growth, and development. Even at low levels of exposure, it can lead to brain damage, reduced IQ, diminished intellectual and academic abilities, academic failure, juvenile delinquency, developmental delay, and learning disabilities.[32] It can result in neurobehavioral disorders, including hyperactivity, attention deficit, and other problems. At high levels, it triggers encephalopathy, convulsions, and coma.[33] Ultimately, lead poisoning can result in death.[34]

Once a child is lead poisoned, the effect on the brain is immediate and permanent, even after the toxin is removed from the body;[35] the harm is irreparable and no interventions can reverse it.[36]

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[28] Benfer, *supra* note 2.

[29] *Id.* When the paint deteriorates or chips, it creates paint chips, lead-contaminated dust, and lead-contaminated soil that is ingested or inhaled. *See* NATIONAL SURVEY OF LEAD AND ALLERGENS IN HOUSING 1, at ES-2 (2001).

[30] Benfer, *supra* note 2.

[31] *Id.* at 9.

[32] *Id.*; *see also* Bruce P. Lanphear et al., *Cognitive Deficits Associated with Blood Lead Concentrations <10 µg/dL in US Children and Adolescents*, 115 PUB. HEALTH REP. 521, 526–28 (2000); Bruce P. Lanphear et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSP. 894, 897–99 (2005); Letter from Sheela Sathyanarayana, Chair, Children's Health Prot. Advisory Comm., to Gina McCarthy, Adm'r, EPA (Jan. 8, 2015), https://www.epa.gov/sites/production/files/2015-01/documents/naaqs_for_lead_letter.pdf [https://perma.cc/D4VP-GCYQ] (noting that at blood lead level of 0.1 µg/dL, lead poisoning was associated with a one-point IQ loss, as well as other neurological and other health and developmental harms).

[33] Benfer, *supra* note 2, at 9; *see also* U.S. DEP'T OF HEALTH & HUMAN SERVS., THE NATURE AND EXTENT OF LEAD POISONING IN CHILDREN IN THE UNITED STATES: A REPORT TO CONGRESS 1 (1988) [hereinafter NATURE AND EXTENT OF LEAD POISONING].

[34] Benfer, *supra* note 2; *see also* Council on Envtl. Health, *Prevention of Childhood Lead Toxicity,* 138 PEDIATRICS 1 (2016); NATURE AND EXTENT OF LEAD POISONING, *supra* note 33, at 1. Before chelation therapy was developed in the 1950s, two-thirds of children who ingested lead paint, thereby suffering convulsions and swelling of the brain, died as a result. David Rosner & Gerald Markowitz, *Building the World That Kills Us: The Politics of Lead, Science, and Polluted Homes, 1970 to 2000*, 42 J. URB. HIST. 323, 326 (2016). Chelation therapy introduces Dimercaprol and Ethylenediaminetetraacetic acid into the blood stream to bind with lead and allow it to pass from the body. *Id.*

[35] Rosner & Markowitz, *supra* note 34, at 340.

[36] Benfer, *supra* note 2, at 8–9; *see also* LEAD AND CHILDREN'S HEALTH, *supra* note 2.

2. Asthma & Respiratory Distress

Environmental factors in substandard housing conditions, such as the presence of cockroaches, rodents, mold, excess moisture, and poor air quality, can cause and contribute to severe asthma.[37] Eighty-four percent of homes in the United States have dust mite allergens,[38] eighty-two percent have mouse allergens, and sixty-three percent have detectable levels of cockroach allergens.[39] Older homes and housing units located in low-income neighborhoods have high concentrations of mouse and cockroach allergens.[40] In one study, eighty-one percent of apartments in Gary, Indiana had cockroach, mice, ants, spiders, or fly infestations.[41] In the apartments evaluated, ninety-eight percent had detectable levels of allergens.[42] In another study of several countries in Europe, Canada, and the United States, at least twenty percent of buildings had one or more signs of conditions that would cause mold.[43] Several studies conducted in the United States estimated that the prevalence of dampness or mold in houses is approximately fifty percent.[44]

Forty percent of asthma episodes are triggered by household presence of mold, dust mites, or rodents.[45] Both the Institute of Medicine and the World Health Organization Guidelines for Indoor Air Quality found sufficient evidence of an association between exposure to indoor dampness and mold and upper respiratory tract symptoms, wheezing, coughing, and asthma symptoms in sensitized people.[46] The President's Task Force on Environmental Health Risks and Safety Risks to Children cited to environmental issues in the home as one of the barriers to effective asthma care.[47]

Asthma places severe limitations on an individual's ability to engage in activities of daily living.[48] For example, asthma alone results in fourteen mil-

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[37] *See* Johnna S. Murphy & Megan T. Sandel, *Asthma and Social Justice: How to Get Remediation Done*, 41 AM. J. PREVENTIVE MED. 57, 57 (2011); *see also* THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 10, at 7.

[38] THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 10, at 7–8.

[39] *See id.* at 8.

[40] *See id.*

[41] *See* Changlu Wang et al., *Survey of Pest Infestation, Asthma, and Allergy in Low-Income Housing*, 31 J. COMM. HEALTH 31, 31 (2008).

[42] *Id.*

[43] *Id.*

[44] *See* WORLD HEALTH ORG., EUROPE, WHO GUIDELINES FOR INDOOR AIR QUALITY: DAMPNESS AND MOULD 7 (2009).

[45] Tracey Ross et al., *Creating Safe and Healthy Living Environments for Low-Income Families*, CTR. FOR AM. PROGRESS 3 (July 20, 2016), https://www.americanprogress.org/issues/poverty/reports/2016/07/20/141324/creating-safe-and-healthy-living-environments-for-low-income-families/ [https://perma.cc/3T3S-PHYU].

[46] *See* WORLD HEALTH ORG., *supra* note 44, at 66–67.

[47] *See id.*

[48] For a description of a typical tenant experience with mold and health effects, *see* Emily A. Benfer & Amanda M. Walsh, *When Poverty is the Diagnosis: The Effects of Living Without on the Individual,* 4 IND. J. OF L. & SOC. EQUITY 1, 6–9 (2014).

lion missed work days each year.[49] Asthma is the leading cause of school absences.[50] Each year, 10.5 million school days are missed due to asthma.[51] In 2013, asthma caused 13.8 million missed school days among children ages five to seventeen.[52] These absences, compounded by the negative effects of asthma-related oxygen depletion, can have long-term consequences on child development, behavior, and academic achievement.[53] Ultimately, asthma costs the United States $56 billion annually, including $50.1 billion in direct health care costs, including the costs of 1.8 million asthma-related visits in United States emergency departments every year.[54] Left untreated, the indoor environmental threats that cause and trigger asthma can have lifelong effects on individual health.[55]

3. Cancer

Lung cancer can be caused by exposure to environmental toxins found in the home, such as radon gas and asbestos. Radon is a colorless, odorless, radioactive gas found naturally in the earth. The natural outdoor level and target level for indoor levels of radon gas is 0.4 picoCuries per liter of air (pCi/L).[56] Although radon can be present in well water, it presents the greatest risk in soil, since it is the natural byproduct of uranium decay.[57] Since radon is most often found in soil, it enters a home through the ground, passing through cracks in the foundation and fissures in the structure of the home.[58] Radon can enter a home irrespective of the building's age or structure, and once inside the home it is trapped and accumulates, affecting occupants.[59]

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[49] *See* ASTHMA AND ALLERGY FOUND. OF AMERICA, ASTHMA FACTS AND FIGURES (2015), http://www.aafa.org/page/asthma-facts.aspx [https://perma.cc/YV32-H8YT].

[50] *See* CTRS. FOR DISEASE CONTROL AND PREVENTION, ASTHMA AND SCHOOLS (2015), https://www.cdc.gov/healthyschools/asthma/ [https://perma.cc/8YSW-Y28Y].

[51] *See* U.S. ENVTL. PROT. AGENCY, MANAGING ASTHMA IN THE SCHOOL ENVIRONMENT (Mar. 15, 2017), https://www.epa.gov/iaq-schools/managing-asthma-school-environment [https://perma.cc/PCM4-TWKG].

[52] *See* ASTHMA AND ALLERGY FOUND. OF AMERICA, *supra* note 49.

[53] *See* Joel L. Bass et al., *The Effect of Chronic or Intermittent Hypoxia on Cognition in Childhood: A Review of the Evidence*, 114 PEDIATRICS 805, 814 (2004).

[54] *See* Tiffany Wang et al., *Emergency Department Charges for Asthma-Related Outpatient Visits by Insurance Status*, 25 J. HEALTH CARE FOR POOR AND UNDERSERVED 396, 396 (2014).

[55] *See* ASTHMA AND ALLERGY FOUND. OF AMERICA, *supra* note 49.

[56] U.S. ENVTL. PROT. AGENCY, BASIC RADON FACTS (Feb. 2013), https://www.epa.gov/sites/production/files/2016-08/documents/july_2016_radon_factsheet.pdf [https://perma.cc/BSB5-TWJK].

[57] Radon is a naturally occurring radioactive gas emitted by the normal decay of uranium, which is found in most soils; some soils have higher levels than others. *See* U.S. ENVTL. PROT. AGENCY, RADON IN HOMES AND BUILDINGS, https://www3.epa.gov/radtown/radon-homes-buildings.html [https://perma.cc/83DW-G2YE] [hereinafter RADON IN HOMES AND BUILDINGS].

[58] Klaus Schmid, *Radon in Indoor Spaces, An Underestimated Risk Factor for Lung Cancer in Environmental Medicine*, 107 DTSCH ARZTEBL INT. 181, 183 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2853156/ [https://perma.cc/C3FC-F29Z].

[59] RADON IN HOMES AND BUILDINGS, *supra* note 57.

Nearly one in fifteen homes in the United States have radon levels above the U.S. Environmental Protection Agency (EPA) action level of 4pCi/L.[60] Homes in the Midwest and Eastern states are more likely to have elevated radon levels than Southern or West Coast states. In one Midwestern state, sixty percent of houses tested above the EPA's action level.[61] Occupants of single-family homes are twice as likely to know about radon and whether their house has been tested than occupants of apartments.[62]

Residents of the home breathe in the radon gas, and radioactive particles become trapped in their lungs, damaging the tissue and increasing their risk of lung cancer.[63] Radon is the second leading cause of lung cancer in the United States[64] and the leading cause of lung cancer among nonsmokers, causing an estimated 15,400 to 21,800 lung cancer deaths annually.[65]

B. Environmental Hazards in the Community

The location of a home also has an influence on individual health.[66] "[O]ne's health and life expectancy is determined more by zip code than genetic code."[67] In fact, over 131 million Americans, or forty percent, live in neighborhoods with bad air quality.[68] Communities with large concentrations of low-income and minority residents are especially likely to live near industrial areas and be exposed to high levels of pollutants.[69] These communities are less likely to be protected by zoning laws and are frequently in close proximity to waste facilities, bus depots, and highways.[70] Even low levels of pollution can increase morbidity and mortality.[71] Asthma rates increase near high pollution areas, such as freeways or factories.[72] Similarly, lead poison-

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[60] *Id.*

[61] THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 6, at 7; *see also* U.S. ENVTL. PROT. AGENCY, BASIC RADON FACTS (Feb. 2013), https://www.epa.gov/sites/production/files/2016-08/documents/july_2016_radon_factsheet.pdf [https://perma.cc/BSB5-TWJK].

[62] *See* Laura S. Larsson et al., *Householder Status and Residence Type as Correlates of Radon Awareness and Testing Behaviors*, 26 PUB. HEALTH NURSING 387, 387 (2009).

[63] RADON IN HOMES AND BUILDINGS, *supra* note 57.

[64] U.S. ENVTL. PROT. AGENCY, HEALTH RISK OF RADON (Apr. 19, 2017), https://www.epa.gov/radon/health-risk-radon [https://perma.cc/5J5L-YKW5].

[65] *See* Warren E. Leary, *Research Ties Radon to as Many as 21,800 Deaths Each Year*, N.Y. TIMES (Feb. 20, 1998), http://www.nytimes.com/1998/02/20/us/research-ties-radon-to-as-many-as-21800-deaths-each-year.html?mcubz=2 [https://perma.cc/3ESV-J395].

[66] *See* Ruchi S. Gupta et al., *The Protective Effect of Community Factors on Childhood Asthma*, 123 J. ALLERGY CLINICAL IMMUNOLOGY 1297, 1297 (2009).

[67] Ross et al., *supra* note 45.

[68] *Air Pollution: Everything You Need to Know*, NAT. RES. DEF. COUNCIL (Nov. 1, 2016), https://www.nrdc.org/stories/air-pollution-everything-you-need-know [https://perma.cc/8THX-XHE2].

[69] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51.

[70] *Id.*

[71] *Id.*

[72] Emily Benfer, *Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Injustice*, 65 AM. U.L. REV. 275, 297 [hereinafter Benfer, *Health Justice*].

ing increases in high-traffic areas and near former or existing industrial sites where lead contamination in the soil and vegetation is common.[73]

The school environment can also be a source of poor health. School bus exhaust, mold, pests, poor ventilation can be sources of asthma.[74] Even drinking water in schools may have lead contamination, especially in under-financed school systems that have few resources to remedy the problem.[75] The majority of schools, especially in low-income and minority communities, are in need of repairs or updates to improve safety and decrease harmful exposures to health and other risks.[76] Children are particularly sensitive to these unhealthy conditions.

The presence, or absence, of opportunities within a community also has an effect on health. The number of educational and economic resources across U.S. communities varies widely, contributing to the gradient seen in educational attainment, income, and job status.[77]

C. Lack of Affordable Housing

The United States has an extreme and chronic affordable housing crisis.[78] For approximately two million families with low socioeconomic status, housing is severely deficient.[79] As noted by the Joint Center for Housing Studies of Harvard University in *State of the Nation's Housing 2016*, there were "only thirty-one rental units affordable and available for every one hundred extremely low-income[80] renters, and fifty-seven rental units affordable and available for everyone one hundred very low-income[81] renters."[82] The lack of affordable housing is directly linked to poor health outcomes.[83] Due to the high cost of housing and since the "rent eats first,"[84] low-income families are forced to dedicate fewer resources to health and health care, as well as heat food and other basic needs.[85] Lack of affordable housing is associated with increased prevalence of relocation and mobility, causing a

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[73] Miller et al., *Healthy Homes and Communities, supra* note 15, at S51.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *Id.* at S49.

[78] Josh Leopold et al., *The Housing Affordability Gap for Extremely Low-Income Renters in 2013*, Urban Inst. (June 15, 2015), http://www.urban.org/research/publication/housing-affordability-gap-extremely-low-income-renters-2013/view/full_report [https://perma.cc/VR9L-H332].

[79] *Id.*

[80] Joint Ctr. for Hous. Studies of Harvard Univ., State of the Nation's Housing 2016, *Executive Summary*, 5 (2016), http://www.jchs.harvard.edu/sites/jchs.harvard.edu/files/son_2016_200dpi_ch1.pdf [https://perma.cc/4D2Z-VTP6] (defining extremely low-income as "earning 30 percent or less of area median").

[81] *Id.*

[82] *Id.*

[83] In 2007, roughly forty million Americans spent more than thirty percent of their income on housing expenses. Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51.

[84] *See generally* Matthew Desmond, Evicted: Poverty and Profit in the American City (2016); Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51.

[85] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51.

disruption in schooling, health care, and social networks.[86] As a result, it is common for low-income households to experience delays in seeking preventive and routine medical care, have difficulty adhering to medication schedules, and have increased emergency department utilization.[87]

Low-income individuals and families are often hard pressed to find adequate affordable housing and may need to move often to avoid homelessness.[88] Thirty percent of low-income children live in households with housing instability, defined as "frequent moves, difficulty paying rent, spending more than fifty percent of household income on housing, being evicted or living in overcrowded conditions."[89] "People with low-household incomes, the elderly, people with disabilities, and minority populations are least likely to have access to safe, healthy, affordable, and accessible homes."[90] Housing instability is associated with delay in receipt of health care and increased emergency department use for primary care among children.[91]

People with low incomes may not be able to secure adequate, affordable homes and may be forced to move often.[92] Further, affordability does not connote the condition of the property. Therefore, even if an individual is able to identify affordable replacement housing, it may also contain hazards to health. Often, the only alternative is homelessness, a situation experienced by an estimated 2.1 million adults and 1.3 million children annually.[93] "Homelessness and housing instability contributes to adverse health outcomes, including increased asthma morbidity, tuberculosis, and developmental delay, as well as school failure and delinquency," and increased complications with ongoing illnesses and disabilities.[94] Until the United States addresses the affordable housing crisis, healthy homes and communities cannot be achieved.

D. Disproportionate Effect on Low-Income People and Communities of Color

People with low socioeconomic status and racial and ethnic minorities are exposed to environmental health risks in the home and community at a disproportionately high rate.[95] There has been a dramatic increase in the number of high-poverty neighborhoods, with the number of people living in high-poverty areas nearly doubling since 2000 from 7.2 million to 13.8 mil-

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[86] *Id.*
[87] *Id.*
[88] THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 10, at 18.
[89] Wilhelmine D. Miller et al., *Healthy Starts for All: Policy Prescriptions*, 40 AM. J. PREVENTIVE MED., S19, S22 (2011) [hereinafter Miller et al., *Healthy Starts for All*].
[90] THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 10, at 18.
[91] Miller et al., *Healthy Starts for All*, *supra* note 89, at S22.
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.* at S48.

lion.[96] Poverty is becoming more concentrated in communities of color. The highest rate of poverty at 24.1% is in the black population, followed by the Hispanic population at 21.4%.[97] One in four black people in poverty and one in six Hispanic people in poverty live in extreme poverty neighborhoods compared to one in thirteen of white poor.[98]

Close to half of children five and under live in low-income families.[99] For children, health outcomes are dramatically affected by income, education, and racial or ethnic group.[100] For example, children in poor families are five times more likely to be in less than optimal health, compared with families in the highest income levels.[101] Child poverty is more common among African Americans and American Indians, with thirty-eight percent of African American children and thirty-six percent of American Indian children living in poverty in 2014.[102] This is *nine* times the rate for poor white children (four percent).[103]

Low-income minority renters have a higher incidence of exposure to substandard housing conditions compared to other renters or homeowners.[104] Indoor environmental hazards are common in low-income housing and this type of exposure is common in housing developments.[105] In one study, living in public housing was associated with exposure to higher levels of cockroach and mouse allergens, which is a cause of asthma.[106] In addition, low-income minority groups are the most exposed to air pollution and toxins in their community.[107] The majority of people who live adjacent to commercial

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[96] *See* Norris & Howard, *supra* note 4.

[97] Bernadette D. Proctor et al., U.S. Census Bureau, Income and Poverty in the United States: 2015 Current Population Reports 14 (2016).

[98] Michael B. Sauter, et al., *Cities Hit Hardest by Extreme Poverty*, 24/7 Wall St., (Apr. 7, 2017), http://247wallst.com/special-report/2017/04/07/cities-hit-hardest-by-extreme-poverty-2/ [https://perma.cc/ATP6-4WPA].

[99] Proctor et al., *supra* note 97, at 10.

[100] Miller et al., *Healthy Starts for All*, *supra* note 89, at S23.

[101] *Id.*

[102] Annie E. Casey Found., Kids Count: Data Book: State Trends in Child Well-Being 16, 22 (2016), http://www.aecf.org/m/resourcedoc/aecf-the2016kidscountdatabook-2016.pdf [https://perma.cc/2AG3-RJMU].

[103] *Id.* at 19.

[104] The Surgeon General's Call to Action, *supra* note 10, at 15 (citing Joint Ctr. for Hous. Studies of Harvard Univ., *supra* note 80).

[105] Gary Adamkiewicz et al., *Environmental Conditions in Low-Income Urban Housing: Clustering and Associations with Self-Reported Health*, 104 Am. J. Pub. Health 1650, 1653 (2014).

[106] Lindsay Rosenfeld et al., *Are Building-Level Characteristics Associated with Indoor Allergens in the Household?*, 88 J. Urb. Health 14, 18 (2011).

[107] *See* Marie Lynn Miranda et al., *Making the Environmental Justice Grade: The Relative Burden of Air Pollution Exposure in the United States*, 8 Int'l J. Envtl. Res. & Pub. Health 1755, 1757 (2011); *see also* Benfer, *supra* note 2 ("[S]tudies have documented limited access to clean water in low-income communities of color. Water contamination has largely affected children of color who live in rural areas, indigenous communities, and migrant farmworker communities. Contaminated water can cause an abundance of health-related issues, particularly for young children. Depending on the contaminant, possible health problems can include waterborne diseases, blood disorders, and cancer.").

waste facilities in the United States are minorities.[108] Data spanning a twenty-year time period indicates that half of the people who live within 1.86 miles of a toxic waste facility in the United States are minorities.[109] Approximately 70% of Superfund sites, with dangerously high levels of contaminants including neurotoxins and carcinogens, are within a mile of low-income public housing or federally assisted housing that is predominately occupied by people of color.[110] Minorities are nearly twice as likely as white people to live within a "fenceline zone"[111] of an industrial facility that contributes to air pollution, safety issues, and health concerns.[112] The percentage of blacks within fenceline zones is seventy-five percent greater than for the United States as a whole, and the percentage of Latinos is sixty percent greater.[113] The poverty rate in the fenceline zones is fifty percent higher than for the United States as a whole.[114] In many cases, the siting of these communities was due to deliberate government action.[115] For example, government actors intentionally located federally assisted housing in toxic environments.[116]

The burden of environmentally induced asthma falls largely on low-income minorities and is evident in disparities in asthma epidemiology.[117] The public health field identified racial differences in asthma prevalence as an important public health concern.[118] Forty percent of the risk of asthma in

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[108] *See* Jane Kay & Cheryl Katz, *Pollution, Poverty, People of Color: The Factory on the Hill*, ENVTL. HEALTH NEWS (June 4, 2012), http://www.environmentalhealthnews.org/ehs/news/2012/pollution-poverty-and-people-of-color-richmond-day-1 [https://perma.cc/8P48-4LJZ].

[109] Jasmine Bell, *5 Things to Know About Communities of Color and Environmental Justice*, CTR. FOR AM. PROGRESS (Apr. 25, 2016), https://www.americanprogress.org/issues/race/news/2016/04/25/136361/5-things-to-know-about-communities-of-color-and-environmental-justice/ [https://perma.cc/THQ4-RLA2].

[110] Sylvia Carignan, *Majority of Superfund Sites Near Low-Income Housing*, BLOOMBERG (May 9, 2017), https://www.bna.com/majority-superfund-sites-n73014450645/ [https://perma.cc/3ALN-2UT4].

[111] A fenceline zone is an "area designated as one-tenth the distance of the vulnerability zone, in which those affected are least likely to be able to escape from a toxic or flammable chemical emergency, but not representing the outer bounds of potential harm. For example, if the vulnerability zone is a radius of 10 miles around the facility, then the fenceline zone is a radius of one mile around the facility." ENVTL. JUSTICE AND HEALTH ALLIANCE FOR CHEM. POLICY REFORM, A DEMOGRAPHIC ANALYSIS OF CHEMICAL DISASTER VULNERABILITY ZONES (2014), http://comingcleaninc.org/assets/media/images/Reports/Who%27s%20in%20Danger%20Report%20FINAL.pdf [https://perma.cc/H37E-PB64].

[112] *See* Bell, *supra* note 109.

[113] ENVTL. JUSTICE AND HEALTH ALLIANCE FOR CHEM. POLICY REFORM, WHO'S IN DANGER? RACE, POVERTY AND CHEMICAL DISASTERS 3 (2014), http://comingcleaninc.org/assets/media/images/Reports/Who's%20in%20Danger%20Report%20FINAL.pdf [https://perma.cc/6H3N-VB28].

[114] *Id.*

[115] *Id.*

[116] *See* Benfer, *supra* note 2.

[117] *See* Gupta et al., *supra* note 66, at 1301; *see also* ASTHMA AND ALLERGY FOUND. OF AM & NAT'L PHARMA. COUNCIL, ETHNIC DISPARITIES IN THE BURDEN AND TREATMENT OF ASTHMA (2005), http://www.aafa.org/media/Ethnic-Disparities-Burden-Treatment-Asthma-Report.pdf [https://perma.cc/D9PW-4T8Y].

[118] *See* Gupta et al., *supra* note 66, at 1297.

minority children is due to exposure to residential allergens that could be reduced, if not eliminated.[119] African American children are twice as likely to be hospitalized, more than twice as likely to have an emergency department visit, and four times more likely to die due to asthma than white children.[120] A study of asthma prevalence among school children in Chicago demonstrated the disparity, with African American children having asthma prevalence at twenty percent, twice that of white (ten percent) and Hispanic children (eleven percent).[121] The study revealed that as the African American population increased in a community, so did the asthma prevalence.[122] According to the President's Task Force on Environmental Health Risks and Safety Risks to Children, the percent of children from households below the federal poverty line with asthma is higher than children from higher-earning households.[123] "Children living in poverty are more likely to be diagnosed, to experience more severe symptoms, and to have ongoing asthma symptoms than their more affluent peers."[124] Thus, the long-term and societal consequences of asthma threaten already vulnerable populations.[125]

The cost of treating asthma symptoms can be crippling to an individual experiencing financial hardship and perpetuate the problem by limiting the ability to pay for care.[126] The majority of emergency department visits for asthma occur among minorities, those of lower socioeconomic status, Medicaid patients, and the uninsured.[127] According to one study:

> [T]he 16% of Americans who are uninsured often wait for symptoms to deteriorate due to financial barriers to care, and eventually must seek urgent care in the ED. In fact, visits to the [emergency department] accounted for 39% of all health care visits for asthma among uninsured patients, compared with 14% for the privately insured and those insured by Medicaid.[128]

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[119] *See* ASTHMA AND ALLERGY FOUND. OF AMERICA ET AL., *supra* note 117, at 17.
[120] *Id.* at 6.
[121] *See* Gupta et al., *supra* note 66, at 1299.
[122] *Id.*
[123] *See* Benfer, *Health Justice*, *supra* note 72, at 297; U. S. ENVTL PROT. AGENCY, PRESIDENT'S TASK FORCE ON ENVIRONMENTAL HEALTH RISKS AND SAFETY RISKS TO CHILDREN 2 (2012), https://www.epa.gov/sites/production/files/2014-08/documents/federal_asthma_disparities_action_plan.pdf [https://perma.cc/UUB4-PYLV].
[124] *See* Benfer, *Health Justice*, *supra* note 72, at 297; *see also* Johnna S. Murphy & Megan T. Sandel, *Asthma and Social Justice: How to Get Remediation Done*, 41 AM. J. PREVENTIVE MED., S57 (2011).
[125] *See* ASTHMA AND ALLERGY FOUND. OF AM & NAT'L PHARMA. COUNCIL, *supra* note 117.
[126] *See* Tiffany Wang, et al., *Emergency Department Charges for Asthma-Related Outpatient Visits by Insurance Status*, 25 J. HEALTH CARE FOR THE POOR AND UNDERSERVED 396, 400 (2014).
[127] *See id.* at 396.
[128] *Id.*

"Access to care is hampered by socioeconomic disparities, shortages of primary care physicians in minority communities, and language and literacy barriers."[129]

Further, community factors make a difference in asthma prevalence.[130] For example, as one study found, neighborhoods with more civic engagement and community diversity, economic vigor and commercial vitality, buying power, and workforce potential had lower levels of childhood asthma.[131] Lower asthma rates were also common in neighborhoods with many cultural and entertainment facilities and restaurants.[132] In contrast, neighborhoods with high asthma rates had little community interaction and community members were less likely to move.[133]

Racial segregation is a key factor underlying the differences in exposure to residential and environmental toxins and pollutants.[134] In a recent study of the one hundred largest metropolitan areas in the United States, researchers determined that segregation produces large differences in opportunities for growth and development for children.[135] The researchers concluded that "high levels of segregation lead to entrenched disparities in wealth, educational attainment, and income between blacks and whites that can be attributed to the lower property values, inadequate schools, and paucity of job opportunities in minority communities."[136] Thus, the United States's legacy of race-restrictive covenants and investment in segregated communities resulted not only in today's segregated housing communities but also in urban squalor and overcrowded housing.[137] Despite civil rights laws, high levels of segregation persist,[138] with blacks residing in greater segregation than any other group in United States history.[139] Demonstrative of the pervasiveness of racial segregation, research shows that even high-income blacks live under higher levels of segregation than the poorest Hispanic and Asian populations.[140]

Federal housing programs meant to promote access to affordable housing perpetuate this segregation. For example, despite the fact that studies show the Housing Choice Voucher Program (HCVP) can successfully help families access healthier communities and better health outcomes,[141] partici-

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[129] Asthma and Allergy Found. of Am & Nat'l Pharma. Council, *supra* note 117.
[130] *Id.*
[131] *Id.* at 1300.
[132] Gupta et al., *supra* note 66, at 1300.
[133] *Id.* at 1301.
[134] *See generally* Benfer, *Health Justice*, *supra* note 72, at 282–87.
[135] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S49.
[136] *Id.* at S49–50.
[137] Benfer, *supra* note 2.
[138] Gregory Acs et al., *The Cost of Segregation: National Trends and the Case of Chicago, 1990–2010*, Urban Inst. (Mar. 28, 2017), http://www.urban.org/research/publication/cost-segregation [https://perma.cc/VZX5-48Z3].
[139] Miller et al., *supra* note 15, at S49.
[140] *Id.*
[141] Philip Tegeler & Salimah Hankins, *Prescription for a New Neighborhood*, Shelterforce (2012), http://www.shelterforce.org/article/2769/prescription_for_a_new_neighborhood/ [https://perma.cc/ZT7F-DPTR] (discussing studies linking moves from low to

pants are concentrated in neighborhoods that are "poorer, more racially segregated, and of lower quality than other neighborhoods."[142] Specifically, short periods of time in which to identify housing,[143] barriers to using vouchers outside of narrow jurisdictional lines,[144] the ability of landlords in many jurisdictions to refuse to rent to HCVP families,[145] and the failure of developers and landlords who receive federal housing subsidies to engage in affirmative marketing to low-income and minority families[146] segregate families and exacerbate barriers to achieving good health.

Communities of color and ethnic minorities experience environmental-related health problems at a greater rate than non-minorities.[147] Poverty and segregation create enormous barriers to achieving positive health outcomes.[148]

II. Traditional Approaches to Healthy Housing and Communities

Current law addresses healthy housing and communities through regulations governing homes coupled with policies regarding community development. There are five approaches most commonly employed by federal, state, and local jurisdictions to combat exposure to in-home health hazards.[149] These approaches include education and research, regulation of real estate transactions, implementation of standards for special populations, enactment of baseline habitability standards, and hazard mitigation. Current approaches to address sources of health hazards within the surrounding area

high opportunity areas with "significant reductions in obesity and diabetes for women . . . significant mental health improvements for women and girls").

[142] Poverty & Race Research Action Council, Urban Inst., Expanding Choice: Practical Strategies for Building a Successful Housing Mobility Program 3 (2012), http://prrac.org/pdf/ExpandingChoice.pdf [https://perma.cc/F43T-AETL].

[143] *Id.* at 8 ("The standard 60-day search process may put pressure on households to locate a unit more quickly than possible, leading to unit selection in higher poverty neighborhoods with lower performing schools.").

[144] *Id.* at 11 ("Portability enables a household to use a voucher issued in one jurisdiction when moving to another jurisdiction where the program is administered by a different local PHA . . . a series of barriers may await city households who apply directly to suburban PHA voucher programs, including lack of notice of waiting list openings, residency preferences for admission, first-come-first-served waiting list rules, and in-person application requirements at some PHAAs.").

[145] Poverty & Race Research Action Council, State and Local Source-of-Income Nondiscrimination Laws: Protections that Expand Housing Choice and Access to Healthy, Stable Homes, Appendix B: State, Local, and Federal Laws Barring Source-of-Income Discrimination (2017), http://prrac.org/pdf/AppendixB.pdf [https://perma.cc/QK6F-S5HY] (discussing how source-of-income anti-discrimination laws only exist in twelve states, the District of Columbia, and a handful of cities).

[146] *See generally* Megan Haberle et al., Poverty & Race Research Action Council, Accessing Opportunity: Affirmative Marketing and Tenant Selection in the LIHTC and Other Housing Programs (2012), http://www.prrac.org/pdf/affirmativemarketing.pdf [https://perma.cc/FD46-MT75].

[147] Benfer, *supra* note 2.

[148] Miller et al., *Healthy Starts for All*, *supra* note 89, at S49.

[149] This part only concerns the most commonly employed approaches and does not include programs or policies jurisdictions employed on an individual basis.

include community development, urban policy development, and community-based measures. However, despite varied approaches, the law fails to safeguard the health and safety of residents. Taken together, current policy concerning healthy communities and homes is fragmented, reactive, rather than preventive, and under-resourced. These systemic limitations impede program efficacy, resulting in resident exposure to, and injury from, health hazards.

A. Education and Research

Jurisdictions commonly employ campaigns to educate residents about the dangers of health hazards. This low-cost intervention provides policymakers with the opportunity to reach a wide audience with the goal of preventing harm from hazard exposure. In addition, many jurisdictions commission studies to gather data on issues related to health hazards, such as sources of exposure and effectiveness of programs. These studies yield empirical data that policymakers can use to implement programs and enact laws.

1. Educational Materials

Providing materials is one of the easiest things policymakers can do to address healthy housing. Materials can raise awareness among residents of the threats posed by health hazards, which may prevent future harm. By engaging with community partners, jurisdictions can more effectively educate residents on health hazards as well as their rights.[150] Reflecting this low-cost and relatively easy to implement method of harm prevention, several government entities make information on health hazards readily available to residents. For example, at the federal level, the EPA provides extensive information on mold safety and remediation.[151] The EPA sources are intended to educate residents about mold exposure and health effects, testing and sampling for mold, prevention, control, remediation in schools and commercial areas, and guidelines for cleanup, including how to address water leakage and when to consult a specialist.[152] Similarly, the federal Residential Lead-Based Paint Hazard Reduction Act[153] works to eliminate lead-based paint hazards and prevent childhood lead poisoning in part through a public education outreach component.[154]

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[150] Beth McKee-Hughes, *Partner with Community Organizations*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 10, 11 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/SM5Y-9GZ6].

[151] *See generally* U.S. ENVTL. PROT. AGENCY, THE KEY TO MOLD IS MOISTURE CONTROL (2017), www.epa.gov/mold [https://perma.cc/AGY2-ZGC4].

[152] *Id.*

[153] *See* 42 U.S.C.A § 4851 (1992).

[154] *See* U.S. ENVTL. PROT. AGENCY, RESIDENTIAL LEAD-BASED PAINT HAZARD REDUCTION ACT OF 1992-TITLE X (2016), https://www.epa.gov/lead/residential-lead-based-paint-ha

Development and dissemination of educational materials is not limited to federal policymakers. States, too, commonly engage in public education initiatives to curb the incidence of injury from indoor environmental health hazards. Many states accomplish this through educational provisions in statutes addressing a specific health hazard. For example, the Illinois Structural Pest Control Act directs any fines collected pursuant to the Act to be "deposited into the Pesticide Control Fund. . . for the purposes of *conducting a public education program* on the proper use of pesticides."[155] Under Washington State Code, landlords must provide tenants written or posted information on the negative health effects posed by mold as well as steps to take to minimize health risks.[156]

In addition to provisions in hazard-specific statutes, some jurisdictions mandate education through general code sections. California's Business and Professions Code requires the state to develop a booklet to educate consumers about several common environmental hazards related to real property.[157] These hazards include, but are not limited to, asbestos, radon gas, lead-based paint, formaldehyde, fuel and chemical storage tanks, and water and soil contamination.[158] Under the law, the booklet must include information on the hazard's significance, mitigation techniques, and additional sources of information.[159]

Research suggests that education can be an effective intervention.[160] A study on the effectiveness of hazard awareness training in construction building trades found an improved safety climate after employees participated in a union-delivered safety training.[161] However, unlike the study participants, who received dedicated training from an instructor, residents, particularly those that are low-income, may lack access to educational materials, the time necessary to absorb the information, and the ability to

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zard-reduction-act-1992-title-x [https://perma.cc/2UFF-EFMK] (noting that education and outreach is intended to increase public awareness of "the scope and severity of lead poisoning from household sources; potential exposure to sources of lead in schools and childhood day care centers; the implications of exposures for men and women, particularly those of childbearing age; the need for careful, quality, abatement and management actions; and the need for universal screening of children," among others).

[155] ILL. COMP. STAT. ANN. 225 § 235/9(b) (West 1975) (emphasis added); *see also* STATE OF CAL., DEP'T OF CONSUMER AFF., STRUCTURAL PEST CONTROL BD., BUSINESS AND PROFESSIONS CODE AND RULES AND REGULATIONS (2015), http://www.pestboard.ca.gov/pestlaw/pestact.pdf, [https://perma.cc/NZC4-M838].

[156] WASH REV. CODE ANN § 59.18.060 (West 2013).

[157] CAL. BUS. & PROF. CODE. §10084.1 (West 1989).

[158] *Id.* at § 10084.1(a)(1).

[159] *Id.*

[160] Rosemary K. Sokas et al., *An Intervention Effectiveness Study of Hazard Awareness Training in the Construction Building Trades*, 124 PUB. HEALTH. REP. 161, 168, (2009). The study "evaluated knowledge, attitudes, and self-reported work practices among apprentice and journeyman trainees in two construction trades at baseline and three months after participation in two training sessions as part of a 10-hour Occupational Safety and Health Administration hazard awareness training program . . . . Follow-up surveys were completed by 92 (53%) of respondents and documented significant increases" in safety knowledge. *Id.*

[161] *Id.*

consult with an expert on information contained therein. Without this support, the effectiveness of publishing educational information will be limited.

2. Research on Hazards

Many jurisdictions, both at the federal and state level, use empirical analysis to develop policies related to environmental health hazards. Using the best available research and information to guide decision-making, or evidence-based policy, allows governments to maximize resources while advancing policies that positively affect people's lives.[162] Applying this approach, Illinois,[163] Louisiana,[164] Maine,[165] New York,[166] and Oklahoma[167] laws direct relevant agencies to establish a task force to research the threat of mold, with the goal of making recommendations to policymakers. Similarly, a 2002 Pennsylvania Senate Resolution urged the Department of Health to establish a task force to investigate mold in homes, schools, and other buildings.[168] In 2013, the New Mexico House of Representatives voted to direct the state's Department of Health to conduct a literature review on scientific studies on the relationship between Parkinson's Disease and pesticide use.[169]

The ability of this approach to improve the health of residents rests on the assumption that there is adequate research into the relationship between interventions and health outcomes, that lawmakers read such reports, and that they act in a timely matter.[170] Whether policy mandates adequate research to thoroughly understand and identify health hazards remains an open question. This approach relies on lawmakers being well-informed enough to initiate policy that requires such research in the first place. Even when research exists and is readily available, lawmakers may be slow to incorporate findings into policy. Furthermore, disagreement over how to interpret scientific findings may also lead lawmakers to disregard findings or even overturn previous policy decisions.

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[162] PEW CHARITABLE TRUSTS, MACARTHUR FOUND., EVIDENCE-BASED POLICYMAKING, A GUIDE FOR EFFECTIVE GOVERNMENT 2 (2014), http://www.pewtrusts.org/~/media/assets/2014/11/evidencebasedpolicymakingaguideforeffectivegovernment.pdf [https://perma.cc/FNP2-R36H] (stating that an evidence-based policy approach allows governments to reduce spending, expand innovative programs, and strengthen accountability).

[163] HJR0012, 93rd Gen. Assemb., Reg. Sess. (Ill. 2004).

[164] LA. STAT. ANN. § 40:1289.1 (West 2015).

[165] ME. REV. STAT. ANN. tit. 10, § 1480 (West 2007).

[166] N.Y. PUB. HEALTH LAW § 1384 (McKinney 2012) (repealed 2012).

[167] OKLA. STAT. ANN. tit. 15 § 765.4 (West 2004).

[168] S.J. Res. 171, 107th Leg. (Pa. 2001).

[169] H 50-042, 1st sess., at 1–3 (N.M. 2011).

[170] *See generally* ChangeLab Solutions, *Evaluate the Code Enforcement Program*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 24, 26 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/SM5Y-9GZ6] ("Data collection and analysis can provide valuable information to both government agencies and the community.").

B. Regulation of Real Estate Transactions

The transference of an interest in a property from one party to another, whether seller and buyer or landlord and tenant, is an area in which jurisdictions impose rights and obligations concerning healthy housing. The most common approaches concerning real property involve disclosure of hazards prior to transfer and standards for new construction.

1. Mandatory Disclosure

The law imposes several obligations on the transferor of property during a real estate transaction. This nearly always includes a responsibility to disclose defects related to a property, including indoor environmental health hazards. Many jurisdictions specifically require the transferor to inform the transferee of the presence of any such hazards when the transaction involves the sale of real property.

Michigan's Seller Disclosure Act[171] exemplifies this obligation. Under the Act, the seller of real property must disclose the presence of environmental hazards, "such as, but not limited to, asbestos, radon gas, formaldehyde, lead-based paint, fuel or chemical storage tanks, and contaminated soil on the property."[172] In instances in which the seller fails to disclose a risk, the law typically gives several rights to the buyer. Under the Illinois Radon Awareness Act, if a seller does not inform a buyer of a radon risk prior to the buyer making an offer, the seller is required to disclose the radon risk and allow the buyer to amend their offer.[173]

While it is less common to mandate a general disclosure when the transfer of interest in property concerns a tenancy, federal law requires a landlord to share information concerning certain health hazards with perspective tenants. Under the Lead-Based Paint Hazard Reduction Act and the Lead Disclosure Rule, landlords must share any information about a known lead risk on the property before a tenant enters into a rental agreement.[174] In the absence of federal disclosure requirements for other hazards, some states have adopted their own approach. Pursuant to Virginia law, for example, landlords must disclose, in writing, the presence of mold in a rental unit.[175] Virginia tenants have the right to terminate the tenancy if the landlord's disclosure states there is visible mold in the unit.[176] If the tenant elects to take possession of the unit despite the presence of the hazard, the landlord is

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[171] Seller Disclosure Act §1, MICH. COMP. LAWS. ANN. § 565.951 (West 1994). The Act only applies to sellers of residential property consisting of up to four dwelling units. *Id.*

[172] Seller Disclosure Act § 7, MICH. COMP. LAWS. ANN. § 565.957 (West 2006).

[173] Radon Testing and Disclosure Act 46, ILL. COMP. STAT. ANN. ch. 420 § 10 (West 2013).

[174] 42 U.S.C.A § 4852d (West 1992); Lead Disclosure Rule, 40 C.F.R. § 745.61 (2017), https://www.gpo.gov/fdsys/pkg/FR-1996-03-06/pdf/96-5243.pdf [https://perma.cc/7YUJ-VHUC].

[175] Disclosure of Mold in Dwelling Units, VA. CODE. ANN. § 55-248.11:2 (West 2008).

[176] *Id.*

obligated to remediate and obtain a re-inspection of the unit to confirm the there is no "visible evidence of mold."[177]

The effectiveness of disclosure rests on a transferee's ability to weigh information and make meaningful choices regarding housing accommodations. This is undermined by two assumptions. First, the transferor is typically only obligated to disclose "known" information. The law does not impose a duty to discover any health hazard via inspection or other means. In the absence of such an obligation, and in the interest of preserving a transaction as well as not incurring liability to remediate, the transferor may opt to refrain from taking steps, such as hiring an inspector who would surface an issue. In such instances, because the transferor does not "know" of a hazard, the threat is passed to the transferee. The second assumption is that the transferee can make a meaningful choice based on disclosure. The ability to use disclosed information to make decisions is severely limited for low-income residents, who are disproportionately affected by the affordable housing shortage.[178]

Creating additional difficulty for low-income residents in search of healthy housing is the fact that many jurisdictions lack a centralized, easy to navigate system to track data on unhealthy housing. While large cities, such as Chicago,[179] Houston,[180] and Seattle,[181] have searchable databases, they may not be comprehensive or reliably updated. Most suburban and rural municipalities do not have any system that allows residents to easily acquire health and safety information about prospective housing. The absence of a repository of information contributes to residents' vulnerability to environmental health hazards. Without this information, prospective tenants and homebuyers may not discover a hazard until it causes injury. Ultimately, unless there is an adequate supply of affordable healthy housing, and until residents have an easy, reliable mechanism to obtain information about properties, transferees will not be able to fully reap the benefit of hazard disclosure requirements.

2. Requirements for New Construction and Home Improvement

As policymakers increase their understanding of the threats posed by environmental health hazards, many elect to update local building codes. This is evident when examining building standards for new residential

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[177] *Id.*

[178] *See generally* Allyson E. Gold, *No Home for Justice: How Eviction Perpetuates Health Inequity Among Low-Income and Minority Tenants*, 24 GEO. J. ON POVERTY L. & POL'Y 59, 68 (2016) (discussing how recent changes in the housing market have created a shortage of affordable housing options).

[179] *See* CITY OF CHICAGO BUILDING VIOLATIONS SEARCH, https://www.cityofchicago.org/city/en/depts/bldgs/provdrs/inspect/svcs/building_violationsonline.html [https://perma.cc/K8RA-VQMV].

[180] *See* CITY OF HOUSTON BLIGHT TRACKER, http://mycity.houstontx.gov/nuisancetracker/ [https://perma.cc/5AMU-R5EC].

[181] *See* SEATTLE CODE VIOLATION CASES, https://data.seattle.gov/Community/Code-Violation-Cases/dk8m-pdjf [https://perma.cc/D29T-EX4D].

properties. For example, several states, including Illinois[182] and Massachusetts,[183] require that all new residential construction include radon-resistant construction techniques. In addition to new construction, lawmakers' understanding of the threat of environmental health hazards may lead to the termination of certain practices that previously threatened the health of residents. The federal government famously accomplished this when Congress banned the use of lead-based paint from residential dwellings in 1978, and the EPA promulgated the Repair, Renovation and Painting Rule.[184]

Requirements for new construction safeguard future housing. However, without retroactive applicability, it is insufficient to eliminate hazards from the vast majority of housing stock. Moreover, characteristics of new housing stock suggest that benefits realized will accrue primarily to wealthier residents. In 2015, the size of new single-family homes hit a record 2,467 square feet[185] and home prices rose 6.6 percent.[186] In contrast, "growth in the low-rent supply is largely driven by downward filtering of older units,"[187] which do not benefit from policy changes that update requirements for new construction. As a result, individuals who are most vulnerable to environmental health hazards are excluded from changes in real estate law enacted to protect residents.

C. Common Approaches for Special Populations

Policies often govern environmental health hazards differently for special groups than for the general population. This is typically informed by the particular needs or vulnerabilities unique to that population. In particular, the law generally places increased protections on spaces occupied by children and persons living with disabilities.

1. Children

Children are particularly vulnerable to indoor environmental health hazards. Relative to adults, their nervous systems, immune systems, and bodies are underdeveloped and they spend a greater portion of their day indoors.[188] The law recognizes the vulnerability of children and imposes greater regulation on spaces they will occupy. Several states require increased scrutiny to ensure that schools and daycares are free from health

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[182] Radon Resistant Construction Act, ILL. COMP. STAT. ANN. Ch. 420 § 52/1 (West 2013).

[183] MASS. GEN. LAWS ch. 43, § 93-100 (West 1938).

[184] Consumer Protection Safety Act of 1977 § 1303, 15 U.S.C.A §§ 2057, 2058 (1972); Lead Renovation, Repair and Painting Rule 40 C.F.R. 745 Part E, https://www.ecfr.gov/cgi-bin/text-idx?SID=CD05f748c481fd0ec85ffb94b9193066&node=SP40.31.745.e&rgn=div6 [https://perma.cc/4M8S-JZBK].

[185] JOINT CTR. FOR HOUS. STUDIES OF HARVARD UNIV., *supra* note 80, at 8.

[186] *Id.* at 10.

[187] *Id.* at 27.

[188] *See* Gold, *supra* note 178, at 70.

hazards. In North Carolina, for example, local school boards have a "duty to protect the health of school-age children from toxicants at school."[189] Pursuant to this duty, the school boards must "study methods for mold and mildew prevention and mitigation," incorporating recommendations into public school facility management as well as take certain steps to address the use of pesticides, arsenic-treated wood, mercury, and exposure to diesel exhaust fumes on school grounds.[190] In Illinois, the Smoke-free Act bans indoor smoking and smoking anywhere within fifteen feet of an entrance to a public building.[191] However, the Act applies to private residences only when they serve as a daycare, childcare, or other special facilities.[192]

To mitigate the devastating effects of lead exposure, many jurisdictions require mandatory home inspection if a child has an elevated blood lead level. In Connecticut, primary health care providers must conduct a blood lead screening for all children under the age of three and any child between the ages of thirty-six and seventy-two months who has not been previously screened.[193] If a child has an elevated blood lead level,[194] the local health department will conduct an epidemiological investigation and inspection to identify sources of lead exposure, including within the home.[195] Once the sources of lead are identified, the public health department director will order an abatement or remediation order.[196]

2. Persons with Disabilities

The law also provides special protections to persons with disabilities. Section 504 of the Rehabilitation Act prohibits discriminatory action against people with disabilities who live in federally funded housing programs.[197] Under Section 504, federally funded housing providers may not refuse to provide services or decline to make repairs that would be available to able residents.[198] Further, it requires that the federally funded housing providers make reasonable accommodations to the property so that disabled residents are able to fully enjoy their housing.[199] Such accommodations include modifications to a policy, alterations to the actual property, or changes in services or programs offered.[200]

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[189] N.C. GEN. STAT. ANN. § 115C-12(34) (West, 1981).
[190] N.C. GEN. STAT. ANN. § 115C-47(47) (West, 1981).
[191] 410 ILL. COMP. STAT. ann. § 82/15 (West, 2008).
[192] *Id.* § 82/10.
[193] CONN. GEN STAT §19a-111g (West 2007); Conn. Dept. of Pub. Health, *Mandatory Universal Blood lead Screening begins in Connecticut* (Jan. 6, 2009) http://www.ct.gov/dph/cwp/view.asp?Q=434526&A=3659 [https://perma.cc/WWV7-2LXF].
[194] *Id.*
[195] *Id.*
[196] *Id*.
[197] 29 U.S.C.A § 701 (2014); 24 CFR § 8.1(a) (2017).
[198] 24 CFR § 8.4 (2017).
[199] *Id.*
[200] 29 U.S.C.A. § 701 (1998).

The Americans with Disabilities Act (ADA) extends protections under Section 504 to people living in non-federally assisted entities. The ADA requires state and local governments, as well as private businesses, to provide the protections of Section 504 to people with disabilities.[201] Title II of the Act bars public entities from discriminating against people with disabilities in any of the services or programs they offer and Title III bars discrimination in common use, public spaces of residential buildings.[202] For these purposes, discrimination includes failing to make alterations that would make the housing accessible or in condition to be used by disabled persons.[203]

The rights articulated by Section 504 and the ADA can provide relief for residents living in substandard housing conditions. For example, the U.S. Department of Housing and Urban Development (HUD) does not include lead hazards in the definition of life threatening conditions or the circumstances qualifying a family to move with continued assistance.[204] Because the Lead Safe Housing Rule does not require pre-rental lead hazard risk assessments in all federally assisted housing, a child has a high likelihood of developing lead poisoning.[205] As a result, a family living in federally assisted housing whose child developed lead poisoning did not have a right to relocate under HUD regulations.[206] However, because lead poisoning substantially limits major life functions of learning and interacting, as well as major bodily functions related to neurological development and kidney function among others, it qualifies as a disability under the law.[207] In light of the effect of exposure to lead, a family with a child experiencing lead poisoning is entitled to a modification of policies and practices so that they have the opportunity to use and enjoy housing that will not threaten their health and well-being, such as immediate transfer to a lead-free home. Such reasonable accommodations under Section 504 and the ADA give families the opportunity to use and enjoy housing that will not threaten their health and well being.

D. Enactment of Minimum Habitability Standards

Jurisdictions commonly establish a threshold that housing must satisfy to meet basic health and safety standards. Doing so allows jurisdictions to place the onus of property maintenance on homeowners. The standards set by a local jurisdiction may follow federal guidance. However, more commonly, the federal government is silent on building requirements regarding

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[201] 42 U.S.C.A. 12131 (1990).

[202] *Id.* §§ 12132; *see* Dep't of Justice, Title III Technical Assistance Manual, § III-1.2000 (1993), http://www.ada.gov/taman3.html [https://perma.cc/SQZ2-DPVC].

[203] *Id.* § 12131.

[204] 24 C.F.R. 982.354 (2017).

[205] 24 C.F.R. 35 et seq.

[206] *See* Benfer, *supra* note 2, at 41.

[207] *See* 42 U.S.C. § 12102(1)(A); Emily Benfer, *Overview of the ADA Amendments Act of 2008*, Am. Const. Soc'y Advance (2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2341414 [https://perma.cc/W35Q-Y5GL].

particular health hazards. In these circumstances, state and local governments develop their own regulations.

1. With Guidance from the Federal Government

The federal government provides support to state and local jurisdictions to address certain indoor environmental health hazards. The Department of Housing and Urban Development, for example, sets minimum housing quality standards for properties that receive funding under the Housing Choice Voucher Program.[208] The EPA Federal Radon Action Plan brings together nine federal agencies in an EPA-led committee to address the threat of radon exposure.[209] In addition to the EPA, the agencies include the Departments of Health and Human Services, Agriculture, Defense, Energy, Housing and Urban Development, Interior, Veterans Affairs, and the General Services Administration.[210] Together, these organizations work to diminish the risk of exposure to radon in residences, schools, daycare facilities, and new construction sites. The Plan draws particular attention to the economic benefits of decreasing radon exposure and the financial incentives around radon testing and mitigation and supports risk reduction programming through grant funding.[211]

In addition, the EPA promulgated recommendations concerning the maximum average level of indoor radon. Under the EPA recommendation, the highest level of indoor radon is four picocuries per liter (pCi/L).[212] This standard serves as a guideline for state and local jurisdictions, which may enact their own laws concerning radon. Following the EPA action level, six states (Connecticut,[213] Florida,[214] Illinois,[215] Iowa,[216] Kentucky,[217] and Michigan[218]) have laws that set four picocuries per liter as the recommended radon safety standard. These jurisdictional responses to radon illustrate how state law may evolve under guidance from the federal government.

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[208] *See generally* DEP'T HOUS. & URBAN DEV., HOUSING CHOICE VOUCHER PROGRAM GUIDEBOOK, at ch. 10 (2001), https://portal.hud.gov/hudportal/documents/huddoc?id=DOC_11754.pdf [https://perma.cc/FA3N-3GKC].

[209] ENVTL. PROT. AGENCY, THE NATIONAL RADON ACTION PLAN-A STRATEGY FOR SAVING LIVES (2015).

[210] *Id.*

[211] *Id.*

[212] ENVTL. PROT. AGENCY, THE GUIDE TO PROTECTING YOURSELF AND YOUR FAMILY FROM RADON (2016). *See generally* 15 U.S.C. § 2661 ("The national long-term goal of the United States with respect to radon levels in buildings is that the air within building in the United States should be as free of radon as the ambient air outside of buildings.").

[213] CONN. AGENCIES REGS. § 19a-79-7a(e)(17)(B) (2014).

[214] FLA. STAT. § 404.056 (2017).

[215] 105 ILL. COMP. STAT. § 5/10-20.48 (2012).

[216] 441 IOWA ADMIN. CODE §109.11(7) (237A) (2016).

[217] 902 KY. ADMIN. REGS. 95:040 (2014).

[218] MICH. ADMIN. CODE R. 400.1934 (2014).

2. In the Absence of Federal Guidance

Given that federal law does not comprehensively address substandard housing conditions, state and local jurisdictions have enacted their own approaches to specific environmental health hazards. Some jurisdictions accomplish this on a hazard-by-hazard basis. For example, long before the federal government adopted the CDC's definition of an intervention blood lead level, the Chicago Municipal Code defined lead poisoning as an elevated blood lead level of five micrograms per deciliter (µg/dL) or higher and requires that property owners maintain their residential buildings "in such a manner so as to prevent the existence of a lead hazard."[219] Likewise, in the absence of federal bedbug guidance, the Maine legislature enacted law regarding a landlord's duties and responsibilities in the event of a known or suspected bedbug infestation.[220]

However, rather than enact a law for every type of substandard housing condition, most jurisdictions opt to include guidance on exposure to hazards through building, residential, and public health codes. Every jurisdiction has municipal codes that affect resident exposure to environmental health hazards. Building codes endeavor to protect public health, safety, and natural resources by setting minimum requirements for building design, construction, and operation.[221] The International Building Code (IBC) is in use or adopted in all fifty states as well as the District of Columbia and New York City.[222] The International Residential Code (IRC) is in use or adopted by forty-nine states and the District of Columbia.[223]

The purpose of both the IRB and IRC is to protect the public safety, health and general welfare.[224] Taken together, these Codes comprehensively govern the construction, alteration, relocation, enlargement, replacement, repair, equipment, use and occupancy, location, maintenance, removal, and demolition of all buildings and structures. This includes regulating exposure to environmental hazards such as pest infestation, factors that affect mold

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[219] CHI., ILL., MUN. CODE §7-4-030 (2016); CITY OF CHI., DEP'T OF PUB. HEALTH, CONTROL AND MITIGATION OF LEAD-BEARING SUBSTANCES, RULES AND REGULATIONS 1.1 (2008), http://www.cityofchicago.org/content/dam/city/depts/cdph/statistics_and_reports/SR_CntrlMitigationofLeadBearingSubstancesRegs.pdf [https://perma.cc/3U83-JMKK] ("Lead Poisoning [is defined as a] confirmed level of lead in human blood of greater than 5 mg/dL (five micrograms per deciliter)").

[220] 14 ME. REV. STAT. ANN. § 6021-A (2011).

[221] ELLEN VAUGHAN & JIM TURNER, ENVTL. & ENERGY STUDY INST., THE VALUE AND IMPACT OF BUILDING CODES (2014).

[222] INT'L CODE COUNCIL, INTERNATIONAL CODE ADOPTIONS, UNITED STATES USAGE OF THE I-CODES (2015).

[223] *Id.*

[224] *See* INT'L BUILDING CODE § 101.3 (INT'L CODE COUNCIL 2015); INT'L RESIDENTIAL CODE § 101.3 (INT'L CODE COUNCIL 2015). Though, notably, the purpose of the IBC is to "provide a reasonable level of safety, public health and general welfare," while the IRC does not use any qualification. *Id.*

growth such as ventilation and moisture accumulation, and other conditions that affect resident health.[225]

Similarly, to protect tenants from the harmful effects of exposure to health hazards, many states have adopted all or part of the provisions of the Uniform Residential Landlord Tenant Act (URLTA).[226] First promulgated in 1974, the URLTA imposes six duties on landlords that pertain to healthy housing: (1) comply with applicable building and house code requirements that affect health and safety; (2) make all repairs and do what is necessary to maintain the property in fit and habitable condition; (3) keep all common areas of the premises in a clean and safe condition; (4) maintain systems in good and safe working order; (5) provide and maintain appropriate receptacles for removal of trash and hazardous materials; and (6) supply running water, hot water, and reasonable amounts of heat.[227] In 2015, the Uniform Law Commission released the Revised Uniform Residential Landlord Tenant Act (RURLTA). RURLTA eliminates elements of common law, instead basing all provisions of the lease agreement on contract law doctrine.[228] RURLTA expands the duties of the landlord to maintain the premises.[229] For example, RURLTA explicitly requires a landlord to "have reasonable measures in place to control the presence of rodents, bedbugs, and other vermin and to prevent exposure to unsafe levels of radon, lead paint, asbestos, toxic mold, and other hazardous substances."[230] For tenants living in states that adopt RURLTA, these revisions expand the baseline standards for habitability in residential dwellings.

While regulations governing baseline habitability are critical to ensuring the health of residents, their effectiveness is limited without specific criteria and guidance.[231] For example, URLTA's requirement to "do what is necessary to maintain the property in fit and habitable condition," is ambiguous and does not adequately define what constitutes a "fit and habitable condition." In the absence of specific guidance, "property owners, residents,

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[225] *See generally* Int'l Building Code (Int'l Code Council 2015), https://codes.iccsafe.org/public/document/toc/542/ [https://perma.cc/Q4JK-WTXQ]; Int'l Residential Code (Int'l Code Council 2015), https://www.iccsafe.org/codes-tech-support/codes/2015-i-codes/irc/ [https://perma.cc/HUB5-GMTS].

[226] Adopted by the Uniform Law Commission in 1972, the URLTA set standards to govern the landlord and tenant relationship. Twenty-one states adopted the URLTA, with more influenced by particular sections. John Ahlen & Lynn Foster, *Uniform Residential Landlord-Tenant Law: Changes on the Way*, 28 Prob. & Prop. Mag. 4 (2014).

[227] Unif. Residential Landlord & Tenant Act § 2.104(a) (Nat'l Conference of Comm'rs of Unif. State Laws 1974).

[228] *See generally* Revised Unif. Residential Landlord & Tenant Act (Nat'l Conference of Comm'rs of Unif. State Laws 2015).

[229] *Id.* § 302 cmt. ("This section somewhat expands the provision of URLTA (1972) § 2.104 . . . . This section sets forth a landlord's duties to assure a rented dwelling unit is habitable . . . . Consistent with the practice of nearly every state, Section 302 recognizes that modern conditions require the proper maintenance and operation of rental housing.").

[230] *Id.* § 302(a)(7).

[231] Tom Neltner, *Adopt a Strong Housing Code*, *in* ChangeLab Solutions, Up to Code: Code Enforcement Strategies for Healthy Housing 4, 5 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/9ADF-8XYQ].

and code enforcement officers can interpret housing codes differently, leaving compliance decisions subject to challenges and residents vulnerable."[232]

Robust enforcement is also necessary to protect health and well-being. Notably, for example, both the IBC and the IRC lack enforcement mechanisms. Instead, it is up to the individual jurisdictions that adopt these Codes to establish rights of parties, bases of liability, and remedies, in the event the outlined standards are not achieved. The most common enforcement mechanisms adopted by jurisdictions are administrative, civil, and criminal.[233] Enforcing regulations further requires comprehensively training inspection officers to identify health hazards.[234] If jurisdictions od not take additional steps to enforce these standards, residents will continue to experience harm resulting from exposure to health hazards.

E. Hazard Mitigation

If a hazard exists on a property, there are several steps parties must take in order to mitigate. First, parties must discover the hazard and determine liability. Depending on the jurisdiction, a resident may initiate discovery or the municipality itself may take proactive steps to identify threats to health and safety. After the discovery, the responsible party may apply for funds demarcated for hazard mitigation. Depending on the type and severity of the hazard, many jurisdictions require a licensed professional to perform the mitigation. In the event that the responsible party does not mitigate, or the resident suffers an injury from exposure to the hazard, various avenues of relief exist to recuperate damages.

1. Identification of, and Liability for, Environmental Health Hazards

The first step in hazard mitigation is identification. Traditionally, and in most jurisdictions, code enforcement relies on a complaint-based system.[235] Under this system, the onus is on occupants to identify and report environmental health hazards.[236] Once an occupant reports an issue, "a municipal

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[232] *Id.*

[233] ChangeLab Solutions, *Enforce the Local Housing Code*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 18, 19–20 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/C8AE-WNWU].

[234] Larry Brooks, *Train Officers Comprehensively*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 8, 9 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/5WEJ-Q53P] ("Effective code enforcement programs require well-trained code enforcement officers to enforce the local housing code.").

[235] *See* CHANGELAB SOLUTIONS, HEALTHY HOUSING THROUGH PROACTIVE RENTAL INSPECTION (2014).

[236] *See id.*

code enforcement officer conducts a housing inspection, and if the complaint is substantiated, the officer begins enforcement proceedings."[237]

This approach is problematic for multiple reasons. First, tenants, unlike trained personnel, do not have the expertise to identify all indoor environmental health hazards. By outsourcing the responsibility, some hazards, such as radon or asbestos, may not be identified until they cause an injury.

Second, tenants whose homes contain health hazards are poorly positioned, relative to a government entity, to initiate an adverse action against a landlord. As discussed, substandard housing conditions disproportionately affect low-income tenants as well as minority tenants. Tenants living in such conditions are nearly all low-income. As a result, there is a great imbalance of power between the tenant and the landlord. Many tenants are reluctant to report a problem for fear of being labeled a "troublemaker" or experiencing retaliation from the landlord.[238] In light of the current executive administration's immigration policies,[239] undocumented tenants, in particular, may be reluctant to report conditions to governmental entities for fear that it may result in deportation.

In contrast to complaint-based systems, some jurisdictions have adopted proactive rental inspection (PRI) programs. Under PRI, "rather than wait for a complaint to inspect housing, the locality inspects all covered rental housing on a periodic basis to ensure that all rental properties are safe and habitable."[240] This system shifts the burden of hazard identification and reporting from layperson occupants to trained experts. For example, numerous cities require pre-rental lead hazard inspections ranging from visual assessments, dust swipes, clearance testing, to risk assessments.[241]

Studies demonstrate the effectiveness of PRI programs. After the city of Sacramento, California adopted a citywide housing inspection program to address substandard conditions, dangerous housing and building cases dropped by twenty-two percent.[242] Similarly, the establishment by Los Angeles, California of a Systemic Code Enforcement Program has resulted in the inspection of over ninety percent of the city's multifamily housing accommodations and the correction "of more than one and half million habitability

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[237] *Id.* at 2.

[238] *See generally* Gold, *supra* note 178 (noting that a tenant who exercise her rights may be labeled as a troublemaker).

[239] *See generally* Michael D. Shear & Ron Nixon, *New Trump Deportation Rules Allow Far More Expulsions*, N.Y. Times, Feb. 21, 2017, at A1.

[240] ChangeLab Solutions, *supra* note 235, at 2.

[241] Detroit, Mich., City Code 9-1-82(d), 9-1-83; MD Code 6-815 (2017); Rochester Munc. Code 90-55; Phil. Munc. Code 6-803(3)(b); Grand Rapids, MI City Code 304.2.1; 1000.3; San Diego Munc. Code 54.1009; Toledo Munc. Code 1760.04(14); Burlington, VT Code 18-112(a)(2).

[242] City Council Report, *Ordinance Revisions to City Code Chapter 8.120 Relating to the Rental Housing Inspection Program*, City of Sacramento (May 28, 2013), http://sacramento.granicus.com/MetaViewer.php?view_id=22&clip_id=3277&meta_id=399614 [https://perma.cc/69AL-5FJM].

violations," resulting in the reinvestment of $1.3 billion in the city's housing supply.[243]

Landlords have challenged the legality of PRI systems. In 1997, the city of Pasco, Washington enacted an ordinance requiring all landlords to submit an inspection certificate every two years proving compliance with applicable health and safety standards.[244] A landlord disputed the legality of the ordinance, alleging a violation of state and federal privacy grounds as well as a violation of due process rights.[245] Ruling against the landlord, the court found that because the ordinance gives landlords the ability to hire an inspector and schedule the inspection at their convenience, it does not violate privacy rights.[246] Further, the court rejected the landlord's argument that the ordinance is vague, finding that it gives specific instruction on who is qualified to be an inspector and when inspections must be completed.[247]

While the court upheld the constitutionality of Pasco's PRI ordinance, the result does not address privacy concerns of tenants living in the property. As opposed to inspection only when a property is turned over, Pasco's ordinance mandates inspection every two years.[248] This frequency necessarily results in inspections of tenant-occupied property. For tenants who wish to minimize contacts with government officials, for example, due to deportation concerns, collateral consequences of frequent government contact may outweigh the benefit of proactive municipal inspection. PRI, when carried out in occupied properties, creates a tension between effectively uncovering unhealthy housing conditions and addressing other resident concerns. Lawmakers must be aware of, and sensitive to, this balance when adopting policy to achieve healthy communities and housing.

Once a code enforcement officer identifies a hazard, he typically issues a violation notice informing the property owner of his responsibility to remediate.[249] As discussed previously, the law establishes baseline habitability standards that property owners must follow, whether or not they plan to occupy the property themselves.[250] But there exists a liability exception if someone other than the homeowner caused the issue. For example, California law places responsibility for rental property maintenance on the land-

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[243] *Systemic Code Enforcement Program*, HARVARD KENNEDY SCH., ASH CTR. FOR DEMOCRATIC GOVERNANCE AND INNOVATION, GOVERNMENT INNOVATORS NETWORK, https://www.innovations.harvard.edu/systematic-code-enforcement-program [https://perma.cc/SG7K-TNGM].

[244] Pasco v. Bernard N. Shaw, 166 P.3d 1157, 1159 (Wash. 2007).

[245] *See id.* at 1160.

[246] *See id.* at 1163.

[247] *See id.*

[248] *Id.* at 1160.

[249] Larry Brooks, *Develop a Cooperative Compliance Model*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 15, 16 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/4RNH-SRQ3].

[250] *See infra* Part II.D.

lord.[251] The landlord is discharged of his duty to repair defects, however, if the tenant negligently or deliberately causes the damage to the property.[252]

The traditional code enforcement practice may allow the owner "to do the bare minimum to correct the violation, often to avoid being fined and/or prosecuted."[253] In contrast, a cooperative compliance model promotes mutual cooperation between the enforcement officer and the liable party, typically the homeowner.[254] In this system, "the code enforcement officer works cooperatively with property owners to help them understand the elements of healthy housing, the importance of code compliance, and how to bring the property into compliance."[255] The cooperative approach may result in healthier housing stock, beyond what the baseline habitability standards require.[256]

2. Funding for Hazard Removal

Even after liability is established, mitigation of environmental health hazards can be cost prohibitive. According to Cooper Pest Solutions, a pest control company serving clients in Pennsylvania and New Jersey, the cost of bedbug remediation can range from one thousand to three thousand dollars.[257] Likewise, a survey conducted by HomeAdvisor.com found that the average self-reported cost of residential mold removal is $2,161.[258] If a property is experiencing several health hazards, the costs can quickly surpass the property owner's resources.

To address this issue, the federal government may make funds available to offset the cost of hazard remediation. For example, the Office of Lead Hazard Control and Health Housing provides grants for lead hazard remediation and under the State Indoor Radon Grant (SIRG), states and tribes can apply for funds to reduce and prevent instances of radon-related lung cancer.[259] Grantee jurisdictions may use SIRG funds to conduct radon surveys, develop public information and education materials, implement programs to control radon in existing as well as new structures,[260] purchase measurement equipment or devices and analytical equipment, train employees on aspects related to radon, program administration, data storage and

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[251] *See* CAL. CIV. CODE § 1941.1(a) (2013).
[252] *See id.* at § 1941.2(a).
[253] Larry Brooks, *supra* note 249, at 16.
[254] *Id.*
[255] *Id.*
[256] *Id.*
[257] Cooper Pest Solutions, *How Much Does a Bedbug Treatment Cost for My Home*?, (Dec. 9, 2016), http://www.cooperpest.com/blog/how-much-does-a-bed-bug-treatment-cost-for-my-home [https://perma.cc/93YQ-89TB].
[258] *How Much Does it Cost to Remove Mold and Toxic Materials?*, HOMEADVISOR, http://www.homeadvisor.com/cost/environmental-safety/remove-mold-and-toxic-materials/ [https://perma.cc/9VKY-5L35].
[259] *See generally* ENVTL. PROT. AGENCY, STATE INDOOR RADON GRANTS PROGRAM GUIDANCE AND HANDBOOK (2005).
[260] *See id.* at 14 ("The bulk of a SIRG recipient's radon program will be in this area, as implementation of radon control programs brings bottom-line risk reduction to the population.").

management, mitigation demonstrations, establishment of a radon hotline to provide information and technical assistance, and assistance to local government and agencies.[261] Individuals may not apply directly to the EPA for SIRG funds.[262] However, they may apply to their state or tribal organization to use funds to abate a radon hazard in their home. In 2016, the SIRG Program granted nearly eight million dollars to jurisdictions across the country.[263]

In addition to federal funding sources, many local jurisdictions have established their own programs to enable parties to effectively remove indoor environmental health hazards. For example, under the Comprehensive Education, Reduction, and Window Replacement Program Act, the Illinois Department of Public Health developed the CLEAR-WIN Program to help eliminate home-based lead hazards.[264] The legislature piloted the program in two communities: Peoria and Chicago's Englewood and West Englewood neighborhoods,[265] providing grants and loans to replace lead contaminated windows.[266] Similarly, several municipalities in New York offer home rehabilitation grants to address substandard housing conditions related to heating, plumbing electrical, roofing, carpentry, masonry, insulation, replacement windows and doors, and exterior paint, among others.[267]

However, the limited availability of such funding sources results in many properties that do not conform to applicable codes and statutes. In such instances, occupants may have little recourse to secure necessary repairs to attain healthy housing. This is particularly problematic for tenants, who have scant options if a landlord refuses to make repairs. Tenants may elect to pursue legal action to compel a landlord to remediate. This time consuming process often requires tenants to remain in the property during the pendency of the case, exposing the family to the underlying hazards. Furthermore, even if the tenant prevails, there is no guarantee that the landlord will have adequate resources to remediate the issue.

Even when the law allows tenants to reallocate rent monies to address substandard conditions, it is typically insufficient to fully address the issue. For example, the Chicago Residential Landlord Tenant Ordinance (RLTO) allows tenant to take remedial action if the home does not satisfy habitability standards.[268] In buildings to which the RLTO applies,[269] tenants may withhold or deduct rent, seek reimbursement, or terminate their lease early if

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[261] *See id.* at 16–22.

[262] *See id.* at 2.

[263] ENVTL. PROT. AGENCY, STATE INDOOR RADON GRANT (SIRG) PROGRAM (2016), https://www.epa.gov/radon/state-indoor-radon-grant-sirg-program [https://perma.cc/9MRN-A2TA].

[264] 410 ILL. COMP. STAT. § 43/15 (2010).

[265] LEAD SAFE ILL., PREVENTION PROGRAMS (2017), http://www.leadsafeillinois.org/prevention/ [https://perma.cc/UC7L-X8DT].

[266] 410 ILL. COMP. STAT. § 43/15 (a); *see also* LEAD SAFE ILL., *supra* note 265.

[267] *See*, *e.g.*, CITY OF OSWEGO, HOUSING REHABILITATION PROGRAM (2017), http://www.oswegony.org/government/housing-rehabilitation-program [https://perma.cc/QM4M-FFLZ].

[268] CHI., ILL., MUN. CODE § 5-12-100, 110 (2016).

there is a violation of the warranty of habitability. However, the RLTO only permits tenants to deduct from the rent the cost of "minor repairs," defined as the greater of five hundred dollars or half the monthly rent.[270] As discussed, health hazards such as mold remediation, lead abatement, or radon remediation will quickly exceed allowable expenses, leaving tenants to choose between remaining in unsafe conditions or the difficult job of identifying healthy and affordable replacement housing.

3. Licensing of Mitigation Professionals

It is common for jurisdictions to adopt licensing standards for professionals who perform mitigation services. Louisiana's mold remediation laws typify the approach adopted by several states to regulate the hazard reduction. Recognizing that "it is in the best interest of the citizens of the state, to require the licensure and regulation of those persons who perform mold remediation,"[271] Louisiana requires the State Licensing Board for Contractors to license and regulate professionals who conduct mold remediation.[272] Likewise, jurisdictions commonly adopt licensing standards for professionals who address radon, lead, infestation, and other indoor environmental health hazards.[273]

Licensing is meant to ensure that hazard remediation itself does not inadvertently expose residents to harm, which may happen when laypersons with no training undertake efforts on their own. For example, the Health Justice Project represented a tenant whose children were lead poisoned after a landlord, who lacked certification and training in lead mitigation and abatement, performed removal of lead on the walls using an unsanctioned dry scraping method. Rather than reduce the hazard, the dry scraping spread lead dust throughout the home, which caused the children's blood lead levels to spike.[274] Had the landlord hired a licensed professional pursuant to federal and Illinois law,[275] the children would not have been exposed to the toxic hazard. However, as this case demonstrates, licensing requirements are only effective if they are followed. If landlords, through negligence or intentional disregard, fail to abide by the laws regarding licensing of mitigation professionals, individuals will continue to experience negative health consequences of exposure to indoor environmental hazards.

It is also important for lawmakers to revisit standards to ensure that approved hazard mitigation practices effectively protect the health of residents. If they are not consistently reviewed in light of advances in science

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[269] *See id.* § 5-12-020. The RLTO applies to all residential buildings excluding owner-occupied buildings with six or fewer units.

[270] *Id.* at § 5-12-010(c).

[271] LA. STAT. ANN. § 37:2181 (2017).

[272] *See id.* § 37:2181–2188.

[273] For example, Minnesota requires professionals who perform radon testing to be licensed annually. *See* MINN. STAT. § 144.4961 (2016).

[274] *See* Benfer, *Health Justice*, *supra* note 72, at 329.

[275] *See* 410 ILL. COMP. STAT. § 45/8.1 (2015); 40 C.F.R. § 745 (2016).

and medicine, approved interventions may cause greater health harms. As one study of pesticide use in low-income public housing found, use of conventional chemical-based applications for pest controls resulted in residual pesticide contamination for all participant families.[276] Most alarming, researchers found the greatest levels of contamination in the living room and children's bedrooms.[277] Similarly, EPA's current lead hazard standards are not aligned with science. For example, the current definition of lead paint as 5,000 parts per million does not capture lead content that would create a lead dust hazard if dry sanded.[278] In one study, dust-lead levels much lower than the current floor standard of 40 micrograms per square foot "were associated with a considerable excess risk of children having blood lead levels [greater than or equal to] 10 [micrograms per deciliter]."[279] In another, tests using the current residential floor standard failed to identify 85% of housing units of children who had a blood lead concentration of 10 micrograms per deciliter.[280] In response to a 2009 petition for rulemaking, EPA has acknowledged the need to update the standards for lead in dust and lead in paint and EPA's Science Advisory Board issued a final report that supported updated standards.[281] Despite these agency findings, citizen complaints, and litigation, the EPA has taken no action.[282] These studies demonstrate the necessity of frequent evaluation of standards to safeguard community health.

4. Remedies for Failure to Mitigate

When responsible parties fail to adequately remediate or prevent substandard housing conditions, they may be liable for damages that occur when occupants are exposed to hazards. This most commonly occurs when a landlord fails to mitigate a hazard, causing injury to a tenant. Though in instances of widespread hazard creation, a state's attorney general may initiate an action to vindicate the rights of a class of residents.

Hazard specific statutes rarely create a private right of action for tenants when a landlord fails to safeguard the health of residents. For example, the Illinois Lead Poisoning Prevention Act only provides recourse to "the State's Attorney of the county in which the violation occurred or the Attorney Gen-

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[276] Chensheng Lu et al., *Household Pesticide Contamination from Indoor Pest Control Applications in Urban Low-Income Public Housing Dwellings: A Community-Based Participatory Research*, 47 ENVTL. SCI. & TECH. 2018, 2023 (2013).

[277] *See id.*

[278] *See* 40 C.F.R. § 745.223 (2001); 24 C.F.R. § 35.86 (1999).

[279] Bruce Lanphear et al., *Screening Housing to Prevent Lead Toxicity in Children*, 120 PUB. HEALTH REP. 305, 308 (2005).

[280] *Id.*

[281] EPA Sci. Advisory Bd., *Lead Paint Hazard Standards for Residential Buildings, Public and Commercial Buildings, and Renovations of Exteriors of Public and Commercial Buildings*, UNITED STATES ENVTL. PROT. AGENCY (2012) https://yosemite.epa.gov/sab/sabproduct.nsf/0/9c733206a5d64257852576950004f0cb1!OpenDocument&TableRow=2.3#2 [https://perma.cc/6F37-RV7V].

[282] For a detailed discussion of the legislative history and current status of federal lead hazard standards, see Benfer, *Contaminated Childhood*, *supra* note 25.

eral shall bring such actions in the name of people" across the state.[283] Instead, tenants typically pursue recovery via contract and tort actions.

Tenants may be able to recover damages related to exposure to health hazards by pursuing an action for violations of the lease. Historically, there was no covenant or warranty that the leased premises would be fit or habitable.[284] However, over time, the law recognized that tenants did not contract for merely the right to occupy a certain area of land, but rather, they contracted for the right to live in the subject premises.[285] Reflecting this shift, many jurisdictions acknowledged an implied warranty of habitability present in all lease agreements. As the District of Columbia Court of Appeals found, "the old no-repair rule cannot coexist with the obligations imposed on the landlord by a typical modern housing code, and must be abandoned in favor of an implied warranty of habitability."[286] Tenants may successfully assert their rights under the implied warranty of habitability to remedy housing code violations such as "bug and rodent infestations, mold, lack of insulation, absences of heat and hot water, broken door locks, and defective appliances, among others."[287] Judicial recognition of the implied warranty of habitability gives tenants the ability to initiate an action for contract violation when a landlord refuses to address substandard housing conditions.

Tenants may also seek recourse through tort actions. For example, in *New Haverford Partnership v. Stroot*, the Supreme Court of Delaware considered an action tenants initiated against their landlord for failure to maintain the leased premises in a manner free from health hazards.[288] In holding for the tenants, the court held that "the [local] Landlord Tenant Code imposes a duty on landlords to maintain the leased premises in a safe, sanitary condition and that an injured tenant may recover for personal injuries sustained as a result of landlord's negligent failure to do so."[289]

While tenants have the right to bring such actions against their landlords, it may be difficult for a tenant to prevail on a negligence claim, limiting the utility of the remedy. For example, in *Beck v. J.J.A. Holding Corp.*,

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[283] 410 ILL. COMP. STAT. ANN. 45/12.2 (West, Westlaw through P.A. 99-983 of 2016 Reg. Sess.); *see also* Abbasi *ex rel.* Abbasi v. Paraskevoulakos, 718 N.E.2d 181, 186 (1999) ("In this case, both the common law and the Act itself provide incentives for plaintiffs to pursue remedies. We therefore conclude that a private right of action under the [Lead Poisoning Prevention] Act is not necessary to implement the public policy behind the Act, and that plaintiff has an adequate remedy without creation of a private cause of action under the Act.").

[284] Mark S. Dennison, *Landlord's Liability for Breach of Implied Warranty of Habitability*, 43 AM. JUR. 3D *Proof of Facts* § 3, at 329 (1997). This was based on the "common law rule of caveat emptor, as applied to lease transactions, [which] was predicated on the assumption that both landlord and tenant possessed equal knowledge of the condition of the land being leased." *Id.*

[285] *Id.*

[286] Javins v. First Nat'l Realty Corp., 428 F.2d 1071, 1076–77 (D.C. Cir. 1970); *see also* Jack Spring, Inc. v. Little, 280 N.E.2d 208 (Ill. 1972) (finding that there is an implied warranty of habitability in all leases, both written and oral, by looking to the earlier ruling in *Javins*).

[287] Paula A. Franzese et al., *The Implied Warranty of Habitability Lives: Making Real the Promise of Landlord-Tenant reform*, 29 RUTGERS U.L. REV. 1 (2017).

[288] New Haverford P'ship v. Stroot, 772 A.2d 792 (Del. 2001).

[289] *Id.* at 794.

New York addressed the issue of whether a landlord is liable for injury resulting from exposure to toxic mold infestation following a flood in the leased premises.[290] As the court explained, for a tenant to prevail on a negligence claim, she must "first establish that the landlord either created or had actual or constructive notice of the hazardous condition which precipitated an injury."[291] Holding for the landlord, the court rejected the tenant's argument that mold is a foreseeable consequence of flooding in an apartment.[292]

States may also initiate a cause of action against parties for failure to remediate or prevent harm from exposure to health hazards. California and Rhode Island courts specifically examined the liability of paint manufacturers for lead poisoning in residential units under public nuisance doctrine. The plaintiff municipalities in *California v. Atlanta Richfield Company* alleged that the defendant paint manufacturers' sale of lead-based paint created a public nuisance.[293] As a result, plaintiffs argued, the defendants should incur the cost of abatement.[294] The California Court of Appeal found that the defendants were liable under public nuisance based on their promotion of lead paint for interior use coupled with their knowledge of the hazards that such use would create.[295] The court found that the defendants' advertising and publicity campaigns evidenced their promotion of hazards lead-based paint.[296] While the court found the paint manufacturers had actual knowledge of lead-based paint hazards, it stated that constructive notice alone is sufficient for public nuisance liability.[297]

However, in the case of *State v. Lead Industries*, the court arrived at a vastly different conclusion.[298] In Rhode Island, more than thirty thousand children experienced lead poisoning from exposure to toxic paint.[299] In response, the Rhode Island Attorney general brought a case against the paint manufacturers under public nuisance law.[300] At trial, the court found the manufacturers liable for obscuring the risk of lead paint.[301] However, on appeal, the Rhode Island Supreme Court reversed the decision, stating "public nuisance law simply does not provide a remedy for this harm . . . [T]he public nuisance claim should have been dismissed at the outset because the state has not and cannot allege that defendants' conduct interfered with a

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[290] Beck v. J.J.A. Holding Corp., 785 N.Y.S.2d 424 (2004).
[291] *Id.* at 425.
[292] *Id. But see* Brooks v. Lewin Realty III, Inc., 378 Md. 70, 72 (2003) ("[I]n the context of a tort action against a Baltimore City landlord, based upon a child's consumption of lead-based paint which was present in the form of flaking, loose, or peeling paint in the leased premises, in violation of the Housing Code, the [tenant] plaintiff does not have to show that the landlord had notice of the violation to establish a *prima facie* case.").
[293] Statement of Decision, *California v. Atl. Richfield Co.*, Case No. 1-00-CV-788657 (Super. Ct. Mar. 28, 2014).
[294] *Id*. at 7.
[295] *Id*. at 8–9; *California v. Atl. Richfield Co.* 2013 WL 6687953 (Sup. Ct. Dec. 16, 2013).
[296] Statement of Decision, *supra* note 293, at 8–9.
[297] *Id*.
[298] No. PC 99-5226, 2007 WL 711824, at *1 (R.I. Super. Ct. Feb. 26, 2007).
[299] *Id.*
[300] *Id.*
[301] Rhode Island v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 434 (R.I. 2008).

public right or that defendants were in control of lead pigment at the time it caused harm to children in Rhode Island."[302]

As these cases illustrate, the ability of residents or localities to recoup damages from exposure to toxic health hazards varies by jurisdiction. While courts generally recognize an implied warranty of habitability, allowing tenants to pursue damages under breach of contract, variance in tort and public nuisance rulings creates uncertainty and limits avenues of relief. Moreover, even if the harm occurs in a jurisdiction that recognizes such causes of action, cases are time consuming, difficult to win, and ultimately only arise after a harm has occurred. Because residents must first suffer injury in order to have a viable cause of action, the available remedies fall short of preventing the consequences of exposure to health hazards.

F. Community Level Interventions

In addition to the home environment, conditions within the community affect residents' exposure to hazards. As such, community interventions have the potential to greatly influence health and well-being. There are three common approaches within the community intervention framework: community development, urban policy development, and community-based measures. These approaches address underlying causes of poverty as well as social determinants of health.

1. Community Development

Community development is an approach to eliminating poverty that typically includes "a range of efforts to improve the physical, economic, and social environment by promoting affordable housing, small-business development, job creation, and social cohesion in low-income neighborhoods."[303] The actors often include bankers, policy makers, entrepreneurs, real estate developers, financial institutions and other investors, community organizations, local governments, and other entities focused on improving low-income communities.[304] In the community development model, corporations and financial institutions secure capital, in the form of "government subsidies, foundation grants, bank loans, and investments, equity investments for tax credits—to revitalize neglected communities."[305] At the same time, ideally, the effort also strengthens "the social bonds within communities . . . by

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[302] *Id.* at 435, 443.

[303] *Community Development and Health*, HEALTH POLICY BRIEF (Health Affairs/ Robert Wood Johnson Found.), Nov. 10, 2011, at 1 [hereinafter HEALTH POLICY BRIEF] (stating that organizations promoting jobs, housing, and better conditions in low-income neighborhoods also focus on health).

[304] *See id.*; Sandra Braunstein & Risa Lavizzo-Mourey, *How the Health and Community Development Sectors are Combining Forces to Improve Health and Well-Being*, 30 HEALTH AFF. 11, at 2444–45 (2011).

[305] HEALTH POLICY BRIEF, *supra* note 303, at 2.

involving residents in the conceptualizing, designing, building, and operating stages of development."[306]

Although traditionally community development efforts are not explicitly connected to public health improvement initiatives, in effect, they target many of the root causes of social determinants of health. Typical activities usually include building affordable housing, supporting small businesses, and creating jobs.[307] For example, "[t]he community development network builds affordable housing that often includes social services on site; fosters small-business development; and finances buildings that address specific community needs such as child care centers, health clinics, and charter schools."[308]

This approach to poverty elimination is an outgrowth of the "War on Poverty."[309] In August 1964, Congress passed the Economic Opportunity Act,[310] which was amended in 1966 by adding the "Special Impact Program" to fund community development ventures in urban poverty areas, leading to the first community development corporation.[311] The Community Reinvestment Act of 1973 laid the foundation for the community development finance system by requiring banks to meet the credit needs of the low-income communities in which the bank operates.[312] The community development sector has leveraged the Low-Income Housing Tax Credit,[313] building more than 2.5 million homes for low-income families and financing over 126 million square feet of commercial space for small businesses in low-income neighborhoods since 1987.[314] Community development financial institutions (CDFI), which serve as nonprofit lending institutions, were first developed in 1994.[315] Today, there are over one thousand CDFIs with over twenty-five billion dollars in assets.[316]

The community development sector is a well-developed enterprise that has gained the attention of federal and foundation funders. The Ford Foundation and other investors provided funding for the Local Initiatives Support Corporation. Since its inception in 1980, Ford Foundation's Local Initiatives Support Corporation has invested $11.1 billion in community development, which contributed to $33.9 billion in total development of 277,000 affordable homes, in addition to retail and community space, such as schools, child care facilities, and children's playing fields.[317] Similarly, since 1982, Enter-

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[306] Braunstein & Lavizzo-Mourey, *supra* note 304, at 2444.
[307] HEALTH POLICY BRIEF, *supra* note 303, at 1.
[308] Braunstein & Lavizzo-Mourey, *supra* note 304, at 2444.
[309] Alexander von Hoffman, *The Past, Present, and Future of Community Development in the United States*, INVESTING IN WHAT WORKS FOR AMERICA'S COMMUNITIES 21 (2012).
[310] Economic Opportunity Act PL 88-452 (1964).
[311] *Id.* at 21–22.
[312] *See Community Reinvestment Act*, FED. FIN. INSTS. EXAMINATION COUNCIL, http://www.ffiec.gov/cra/ [https://perma.cc/R9EJ-9Q3V].
[313] 26 U.S.C. § 42 (2017); 26 CFR § 1.42 (2017).
[314] Braunstein & Lavizzo-Mourey, *supra* note 304, at 2044.
[315] *Id.*
[316] *Id.*
[317] Hoffman, *supra* note 309.

prise Community Partners has collected more than $11 billion in equity, grants, and loans to help build or preserve nearly 300,000 affordable rental and for sale homes and provide more than 410,000 jobs nationwide.[318] The Neighborhood Reinvestment Corporation, now known as NeighborWorks America, which grew out of a federal task force and evolved into the creation of a national housing network, reached an annual direct investment in economically distressed communities of $1 billion between 1978 and 2000.[319] Despite these efforts, community development efforts "address a relatively small proportion of the immense need to revitalize America's low-income neighborhoods."[320]

2. Urban Policy Development Approaches

In 2009, Executive Order 13503 established the White House Office of Urban Affairs to investigate and develop urban policy for cities and metropolitan areas.[321] The Office's Urban Policy Working Group engaged in four initiatives: place-based policy review, sustainable communities, regional innovations clusters, and neighborhood revitalization.[322] The Neighborhood Revitalization Initiative aimed to transform high-poverty communities by better aligning federal funds and recognizing interconnected problems and solutions.[323] The effort engaged the White House and a wide range of federal government agencies, including the Departments of Health and Human Services, Housing and Urban Development, Education, Justice, and the Treasury in support of local solutions to revitalize neighborhoods.[324] The strength of the program was its interagency collaboration.[325] For example, it served to align federal housing programs (e.g., Choice Neighborhoods) with education, health services, and public safety initiatives.[326] The goal of the initiative and reason for federal coordination was the creation of "neighborhoods of opportunity" that would maximize life outcomes for low-income children no matter where they live, from the inner city to struggling suburbs.[327]

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[318] *Id.*
[319] *Id.* at 26, 49.
[320] *Id.*
[321] Exec. Order No. 13,503, 74 Fed. Reg. 8139 (Feb. 19, 2009). The website for the office no longer exists under the Trump administration and does not appear to be a priority. *Compare The Office of Urban Affairs*, THE WHITE HOUSE: PRESIDENT DONALD J. TRUMP, https://www.whitehouse.gov/administration/eop/oua [https://perma.cc/5C8C-KU4A], *with The Office of Urban Affairs*, THE WHITE HOUSE: OBAMA WHITE HOUSE ARCHIVES, https: //obamawhitehouse.archives.gov/urbanaffairs [https://perma.cc/RTC8-5862].
[322] *Urban Policy Working Grp.*, THE WHITE HOUSE: OBAMA WHITE HOUSE ARCHIVES, https://obamawhitehouse.archives.gov/administration/eop/oua/initiatives/working-groups [https://perma.cc/PMQ8-K2ME].
[323] The White House Neighborhood Revitalization Initiative, THE WHITE HOUSE: OBAMA WHITE HOUSE ARCHIVES, https://obamawhitehouse.archives.gov/sites/default/files/nri_description.pdf [https://perma.cc/HD32-GF8R].
[324] *Id.*
[325] *Id.*
[326] *Id.*
[327] *Id.*

At the same time, the initiative required a place-based policy review. "For the first time in decades, the Federal Government [analyzed]. . . how its policies impact[ed] the way urban and rural areas develop and how well those places support the people who live there, in all aspects of their lives—education, health, housing, energy, and transportation."[328] According to Obama White House archives, "[a]n effective place-based policy requires comprehensive interagency collaboration and investment that can ensure an increased impact of federal dollars and a greater return on federal investments." "A place-based policy is about finding the place-specific triggers not only to localized neighborhood and community growth but also to metropolitan and regional growth" and meeting urban and rural areas "where they are."[329]

3. Affordable Care Act and Community Based Measures

Under the Patient Protection and Affordable Care Act (ACA), nonprofit hospitals are required to regularly assess the social, economic, environmental, and health challenges facing their communities.[330] In the move from volume to value, prevention becomes the priority. Under the ACA, tax exempt hospitals are required to file community health needs assessment (CHNA) with the Internal Revenue Service.[331] The CHNA involves a comprehensive review of local health data and the community input. At the same time, the hospital must prepare an implementation strategy that shows how it will address prioritized health needs through the use of its charitable resources or community benefit.[332] In addition, the ACA authorizes a program of community transformation grants to public agencies and "community-based organizations for the implantation, evaluation, and dissemination of evidence-based community" prevention measures.[333] It also requires "15 billion dollars over ten years in mandatory spending under a Prevention and Public Health Fund to help reshape the physical and social environments of communities that face long-standing barriers to healthy living" and environments.[334]

G. Limitations of Current Approaches to Healthy Housing

While each approach has its own limitations, taken together they pose clear barriers to achieving healthy communities and housing. Current regulations and programs addressing environmental hazards are siloed, reaction-

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[328] Derek Douglas, *Place-Based Investments*, THE WHITE HOUSE: OBAMA WHITE HOUSE ARCHIVES (June 30, 2010), https://obamawhitehouse.archives.gov/blog/2010/06/30/place-based-investments [https://perma.cc/86XW-QRNR].

[329] *Id.*

[330] Norris & Howard, *supra* note 4.

[331] *Id.* at 13.

[332] *Id.*

[333] 42 U.S.C. § 300u-13(a) (2012).

[334] Miller et al., *Healthy Starts for All*, *supra* note 89, at S31.

ary, and under-resourced, which severely limits their ability to promote health and safety of residents.

1. Fragmented Responses to Healthy Communities and Homes

Departments tasked with achieving healthy communities and housing rarely coordinate their efforts, leading to disjointed, ineffective results. Each department has its own procedures to evaluate needs, applying interventions, and measuring outcomes.[335] Agencies typically operate on individualized timelines that do not align with those of other departments.[336] Perhaps most damaging, health, housing, environmental, and community development entities rarely coordinate efforts to address healthy communities and housing.

Individualized budget processes also present obstacles to collaboration. Funding for programs related to environmental hazards, such as health, housing, economic development, and community revitalization, is accomplished through different agencies and reviewed by different Congressional committees.[337] Moreover, budgets are scrutinized individually such that an expenditure by one agency that results in cost savings to a second agency is not recognized or appreciated.[338]

At the local level, fragmented policies make it difficult for residents to navigate the bureaucracy responsible for addressing an environmental health hazard.[339] For example, in Chicago, the Department of Buildings is responsible for home inspections to identify hazards such as cracks in the foundation, holes in the walls or floor, or lack of running water.[340] Noticeably absent from the Department of Buildings inspection protocol is a lead inspection. For that, Chicago residents must contact the Department of Public Health.[341]

Residents living in private property funded by the federal Housing Choice Voucher Program (HCVP) are also subject to disjointed inspection procedures. The local housing authority inspects all properties that receive HCVP funding to ensure compliance with HUD's Housing Quality Standards (HQS).[342] However, HQS does not require a lead hazard risk assess-

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[335] *See* HEALTH POLICY BRIEF, *supra* note 303, at 3–4.

[336] *See id.* at 3.

[337] *See id*. at 4.

[338] *See id.* ("For example, lower health costs associated with a program funded by the Department of Housing and Urban Development might not be identified as savings because those effects are seen in the jurisdiction of another agency or congressional committee.").

[339] Aaron Haier, *Promote Cross-Agency Coordination*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 13(2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/PE5L-W5PE] ("Because responsibility for health and safety is usually divided among various city agencies or departments, intragovernmental communication and collaboration can help make code enforcement more efficient and effective, and less like a series of disjointed, isolated efforts.").

[340] Health Justice Project, *Reshaping the Regulatory Landscape* (2014).

[341] *Id.*

[342] DEP'T OF HOUS. & URBAN DEV., 7420.10G, HOUSING CHOICE VOUCHER PROGRAM GUIDEBOOK 10–1 (2001), https://portal.hud.gov/hudportal/documents/huddoc?id=DOC_11754.pdf ("The goal of the housing choice voucher program is to provide 'decent, safe, and sani-

ment.[343] Many, if not all, tenants are unaware of this omission, and understandably assume that an inspection includes all hazards. As a result, tenants move into these properties and only discover the presence of lead hazards after their children experience irreversible effects of poisoning.

Fragmented policies can result in a lack of responsibility. When multiple government agencies are implicated in a case involving environmental health hazards, it can be difficult to determine which department has authority and a duty to address the issue. Without a clear division of tasks and responsibility, it can be frustrating for both the occupants of unhealthy homes, who do not know where to turn, as well as government officials, who may feel unsure of what steps to take.

Additionally, when departments do not collaborate, it is difficult to pinpoint program deficiencies or gaps in policy, making it hard to improve upon the existing approaches. Moreover, current research on interventions "is frequently very limited for informing policy and programming decisions, underscoring the need to document pilot projects and to collect and analyze health outcomes data for small areas and for population subgroups."[344] Building a collaborative base of empirical evidence regarding the efficacy of interventions is critical for advancing healthy housing and communities.[345]

2. Reactive and Secondary Prevention Policy

One of the most pressing barriers is that current policies are not structured to adequately prevent exposure to health hazards. Regulations surrounding lead exposure and poisoning among children highlight the failure of reactive approaches. Owners of Chicago residential buildings are required to maintain their property "in such a manner so as to prevent the existence of a lead hazard."[346] However as discussed previously, the law does not recognize a private right of action and is haphazardly enforced. Thus, the child identifies the lead hazard with his or her rising blood lead levels and the resident is left to initiate a costly contract or tort action to recover damages after the child has already suffered irreversible neurological damage.

While baseline standards are intended to provide a foundation of healthy communities and families, the reality is that if they are not followed and enforced, residents have little recourse until injury occurs. This is an ineffective strategy that fails to prevent poor health outcomes or achieve primary prevention. Reactive, rather than preventive law amounts to secon-

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tary' housing at an affordable cost to low-income families. To accomplish this, program regulations set for basic housing quality standards (HQS) which all units must meet before assistance ban be paid on behalf of a family and at least annually throughout the term of the assisted tenancy. HQS defines 'standard housing' and establishes the minimum criteria necessary for the health and safety of program participants.").

[343] Benfer, *supra* note 2, at 40–41.

[344] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at 491.

[345] *See generally* HEALTH POLICY BRIEF, *supra* note 303, at 4 ("[I]t will be critical to build a base of evidence demonstrating which interventions truly improve health outcomes.").

[346] CHI., ILL., MUN. CODE § 7-4-030.

dary prevention and is further problematic given that such policies wait until the hazard has grown to such a scale that it is often difficult and costly to remediate the situation.

3. Inadequate Resources

Programs to achieve healthy communities and housing require adequate funding in order to be successful.[347] Resource limitations severely constrain the ability of agencies to implement projects. In a 2014 survey conducted by the Health Justice Project, Illinois stakeholders stated that difficulty obtaining the resources, staff, funding, and technology needed to establish and enforce regulations were the principal obstacles to achieving healthy communities and housing.[348] For example, stakeholders in the Cook County Department of Public Health (CDPH) reported that limited resources coupled with responsibility for an expansive jurisdiction that includes unincorporated area severely hampered their ability to enforce regulations and provide effective interventions.[349] As a result, CDPH is only able to provide educational resources and consultations, rather than more resource-demanding active services, to unincorporated parts of the county.[350] Other county stakeholders across Illinois reported the same issue: lack of resources prevented departments from adequately addressing issues related to healthy communities and housing.[351]

The budget proposed by the Trump administration[352] will exacerbate these limitations. If enacted, it will impose deep cuts—over six billion dollars—on HUD,[353] affecting rental assistance and eliminating aid for utilities like heating and air conditioning, among others.[354] The budget would also eliminate the Community Development Block Grant Program,[355] which pro-

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[347] ChangeLab Solutions, *Fund the Code Enforcement Program Sufficiently*, *in* CHANGELAB SOLUTIONS, UP TO CODE: CODE ENFORCEMENT STRATEGIES FOR HEALTHY HOUSING 6, 7 (2015), http://www.changelabsolutions.org/sites/default/files/Up-tp-Code_Enforcement_Guide_FINAL-20150527.pdf [https://perma.cc/43CX-N22X("Sufficient funding is key to the success of a code enforcement program, granting communities the resources to maintain valuable housing stock and ensure residents live in safe and healthy homes.").

[348] Health Justice Project, *supra* note 340, at 9.

[349] *Id.*

[350] *Id.*

[351] *Id.*

[352] OFFICE OF MGMT. & BUDGET, AMERICA FIRST: A BUDGET BLUEPRINT TO MAKE AMERICA GREAT AGAIN (2017) [hereinafter BUDGET BLUEPRINT], https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/2018_blueprint.pdf [https://perma.cc/MM94-HXMP].

[353] *See* Jose A. DelReal, *Trump Budget Asks for $6 Billion in HUD Cuts, Drops Development Grants*, WASH. POST (Mar. 16, 2017), https://www.washingtonpost.com/politics/trump-budget-asks-for-6-billion-in-hud-cuts-drops-development-grants/2017/03/15/1b157338-09a0-11e7-b77c-0047d15a24e0_story.html?utm_term=.C778d8c869e1 [https://perma.cc/4CN4-45KH].

[354] *See* Yamiche Alcindor, *In Ohio County that Backed Trump, Word of Housing Cuts Stirs Fear*, N.Y. TIMES (Apr. 2, 2017), https://www.nytimes.com/2017/04/02/us/politics/trump-housing-budget-cuts.html?emc=eta1&_r=0 [https://perma.cc/X36Y-9X9S].

[355] *See* DelReal, *supra* note 353.

vides grants to 1,209 state and local governments to address issues such as decent affordable housing, community development, neighborhood rehabilitation and stabilization, and more.[356] In addition to housing programs, the proposed budget contemplates significant cuts to environmental and health programs.[357] Adequate funding is necessary to achieve healthy communities and housing. Until agencies have the resources they need to implement programs, residents will continue to be exposed to toxic health hazards and stakeholders will need to narrow their focus in order to align resources with others.

III. Recommendations

The previous parts documented several threats to health experienced disproportionately by low-income individuals and minority communities, and provided examples of the current approaches that fall short of addressing home and environmental health hazards. This part discusses some of the most successful approaches to creating healthier environments, including advancing health justice, coordination among disciplines and the elimination of silos, engaging the community in the development and implementation of any response or intervention, and increasing funding and dedicated research to inform public policy.

A. Advancing Health Justice

It is critical to advance health justice in order to improve health outcomes, especially among low-income and minority communities. The principle of health justice requires that all persons "have the same chance to be free from hazards that jeopardize health, fully participate in society, and access opportunity."[358] Health justice can only be realized when barriers to personal freedoms and the social determinants of health, from environmental hazards to policy decision that impact health outcomes, are addressed.[359] "Health justice requires a regulatory and jurisprudential approach that consistently and reliably considers the health ramifications of judicial and legis-

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[356] Dep't. Hous. & Urban Dev., *Community Development Block Grant Program-CDBG*, HUD.GOV, https://portal.hud.gov/hudportal/HUD?src=/Program_offices/comm_planning/communitydevelopment/programs [https://perma.cc/64FD-33PZ].

[357] *See* Budget Blueprint, *supra* note 352, at 21, 41; *see also* Brett Theodos et al., Urban Inst., Taking Stock of The Community Development Block Grant (2017), http://www.urban.org/research/publication/taking-stock-community-development-block-grant [https://perma.cc/64PM-ULY8] ("For many jurisdictions, [Community Development Block Grants are] a steady source of funding benefiting low-income individuals and communities, which allows them to focus on implementation rather than fundraising. [The program's] flexibility also allows localities to tailor solutions to their own needs and fund a wide range of activities, from providing housing loan counseling to supporting local attractions that generate economic activity.").

[358] Benfer, *Health Justice*, *supra* note 72, at 277–78.

[359] *See generally id.*

lative decisionmaking."[360] It envisions the integration of the knowledge of social determinants of health into policies, laws, legal systems, social structures, and funding rubrics.[361] Health justice encompasses principles of health equity, health in all policies, and the capabilities approach.[362]

The health equity approach to health care integrates health-promoting community assets, such as healthy food, safe housing, and transportation, into the health care services delivery system.[363] Health in all policies is premised in the understanding that, to address the social determinants of health, policy makers engage in various interventions, many of which involve law.[364] Health in all policies is an "approach that integrates health considerations into non-health sectors; it recognizes that 'corporate boardrooms, legislatures, and executive branches' make choices that profoundly impact health."[365] For example, in 2011, the Obama Administration released an action plan that included a "health in all policies" approach to considering the impact of health inequalities of policy and program decisions beyond the health sector with the goal of identifying possible health consequences.[366] The Institute of Medicine recommends that governments engage in health in all policies examination when considering "major legislation, regulations, and other policies that could potentially have a major impact on public health."[367] Greater and mandatory collaboration across sectors is necessary to fully realize the aims of this approach.

The Health Impact Assessment (HIA) emerged in the public health field as a systematic approach to analyzing potential health consequences of an intervention or policy.[368] HIA is "a combination of procedures, methods, and tools by which a policy, program, or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population."[369] The approach originated and was widely adopted in Europe and other developed nations.[370] It has increased in application in the United States over the last decade with Robert Wood Johnson Foundation's and Pew Charitable Trusts's launch of a capacity-building program to support the development of HIAs at local, regional, and national levels.[371] The HIA may be applied to policies that include land use, zoning, transportation, building developments, paid sick days, prison reform, utility usage,

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[360] *Id.* at 337.
[361] *Id.*
[362] *Id.*
[363] *See* NORRIS & HOWARD, *supra* note 4, at 10–11.
[364] Maxim Gakh, *Law, the Health in All Policies Approach, and Cross-Sector Collaboration*, 130 PUB. HEALTH REPS. 96, 96 (2015).
[365] *Id.*
[366] AMANDA CASSIDY, HEALTH AFFAIRS, HEALTH POLICY BRIEF: COMMUNITY DEVELOPMENT AND HEALTH 3 (2011).
[367] Gakh, *supra* note 364, at 96.
[368] CASSIDY, *supra* note 366, at 2–3.
[369] *Id.*
[370] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51–53; *see also HIA Case Stories*, HUMAN IMPACT PARTNERS, http://www.humanimpact.org/projects/hia-case-stories/ [https://perma.cc/YW5L-D7GA].
[371] CASSIDY, *supra* note 366, at 3.

among others.[372] For example, the HIA could be used to examine the application of building code requirements for new construction to older homes.[373] Ideally, the HIA will highlight health-related issues that should be considered during policy planning and implementation and create incentives for positive health impacts.[374]

The HIA is an example of how to apply and consolidate existing tools and literature on health to anticipate the potential impact of policies on health disparities.[375] Thus, the reliability of the HIA is dependent upon a strong evidence base from which to draw information.[376] Where there is a gap in research, it may be challenging to identify the actual scope of health impacts.[377] Thus the recommendation below to increase ongoing research is critical to its accuracy and utility.

Other tools include the Community Health Needs Assessment, used by hospital organizations and public health agencies to assess community health needs; the Social Impact Calculator that measures the financial aspect of economic, health, and social impacts of a community development intervention; and Success Measures Data System, developed by NeighborWorks America, which is comprised of 250 data collection tools that can measure effectiveness of health-related interventions.[378] To be holistic and wide-reaching, interventions should engage in an assessment framework that combines multiple tools, including health status of the population, neighborhood influences, building design, community engagement, and capacity-building activities.[379]

B. Coordination, Eliminating Silos, and Engaging the Hospital as a Partner in Community Development

There is growing recognition that the community development and public health fields have similar objectives, targets, and challenges,[380] and national momentum towards cross-sector collaboration is increasing.[381] In the same way that law should be examined for health consequences, it can also be used to require collaboration and prescribe collaborative processes to coordinate efforts and foster partnerships.[382] This requires an understanding of

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[372] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51–53; *see also HIA Case Stories*, *supra* note 370.

[373] *See infra* Part II.

[374] CASSIDY, *supra* note 366, at 3.

[375] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S53.

[376] *Id.* at S48.

[377] *Id.* at S49.

[378] *See* Ctr. on Social Disparities in Health et al., Making the Case for Linking Community Development and Health 34 (2015).

[379] *See* Bethany Rogerson et al., *A Simplified Framework for Incorporating Health Into Community Development Initiatives*, 33 HEALTH AFF. 1028, 1028 (2014).

[380] *Id.*

[381] Paul Mattessich & Ela Rausch, *Cross-Sector Collaboration to Improve Community Health: A View Of The Current Landscape*, 33 HEALTH AFF. 1968, 1968 (2014).

[382] Gakh, *supra* note 364, at 98.

the various legal tools, from legislation to executive orders to court procedures.[383] Resolving the social determinants of health in the home and community requires the removal of structural barriers that complicate cross-sector and -system initiatives and creating incentives or mandates for increasing collaboration.[384] For example, at the federal level, identifying, designing, and implementing health-based solutions would require multiple entities, including the Departments of Health and Human Services, Education, Agriculture, Housing, Transportation, and the Internal Revenue Service, Environmental Protection Agency (EPA). Yet, each department and agency has different deadlines, evaluation systems, and reporting requirements, complicating partnerships. The Partnership for Sustainable Communities is an example of a successful interagency program between HUD, Department of Transportation, and the EPA to coordinate resources and achieve agency mission.[385] Similar and more expansive partnerships and resource sharing are critical to addressing the health of low-income communities.

In 2015, HUD promulgated the Affirmatively Furthering Fair Housing (AFFH) Rule, directing program participants to take "significant actions to overcome historic patterns of segregation."[386] "This is not only a mandate to refrain from discrimination but also a mandate to take the type of actions that undo historic patterns of segregation and other types of discrimination and afford access to opportunity that has long been denied."[387] The AFFH Rule, which is designed to address entrenched segregation and its consequences, provides a framework for coordinated, cross-agency consultation and planning.[388] It requires that participants examine barriers to fair housing, including environmental hazards, using HUD's Environmental Health Index.[389] The AFFH Rule is a critically important public health tool because it both facilitates cross-agency and sector collaboration and targets residential segregation, which is the underlying cause of health disparities among minorities.[390]

On the community level, numerous organizations and community development agents have worked to improve the physical and economic design of low-income neighborhoods with the goal of eliminating poverty. At the same time the public health and medical fields focus on improving the health of low-income populations through community investment and healthy

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[383] *Id.*

[384] Miller et al., *Healthy Starts for All*, *supra* note 89, at S30.

[385] *See* Ctr. on Soc. Disparities in Health et al., *supra* note 378, at 25.

[386] 80 Fed. Reg. 42,272 (July 16, 2015).

[387] 80 Fed. Reg. 42,274 (July 16, 2015).

[388] 24 CFR 5.154 (2017).

[389] 24 CFR 5.150-5.168 (2017); Poverty and Race Research Council, Comment Letter on Environmental Protection Agency Draft EJ 2020 Action Agenda (Jul. 28, 2016), http://prrac.org/pdf/EPA_2020_AFFH_letter.pdf [https://perma.cc/9RLP-UTNR].

[390] Brian D. Smedley & Philip Tegler, *"Affirmatively Furthering Fair Housing": A Platform for Public Health Advocates*, AJPH PLACE BASED INTERVENTIONS, http://prrac.org/pdf/place_based_interventions.pdf [https://perma.cc/U3TZ-C8U5].

homes approaches.[391] These entities are often working in the same communities without coordination of efforts.[392] As David Erickson, the Director of the Center for Community Development Initiatives at the Federal Reserve Bank of San Francisco said:

> There is an entire industry—community development—with annual resources in the tens of billions of dollars that is in the 'ZIP-code- improving' business. And in the health field, there is increasing recognition of the need to act on the social determinants of health. The time to merge these two approaches—improving health by addressing its social determinants and revitalizing low-income neighborhoods—is now.[393]

Hospitals and health systems must identify ways to collaborate and utilize their resources to measure and achieve health communities. In the long run, it will benefit the health system through lower readmission rates and better health outcomes. Together, the community development and health sectors can design holistic interventions to improve the health and environment of the community.[394]

In practice, the health care entity should regard the entire neighborhood, and not just the individual, as the patient.[395] Hospitals spend more than $340 billion each year on goods and services.[396] "Redirecting even a small portion of that spending could have a tremendous impact on helping to restore local economic vitality, providing jobs for hard-to-employ people, and rebuilding urban fabrics and rural value chains."[397] In a high impact approach, "hospitals and integrated health systems are increasingly stepping outside of their walls to address social, economic and environmental conditions that contribute to poor health outcomes, shortened lives, and higher costs in the first place."[398] For their efforts to be effective, cross-sector collaboration is critical.

Numerous elements are necessary to plan and execute cross-sector initiatives. For example, vision, leadership, and mutual understanding are essential, as is strong leadership and community engagement techniques.[399] In one study, the leadership attributes of local actors were central to major place-based health initiatives and the most successful interventions involved

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[391] David Zuckerman, HOSPITALS BUILDING HEALTHIER COMMUNITIES: EMBRACING THE ANCHOR MISSION, 1 (Mar. 2013), http://community-wealth.org/sites/clone.community-wealth.org/files/downloads/Zuckerman-HBHC-2013.pdf [https://perma.cc/2EM3-TX7V].

[392] CASSIDY, *supra* note 366, at 4.

[393] CTR. ON SOC. DISPARITIES IN HEALTH ET AL., *supra* note 378, at 2.

[394] *Id.* at 15.

[395] Matthew E. Dupre et al., *Place-Based Initiatives to Improve Health in Disadvantaged Communities: Cross-Sector Characteristics and Networks of Local Actors in North Carolina*, 106 AM. J. PUB. HEALTH 1548, 1548 (2016).

[396] *See* NORRIS & HOWARD, *supra* note 4, at 2.

[397] *Id.* at 13.

[398] *Id.* at 1.

[399] *See* Ctr. on Social Disparities in Health et al., *supra* note 378, at 29.

collaboration with community health sector.[400] The approach requires working with a variety of stakeholders to identify community needs and interests before the design of any solutions.[401] By taking a "collective impact" approach, actors from numerous sectors can collaborate under a common goal and shared infrastructure for solving a complex social problem.[402]

Ultimately, the revitalization of low-income communities is critical to improving and promoting health and healthy homes, community development, public health, medical, design, and other fields are all critical to improving health outcomes.[403] Neither field will be successful without collaboration. At the same time, as cross-sector efforts increase across the United States, it is critical to assess the impacts of these health improvements.[404]

C. Engaging the Community in the Response

The success and sustainability of community-based interventions are dependent upon community engagement in identifying and defining the problems as well as setting and achieving goals for improvement.[405] The community-based participatory approach allows the members of the community to develop strategies that will address social determinants of poor health and is well suited to public health interventions.[406] Participatory approaches are instrumental in poverty reduction strategies and improve health outcomes by: (1) recognizing the community as a unit of identity; (2) building on strengths and resources within the community; (3) facilitating a collaborative, equitable partnership that increases community ownership and control; (4) integrating knowledge and action for mutual benefit of all partners; (5) promoting a co-learning and empowering process that attends to social inequalities; and (6) disseminating findings and knowledge gained to all partners.[407] In order to successfully engage disadvantaged communities, it is critical to provide technical and material support as well as the transfer of expertise, equal decision-making authority, and the ownership of the research.[408] "Participating in and sharing control of important events affecting their lives might be especially key for socially disadvantaged individuals, who have few opportunities to weigh in on such matters and often cannot prevent undesirable events or bring about good things."[409] Community based approaches that empower community members may also lead to increased

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[400] *See* Matthew E. Dupre et al., *supra* note 395, at 1554.
[401] *See* Ctr. on Social Disparities in Health et al., *supra* note 378, at 34.
[402] *Id.* at 29.
[403] CASSIDY, *supra* note 366, at 1–3.
[404] *See* Mattessich & Rausch, *supra* note 381, at 1968.
[405] *See* Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S49.
[406] Benfer, *Health Justice*, *supra* note 72, at 346.
[407] *See* Barbara A. Israel et al., *Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health*, 19 ANN. REV. PUB. HEALTH 173, 178–80 (1998).
[408] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S49.
[409] *Id.*

political and community participation, which can result in the reduction of social inequity and improved community health common in bonded communities.[410]

D. Dedicating Funding and Increasing Research

Achieving healthy communities and homes requires additional investment into funding and research. Increased investments in housing as well as spending to address other social determinants correlate with improvements to resident health.[411] This funding should target several spheres related to exposure to health hazards, including housing stock, community resources, and entities that provide health interventions. For example, research consistently shows that increasing funds to create affordable housing improves health outcomes of residents.[412] These resources must be purposefully directed to projects that will protect and improve resident health, not concentrate low-income and minority residents in high poverty, hazardous communities.

Recent litigation highlights this issue in the context of the Low Income Housing Tax Credits (LIHTC) program. LIHTC, regarded as "the most important resource for creating affordable housing in the United States today," provides state and local agencies with nearly $8 billion each year to "issue tax credits for the acquisition, rehabilitation, or new construction of rental housing targeted to low-income households."[413] In 2008, the Inclusive Communities Project (ICP) brought an action against the Texas Department of Housing and Community Affairs[414] (TDHCA), stating "two decades of racially discriminatory allocation decisions had placed 94% of the 18,710 9% and 4% LIHTC families in the City of Dallas in predominantly minority locations as of 2008."[415] Many of the housing accommodations were sited in distressed neighborhoods containing environmental health hazards including "industrial uses and obnoxious facilities such as illegal landfills."[416] ICP's

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[410] Benfer, *Health Justice*, *supra* note 72, at 347.

[411] Nancy E. Adler, *Assessing Health Effects of Community Development*, INVESTING IN WHAT WORKS FOR AMERICA'S COMMUNITIES 275, 277 (2012) ("This interpretation is consistent with findings from a number of U.S. studies linking specific aspects of housing and other community factors with health outcomes.").

[412] NABIHAH MAQBOOL ET AL., CTR. FOR HOUS. POLICY, THE IMPACTS OF AFFORDABLE HOUSING ON HEALTH: A RESEARCH SUMMARY 2 (2015).

[413] Office of Policy Dev. & Research, *Low-Income Housing Tax Credits*, U.S. DEP'T OF HOUS. AND URBAN DEV., https://www.huduser.gov/portal/datasets/lihtc.html [https://perma.cc/T87F-FWE3].

[414] Inclusive Cmtys. Project, Inc. v. Texas Dept. of Hous. and Cmty. Affairs, No. 3:08-CV-0546-D., 2008 U.S. Dist. WL 5191935, at *1 (N.D. Tex., Dec. 11, 2008).

[415] *Big Results for D/FW from ICP v. TDHCA Litigation: Increase in Housing Access Outside Racially Segregated Areas & Reformed 9% LIHTC Allocation Process*, INCLUSIVE CMTYS. PROJECT (2016), http://www.inclusivecommunities.net/wp/wp-content/uploads/2016/12/Big-Results-from-ICP-v-TDHCA-BLOG-POST.pdf [https://perma.cc/Z8R9-ESXH].

[416] Complaint at 10, Inclusive Cmtys. Project, Inc. v. Texas Dept. of Hous. and Cmty. Affairs, 3:08-cv-00546-D (N.D. Tex., Mar. 3, 2008), https://www.clearinghouse.net/chDocs/public/PH-TX-0004-0002.pdf [https://perma.cc/E4F9-2HPB].

litigation ultimately resulted in adoption of new policies to increase housing opportunities for low-income, minority residents.[417] As this case illustrates, it is not enough to create a funding supply; resources must be used in such a way as to promote health and well being.[418]

While the government traditionally funds these types of programs,[419] financial support may come from private entities. For example, recognizing the outsized effect that homes have on resident health, UnitedHealth invested fifty million dollars to construct low-income housing units in Minnesota and the Upper Midwest.[420] Similarly, public-private partnerships offer opportunities to increase resources within communities. Community Development Financial Institutions Fund invests federal and private sector capital to promote growth in low-income communities.[421]

In addition to funding, "[r]igorous evaluation of emerging models is essential. As communities across the country develop their own population health coalitions, research can and should be called upon to evaluate the efficacy of a range of governance models in real time."[422] Research and evaluation are critical to "generate strong evidence of impact in order to guide policy and secure future investments."[423] For example, researchers suspect that issues related to building size and public housing may be crucial to reduce asthma morbidity.[424] However, additional research on policies related

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[417] INCLUSIVE CMTYS. PROJECT, *supra* 415. *But cf.* CHANGELAB SOLUTIONS, A PRIMER ON QUALIFIED ALLOCATION PLANS LINKING PUBLIC HEALTH & AFFORDABLE HOUSING 4 (2015), http://kresge.org/sites/default/files/Primer-Public-Health-Affordable-Housing2015.pdf [https://perma.cc/A6EW-7CZE] ("The government awards financial benefits (tax credits) as part of the LIHTC program. In order to decide who receives these benefits each year, states revise and finalize their Qualified Allocation Plans (QAPs).").

[418] After satisfying minimum requirements, states have broad discretion in formulating QAPs, which may include incentives to develop housing in healthier areas. "QAPs can ensure that affordable housing is constructed with public health issues in mind, and health-promoting QAP criteria can result in healthier places to live for low-income residents." CHANGELAB SOLUTIONS, *supra* note 417, at 4.

[419] For example, "the community development field acquires nearly $16 billion each year in federal government subsidies. These subsidies and additional funds from state and local governments and foundations serve as seed capital to attract market-rate capital from insurance companies, pension funds, and social investors." For an overview of federally funded community development sources, *see* Ctr. on Soc. Disparities in Health et al., *supra* note 378, at 14–15.

[420] Jackie Crosby, *UnitedHealth Invests $50 million in Low-Income Rental Housing*, MINNEAPOLIS STAR TRIB. (Nov. 14, 2013), http://www.startribune.com/unitedhealth-invests-50-million-in-low-income-rental-housing/231933561/ [https://perma.cc/NS3F-GBAD].

[421] *See What Does The CDFI Fund Do?*, U.S. DEP'T OF THE TREASURY: COMMUNITY DEV. FIN. INSTITUTIONS FUND (Apr. 9, 2017, 11:28 PM), https://www.cdfifund.gov/Pages/default.aspx [https://perma.cc/ND3H-JF6H]; *see also* Miller, *Healthy Homes and Communities*, *supra* note 15, at S53 ("Another strategy for securing ongoing support for place-based demonstrations is to engage community development financial institutions (CDFIs).").

[422] Lauren Taylor et al., *Defining the Health Care System's Role in Addressing Social Determinants and Population Health*, HEALTH AFF. BLOG (Nov. 17, 2016), http://healthaffairs.org/blog/2016/11/17/defining-the-health-care-systems-role-in-addressing-social-determinants-and-population-health/ [https://perma.cc/MD8L-BRFG].

[423] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S48.

[424] Lindsay Rosenfeld et al., *Are Building-Level Characteristics Associated with Indoor Allergens in the Household?*, 88 J. URB. HEALTH: BULL. N.Y. ACAD. MED. 14, 15 (2011).

to amending the building code, violations adherence, building design standards, and landlord incentives are essential to better understand the issue.[425] Such research has the potential to provide lawmakers with necessary data to incorporate health into public and private policies and programs.[426]

The utility of increased research will be limited if the results are not routinely included in the policymaking process. The lack of investment in "translation and dissemination of research and evaluation" prevents decision makers from incorporating findings into improved policies.[427] However, as data is better integrated into policymaking, "health services researchers should be careful about importing their expectations of bio-medical interventions into the realm of organizational and social change."[428] Finally, the relationship between research and funding is circular. As research proves the efficacy of particular interventions, resources must be available to fund replication of these programs in local communities.[429] Sustainability measures must be part of any approach.[430] Doing so will achieve long lasting healthy communities and homes, thereby improving the health of residents.

Conclusion

As described herein, it is well-known that factors beyond access to health care influence health outcomes. Where we live impacts our health and our ability to access opportunity throughout our lives. This is particularly true with regard to housing conditions and community factors. At the same time, policies and lack of coordination between sectors can create barriers to addressing the social determinants of health and poverty on the community and environmental levels. In recognition of these facts, decision makers must implement processes to connect the evidence, increase collaboration between traditionally siloed sectors, and engage in health justice policy making. As diverse sectors increasingly recognize the relationship between poverty and poor health outcomes, it is of paramount importance that our policies foster and support collaboration. This type of action and the adoption of multi-faceted, comprehensive approaches are necessary to address the challenging, complex, interrelated issues of poverty reduction, eliminating racial disparities, and increasing health among all populations. The problem of poverty and social determinants of health are human constructs that society can solve with a coordinated, resourced, and determined effort. But it

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[425] *Id.*

[426] Miller et al., *Healthy Homes and Communities*, *supra* note 15, at S51.

[427] Miller et al., *Healthy Starts for All*, *supra* note 89, at S30.

[428] Taylor et al., *supra* note 422.

[429] Miller et al., *Healthy Starts for All*, *supra* note 89, at S30 ("Despite an abundance of evidence on interventions that are effective in improving the social conditions of children and their families, investments in replicating these strategies in local communities or states have been modest to date.").

[430] Meghan Hazer, *Sea View Community in New York City Ties Sustainability to Human Health*, U.S. Green Bldg. Council (Mar. 28, 2017), http://www.usgbc.org/articles/sea-view-community-new-york-city-ties-sustainability-human-health [https://perma.cc/8Z6U-2GJR].

will require our best assets and skills and unwavering collective commitment. When interprofessional partnership is commonplace, when the community is seen as an indispensable partner, and the evidence is targeted, poverty and the social determinants of health will be eliminated, human beings will have the ability to flourish in good health, and health justice will be achieved.

A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels

Jennifer L. Pomeranz, JD, MPH

Abstract

The modern food environment is considered a primary driver of obesity and other nutrition-related chronic diseases. A significant contribution to this environment is the proliferation of claims on food packaging that provides a misleading picture of a product's healthfulness. The Food and Drug Administration (FDA) is the agency responsible for food labels but it lacks the regulatory authority and adequate resources to address the majority of questionable labeling practices. The FDA's current system of enforcement is thus essentially based on voluntary compliance. Consumer- and manufacturer-initiated litigation has not successfully filled the regulatory gap. This manuscript reviews the current state of food labeling claims and the FDA's inadequate authority over misbranded food products. It analyzes competing views on regulatory compliance strategies and argues that a regulatory overhaul consistent with the best science and the First Amendment is necessary. With increased resources and authority, the FDA can meet current public health challenges and adequately ensure that labels are clear and consumers are properly informed and protected.

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A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels

Jennifer L. Pomeranz, JD, MPH

I. Introduction

The greatest challenge to public health in the United States stems from chronic diseases related to poor nutrition. n1 Over thirty-five percent of adults and almost seventeen percent of children and adolescents are obese in the United States. n2 Studies reveal that obesity increases as people consume a higher proportion of processed food and beverages (collectively "food") in their diets. n3, n4 Technological innovation in processed food manufacturing has led to the creation of thousands of new products a year, adding to the abundance of products (more than 300,000) on U.S. store shelves. n5 Experts point to this modern food environment as the primary driver of the obesity epidemic. n6

A significant development within this current food environment is the proliferation of claims on food packaging that gives a misleading picture of a product's healthfulness. n7 Current food labeling practices include both actual misbranding and permissible but potentially misleading claims about the healthfulness of processed foods. The latter is due to regulations that are too lax or do not reflect the most current science on nutrition. Such confusing food labels undermine public health and have become a widespread problem of their own, in need of regulatory response.

Congress granted the Food and Drug Administration (FDA) the authority to protect consumers and the public health from misbranded products such as prescription drugs, food, medical devices, and cosmetics. n8 However, the agency's enforcement authority is not uniform. In the area of food labeling, the FDA lacks particular authorities that it holds over other products or that Congress has granted to another consumer protection agency, the Federal Trade Commission (FTC). n9 The FDA does not have the resources to sufficiently address the current state of labeling, nor is there funding allocated to feasibly increase its enforcement power. Due to competing interests and First Amendment concerns, the FDA has not utilized what little authority it does have to adequately address food misbranding or revise current regulations on permissible claims. n10 Thus, the FDA's current system of enforcement is essentially based on voluntary compliance. The agency issues a Warning Letter to put a company on notice that it violated a regulation; this is typically the extent of its enforcement activity.

As a result of these regulatory deficiencies, consumers and manufacturers have turned to litigation to reign in questionable claims. There is no private right of action under the Food Drug and Cosmetic Act (FDCA). Consumers thus sue food manufacturers under theories of tort liability and pursuant to state consumer protection acts. Similarly, manufacturers litigate pursuant to the Lanham Act n11 as a method to police their competitors' false or misleading labels. The premise underlying these lawsuits is that labels should be truthful and not misleading to ensure a fair and efficient marketplace. But litigation is not a global solution and has not corrected the problematic labeling environment or provided an adequate substitute for stronger regulations.

The FDA’s forced reliance on a system of voluntary compliance has led to an overwhelming number of legal (but questionable) and non-legal claims and statements on food packaging. There currently seems to be little business incentive to comply with food labeling regulations (or FDA guidance documents). Whatever practical threat a Warning Letter holds, this is not a primary disincentive to follow food labeling regulations. The potential for negative publicity and the threat of a

lawsuit likely are more compelling incentives to comply; however, these are also not very imposing. So far, labeling non-compliance has not resulted in significantly adverse consequences for companies. n12 The high rate of non-compliance and questionable claims are due to lax enforcement, no threat of penalty, ineffectiveness of litigation as a regulatory mechanism, and little threat of reputational tarnish.

This paper will review the current state of food labeling claims in Part II. Part III will discuss the FDA's inadequate authority over misbranded food products and the need for increased regulations to control the use of misleading claims. In Part IV, the paper will analyze competing views on regulatory compliance strategies and argue that a regulatory overhaul to require all claims be preapproved is necessary. This is consistent with the First Amendment and would support honest competition and informed consumer decision making. The paper argues that Congress should ensure the FDA is properly funded through a registration fee structure and amend the FDCA to expressly provide the FDA with revised authority to enforce its regulation. Specifically, the FDA needs the authority to seek civil penalties, prohibit claims proven to be deceptive, and compel companies to turn over their substantiation documents when new claims are proffered. With increased resources and authority, the FDA can meet current public health challenges and adequately ensure that labels are clear and consumers are properly informed and protected.

II. Current Food Labeling Claims

A. Misleading Food

In the food labeling context, it is unlawful to introduce misbranded food into interstate commerce. n13 A food meets the definition of misbranded if it has a false or misleading label, is not properly named or identified, is missing required disclosures or nutrition information, or if health and nutrition claims are not made according to specified requirements. n14 Although the definition includes "misleading" as a condition of misbranding, this is one area the FDA does not generally address, meaning it does not send Warning Letters or otherwise seek correction for labels solely deemed misleading. Misleading labels are their own issue; the prohibition against them is in need of enforcement. Further, although there are specific requirements for certain permissible health-related claims, others are permitted based on the manufacturers' representation of accuracy. n15 The requirements for the former have become too permissive in light of the proliferation of food-based claims and the allowances made for the latter leaves labels susceptible to a variety of questionable claims. n16 This paper will refer to the dual issue of misbranded claims and permissible but questionable claims as "misleading" food claims.

Misleading food claims are a barrier to a fair and efficient marketplace. Research shows that from 2001 to 2010, the number of health- and nutrition-related claims on new products increased from 2.2 to 2.6 per product. n17 However, research also reveals that consumers are confused by the intent of commonly used claims on food packaging n18 and are misled by such claims to underestimate total calorie content in the product and overestimate a product's overall positive attributes. n19 Claims create a "health halo" around the product, whether or not the consumer is seeking a healthier choice. n20 This means that consumers misperceive the total nutritional quality of the food and may eat more of it than in the absence of such a claim. n21 Despite the confusion, health and nutrition claims increase consumers' intent to purchase the products bearing them. n22 Consumers are in fact increasingly seeking healthier foods, n23 so it is not surprising that sales of new

products with such claims are higher than those without them. n24 Therefore, accurate information is necessary for consumers to make appropriate choices. n25

Manufacturers additionally have a financial interest in consumers choosing their products over their competitors' products; thus, they have a stake in ensuring that consumers are not deceived by the competition through misleading labels. Clear factual information is necessary to meet these compatible interests.

The current food labeling environment suffers from dual problems of lack of regulations that restrict questionable claims and inadequate enforcement of questionable claims that do violate the regulations. The first problem stems from the evolution of permissible claims so that now even misleading and deceptive claims are expressly permitted or tactically ignored. The second problem stems from a lack of authority and resources granted to the FDA to properly address misleading claims or misbranded food products. Both are reviewed below.

B. Claims

Food manufacturers are permitted to utilize four types of claims on food packaging, but in practice, over eighty-five percent of them are nutrient content or implied nutrient content claims (collectively, nutrient content claims). n26 The remaining claims are health claims, qualified health claims, and structure/function claims. n27 Nutrient content claims expressly or implicitly characterize the level of a nutrient of the type required to be disclosed in nutrition labeling, such as "low sodium," n28 and must be made in accordance with Reference Amounts Customarily Consumed or the Recommended Daily Value of a food or nutrient. n29 Health claims characterize the relationship of a substance to a disease or health-related condition and must be based on a "significant scientific agreement standard." n30 An example is: "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect." n31 Qualified health claims are permitted when credible emerging or limited scientific evidence supports a relationship between a food and reduced risk of a disease or health-related condition. n32 They are similar in intent to health claims but additionally must contain a disclaimer such as, "very limited and preliminary scientific research suggests" and a notation that the "FDA concludes that there is little scientific evidence supporting this claim." n33, n34 The final category, structure/function claims, describes the role of a nutrient or ingredient intended to affect or maintain normal structure or function in the body; for example, "calcium builds strong bones." n35 Structure/function claims do not need preapproval and there are no specific requirements for their use, so the manufacturer alone is responsible for their accuracy. n36 The general requirement that claims on food packaging must be truthful and not misleading applies to all claims, including structure/function claims, n37 but the FDA does not routinely enforce this general prohibition. Misleading or suspect structure/function claims may be and have been ignored. n38

Legally permissible health and nutrition claims on product packaging may present a misleading picture of a product's overall healthfulness because they are permitted on food despite other less healthful characteristics of the product. Health claims are not permitted on products that contain "disqualifying nutrient levels" of total fat (13 grams), saturated fat (4 grams), cholesterol (60 milligrams) or sodium (480 milligrams). n39 The FDA has not instituted a disqualifying level of artificial trans fat or added sugar in order for manufacturers to make claims. n40 Thus, products containing artificial trans fat and high levels of added sugar may bear health claims.

The regulations for nutrient content claims are more permissive because the disqualifying nutrient list above does not prevent a manufacturer from making such a claim. Manufacturers are permitted to make nutrient content claims even if a nutrient in the product exceeds the level indicated above as long as the package bears a statement about the suspect nutrient as follows: "See nutrition information for [subject nutrient] content." n41 It is unclear how effective this directive to examine the Nutrition Facts Panel is in terms of consumer education or attention. Regardless, this requirement likewise does not apply to foods high in artificial trans fat or added sugar. n42 Thus, products containing high levels of total and saturated fat, cholesterol, sodium, artificial trans fat, and added sugar can bear nutrient content claims, the latter two without any note to consult the Nutrition Facts Panel.

Perhaps the most problematic result of these lax regulations is that products high in added sugar carry a wide variety of nutrient content claims, which misleadingly convey healthfulness in an otherwise unhealthy product. n43 For example, in one study of 115 cereal brands, a large percent of the least healthy cereals that were marketed to children bore the most number of health or nutrition-related claims, at three to four per box. n44 In another study, products bearing the Whole Grain Stamp, a symbol manufacturers pay an organization to use, had the most sugar of the 545 products assessed. n45 Candy manufacturers have also begun advertising the protein content of their products (e.g., Baby Ruth) derived from peanuts as an ingredient. n46 Given that health and nutrition-related claims create a perception of health notwithstanding the actual properties of the food or whether consumers are seeking a healthy product, n47 it is problematic that foods of less than optimal nutritional value increasingly bear such claims.

The proliferation of questionable but legal claims likely has its origin from litigation in the 1990s, which marked the advent of qualified health claims. The FDA had originally disallowed the use of a health claim that did not meet the robust "significant scientific agreement" standard. n48 Marketers of dietary supplements brought litigation against the FDA claiming the restriction violated their First Amendment rights. n49 In *Pearson v. Shalala*, a federal appellate court agreed with the marketers and held that the FDA could not ban health claims that failed to meet this standard. n50 The court held that the agency must allow a modified health claim or one with a clarifying disclaimer. n51 The FDA has since applied this rationale to food products, so claims with substantially less evidence, i.e., qualified health claims, are now permitted. n52 Since *Pearson*, there has been a recognizably more lax environment for all claims, likely due in part to the court's strong language supporting the manufacturer's First Amendment rights. n53

At the time the court decided *Pearson*, the finding was supportable from both an evidence-based and First Amendment perspective. Truthful labeling is considered commercial speech, protected by the First Amendment. n54 However, false, deceptive, and misleading speech on a product label is not protected and may be regulated. n55 The government may ban speech that has been proven to be misleading. n56 If the speech is only potentially misleading, which means that it can be presented in a way that is not deceptive, or can be explained through disclaimers or disclosures, it cannot be banned. n57 The government can only require that potentially misleading speech be presented in a non-misleading manner by requiring factual disclosures or explanations to cure the potential deception. n58 At the time of *Pearson*, there were no studies to indicate the proposed claim was misleading. Thus, the court prescribed further explanation through disclosures consistent with First Amendment jurisprudence. Since *Pearson*, however, several studies confirm that qualified health claims are in fact confusing to consumers. n59 Still, the FDA has not indicated a renewed interest in addressing qualified health claims. Practically, the food industry rarely uses qualified

health claims. n60 Legally, since *Pearson*, the Supreme Court's interpretation of the First Amendment has provided increasing protection to commercial speech (and other forms of business-related speech), n61 creating a disincentive for the agency to address questionable marketing practices and risk negative judgment in court. At this point, no activity on health-related claims seems imminent and these four types of claims remain permissible.

In addition to confusing but legally permissible claims, a whole range of questionable labeling practices can be found on food product packaging. Some of them directly violate FDA regulations or guidance documents; others are perfectly legal but highly questionable. Consumers, competitors, and government officials seeking to protect the public have initiated litigation or issued formal requests to the FDA to address such claims utilized on food and beverages. n62 An examination of select cases related to labeling deficiencies provides a useful lens to review the different types of misleading claims that adorn processed food products. The confusing nature of these claims helps shed light on the need for increased FDA oversight, authority, and resources.

C. Misleading Label Examples

1. Product Names

FDA regulations require that the principal display panel of a food bear a statement of identity of the product. n63 Unless there is a legally required name, this is generally the common name of the food or a "fanciful name commonly used by the public for such food," n64 such as "Vanilla Wafers." n65 FDA regulations also explain that the name of a food "shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." n66 However, products have names that do not follow this directive; for example, popular ready-to-eat cereals have "blueberry" named versions of a product line that do not actually contain any blueberries. n67

A regulation in the beverage context explicitly permits confusing names, which undermines the force of the general naming regulation. Specifically, the name of juice may reflect one of many juice ingredients as long as there is a qualifying word, such as "blend." n68 This results in misleading product names, such as a Minute Maid juice named, "Pomegranate Blueberry," but which contains 99.4% apple and grape juices (and only 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice). n69 Pom Wonderful, manufacturer of 100% pomegranate juice, sued Minute Maid's manufacturer, Coca-Cola, under the Lanham Act. Pom Wonderful claimed that the name of Minute Maid's juice misled consumers to believe that it primarily consists of pomegranate and blueberry juices. n70 Pom was unsuccessful because the product adhered to FDA regulations. n71 In pursuit of its claim, Pom conducted a survey that determined that more than 30% of consumers misunderstood the juice's ingredients based on the label. n72 As noted by the Ninth Circuit in this case, this is an area where the FDA would need to amend the regulations to prevent such deception. n73

2. Fortification

Fortification is the addition of nutrients to a food n74 and nutrient content claims are permitted when the nutrient is added to a product through fortification. n75 It is unclear whether there are health benefits or detriments to consuming a diet largely derived from fortified products, but it is clear that fortification increases the perception of healthfulness for consumers. n76 Market research

indicates that health-seeking consumers look for specific ingredients or fortification elements including antioxidants, among others. n77 This has led to carbonated beverages touting fortification in direct violation of the FDA's Fortification Policy against fortifying candy and carbonated beverages. n78 Diet Coke Plus n79 and 7Up with Antioxidants n80 are two such products. The FDA sent a Warning Letter to Coca-Cola for Diet Coke Plus, n81 but the agency failed to send a Warning Letter to the manufacturer of 7UP with Antioxidants, Dr. Pepper Snapple Group, despite the fact that the products violated the same regulations. n82 Consumer groups have sued over both products with few results. n83, n84

3. Definitions

Due to evolving preferences, fads, and dietary guidelines, among other influences, certain properties of food become more or less attractive to consumers over time. The food processing industry reported that in 2010, the majority of the top ten most successful new products in the packaged food and beverage genre focused on "health and wellness." n85 This trend is evident by the increasing use of organic and eco-friendly labels, n86 with the newest descriptor, "natural," spurring litigation over the accurate definition of the term. n87

Products ranging from cereals, savory chips, sugary beverages, dairy creamers, and artificial sweeteners have labels claiming that they are "natural." In the beverage context, several plaintiffs have sued manufacturers alleging that the addition of high fructose corn syrup and citric acid renders the "natural" claim on the product false or misleading. These lawsuits have generally not been successful. Courts have dismissed such claims due to lack of FDA guidance on a precise definition of the term. n88 Plaintiffs have not been successful even when a court is willing to entertain the claim; in one case the judge dismissed the case despite recognizing that the ingredients were "produced" and not "grown in a garden or field," because he found plaintiffs' arguments were simply "rhetoric." n89

Notwithstanding repeated requests by both consumers and companies, n90 the FDA has declined to define the term "natural" beyond its statement that it will not "restrict the use of the term 'natural' except for added color, synthetic substances, and flavors . . . ." n91 The FDA explained that "resource limitations and other agency priorities" prevent the agency from "undertaking rulemaking to establish a definition for 'natural' . . . ." n92

4. Misbranding

New products and product categories provide ongoing challenges for regulators. n93 Energy drinks are a relatively new category of beverages marketed as sources of increased energy. n94 They generally contain, and tout, high levels of caffeine and a wide array of approved food additives and unapproved ingredients. n95

The FDA issued a non-binding guidance document in 2009, which distinguished between beverages and liquid dietary supplements. n96 According to this guidance, energy drinks are beverages which should be labeled as conventional food and not dietary supplements. n97 The FDA has not enforced this in a comprehensive manner n98 and litigation has not addressed this issue either. When confronted with this issue, one court dismissed the claim, stating that it was a "straightforward misbranding claim best resolved by the FDA." n99

The FDA warned one energy drink manufacturer that labeling its product an "energy supplement" did not make it a dietary supplement, and further that it was adding unapproved additives into the food supply (i.e., Rockstar Roasted Coffee & Energy, containing Ginko). n100 However, the agency is not consistent in even these efforts and ignores other products with the same deficiencies by different manufacturers (e.g., Monster Java containing the unapproved additives taurine and panax ginseng). n101 It is unclear why there is inconsistent enforcement for these two products. n102 But inconsistent enforcement minimizes any deterrent effect Warning Letters may have.

D. Summary

The cases above indicate various types of claims consumers face on a regular basis but which are largely unaddressed by the FDA. The norm is now a supermarket full of food with claims that are misleading or create an impression that even some of the least healthy products are nutritious. n103 Permissible claims adorn highly processed food with unhealthy properties, especially those high in added sugar. Other practices have proven to be confusing or have provoked litigation claiming that they misrepresent a product's overall healthfulness or its true properties. n104 The FDA is faced with a wide array of misleading claims that overwhelm the little regulatory authority it does have. The agency's lack of regulatory authority is explored below.

III. FDA Enforcement Authority

The FDA has regulatory authority over consumer products including drugs, medical devices, dietary supplements, food, and cosmetics. n105 However, the FDA’s enforcement authority differs for each type of product. In various sections of the FDCA, Congress has made its intent clear that the FDA’s power to enforce most food labeling violations is limited as compared to the FDA’s authority in other contexts. n106

The FDA’s authority is also limited as compared to the FTC's authority over false, unfair, and deceptive advertising which includes all other media outside of food packaging. The FDA and FTC divided the responsibility over food marketing pursuant to a Memorandum of Understanding, under which the FDA has primary responsibility for regulating food labeling and the FTC has primary responsibility for regulating food advertising. n107 This division was further solidified when Congress passed the Nutrition Labeling and Education Act of 1990, providing the FDA authority to require standardized nutrition and health related information on food packaging. n108 The following analysis respects this division of authority. However, an alternative method to address problematic food labeling practices would be for the agencies to amend the Memorandum of Understanding to recognize the FTC as the primary entity responsible for misleading claims on food packaging. Congress could also mandate this. Currently, the FTC has more authority to pursue questionable marketing practices, including the authority to obtain civil penalties for unfair and deceptive acts or practices n109 and the dissemination of false advertisements. n110

A. Warning Letters Versus Civil Monetary Penalties

The FDA has the authority to pursue civil penalties in non-food labeling contexts, for example, for the dissemination of false or misleading direct-to-consumer advertisements for drugs. n111 However, Congress explicitly precluded the FDA from exacting penalties in the food context based on advertisements on packaging that are materially false or misleading (or if vitamin or mineral ingredient labeling is incorrect). n112 The definition of materially false or misleading advertising in

this context is quite broad, n113 which would be positive if the FDA had the authority to address it properly. Instead it is a categorical brush away of enforcement authority over a large field of labeling deficiencies.

The FDA does have the authority to issue civil monetary fines in the context of food safety, for the introduction of an article of food containing an unsafe pesticide chemical residue and, since the enactment of the Food Safety Modernization Act of 2011 (FSMA), for violations of a recall order. n114 The FSMA provided the FDA with the authority to enforce compliance with recall orders if the agency finds an article of food is adulterated or misbranded, but *only* in terms of missing allergen information. n115 The purpose of this authority is to protect the public from being exposed to an article that "will cause serious adverse health consequences or death." n116 In the context of food labeling, Congress determined that non-acute health outcomes from misbranding do not rise to the level of requiring such an enforcement mechanism. n117 Thus, the FDA lacks the ability to impose or seek a civil penalty or recall otherwise misbranded or misleading food products that are placed into the stream of commerce.

If the FDA discovers a labeling violation, it has a short list of recourse options available to it. First, the agency is instructed to issue a Warning Letter or hold a regulatory meeting to discuss the labeling violation. n118 The purpose of the Warning Letter is to put the company on notice that a violation occurred. The FDA has explained that this is "the Agency's principal means of achieving prompt voluntary compliance with the Act." n119

Pursuant to the FDCA, the FDA is permitted to condemn and seize misbranded food after the agency gives the company proper notice and an opportunity to respond. n120 This is permissible only when the agency has "probable cause to believe . . . that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer." n121 This does not generally occur in the typical misbranding context (i.e., not related to allergens or pesticides), which is the type of misbranding of concern in this paper.

Another option available to the FDA after issuing a Warning Letter is to work with the Department of Justice (DOJ) to seek an injunction or initiate a criminal prosecution. n122 However, the FDA has little guidance to determine when a food-related violation rises to the level of criminality, n123 and misbranding rarely rises to the level of criminal sanctions. The FDA understandably would be reluctant to pursue violations of the misbranding regulation with the DOJ since Congress did not intend for it to make that a regular practice. The FDCA specifically admonishes the agency from reporting "minor violations" to the DOJ when the Secretary "believes that the public interest will be adequately served by a suitable written notice or warning." n124 Congress seemed to have made its intention clear that it believes the public interest is adequately served by written Warning Letters and the FDA has taken the cue. The FDA seeks relatively few criminal actions for food misbranding, n125 although it uses this remedy widely for other violations of the Act. n126 The result is that the FDA regularly issues Warning Letters alerting the responsible company of the violation and seeks assurance from the company that it will change its practices. n127

The FDA has said that Warning Letters should be issued for violations "that may actually lead to an enforcement action" if not corrected; n128 however, this is not an accurate account of its enforcement activity. Rather, the Warning Letter represents *the* enforcement action for cases of mislabeled food products. There is no other viable enforcement action when a violation occurs and worse, not all violations actually garner a letter. n129, n130 This represents an error of enforce-

ment, which dilutes deterrence. n131 In the area of misbranded food products, seeking voluntary compliance is thus the agency's primary avenue of enforcement for labeling violations.

The FDA database houses Warning Letters dating from 1996 onward. Starting on September 1, 2009, the agency began tracking whether it issued a close-out letter, which it "may issue when, based on FDA's evaluation, the firm has taken corrective action to address the violations contained in the Warning Letter." n132 The FDA states that it requires proof of the corrective action. n133 For all Warning Letters sent, a small percentage have been "closed out" according to the FDA's database n134 and an even smaller percentage have letters of response from the responsible business. n135 The Warning Letter method of enforcement is lax, does not sufficiently deter noncompliance, or definitively lead to corrective actions. As discussed further below, the agency's lack of resources and other authorities necessary to meaningfully enforce the regulations further compound its inability to enforce misbranding regulations.

B. Substantiation Documents

The FDA lacks the authority to require that companies provide the agency with substantiation documents if it questions a claim, which means that the agency cannot compel the responsible company to disclose the research or scientific data that presumably served as the basis for the claim. n136 The burden is on the FDA to conduct its own research. n137 This puts the agency at a disadvantage and hinders it from challenging questionable claims.

Without the authority to obtain substantiation documents, the FDA cannot always effectively challenge questionable claims. Conversely, the FTC has the authority to compel companies to turn over substantiation documents and the Commission successfully uses this power to protect consumers by addressing questionable claims. n138 For example, Kellogg's placed an "Immunity" claim on its Rice and Cocoa Krispies children's cereals. n139 The FDA has jurisdiction over such claims on packaging, but it did not address the "Immunity" claim, likely because it is considered a structure/function claim, where enforcement authority is at its weakest, and also because the FDA could not require the company to submit its scientific basis for the claim. However, the FTC did respond to the related advertising campaign and publicly reprimanded the company. n140

Obtaining substantiation documents is a normal and necessary part of regulatory control. There is no logical basis to bar the FDA from obtaining the scientific data to support a company's questionable claim, especially given that the FTC, and state attorneys general for that matter, are legally permitted to obtain the identical documents based on the same principles of enforcement.

C. Litigation as "Regulation" Has Not Filled Regulatory Gaps

In the food labeling context, private plaintiffs have sought to reign in questionable claims through litigation. Because there is no private right of action under the FDCA, plaintiffs bring cases pursuant to common law tort claims and state consumer protection statutes. The initiation of such lawsuits has been increasing n141 but has not led to a global change in food labeling. Litigation costs a substantial amount of time and resources, n142 and could be avoided by both stricter labeling regulations enforced by the FDA and by manufacturers spending initial resources ensuring their claims are compliant. n143

Only a small handful of cases among the dozens filed have been successful. Courts infrequently find that a plaintiff has brought an actionable claim. n144 Even more rare are the cases that make it

to trial and where the judge or jury finds a claim was sufficiently misleading, deceptive, or false to constitute an injury. n145 One notable example of such a case was when a plaintiff sued Gerber Products Company pursuant to California's unfair business practices statute, arguing that the package of Gerber Fruit Snacks was deceptive because the fruit represented in the picture was not the fruit in the product. n146 The Ninth Circuit agreed, finding that the package could likely deceive a reasonable consumer who should not "be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box." n147 More often than not, however, courts find that reasonable consumers would not be misled by fruit images n148 or that there is no cognizable harm despite violations of the FDCA. n149 Even under the best conditions, the threat of tort liability is a highly imperfect and inconsistent method to reign in questionable claims.

Manufacturers also use litigation pursuant to the Lanham Act to restrain their competitors' use of misleading claims. The Lanham Act provides a cause of action to a company that may be injured by its competitor's false or misleading representation of the latter's product. n150 However, this provides a remedy for direct competitors only and "does not act as a 'vicarious avenger' of the public's right to be protected against false advertising." n151 Some Lanham Act cases do result in the withdrawal of questionable claims from the marketplace, thereby protecting consumers; however, this has not significantly altered the food labeling environment. Moreover, if a claim misleads consumers but does not hurt competition, it would not be subject to such litigation.

Litigation through the Lanham Act suffers from the same deficiencies as private plaintiff-based litigation as a non-viable substitute for regulation. n152 Plaintiffs and manufacturers cannot enforce the FDCA, so they must seek to establish an individualized injury, which, even if successful, does not generally extend to correct a market-wide problem. Thus, violations of the FDCA that do not rise to that level of cognizable injury would remain unresolved. Second, a party that wins monetary damages (as opposed to injunctive relief) is the party that profits, and this does not benefit other similarly situated groups. Third, litigation does not provide a consistent regulatory mechanism to ensure a uniform labeling requirement. It is often protracted, unpredictable, and can have inconsistent (or wrong) outcomes that do not necessarily deter future bad activity. n153 Litigation has not effectively reigned in questionable claims; n154 the more effective solution is to improve the regulatory system. n155

D. Funding

Finally, the FDA is under-funded in the food labeling area. In 2008, the Government Accountability Office found that the FDA's resource constraints and numerous responsibilities made it difficult for the agency to enforce all of its labeling requirements. n156 The same lack of sufficient resources to address food labeling issues remains today. In the FDA's fiscal year 2013 budget, food labeling allocations were the lowest of all nineteen programs under its jurisdiction. n157 The FDA has cited lack of resources as a reason for not addressing pressing labeling issues. n158 In order to address the pervasive labeling problems outlined above, increased resources will be necessary.

E. Summary

Warning Letters are the FDA's primary response to labeling violations. These do not pose a sufficient threat to companies to abide by labeling regulations or avoid misleading claims. Further, the FDA does not have the resources to issue a letter for all violations. The absence of a true penalty,

coupled with errors of enforcement, dilutes deterrence. n159 This lack of regulatory oversight diminishes any concern by food companies about compliance. Against this background, there has been a proliferation of legal and non-legal questionable claims on food products. n160 Litigation has arisen as a method to reign in questionable claims, but this has not been successful for most plaintiffs and certainly has not effectively altered the labeling environment. n161 A new regulatory regime is warranted to enhance the FDA's authority over labeling violations.

IV. Strengthening the FDA

There is not an effective regulatory mechanism in place for the FDA to promote compliance or deter non-compliance for misleading food labels. The FDA lacks the authority necessary to both deter noncompliance and address the non-compliance once it occurs. The regulatory environment for food labeling claims is essentially voluntary based. Thus, left to its own devices, the market has failed to support the utilization of factually accurate non-misleading food labels. A revised regime is necessary.

Pursuant to various theories of regulation, there is a consensus that industry members are more likely to comply with regulations with which they agree, and this includes regulations that support honest competition and protect the integrity of the marketplace. n162 Clear labeling requirements support both goals. The Lanham Act cases dedicated to food claims reveal a business interest in companies' competitors complying with fair labeling standards. Straightforward regulations would benefit competition and minimize the need for inefficient and expensive litigation.

Congress should concurrently increase the FDA's authority and resources to revise food labeling regulations to address misleading labels, and permit the agency to recover penalties for non-compliance.

A. Compliance Versus Deterrence Regulatory System

Two theoretical underpinnings exist to support a regulatory system of government: a cooperative-compliance based system and a deterrence based system. In practice, most enforcement agencies use a hybrid of both strategies and undertake both cooperative and coercive measures. n163

Legal and economic scholars debate the efficacy of a cooperative-compliance based system versus deterrence-based enforcement in other contexts. n164 Discourse in the environmental enforcement area provides a valuable lens to think about a proper regulatory system for food labeling claims. n165 The EPA and FDA are both "protective agencies" n166 that regulate activities to address modern conditions that serve as a barrier to population health.

Under a cooperative system of regulation, an agency seeks to work with the regulated industry to support compliance. n167 The agency's role is to foster conditions that induce compliance so that any sanctions are typically withdrawn if compliance is achieved. n168 This theory of enforcement tends to view industry members as "citizens," "influenced by civic and social motives," seeking to avoid tort liability, and maintain a good corporate image. n169 Agency officials are considered partners to the regulated industry members and they work together to ensure compliance. In the EPA context where this is the case, government officials engage in on-site inspections to confirm compliance with technical requirements, so partnerships are a natural and perhaps positive outcome of the cooperative system. n170 The combination of regulations and inspections reportedly create a "culture of compliance" in the environmental context. n171

The deterrence-based model, on the other hand, is concerned with detecting noncompliance and penalizing violators. This theory of enforcement tends to view industry members as "rational economic actors that act to maximize profits." n172 Therefore, penalties are utilized as a mechanism to punish rule-breakers and deter future violations. This theory of enforcement looks skeptically at partnerships formed out of the regulatory relationship based on concerns of agency capture and the potential for unequal treatment. n173 Penalties thus additionally send a message that everyone is treated uniformly. n174

In the food labeling context, stronger and clearer regulations would need to be enacted, as explored below. Thereafter, the FDA should enforce the regulations through a deterrence-based model, with the threat of civil penalties for noncompliance. In order to comply, food manufacturers need only dedicate an insignificant amount of time and resources to reviewing regulations to ensure compliance. n175 As opposed to the environmental context, where agency partnerships make sense, cooperation would not be a necessary element of addressing violations of the revised food labeling standards. n176 After the questionable package is introduced and the misleading label is in the stream of commerce, it is on store shelves and in home kitchens possibly for years. Post-marketplace cooperative enforcement to ensure a corrected label would not deter future noncompliance or correct the damaging label already present.

Pursuant to the plan delineated below, Congress should require the FDA to overhaul its regulations for permissible food claims and create a deterrence-based enforcement system.

B. Revise Food Labeling Requirements For All Claims

Congress should require the FDA to revise and update its regulations related to all health, nutrition, and structure/function claims. At a minimum, the lax requirements identified above should be corrected. This includes creating a pre-approval structure for structure/function claims, instituting disqualifying levels of trans fat and added sugar for manufacturers to be able to make health claims, extending this disqualifying list to disqualify nutrient content claims, and enabling the FDA to obtain substantiation documents for questionable claims. Further, the FDA should strengthen and enforce its requirements for product names and product fortification. It should define terms such as "natural" and address clear misbranding cases, such as the case of energy drinks labeled as dietary supplements. These remedies would certainly resolve some of the most pervasive problems in need of attention.

The FDA could enact the aforementioned regulatory amendments and stop there. However, resource limitations would remain and this would leave in place a reactionary regulatory system that would not enable the FDA to address noncompliance any better than it does now. In addition, innovative product types and new misleading labeling practices will arise that will require FDA responses not yet conceived. The regulatory system would remain labor and resource intensive and over time these remedies might turn out to be a temporary solution to much larger regulatory deficiencies in FDA authority. Thus, a regulatory overhaul is warranted. The goal of the overhaul will be to address the deficiencies identified but also to ultimately create a system of regulatory control over food labels that would not be possible without greater intervention.

Congress may look to the European Union (EU) for guidance. In 2006, the European Parliament and Council enacted Regulation 1924/2006, setting EU-wide conditions for the use of nutrition and health claims. n177 The goal of the measure was to ensure claims on food are "clear, accurate and based on evidence accepted by the whole scientific community," thereby eliminating claims that

"could mislead consumers." n178 The European Parliament sought to support "informed and meaningful choices" among consumers while fostering "fair competition" and protecting innovation among manufacturers. n179 In the EU, nutrition and health claims must now be authorized prior to use. n180 The European Commission compiled a register of approved and rejected claims to be updated regularly, n181, n182 which provides comprehensive guidance to manufacturers for the thousands of claims previously considered.

The European Commission is supposed to establish specific nutrient profiles with which "food or certain categories of food must comply ... in order to bear nutrition or health claims," n183 but these are outstanding to date. n184 The legislation provides that the nutrient profiles should account for "the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium." n185 Once enacted, this should assist in restricting claims on unhealthy food products.

The United States could likewise move towards a system of prior approval for all claims to minimize the existence of questionable and misleading claims and support fair competition. Through its notice and comment procedures, the agency would gain the perspectives of manufacturers, public health researchers, consumer advocates, and the public. When a manufacturer proffers a new claim, FDA approval will be required prior to the release of a claim. Part of the approval process would be the requirement that manufacturers submit substantiation documents in support of the newly proposed claim. A pre-approval process would require the agency to work cooperatively with stakeholders to ensure claims are truthful, non-misleading, and based on scientific evidence. The FDA would then establish a register of approved and rejected claims and house them in a publically available database. This process would be labor and resource intensive up front but would result in the agency having greater control over food labels in the long run. This will reduce the need to constantly police food labels and rectify inconsistencies in enforcement.

The guidelines for FDA approval of claims should include a requirement that all statements and claims have a scientific basis and not be misleading. The FDCA guides the FDA in determining whether a product meets the definition of misbranding due to misleading labeling or advertising by directing the FDA "take into account" the questionable statements, designs, and words, among other things, but also the extent to which the label "fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles." n186 The definition of misbranding due to misleading labeling thus requires a holistic view of the product and the range of representations made on the packaging. This underutilized requirement should be elevated in import and translate into a comprehensive requirement which restricts health and nutrition-related claims on otherwise unhealthy products.

The positive representation on the front of packaging has been found to increase consumers' perception of health and likelihood to purchase some of the least healthy products in a food category. n187 This is a clear indication that consumers are being misled by the claims. A method to address the misleading nature of claims on unhealthy food is to divide a product into its claim and its properties. For example, if a consumer chooses an orange flavored drink based on a Vitamin C nutrient content claim, but that is composed of high fructose corn syrup and water, and fortified with Vitamin C, the consumer might be getting a benefit from the fortification, but also a larger health detriment from drinking the remainder of the product. There is a strong argument that the health-related claim misrepresents the product as a whole and "fails to reveal" the negative health conse-

quences of consuming the product notwithstanding the Vitamin C fortification. Products that are unhealthy in total should no longer be permitted to bear claims touting a singular positive nutrient.

The United States should further follow the EU's lead and establish nutrient profiles which would permit or prohibit foods from being able to carry claims, n188 and extend this to health, nutrient content and structure/function claims. Consumers seeking a singular positive nutrient can consult the Nutrition Facts Panel and ingredient list. A method for the FDA to accomplish this would be to revise the disqualifying nutrient list and include disqualifies for trans fat and added sugar. This list should be applied to all claims. For example, orange juice would still be able to tout its vitamin C content but the fortified orange flavored drink would not. Studies are necessary to determine the best method to accomplish factually accurate, clear labels that do not mislead consumers about the health benefits of products. The FDA's fortification policy should be re-evaluated in this process to determine if fortification has health benefits for otherwise unhealthy highly processed products and permit or restrict such claims accordingly.

Revised labeling regulations should result in a more fair and efficient marketplace: one where consumers are not misled about a product's healthfulness and thus purchase products based on their true nutritional value.

C. The First Amendment

In addition to its lack of authority, the agency has been hesitant to restrict claims based on First Amendment considerations. n189 However, the government would be well within its authority to create a database of pre-approved claims and restrict manufacturers' ability to claim health benefits to foods meeting an overall nutritional profile.

The Supreme Court has expressed its preference for transparency in commercial transactions in order to support informed consumer decision-making. n190 Food labels are protected as commercial speech under the First Amendment. n191 The foundation of the commercial speech doctrine lies in the understanding that an "advertiser seeks to disseminate information about a specific product or service that he himself provides and presumably knows more about than anyone else" in order to increase profits. n192 Therefore, the Court has explained that the government may "require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers as are necessary to prevent its being deceptive." n193

The Supreme Court created an intermediate test in *Central Hudson Gas & Electric Corporation v. Public Service Commission* to determine if government restrictions on commercial speech are valid, n194 but such restrictions rarely pass the full test. However, the first prong of the test dictates that false, deceptive, and misleading speech is not protected by the First Amendment and may be restricted. n195 The labeling issues of concern here are false, deceptive, and misleading claims and practices. Under the commercial speech doctrine, the government may restrict such speech or require that it be presented in a non-deceptive manner. n196

Under the revised regulatory regime and consistent with the First Amendment, factually accurate claims that do not mislead consumers would be permitted. Conversely, health-related claims on otherwise unhealthy products have proven to be misleading in studies. In developing revised regulation, Congress should direct the FDA to convene the Institute of Medicine to conduct additional studies to fully develop research-based restrictions. Thereafter, claims not based on this scientific evidence, and claims on otherwise unhealthy products as determined by an objective scientific crite-

ria, would not be authorized. The revised approach would additionally address and restrict basic false practices such as conventional foods being mislabeled as dietary supplements and product identity names that misrepresent the contents of the product. Finally, the FDA could define confusing terms used on packaging, such as the descriptor 'natural' based on scientific data; this is within its regulatory authority to prevent deception and misleading representations and supports First Amendment goals.

Under the revised system, if a manufacturer seeks to proffer a new claim that has only the potential to mislead, the FDA could not restrict it but can require revised wording, the addition of a disclaimer, or both. n197 The FDA may also require factual disclosures on product labeling to ensure the representations on the front of the package do not misrepresent the contents as whole. n198 The Supreme Court has sustained the government's ability to require factual commercial disclosures for this purpose. n199 Consumer studies would be necessary to support this rulemaking and would inform the FDA which types of claims are informative and which claims are misleading.

D. Increased Resources Through Registration Fees

Given that financial resources would be required to carry out a regulatory overhaul, a registration fee structure should be implemented to fund increased agency activity. Congress has granted the FDA the authority to collect user fees in a variety of other contexts to allow the agency to "fulfill its mission of protecting the public health and accelerating innovation" in the industry assessed. n200 None are assessed for the specific purpose of enforcing food labeling regulations. The FDA explained that the ability to collect user fees in other areas under its domain have been pivotal to its ability to support safety, effectively review such products, and achieve timely and enhanced premarket review. n201 For example, in the area of prescription drugs, the FDA was "understaffed, unpredictable, and slow," so patients' access to new medicines in the United States "lagged behind other countries." n202 Congress enacted the Prescription Drug User Fee Act, providing the FDA with a stable, consistent source of funding through user fees, which "revolutionized the drug approval process." n203

In the context of food, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, food facilities are required to register with the FDA and re-register every two years under the FSMA, but under neither act are they required to pay a user fee upon registration. n204 Under the FSMA, fees are assessed for "non-compliance materially related to a food safety requirement." n205 Therefore, the fee provisions only apply to those facilities subject to reinspection, to cover reinspection costs, and, for those who do not comply with recall orders, to cover the costs of recall activity. n206 Under the FSMA, it is possible for a fee to be assessed in the context of misbranded food if the food label lacked the required disclosure related to food allergens and the food facility was thus subject to reinspection or failed to follow a recall order. n207 This singular source of fees based on one type of misbranding leaves all remaining mislabeling issues unfunded. n208

Historically, Congress has augmented the FDA’s authority accompanied with user fees to carry out its increased responsibilities. In 2009, Congress expanded the agency's authority over tobacco by passing the Family Smoking Prevention and Tobacco Control Act and funded this mandate through user fees assessed on manufacturers and importers of tobacco products. n209 The Tobacco Control Act prohibits misbranding, which includes false or misleading labeling and advertising for tobacco products, and provides the FDA with the authority to enforce violations of the Act. n210

The fees appropriated under the Act fund the costs associated with FDA's enforcement activity. n211

The FDA will need increased resources to undertake new regulatory activities outlined in this paper. Owners, operators, and agents of a facility engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States are required to register with the FDA. n212 Upon registration, each registrant must list the applicable food product categories for which they are responsible. n213 Congress should enact a registration fee requirement similar to that mandated under the Tobacco Control Act n214 for manufacturers of processed food that is distributed in interstate commerce. The goal would be to capture large manufacturers who produce the majority of packaged food consumed in the United States, and not burden small local producers. Further, facilities exempt from registration under the Bioterrorism Act include those that should not be assessed a registration fee: farms, retail and nonprofit food establishments, restaurants, fishing vessels and USDA regulated facilities that produce meat, poultry, and eggs. n215 The fees appropriated would be available for the costs associated with FDA regulation of food products. n216 This will support the FDA in fulfilling "its mission of protecting the public health" n217 in the food labeling context by creating a clear and factually accurate information environment.

E. Civil Monetary Penalties

Congress should grant the FDA the authority to issue civil monetary penalties for non-compliance of the revised regulations restricting misleading claims on food packaging. Congress and the Supreme Court have discussed the concept behind granting federal agencies the authority to issue civil monetary fines. n218 Specifically, when Congress enacted the Federal Civil Penalties Inflation Adjustment Act of 1990, n219 it explained that "the power of Federal agencies to impose civil monetary penalties for violations of Federal law and regulations plays an important role in deterring violations and furthering the policy goals embodied in such laws and regulations." n220 The very purpose of the Act is to further the dual goals of "maintain[ing] the deterrent effect of civil monetary penalties and promot[ing] compliance with the law." n221 Likewise, the Supreme Court has "recognized . . . that 'all civil penalties have some deterrent effect.'" n222 In the environmental context, the Court explained that Congress' grant of civil penalties promoted immediate compliance and deterred future violations. n223

Penalties should also minimize enforcement errors because the threat of detection resulting in a penalty alone has been found to garner compliance. n224 The same cannot be said of Warning Letters. n225 Penalties additionally provide an expressive function by reminding companies to verify compliance and reassuring compilers that non-compliance is penalized. n226

An optimal penalty covers the cost of enforcement and serves as a proper deterrent notwithstanding the benefits of noncompliance. n227 Economic and legal scholars posit that when an enforcement agency has limited resources, the amount of the penalty should be increased to minimize enforcement costs without sacrificing deterrence. n228 This would be a necessary consideration if Congress does not increase funding for the FDA to address labeling through the user fee provisions discussed above. Regardless, Congress should permit the recovery of civil fines for violations of the misbranding regulations.

F. Summary

Congress should revise the FDA's authority over food labeling claims to require preauthorization for claims. The FDA would work with stakeholders to create the claims database and work with food companies on pre-market compliance. Pursuant to this process, the FDA must have access to substantiation documents when a manufacturer seeks to introduce a novel claim. The goal of the proposed regulations would be to clarify permissible claims and restrict impermissible claims. This will create a transparent regulatory regime for both manufacturers and consumers. Subsequent to this, a deterrence-based system is warranted and Congress should provide the FDA with the authority to issue civil monetary penalties for noncompliance of the revised food labeling standards. This will clarify the FDA's expectations of companies so it is clear when a penalty will be issued. Finally. Congress should provide the FDA the resources to carry out the new directives through registration fees paid by the regulated industry.

V. Conclusion

The FDA is severely underfunded and lacks significant authority necessary to address questionable food labeling practices utilized today. Congress should overhaul the regulatory requirements for manufacturers to make health- and nutrition-related claims by creating a pre-approval process for all claims and house them in a database accessible to the population at large. Claims that are not based on scientific evidence or that misrepresent the healthfulness of a product as a whole should no longer be permitted on food products. Violations of the revised labeling requirements should garner civil monetary penalties to deter violations. The goal of this regulatory overhaul is to eliminate questionable claims from product packaging to support a fair and efficient marketplace. Congress should fund the FDA's revised authority through registration fees required of all food manufacturers and importers subject to the agency's authority. Through this regulatory overhaul, the FDA can achieve its mission in the area of food labeling--something now left to voluntary compliance and inefficient and costly litigation.

Endnotes

1 Loren Cordain et al., *Origins and Evolution of the Western Diet: Health Implications for the 21st Century*, 81 AM. J. CLINICAL NUTRITION 341, 341 (2005).

2 CYNTHIA L. OGDEN ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, PREVALENCE OF OBESITY IN THE UNITED STATES, 2009-2010, 1-2 (2012); Cynthia L. Ogden et al., *Prevalence of Obesity and Trends in Body Mass Index Among U.S. Children and Adolescents*, 1999-2010, 307 J. AM. MED. ASS'N 483, 485 (2012).

3 Abay Asfaw, *Does Consumption of Processed Foods Explain Disparities in the Body Weight of Individuals? The Case of Guatemala*, 20 HEALTH ECON. 184, 184 (2011); Dariush Mozaffarian et al., *Changes in Diet and Lifestyle and Long-Term Weight Gain in Women and Men*, 364 NEW ENG. J. MED. 2392, 2392(2011).

4 David M. Cutler et al., *Why Have Americans Become More Obese?*, 17 J. ECON. PERSP. 93, 93-95 (2003); *see also* Bo MacInnis & Gordon Rausser, *Does food Processing Contribute to Childhood Obesity Disparities?*, 87 AM. J. AGRIC. ECON., 1154, 1154 (2005).

5 FOOD & NUTRITION SERV., USDA, IMPLICATIONS OF RESTRICTING THE USF. OF FOOD STAMP BENEFITS SUMMARY 3 (2007), *available at* www.fns.usda.gov/ora/menu/Published/snap/FILES/ProgramOperations/FSPFoodRestrictions.pdf.

6 KELLY BROWNELL, FOOD FIGHT: THE INSIDE STORY OF THE FOOD INDUSTRY, AMERICA'S OBESITY CRISIS, AND WHAT WE CAN DO ABOUT IT 27 (2004); *cf.* Shu Wen Ng et al., *Use of Caloric and Noncaioric Sweeteners in U.S. Consumer Packaged Foods, 2005-2009*, 112 J. ACAD. NUTRITION & DIET 1828, 1828, 1833 (2012) (noting that because caloric sweeteners represented seventy-seven percent of all calories purchased from consumer packaged goods from 2005-2009, it is critical to focus legislative and research efforts on this issue).

7 *See* Marion Nestle & David S. Ludwig, *Front-of-Package Food Labels: Public Health or Propaganda?*, 303 J. AM. MED. ASS'N 771, 771-72 (2010).

8 *See* Michelle Meadows, *Promoting Safe and Effective Drugs for 10 Years*, FDA CONSUMER MAG. (Jan.-Feb. 2006), http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsforlOOYears/default.htm.

9 *Compare* LISA SHAMES ET AL., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS 13, 18 (2008), *with A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority*, FED. TRADE COMM'N (revised July 2008), http://www.ftc.gov/ogc/brfovrvw.shtm.

10 SHAMES ET AL., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING, at 5-7, 61-64.

11 15 U.S.C. § 1125(a)(1) (2012).

12 For example, one of the more notable cases of a regulatory response to a questionable claim occurred when the FTC reprimanded Kellogg's for its immunity claims in June 2010. During that month, the company's stock prices did not significantly dip and Kellogg's remains a Fortune 500 company. *See Fortune 500: Kellogg*, CNN MONEY, http://money.cnn.com/magazines/fortune/fortune500/2012/snapshots/242.html (last visited Oct, 23, 2013); *Kellogg Company (K): Historical Prices*, YAHOO! FIN., http://finance.yahoo.com/q/hp?s=K&a=04&b=30&c=2010&d=06&e=1&f=2010&g=m (last visited Oct. 23, 2013). In 2012, Kellogg's ranked number four out of fourteen food companies on the Fortune 500 List. *Fortune 500 Industries: Food Consumer Products*, CNN MONEY. http://money.cnn.com/magazines/fortune/fortune500/2012/industries/198/index.html (last visited Oct. 14, 2013).

13 21 U.S.C. § 331(a) (2012).

14 *Id.* § 343.

15 *Id.*

16 For example, food products are permitted to make claims about "whole grain" content, whether or not the product is high in sugar, calories, or contains trans fat. 21 C.F.R. § 101.13 (2013); *id.* § 101.54. Given the current emphasis on consuming a diet rich in whole grains, many products with whole grain claims might be attractive to consumers despite the fact that they contain other ingredients rendering them not healthful. Rebecca S. Mozaffarian et al., *Identifying Whole Grain Foods: A Comparison of Different Approaches for Selecting More Healthful Whole Grain Products*, 15 PUB. HEALTH NUTRITION 2 (2013).

17 Steve Martinez, USDA, *Introduction of New Food Products With Voluntary Health- and Nutrition-related Claims, 1989-2010*, 108 ECON. INFO. BULL, i, iii (2013).

18 Jennifer L. Harris et al., *Nutrition-Related Claims on Children 's Cereals: What Do They Mean to Parents and Do They Influence Willingness to Buy?*, 14 PUB. HEALTH NUTRITION 2207, 2207 (2011).

19 *See* Pierre Chandon & Brian Wansink, *The Biasing Health Halos of Fast-Food Restaurant Health Claims: Lower Calorie Estimates and Higher Side-Dish Consumption Intentions*, 34 J. CONSUMER RES. 301, 302 (2007); Adam Drewnowski et al., *Testing Consumer Perception of Nutrient Content Claims Using Conjoint Analysis*, 13 PUB. HEALTH NUTRITION 688, 692 (2010).

20 *See* Chandon & Wansink, *supra* note 19, at 301-02, 311.

21 *Id.* at 311.

22 Harris, *supra* note 18, at 2207.

23 Press Release, Acad, of Nutrition and Dietetics. How Important Is It to You? Diet and Physical Activity Differ for Men and Women, Says American Dietetic Association Survey (Sept. 27, 2011), *available at* http://www.eatright.org/nutritiontrends/.

24 MARTINEZ, *supra* note 17, at 27.

25 *See* Open Letter from Margaret A. Hamburg, Comm'r of Food & Drugs, FDA, to Industry (Mar. 3, 2010), *available at* http://www.fda.gov/Food/lngredientsPackagingLabeling/LabelingNutrition/ucm202733.htm ("Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States."). Whether or not one views diet and obesity as a personal responsibility issue, truthful factual information is a prerequisite to making an informed choice. Consumers' decisions to purchase the product should be based on the actual properties of the food. Industry associations have publicly stated that nutrition education and information are the best solutions to obesity. *See* Press Release, Am. Beverage Ass'n, Beverage Industry Addresses Sugar-Sweetened Beverages and Obesity Articles in the New England Journal of Medicine (Sept. 21, 2012), *available at* http://www.ameribev.org/news-media/news-releases-statements/more/285/ ("Taxes, bans and other forms of government regulation are not the solution to childhood obesity--nutrition education, information and support for physical education are."); *The Industry's Commitment to Keeping Kids Healthy*, GROCERY MFRS. ASS'N, http://www.gmaonline.org/issues-policy/health-nutrition/responsible-public-policy-solutions/the-industrys-commitment-to-keeping-kids-healthy/ (last visited Oct. 24, 2013) ("The Healthy Weight Commitment Foundation helps kids and adults achieve a healthy weight through energy balance and focuses on three critical areas--the marketplace,

the workplace and schools. The key component is a public education campaign aimed at 6-11 year olds and their parents.").

26 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-102, FOOD LABELING: FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS 13 (2011).

27 *Id.*

28 21 C.F.R. § 101.13(b) (2013).

29 *Id.* § 101.13(j). Nutrient content claims characterize the level of a nutrient of the type required to be disclosed in nutrition labeling, such as "low sodium." *Id.* § 101.13.

30 *Id.* § 101.14.

31 *Id.* § 101.79.

32 *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims--Final*, FOOD & DRUG ADMIN. (Jan. 2009), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm073332.htm.

33 *Id.; Summary of Qualified Health Claims Subject to Enforcement Discretion*, FOOD & DRUG ADMIN., http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073992.htm (last updated Mar. 13, 2013) ("Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.").

34 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-102, FOOD LABELING: FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS 11 (2011) (reporting that the FDA has spent at least $ 12.8 million dollars implementing just health claims and qualified health claims between 2000 and 2010).

35 *Claims That Can Be Made for Conventional Foods and Dietary Supplements*, FOOD & DRUG ADMIN. (Sept. 2003), http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm111447.htm.

36 *Id.*

37 *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-102, FOOD LABELING, at 40-41; *see also Structure/Function Claims*, FOOD & DRUG ADMIN., http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm2006881.htm (last updated Aug. 21, 2013).

38 U.S. GOV'T ACCOUNTABILITY OFFICE. GAO-11-102, FOOD LABELING, at 13 (suggesting that the FDA should provide clear guidance to companies for structure function claims so they are not false or misleading and that the FDA should provide food inspectors with clear instructions to identify false and misleading claims). This is a valid suggestion; however, without the authority to enforce the guidance or obtain substantiation documents, it may not go all the way to change industry practices. *See also* discussion *infra* Part III.B.

39 21 C.F.R. § 101.14(a)(4) (2013).

40 *See id.*

41 *Id.* § 101.13(h)(1). Disclaimers are also required if the statement implicitly characterizes the level of the nutrient in the food but is not consistent with the allowance for the claim, such as "only 200 mg of sodium per serving, not a low sodium food." *Id.* § 101.13(i).

42 *See id.* § 101.13(h).

43 Harris et al., *supra* note 18, at 2207-08.

44 JENNIFER L. HARRIS ET AL., YALE UNIV., RUDD CTR. FOR FOOD POL'Y AND OBESITY, EVALUATING THE NUTRITION QUALITY AND MARKETING OF CHILDREN'S CEREALS 76-77 (2009), *available at* http://www.cerealfacts.org/media/Cereal_FACTS_Report_2009.pdf.

45 Mozaffarian et al., *supra* note 16, at 7-8.

46 The candy bar Baby Ruth states that it has "4 grams protein per bar" (which is accurate due to peanuts as an ingredient), but, because it is a candy bar, it contains thirty-three grams of added sugar. *Baby Ruth Touts Protein Content*, Archived in *Worst Food Marketing Practices*, YALE RIJDD CENTER FOR FOOD POL'Y AND OBESITY (May 2012), http://www.yaleruddcenter.org/bestandworstfoodmarketingarchive.aspx?t=w. Goobers also has packaging stating that it contains 5 grams of protein, which, as with Baby Ruth, comes from its peanut content. *See Nestle Goobers Candy*, WEGMANS, http://www.wegmans.com/webapp/wcs/stores/servlet/ProductDisplay?productId=391582&storeId=10052&langId= (last visited Oct. 17, 2013).

47 Chandon & Wansink, *supra* note 19, at 301-03, 311.

48 Pearson v. Shalala, 164 F.3d 650, 653 (D.C. Cir. 1999).

49 *Id.* at 654.

50 *Id.* at 661.

51 *Id.* at 658-59.

52 *Guidance for Industry*, *supra* note 32; *Summary of Qualified Health Claims*, *supra* note 33 ("Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.").

53 *See, e.g.*, Notice Regarding Implementation of Pearson Court Decision, 65 Fed. Reg. 59,855, 59,856 (Oct. 6, 2000) (stating that the FDA will use its enforcement discretion to allow certain health claims in appropriate circumstances).

54 Rubin v. Coors Brewing Co., 514 U.S. 476, 481 (1995).

55 *In re R.M.J.*, 455 U.S. 191,203(1982).

56 *Id.*

57 *Id.*

58 *Id.*

59 LISA SHAMES ET AL., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS 5 (2008); *see also* Harris et al., supra note 18, at 2209.

60 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-102, FOOD LABELING: FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS 13 (2011).

61 *See. e.g.*, Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2672 (2011).

62 *See* discussion *infra* Part II.C.

63 21 C.F.R. § 101.3(a) (2013).

64 *Id.* § 101.3(b).

65 *Guidance for Industry: A Food Labeling Guide (4. Name of Food)*, FOOD & DRUG ADMIN. (Oct. 2009), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064872.htm.

66 21 C.F.R. § 102.5(a).

67 *See, e.g., Blueberry Cereal*, KELLOG'S FROSTED MINI WHEATS, http://www.frostedminiwheats.com/Products/Blueberry-muffin (last visited Sept. 17, 2013) ("Ingredients: Whole grain wheat, sugar, contains 2% or less of milled corn, brown rice syrup, corn syrup, natural and artificial flavor, modified corn starch, gelatin, soybean oil, glycerin, sorbitol, blue 2 lake, red 40 lake, red 40, BHT for freshness.").

68 21 C.F.R. § 102.33(c).

69 Pom Wonderful L.L.C. v. Coca-Cola Co., 679 F.3d 1170, 1173 (9th Cir. 2012) (showing the label of Coca-Cola's Pomegranate Blueberry Juice which includes both the description "Flavored Blend of 5 Juices" in relatively small type font and a picture of an equally large apple and pomegranate surrounded by berries).

70 *Id.* at 1174.

71 *Id.* at 1177 (citing 21 C.F.R. § 102.33(c), (d)).

72 Pom Wonderful L.L.C. v. Coca Cola Co., 727 F. Supp. 2d 849, 857 n.8 (CD. Cal. 2010), *aff'd in pan and vacated in part*, 679 F.3d 1170 (9th Cir. 2012) ("According to Pom, '36% of the test group in the Field Survey indicated that they believed the Juice mainly contains pomegranate and blueberry juice, and not other types of fruit juice,' . . . '32% of the test group in the Field Survey indicated that they believed the Juice mainly contains pomegranate and blueberry juice, and not other types of fruit juice, *because of the words* 'pomegranate blueberry' on the label.'").

73 *Pom Wonderful L.L.C.*, 679 F.3d at 1178 (stating that by holding that the Lanham Act claim is barred, the court does "not hold that Coca-Cola's label is non-deceptive," instead putting the onus on the FDA to act if "the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers"); *see also Pom Wonderful L.L.C.* 727 F. Supp. 2d at 872 (noting that Pom's only recourse was to "lobby Congress or petition FDA to change its rules").

74 21 C.F.R. § 104.20(a).

75 *Id.* §§ 101.54(e)(ii), 101.65(d)(2)(iv).

76 *See* Caroline Scott-Thomas, *Fortification Drives Consumer Definition of "Healthy"*, FOOD NAVIGATOR-USA.COM (July 25, 2011). http://www.foodnavigator-usa.com/content/view/print/388462.

77 *See id.* (noting that in a nationally representative poll, the four ingredients that grocery shoppers said they looked for most in a product were fiber, whole grain, protein, and omega-3).

78 21 C.F.R. § 104.20(a) ("The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages."). This policy is weakly stated and includes "snack foods" in the list of products that should not be fortified but does not define the term. *See* § 104.20. Regardless, the FDA does not seem to enforce this regulation outside the two products listed, carbonated beverages and candy, because snack products are regularly fortified and bear nutrient content claims. *See, e.g.*, POPTARTS,

http://www.poptarts.com/flavors/chocoIate/hot-fudge-sundae (touting Pop-Tarts as a good source of 7 vitamins and minerals).

79 *See* Warning Letter from Roberta F. Wagner, Dir., Office of Compliance, Ctr. For Food Safety & Applied Nutrition. FDA, to Muhtar Kent, Pres. and Chief Exec. Officer, The Coca-Cola Co. (Dec. 10. 2008), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucml048050.htm.

80 *See* Steve Tanner, *Review: Cherry 7Up Antioxidant*, BEVREVIEW (May 4, 2009), http://www.bevreview.com/2009/05/04/cherry-7up-antioxidant/.

81 *See* Warning Letter, *supra* note 79.

82 An antioxidant claim can be a permissible nutrient content claim when all the conditions of use are met; this includes the conditions for the nutrient claim and those imposed by the FDA's Fortification Policy. *See* 21 C.F.R. §§ 101.54(g), 104.20. In regards to these two regulations, the 7Up antioxidant claim violated the latter. *See id.* § 104.20(a).

83 Mason v. Coca-Cola Co., 774 F. Supp. 2d 699, 705 n.4 (D.N.J. 2011) ("At its core, the complaint is an attempt to capitalize on an apparent and somewhat arcane violation of FDA food labeling regulations. But not every regulatory violation amounts to an act of consumer fraud ... The complaint does not allege that consumers bought the product because they knew of and attributed something meaningful to the regulatory term 'Plus' and therefore relied on it. Rather, they allege merely that they thought they were buying a 'healthy' product that happened to apparently run afoul of FDA regulations.").

84 CSPI sued Dr. Pepper Snapple Group, with Dr. Pepper Snapple Group recently agreeing to stop fortifying with vitamins some of its 7UP drinks as well as to stop claiming that its fortified 7UP drinks contain antioxidants. *See 7UP To Drop "Antioxidant" Marketing*, CTR. FOR SCIENCE IN THE PUB. INTEREST (July 22, 2013), http://www.cspinet.org/new/201307221.html.

85 *Food Trends: The Most Successful Packaged Food Brands of 2010*, FOOD PROCESSING (Mar. 29, 2011), http://www.foodprocessing.com/industrynews/2011/020.html; *see also* A. Elizabeth Sloan, *Top 10 Food Trends*, INST. OF FOOD TECHNOLOGISTS (Apr. 2011), http://www.ift.org/food-technology/past-issues/2011/april/features/food-trends.aspx?page=viewall (food trend number five: "Get Real").

86 *See* Kacey Kulliney, *The Power of Organic: Turning Snacks into Health Foods?*. FOODNAVIGATORUSA (Oct. 18, 2012), http://www.foodnavigator-usa.com/Market/The-power-of-organic-Turning-snacks-into-health-foods; Caroline Scott-Thomas, *Study Reveals the 'Health Halo' of Organic Foods*, BAKERYANDSNACKS.COM (Apr. 12, 2011), http://www.bakeryandsnacks.com/R-D/Study-reveals-the-health-halo-of-organic-foods; Caroline Scott-Thomas, *Too Many Eco-Labels Could Hinder Uptake, Says Organic Monitor*. FOODNAVIGATOR-USA (Jan. 10, 2013), http://www.foodnavigator-usa.com/Market/Too-many-eco-labeIs-could-hinder-uptake-says-Organic-Monitor?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright.

87 *See* Ashby Jones, *Is Your Dinner 'All Natural'?*, WALL ST. J. (Sept. 20, 2011), http://onIine.wsj.com/article/SB10001424053111903374004576580671156407598.html.

88 *See, e.g.*, Holk v. Snapple Bev. Corp., No. 07-3018 (MLC), 2010 U.S. Dist. LEXIS 81596, at *8 (D.N.J. Aug. 10, 2010). Recognizing that the FDA had not officially defined the term "natural." the court stayed the case for six months and deferred to the FDA to determine if the presence of HFCS disqualifies a product from calling itself "natural." *Id.* Nonetheless, the FDA declined to address the issue. *See* Holk v. Snapple Bev. Corp., No. 07-3018 (MLC), 2010 U.S. Dist. LEXIS 110024, at *1 (D.N.J. Oct. 15, 2010). The plaintiff later became a putative class member of a similar action alleging Snapple's "natural" claim violated New York consumer protection laws. *See* Weiner v. Snapple Beverage Corporation, No. 07 Civ. 8742 (DLC), 2011 U.S. Dist. LEXIS 6094 (S.D.N.Y. Jan. 21, 2011).

89 *See* Ries v. Arizona Beverages, No. 10-01139 RS, 2013 U.S. Dist. LEXIS 46013, at *5, *15 (N.D. Cal. Mar. 28. 2013) (decertifying the class previously granted in Ries v. Arizona Beverages, No. 10-01139 RS, 2012 U.S. Dist. LEXIS 169853 (N.D.C.A Nov. 27, 2012)).

90 Among other groups, the Sugar Association petitioned the FDA for clarification of the term "natural." *See* Letter from Andrew C. Briscoe III, Pres. & CEO, Sugar Association, to Docket Mgmt. Branch, Food & Drug Admin. (Feb. 28, 2006), *available at* http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-let0001-vol2.pdf. Significantly, the Corn Refiners Association, producers of high fructose corn syrup, submitted comments opposing such a clarification, stating that the FDA should not "waste scarce agency resources" to define the term but rather should let the marketplace resolve the issue. *See* Letter from Audrae Erikson, Pres., Corn Refiners Association, to Dockets Mgmt. Branch, Food & Drug Admin. (Nov. 14, 2006), *available at* http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-c000004-voll.pdf; *see also* Jones, *supra* note 87.

91 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

92 *Id.; see* Oliver Neiburg, *Frito Lay Hit with Lawsuit on All-Natural Claims*, FOODNAVIGATORUSA (Dec. 20, 2011), http://www.foodnavigator-usa.com/Regulation/Frito-Lay-hit-with-lawsuit-on-all-natural-claims (FDA repeating that it had no plans to define the term "all-natural" due to a lack of agency resources).

93 For example, alcoholic whipped cream. Sarah Schwartz, *Groceries Gel Odd: 10 Weird New Food Products*, DELISH, http://www.delish.com/food-fun/new-food-products#slide-1 (last visited Oct. 24, 2013). In addition to energy drinks, other drinks touting functional benefits are emerging in the marketplace, including drinks that promise you bliss, increased sex drive, and better sleep. *See* NEURO, http://drinkneuro.com/ (last visited Oct. 23, 2013).

94 Hansen Bev. Co. v. Innovation Ventures, LLC, No. 08-CV-1166 IEG (POR), 2008 U.S. Dist. LEXIS 76243, at *8 (S.D. Cal. Sept. 28, 2008). According to the expert representing an energy shot company, the ingredients contained in the drink 5-Hour Energy give users a "perception of 'energy'" that is comparable to illegal drugs, such as methamphetamines, because they similarly "give users the perception of increased energy by suppressing the brain's receipt of fatigue signals."). Id. at * 11 n.3.

95 *See* Jennifer L. Pomeranz et al., *Energy Drinks: An Emerging Public Health Hazard for Youth*, 34 J. PUB. HEALTH POL'Y 254, 254-71 (2013).

96 *See Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages. Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods*, FOOD & DRUG ADMIN. (Dec. 2009), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm192702.htm (explaining that even if a liquid product characterizes itself as a dietary supplement, it may be a beverage for regulatory purposes and can be distinguished based on factors such as packaging, volume, advertising, name, and simi-

larity to other recognized beverages (e.g., soda and juice)). A dietary supplement, on the other hand, is defined as "a product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet." *Q&A On Dietary Suppelements*, FOOD & DRUG ADMIN., http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ (last updated Aug. 28, 2013).

97 *See Draft Guidance for Industry*, *supra* note 96.

98 The FDA has stated that it will issue finalized non-binding guidance. Letter from Jeanne Ireland. Assistant Comm'r for Legislation, Dep't of Health & Human Servs., to Richard J. Durbin, Senator, U.S. Senate (Aug. 10, 2012), *available at* http://www.durbin.senate.gov/public/index.cfm/files/serve?File_id=17eadaal-85e7-4ceb-a827-be244fbddfa5.

99 Hansen Bev. Co. v. Innovation Ventures, LLC, No. 08-CV-1166-IEG (POR), 2009 U.S. Dist. LEXIS 127605 at *29 (S.D. Cal. Dec. 22, 2009).

100 The FDA sent a Warning Letter to another energy drink manufacturer, Rockstar, warning the company that its Roasted Coffee & Energy varieties violated the FDCA, were not dietary supplements, and the addition of Ginkgo to the product rendered it adulterated within the meaning of the Act. See Warning Letter No. 20120NOL-22 from Patricia K. Schafer, Dist. Dir., New Orleans Dist., Food & Drug Admin., to Russell Weiner, CEO, Rockstar, Inc. (May 23, 2012), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm309080.htm.

101 The FDA has not sent a similar letter to Monster regarding its Java energy drink line although it existed simultaneously and suffered from the same problems as Rockstar's coffee variety: they were labeled as dietary supplements despite being coffee-like drinks (containing coffee extract) and containing the unapproved food additives taurine and panax ginseng. Since at least June 2007, Monster has had a Monster Java line. *See Java Monster*, BEVNET, http://www.bevnet.com/reviews/Java_Monster (last visited Oct. 27, 2013). The CEO announced on February 13, 2013 that the company would begin labeling its beverages correctly as beverages and include a nutrition facts panel. See Karen Bleier, *Monster Beverage changes label to qualify as "drink"*, CBS MONEY WATCH (Feb. 13, 2013), http://www.cbsnews.com/8301-505123_162-57569295/monster-beverage-changes-label-to-qualify-as-drink/. However, this will not fix the problems with unapproved additives in the drink.

102 *See* Stephanie Strom, *Drink Ingredient Gets a Look*, N.Y. TIMES, Dec. 12, 2012, http://www.nytimes.com/2012/12/l3/business/another-look-at-a-drink-ingredient-brominated-vegetable-oil.html?pagewanted=all&_r=0 ("A company can create a new additive, publish safety data about it on its Web site and pay a law firm or consulting firm to vet it to establish it as 'generally recognized as safe'--without ever notifying the F.D.A., Mr. Neltner said.").

103 *See* Jennifer L. Harris et al., *supra* note 18 at 2208.

104 *See* Sarah L. Brew et al., *Food Labeling Remains Ripe for Consumer Fraud Class Actions*, HB LITIG. CONFERENCES, http://litigationconferences.com/?p=25005 (last visited Sept. 27, 2013).

105 *See What We Do*, FOOD & DRUG ADMIN. (Sept. 19, 2013), http://www.fda.gov/AboutFDA/WhatWeDo/default.htm.

106 *See* Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER (Food & Drug Admin., Washington, D.C.), June 1981, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

107 *Enforcement Policy Statement on Food Advertising*, FED. TRADE COMM'N (May 1994), http://www.ftc.gOv/bcp/policystmt/ad-food.shtm#5.

108 *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535. (104 Stat. 2353) (codified in part at 21 U.S.C. § 343 (2012)).

109 *See* 15 U.S.C. § 45(m)(2012).

110 *See id.* §§ 52,54.

111 *See* 21 U.S.C. § 333(g) (2012).

112 *See id.* § 333(d).

113 *Id.* § 321(n) ("If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.").

114 *Id.* § 333(f)(2)(A).

115 *Id.* § 351(a) (adulterated pursuant to § 342 or misbranded under § 343(w)).

116 *See id.* § 342.

117 *See id.*

118 DANIEL R. LEVISON, OFFICE OF INSPECTOR GEN., FOOD & DRUG ADMIN., INSPECTIONS OF DOMESTIC FOOD FACILITIES 4 (Apr. 2010).

119 FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, PROCEDURES FOR CLEARING FDA WARNING LETTERS AND UNTITLED LETTERS, 5 (July 2012), http://www.fda.gov/downloads/ICECI/ComplianceManuals/ReguIatoryProceduresManual/UCM176965.pdf.

120 *Inspections, Compliance, Enforcement, and Criminal Investigations, Regulatory Procedures Manual*, FOOD & DRUG ADMIN. (Sept. 13, 2011), http://www.fda.gov/ICECI/ComplianceManuals/ReguIatoryProceduresManual/ucml76733.htm.

121 21 U.S.C. § 334(a)(1).

122 *See id.* § 335. The FDA must issue a Warning Letter to the company before reporting a violation to the DOJ for criminal proceedings. *Id.*

123 *See* FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, CHAPTER 6: JUDICIAL ACTIONS 47-50 (2011), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf

124 21 U.S.C. § 336.

125 *But see* United States v. Randazzo, 80 F.3d 623, 626-27 (1st Cir. 1996).

126 *See Inspections, Compliance, Enforcement, and Criminal Investigations: Press Releases*, FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/CriminalInvestigations/ucm123086.htm (last updated Aug. 15, 2013).

127 FOOD & DRUG ADMIN., PROCEDURES FOR CLEARING FDA WARNING LETTERS AND UNTITLED LETTERS, REGULATORY PROCEDURES MANUAL Exhibit 4-1, at § 4.1 (2012), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf ("Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.").

128 *Id.*

129 If Warning Letter from Roberta F. Wagner, Dir., Office of Compliance, Ctr. for Food Safety & Applied Nutrition, to Brad Alford, Chairman and CEO, Nestle U.S.A. (Dec. 4, 2009) (failing to mention Juicy Juice's "brain development" claim despite the fact that this claim is likely an unsupported structure function claim), *available at* http://www.fda.gov/ICECl/EnforcementActions/WarningLetters/2009/ucm194122.htm.

130 *See 7Up Maker Sued Over Antioxidant Claims*, CBS NEWS (Nov. 8, 2012, 3:44 PM), http://www.cbsnews.com/8301-204_I62-57547263/7up-maker-sued-over-antioxidant-claims/. This is another example of fortification of a soda.

131 A. Mitchell Polinsky & Steven Shavell, *The Economic Theory of Public Enforcement of Law*, 38 J. ECON. LITERATURE 45, 60-61 (2000).

132 *Inspections, Compliance, Enforcement, and Criminal Investigations: About Warning and Close-Out Letters*, FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm278624.htm (last updated Dec. 8, 2011).

133 *Id.*

134 The FDA has closed out 779 Warning Letters as of September 28, 2013. *See List of Warning Letters that have Close-Out Letters*, FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?company=&_1_issueDt=&_2_issueDt=&office=&subject=&hasResponseLetter=Both&hasCloseoutLetter=Yes&recsPerPageDef=500&Search=Search&errMsg= (last visited Sept. 28, 2013).

135 The FDA has received 92 response letters as of September 28, 2013. *See List of Warning Letters with Response Letters Posted*, FOOD & DRUG ADMIN, http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?company=&_l_issueDt=&_2_issueDt=&office=&subject=&hasResponseLetter=Yes&hasCloseoutLetter=Both&recsPerPageDef=500&Search=Search&errMsg= (last visited Sept. 28, 2013).

136 *See* OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., FDA INSPECTIONS OF DOMESTIC FOOD FACILITIES iii (2010) (recommending that the FDA "[s]eek statutory authority to allow FDA access to facilities' records during the inspection process"), *available at* https://oig.hhs.gov/oei/reports/oei-02-08-00080.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 34.

137 *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 25.

138 *See id.* at 26.

139 Bruce Horovitz. *Critics Blast Kellogg's Claim that Cereals Can Boost Immunity*, USA TODAY (Nov. 6, 2009), http://www.usatoday.com/money/industries/food/2009-11-02-cereal-immunity-claim_N.htm. This was during the time period when "swine flu" was making headlines.

140 Press Release, Fed. Trade Comm'n, FTC Investigation of Ad Claims that Rice Krispies Benefits Children's Immunity Leads to Stronger Order Against Kellogg (June 3, 2010), *available at*, http://www.ftc.gov/opa/2010/06/kellogg.shtm (ordering Kellogg's to refrain from making misleading health benefit claims not supported by scientific evidence). Chairman Leibowitz and Commissioner Brill issued a separate opinion expressly admonishing Kellogg's for its actions. *See* Concurring Statement of Commissioner Julie Brill and Chairman Jon Leibowitz, *In the Matter of Kellogg Company*, FTC Docket No. C-4262 (June 3, 2010), *available at* http://www.ftc.gov/os/caselist/0823145/100602kelloggstatement.pdf. The FTC did not issue civil fines. Besides the threat of a fine for breaking the settlement, this settlement essentially just requires Kellogg's to abide by the law, which says that manufacturers cannot make claims not backed by scientific evidence or that are misleading. *See* Susan Carey, *Snap Crackle Slap: FTC Objects to Kellogg's Rice Krispies Health Claim*, WALL ST. J., June 4, 2010, http://online.wsj.com/article/SB10001424052748703340904575284701223216466.html.

141 Elaine Watson, *Improper Nutrient Content Claims Cited in New Wave of Class Action Suits*, FOOD NAVIGATOR-USA (Apr. 19, 2012), http://www.foodnavigator-usa.com/Regulation/Improper-nutrient-content-claims-cited-in-new-

wave-of-class-action-suits (reporting that according to a "leading" attorney practicing in food law, "class action lawsuits alleging labeling violations [are] now 'filed almost daily in California . . .'").

142 *Id.* ("[F]ood manufacturers are spending 'hundreds of thousands of dollars in legal fees and settlement amounts" to resolve cases that are entirely avoidable [by having someone review their labels], according to one leading food law attorney.").

143 *Id. See also* Elaine Watson, *PepsiCo Targeted in New Class Action Lawsuit over Improper Nutrient Content Claim*, FOOD NAVIGATOR-USA (Apr. 4, 2012), http://www.foodnavigator-usa.com/Regulation/PepsiCo-targeted-in-new-class-action-lawsuit-over-improper-nutrient-content-claims. The plaintiffs pointed out a clear regulatory violation. However minor, it was easily avoided by Pepsi following the regulation. Defense attorneys not associated with the case stated that these lawsuits are provoked by plaintiffs' attorneys who scour labels for technical violations. It is unnecessary to take a position on this point. The problem stems from the fact that lax regulatory oversight leads to lax regulatory compliance. The reasons there are so many technical violations is that only plaintiffs' attorneys are seeking to enforce the FDCA.

144 *See, e.g.*, Sugawara v. PepsiCo, Inc., No. 2:08-cv-01335, 2009 U.S. Dist. LEXIS 43127, at *14 (E.D. Cal. May 21, 2009) (finding that Plaintiffs had failed to state a claim that the labeling of Cap'n Crunch with Crunchberries was misleading, even though the cereal contains no actual berries).

145 *See* Watson, *supra* note 143 ("[I]f these cases ever make it to completion, plaintiffs may be hard pressed to prove any significant damage.").

146 Williams v. Gerber Prods. Co., 552 F.3d 934, 936 (9th Cir. 2008).

147 *Id.* at 939.

148 *Sugawara*, 2009 U.S. Dist. LEXIS 43127, at *3 ("This Court is not aware of, nor has Plaintiff alleged the existence of, any actual fruit referred to as a 'crunchberry.' Furthermore, the 'Crunchberries' depicted on the [principal display panel] are round, crunchy, brightly-colored cereal balls ... Thus, a reasonable consumer would not be deceived into believing that the Product in the instant case contained a fruit that does not exist.").

149 Mason v. Coca-Cola Co., 774 F. Supp. 2d 699, 705 (D.N.J. 2011).

150 15 U.S.C. § 1125(a)(1) (2012).

151 Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (3d Cir. 1990) (quoting American Home Prods. Corp. v. Johnson & Johnson, 672 F. Supp. 135, 145 (S.D.N.Y. 1987)).

152 *Cf.* Clifford Rechtschaffen, *Deterrence vs. Cooperation and the Evolving Theory of Environmental Enforcement*, 71 S. CAL. L. REV. 1181, 1233-34 (1998) (explaining that citizen enforcers cannot replace the cooperative system of enforcement in the environment context because, among other reasons, they "do not have the resources, expertise, or access to company information to be consultants" and "do not enjoy continuing relationships with regulated firms").

153 Timothy D. Lytton, *Using Tort Litigation to Enhance Regulatory Policymaking: Evaluating Climate-Change Litigation in Light of Lessons from Gun-Industry and Clergy-Sexual-Abuse Lawsuits*, 86 TEX. L. REV. 1837, 1864-65 (2008).

154 Manufacturers do not seem to be sufficiently threatened by current litigation efforts because they do not invest in the time or resources to confirm that their labels comply with the NLEA prior to releasing the product, as reported by Food Navigator. *See* Watson, *supra* note 143.

155 Proponents of litigation consider it a viable option to fill the gaps left by regulatory control. *See* BRUCE SILVERGLADE & ILLENE HELLER, FOOD LABELING CHAOS: THE CASE FOR REFORM VII1-9 (2010); Jennifer L. Pomeranz et al., *Innovative Legal Approaches to Address Obesity*, 87 MlLBANK Q. 185, 199 (2009). One legal scholar and co-author noted: "The argument against litigation, however, assumes the existence of an effective regulatory process that renders litigation unnecessary, which does not seem to be the case. Regulatory agencies are notoriously understaffed and underfunded, so they often are unable to carry out their regulatory purpose." *Id.* at 199. The current article argues that the better solution is to address the regulatory deficiencies.

156 LISA SHAMES ET AL., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS 42-43 (2008).

157 FOOD & DRUG ADMIN., FISCAL YEAR 2013, JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 548 (2012).

158 Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101); *see also* Oliver Nieburg, *Frito Lay Hit with Lawsuit on All-Natural Claims*, FOOD NAVIGATOR-USA (Dec. 20, 2011), http://www.foodnavigator-usa.com/Regulation/Frito-Lay-hit-with-lawsuit-on-all-natural-claims (noting "the FDA told [another publication] that it had no plans to define the term 'all-natural' because of limited resources").

159 Polinsky & Shavell, *supra* note 131, at 71; *see also* Watson, *supra* note 141.

160 *See* Harris et al., *supra* note 18, at 2207-08.

161 *See* Watson, *supra* note 143.

162 Rechtschaffen, *supra* note 152, at 1193.

163 *Id.* at 1189.

164 Diana Crumley, *Achieving Optimal Deterrence in Food Safety Regulation*, 31 REV. LITIG. 353, 400 (2012); Neil A. Gunningham et al., *Motivating Management: Corporate Compliance in Environmental Protection*, 27 LAW &

POL'Y 289, 289 (2005); Polinsky & Shavell, *supra* note 131; Rechtschaffen, *supra* note 152; Dorothy Thornton et al., *General Deterrence and Corporate Environmental Behavior*, 27 LAW & POL'Y 262, 262 (2005).

165 Rechtschaffen, *supra* note 152, at 1189 (noting that many enforcement agencies use a hybrid of cooperative-compliance and deterrence-based strategies).

166 Rena Steinzor, *The Future of Regulation: The Truth About Regulation in America*, 5 HARV. L. & POL'Y REV. 323, 325 (2011) (identifying six protector agencies with the mission to safeguard people and the environment, including the FDA and EPA).

167 *See* Rechtschaffen, *supra* note 152, at 1184.

168 *Id.* at 1188.

169 *Id.* at 1191, 1195.

170 *See* Gunningham et al., *supra* note 164, at 295-96; *see also* Rechtschaffen. *supra* note 152, at 1204.

171 Gunningham et al., *supra* note 164, at 309. Note also that unlike under the FDCA, in the environmental context, the Clean Water Act expressly permits citizen suits with the potential for civil monetary penalties or injunctive relief. 33 U.S.C. § 1365 (2012). The citizen enforcement provision has been found to play "an extremely valuable role in achieving compliance with environmental law, including . . . provid[ing] an important deterrent to non-compliance when government agencies fail to act either because of lack of resources or political will." Rechtschaffen, *supra* note 152, at 1231.

172 Rechtschaffen, *supra* note 152, at 1186.

173 *Id.* at 1222-23; *see also* Thomas M. Arnold & Jerry L. Stevens, *Mixed Agendas and Government Regulation of Business: Can We Clean Up the Mess?* 45 U. RICH. L. REV. 1059, 1068 (2011).

174 Rechtschaffen, *supra* note 152, at 1188, 1226-27.

175 Hank Schultz, *Protecting Against Label Claims Lawsuits*, FOOD NAVIGATOR-USA (Jan. 19, 2013), http://www.foodnavigator-usa.com/Regulation/Protecting-against-label-claims-lawsuits; *see-also* Watson, *supra* note 143.

176 This presumes the regulatory overhaul discussed below, where cooperative resolution of the underlying permissible and non-permissible claims would be achieved. However, after the revised claim regulations are enacted, post-market cooperative compliance would not effectuate the purpose behind the regulatory overhaul.

177 Council Regulation 1924/2006. 2006 O.J. (L 404) 9 (EC).

178 *Health and Nutrition Claims*, EUROPEAN COMM'N, http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm (last updated Aug. 8, 2013).

179 EUROPEAN RESPONSIBLE NUTRITION ALLIANCE. THE APPLICATION OF THE NUTRITION AND HEALTH CLAIMS REGULATION 1924/2006: GUIDANCE FOR FOOD OPERATORS 17 (2012).

180 *Id.* at 20.

181 *Health and Nutrition Claims*, *supra* note 1 78.

182 *EU Register of Nutrition and Health Claims Made on Foods*, EUROPEAN COMM'N, http://ec.europa.eu/nuhclaims/?event=register.home (last updated June 12, 2013).

183 Council Regulation 1924/2006. 2006 O.J. (L 404) 9, 14-15.

184 *General Conditions for Use of Nutrition and Health Claims*, FOOD SAFETY AUTH. OF IR., http://www.fsai.ie/science_and_health/nutrition_and_health_claims/conditionsforuse.html (last updated Sept. 20, 2012).

185 Council Regulation 1924/2006, 2006 O.J. (L 404) 9, 14. The Commission has progressed by conducting consultations with stakeholders to establish nutrient profiles. *Nutrient Profiles*, EUROPEAN COMM'N, http://ec.europa.eu/food/food/labellingnutrition/claims/nut_profiles_en.htm (last updated Sept. 1, 2009).

186 21 U.S.C. § 32t(n) (2012) ("If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.").

187 *See* Jennifer L. Harris et al., *supra* note 18, at 14. Health representations also create a health halo, which leads to over-consumption of the products carrying such claims. Brian Wansink, *How Do Front and Back Package Labels Influence Beliefs About Health Claims?*, 37 J. CONSUMER AFF. 305, 313-15(2003).

188 Council Regulation 1924/2006, 2006 O.J. (L 404) 9, 14.

189 *See* LISA SHAMES ET AL., *supra* note 9, at 62.

190 *See, e.g.*, Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 765 (1976) ("It is a matter of public interest that [private economic] decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.").

191 Rubin v. Coors Brewing Co., 514 U.S. 476, 478 (1995) (invalidating Section 5(e)(2) of the Federal Alcohol Administration Act, which prohibited beer labels from displaying alcohol content, because it was "inconsistent with the protections granted to commercial speech by the First Amendment . . .").

192 *Virginia State Bd. of Pharmacy*, 425 U.S. at 772 n.24.

193 *Id.*

194 *See* Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 562-63 (1980) ("The Constitution therefore accords a lesser protection to commercial speech than to other constitutionally guaranteed expression. The protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation.").

195 *Id.* at 576.; *In re* R.M.J., 455 U.S. 191, 203 (1982).

196 *See In re R.M.J.*, 455 U.S. at 203 ("[W]hen the particular content or method of the advertising suggests that it is inherently misleading ... the States may impose appropriate restrictions ... [T]he Court in *Bates* suggested that the remedy in the First instance is not necessarily a prohibition but preferably a requirement of disclaimers of explanation.") (citing Bates v. State Bar of Arizona, 433 U.S. 350, 375(1977)).

197 *Id.*

198 *See* Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431 (1919) (stating that commercial entities have "no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold"); *Cf.* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 628 (1985).

199 Zauderer, 471 U.S. at 651 ("[W]e hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers."); see also Milavetz v. United States, 559 U.S. 229, 249-50 (2010) (citing *Zauderer*, 471 U.S. at 651).

200 *User Fees*, U.S. FOOD & AND DRUG ADMIN., http://www.fda.gov/ForIndustry/UserFees/default.htm (last updated June 17, 2013) (The user fees include: Animal Drug User Fee Act, Animal Generic Drug User Fee Act, Biosimilar User Fee Act, Color Certification, Exports Certificate, Family Smoking Prevention and Tobacco Control Act, Food Safety Modernization Act, Freedom of Information Act Fees, Generic Drug User Fee Act, Mammography Quality Standards Act, Medical Device User Fee and Modernization Act, Prescription Drug User Fee Act, Tobacco Product Fees.).

201 *President's Fiscal Year 2013 Budget Request for the FDA: Hearing Before the Subcomm. On Agric, Rural Develop., Food & Drug Admin., and Related Agencies of the H. Comm. on Appropriations*, 112th Cong. (2012) (statement of Margaret A. Hamburg, Comm'r, Food & Drug Admin.).

202 *Id.*

203 *Id.*

204 *See* 21 C.F.R. § 1.231(d) (2013).

205 *Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm274176.htm (last updated Aug. 16, 2013).

206 *See* 21 U.S.C. § 379j-31(a) (2012); *see also* Food Safety Modernization Act Reinspection Fee Rates, 77 Fed. Reg. 45,636, 45,638 (Aug. 1, 2012).

207 *See* 77 Fed. Reg. at 45,637-38.

208 The only other food-related user fee is assessed on color additives. Entities seeking to use color additives for food, drugs, devices and cosmetics must obtain batch certification (unless they are exempt) from the FDA. 21 U.S.C. § 379e(a) (2012). The agency will only admit a color additive to the listing subject to certification upon payment of a fee, determined according to the weight of the batch. *Id.* § 379e(e); *see also* 21 C.F.R. § 80.10(a), (b) (2013); *Listing of Color Additives Subject to Certification*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatorylnformation/ColorAdditiveListingRegulations/Listingof'ColorAdditivesSubjecttoCertification/default.htm (last updated May 19, 2009).

209 Family Smoking Prevention and Tobacco Control Act of 2009, Pub L. No. 111-31, § 919, 123 Stat. 1776, 1826 (codified as amended at 21 U.S.C. § 387s (2012)).

210 *See* 21 U.S.C. § 387c(a)(l), (7).

211 *Id.* § 387s(c)(2)(A) (including the manufacture, distribution, and marketing of tobacco products); *Overview of the Family Smoking Prevention and Tobacco Control Act: Consumer Fact Sheet*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm246129.htm (last updated Apr. 30, 2013).

212 *See* 21 C.F.R. § 1.225.

213 *Id.* (requiring registrants to list applicable food product categories as identified in 21 C.F.R. § 170.3); *see* 21 C.F.R. § 170.3(n) (listing 43 general food categories that group specific related foods together, including the following: baked goods; non-alcoholic beverages, including soft drinks; frozen dairy desserts; snack foods, including chips, pretzels; and soft candy).

214 *See* 21U.S.C. § 387s(c)(2)(A).

215 *See* 21 C.F.R. § 1.226.

216 Calculation of these fees would need to consider whether the manufacturers would pass the cost on to consumers. Consumer access to whole foods and differing responses to potential increased prices stemming from the fee provision due to socio-economic variation is beyond the scope of this paper. For a relevant discussion of strategies to address this point, see Jennifer L. Pomeranz, *A Conditional Funding Strategy to Address the Modern Food Environment: From Public Health Prevention to State and Local Preemption*, 40 DUKE FORUM FOR L. & SOC. CHANGE 39, 41 -44 (2013).

217 *See User Fees*, *supra* note 200.

218 *See* 28 U.S.C. § 2461 (2006); *see* Friends of the Earth, Inc. v. Laidlaw Env. Servs., Inc., 528 U.S. 167, 169-72(2000).

219 *See* 28 U.S.C. § 2461.

220 *Id.* § 2461 (2)(a)(1) (requiring federal agencies to issue regulations to adjust their civil monetary penalties upward due to inflation).

221 *Id.* § 2461(2)(b)(2); *see also* Federal Civil Penalties Inflation Adjustment, 69 Fed. Reg. 43,299, 43,299 (July 20, 2004) (In responding to a comment requesting higher penalties in the context of violations of regulations regarding drugs, the FDA noted that the FCPIAA did not authorize increases in penalties greater than ten percent, even though "higher civil monetary penalties might be a better deterrent.").

222 *Friends of the Earth*, 528 U.S. at 185.

223 *Id.*

224 Polinsky & Shavell, *supra* note 131, at 60-62.

225 Elaine Watson, *supra* note 141 (quoting a lawyer stating that some manufacturers believe the worst thing that can happen from an "improper labeling claim is that they would receive a warning letter [sic] and then they would fix it and move on").

226 Gunningham et al., *supra* note 164, at 295.

227 Crumley, *supra* note 164, at 383-84; Rechtschaffen, *supra* note 152, at 1188.

228 Polinsky & Shavell, *supra* note 131, at 72; Rechtschaffen, *supra* note 152, at 1215.

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Article

The Growing Consumer Exposure to Nanotechnology in Everyday Products: Regulating Innovative Technologies in Light of Lessons from the Past

KATHARINE A. VAN TASSEL & ROSE H. GOLDMAN

Nanoparticles are very small particles that are engineered using innovative technologies to be one to one hundred nanometers in size. Just how small is small? In comparison, a human hair is 80,000 nanometers wide. There are currently hundreds of unregulated and unlabeled consumer products on the market that contain engineered nanotech particles, with more on the way. A growing number of these nanotech products are being marketed for human consumption, including food, dietary supplements, cosmetics, and sunscreens. This expanding market ignores the growing scientific understanding that these unique substances can create unintended human health and environmental risks. This Article discusses the public health, regulatory, legal, and ethical issues raised by the developing appreciation of the health risks associated with nanotech products. This Article proposes a method for regulating nanotech products that protects public health while encouraging technical innovation. This proposal is based on lessons learned from past introductions of new chemicals and innovative technologies such as asbestos, PCBs, DES, Thalidomide, medical X-rays, and Benzene which all had serious, long-term public health consequences.

ARTICLE CONTENTS

The Growing Consumer Exposure to Nanotechnology in Everyday Products: Regulating Innovative Technologies in Light of Lessons from the Past

KATHARINE A. VAN TASSEL[*] & ROSE H. GOLDMAN[**]

I. INTRODUCTION

Consumers in the United States are being exposed to steadily increasing levels of novel, engineered nanoparticles as a result of their contact with everyday consumer products. Engineered nanoparticles are very small particles that are engineered using innovative technologies to be 1 to 100 nanometers in size.[1] Just how small is small? In comparison, a human hair is about 80,000 nanometers wide.[2] Nanoscale materials are

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[1] "Nanotechnology is the art and science of manipulating matter at the nanoscale to create new and unique materials and products." WILLIAM B. SCHULTZ & LISA BARCLAY, WOODROW WILSON INT'L CENTER FOR SCHOLARS, A HARD PILL TO SWALLOW: BARRIERS TO EFFECTIVE FDA REGULATION OF NANOTECHNOLOGY-BASED DIETARY SUPPLEMENTS 8 (2009), *available at* http://www.nanotechproject.org/process/assets/files/7056/pen17_final.pdf. The National Nanotechnology Initiative, the federal research and development program that coordinates the nanoscale research and technology activities of twenty-five different government agencies, including the FDA, defines nanotechnology as activities that include the following characteristics:

> (1) research and technology development at the atomic, molecular or macromolecular level, in the length scale of 1–100 nanometers; (2) creating and using structures, devices and systems that have novel properties and functions because of their small or intermediate size; and (3) ability to control or manipulate on the atomic scale.

Id.

[2] ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES, at vii (2004), *available at* http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf. A nanometer is one billionth of a meter. *What is Nanotechnology?*, NAT'L NANOTECH. INITIATIVE, http://www.nano.gov/nanotech-101/what/definition (last visited Sept. 15, 2011). To attempt to conceptualize just how small a nanoparticle is, compare

increasingly being used in a wide variety of areas, including electronic, magnetic, medical imaging, drug delivery, catalytic, materials applications, and cosmetic products.[3] According to the National Institute of Occupational Safety and Health ("NIOSH"), new nanotechnology consumer products are coming on the market at the rate of three to four per week.[4] Thus, consumers in the United States are being exposed to increasing levels of these novel and relatively untested engineered nanoparticles as a result of their contact with everyday consumer products. There are currently hundreds of unregulated and unlabeled consumer products on the market that contain engineered nanotech particles ("nanotech products"),[5] with more on the way.[6] Thousands of tons of engineered nanomaterials are currently being produced each year.[7] One-hundred-forty-seven billion dollars in manufactured goods using engineered nanotech materials were produced in 2007 and the global market in nanotechnology research and development is predicted to reach $3.1 trillion by 2015.[8] The financial resources put into the development, applications, and production of nanoparticle technology have far outpaced funding to explore health and safety issues.[9] In addition, the expanding market often ignores, or does not seek out, information about the scientific findings that are becoming available concerning the potential unintended human and environmental health risks posed by emerging nanotechnology.[10]

Products that contain nanoparticles include, among many others, sporting goods, cell phones, digital cameras, coatings for eyeglasses, paints, stain resistant clothing, and light emitting diodes used in

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nanoparticles to the size of a human hair, which is approximately 80,000 nanometers wide or the thickness of a sheet of paper, which is roughly 100,000 nanometers wide. *Size of the Nanoscale*, NAT'L NANOTECH. INITIATIVE, http://www.nano.gov/nanotech-101/what/nano-size (last visited on Sept. 15, 2011).

[3] *See, e.g.*, *Nanotechnology: Frequently Asked Questions*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/niosh/topics/nanotech/faq.html (last updated Sept. 22, 2010) (acknowledging the broad array of different categories of products that contain nanoparticles).

[4] *Id.*

[5] *See* SCHULTZ & BARCLAY, *supra* note 1, at 20–23 (explaining that the increasing amounts of products integrating nanotechnology go unregulated, due to the dated FDA regulatory scheme).

[6] *Id.* at 9.

[7] ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at 26–27.

[8] SCHULTZ & BARCLAY, *supra* note 1, at 8; *see also Buyer Beware: Product List Highlights Both Nanotech and Nano-marketing*, ELECTRO IQ (Mar. 16, 2006), http://www.electroiq.com/articles/stm/2006/03/buyer-beware-product-list-highlights-both-nanotech-and-nano-marketing.html (detailing the growing number of products containing nanoparticles); *Nanotechnology: Frequently Asked Questions*, *supra* note 3.

[9] *See infra* note 85 and accompanying text.

[10] *See infra* Section II.D.2.

computers.[11] These products contain nanoparticles that are "fixed" inside a solid matrix which makes them less likely to move into the environment or the human body.[12] Engineered nanoparticles that are produced and then fixed in consumer products are of greatest concern to workers who face heavy exposure to these nanoparticles during the manufacturing process.[13] Of more concern to the general public are the growing numbers of products that contain predominantly "free" nanotech particles which are being used in liquid products. This use of free nanoparticles in drugs,[14] food,[15] dietary

[11] *See* Hope Shand & Kathy Jo Wetter, *Shrinking Science: An Introduction to Nanotechnology*, *in* STATE OF THE WORLD 2006 78, 80–82 (Linda Starke ed., 2006) (listing various consumer products containing nanoparticles); *Nanotechnology Consumer Products Inventory*, PROJECT ON EMERGING NANOTECH., http://www.nanotechproject.org/inventories/consumer/browse/categories/ (last visited Mar. 3, 2011) (same).

[12] While industry takes the position that fixed nanoparticles are unlikely to migrate into the environment or the human body, this conclusion is still being studied and the jury is still out. *See, e.g.*, Natasha Singer, *New Products Bring Side Effect: Nanophobia*, N.Y. TIMES, Dec. 3, 2008, at E1 (stating that some cosmetics industry representatives said there was no evidence that personal care products that contain nano-size components are a health hazard). Dr. Andrew Maynard, the former chief science advisor to the Project on Emerging Nanotechnologies, states that: "I would be very surprised if [fixed carbon nanotubes are] dangerous to use, let us say, [in] a tennis racket or baseball bat[,] . . . [b]ut I do not think it is OK to tell people that we think it is safe—we've got to have evidence." Ann Fernholm, *Carbon Nanotubes May Be as Harmful as Asbestos*, S.F. CHRON., May 21, 2008, at C-1. Dr. Maynard goes on to explain that issues remain over what happens when these products containing engineered nanoparticles break or the surface of one of these products is rubbed against the ground. *Id.* Many recall the level of human exposure to asbestos as car brake pads containing asbestos wore down and roads paved with asbestos-containing materials deteriorated. *See generally* AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH AND HUMAN SERV., ASBESTOS TOXICITY, *available at* http://www.atsdr.cdc.gov/csem/asbestos/docs/asbestos.pdf (last visited Mar. 3, 2011).

[13] NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, DEP'T OF HEALTH & HUMAN SERV., CURRENT INTELLIGENCE BULLETIN: OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBERS 19, 39 (draft, Nov. 2010) [hereinafter NIOSH BULLETIN], *available at* http://www.cdc.gov/niosh/docket/review/docket161a/pdfs/carbonNanotubeCIB_PublicReviewOfDraft.pdf.

[14] *See, e.g.*, Christopher Weldon et al., *Nanotechnology for Surgeons*, 3 WILEY INTERDISCIPLINARY REV.: NANOMED. & NANOBIOTECH. 223, 226 (2011) (explaining that nanotechnology may provide powerful new tools that could have a marked impact on the therapeutic and diagnostic measures available to surgeons); Kevin O'Donnell & Robert O. Williams, *Nanoparticulate Systems for Oral Drug Delivery to the Colon*, 8 INT'L J. NANOTECH. 4, 4–15 (2011) (explaining that encapsulating a drug molecule within nanoparticles offers a highly effective option for controlling drug delivery and targeting the colon, for example for the treatment of colon cancer); Dorothy Farrell et al., *Recent Advances from the National Cancer Institute Alliance for Nanotechnology in Cancer*, 4 ACS NANO 589 (2010) (describing a range of advances, including some showing significant promise in clinical trials, that are poised to make a big impact on cancer).

[15] *See, e.g.*, GEORGIA MILLER & RYE SENJEN, FRIENDS OF THE EARTH, OUT OF THE LABORATORY AND ON TO OUR PLATES: NANOTECHNOLOGY IN FOOD & AGRICULTURE 9 (2008), *available at* http://www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf (identifying nanoadditives found in some margarine, soft drinks, beer, dairy products, sausages, and other processed foods).

supplements,[16] cosmetics,[17] and sunscreens[18] creates a high level of consumer exposure to new and unique substances.[19]

In spite of a mounting scientific awareness of the adverse physical effects and potential health risks associated with the human consumption of engineered nanoparticles, consumers remain uninformed of their exposure to these effects and risks as nanotech ingredients are not commonly listed on product labels. Labeling of nanotech ingredients on product packaging is not required by the Food & Drug Administration ("FDA"). The FDA has only recently begun to acknowledge that nano materials can have chemical, physical, and biological properties that differ from those of their larger counterparts.[20] However, the FDA has not changed its position on the safety of nanoparticles. Thus, the FDA has not yet begun regulating nanotech ingredients differently from their normal size counterparts, although there are task forces to study the issue.[21] In other words, if the large particle version of a product is considered to be safe, the FDA currently presumes that the nanotech version is also safe. Thus, manufacturers of nanotech food, food additives, dietary supplements, cosmetics, and sunscreens are not required to test their products for safety, are not required to obtain premarket approval from the FDA, and are not required to list nanotech ingredients on product labels.[22]

The FDA's presumption of bioequivalence for purposes of safety is based on its position that "[p]article size is not an issue."[23] In fact, nanotech particles have fundamentally different properties than their larger counterparts. These differences manifest themselves on multiple levels as differences in optical, magnetic, bioaccumulation, toxicity, electrical,

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[16] *See, e.g.*, SCHULTZ & BARCLAY, *supra* note 1, at 8. The number of dietary supplements with nanoparticle content has jumped over a two year period from eleven in 2007 to forty-four in 2009. *Id.* at 9.

[17] GEORGIA MILLER ET AL., FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS 2 (2006), *available at* http://www.foeeurope.org/activities/nanotechnology/nanocosmetics.pdf.

[18] *Id.*

[19] *See infra* Section II.D.1.

[20] *Nanotechnology*, FDA, http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm (last updated Jul. 8, 2011) ("The U.S. Food and Drug Administration (FDA) regulates a wide range of products, including foods, cosmetics, drugs, devices, veterinary products, and tobacco products some of which may utilize nanotechnology or contain nanomaterials. Nanotechnology allows scientists to create, explore, and manipulate materials measured in nanometers (billionths of a meter). Such materials can have chemical, physical, and biological properties that differ from those of their larger counterparts.").

[21] *Nanotechnology Task Force*, FDA, http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/default.htm (last updated Apr. 9, 2010).

[22] *See infra* Part III.

[23] *FDA Regulation of Nanotechnology Products*, NANOPHARMACEUTICALS.ORG, http://www.nanopharmaceuticals.org/FDA.html (last visited Nov. 30, 2011).

chemical, explosiveness, and persistence characteristics.[24] Numerous scientific animal studies over the past several years reveal that these unique properties actually produce negative physical effects that may create unintended health risks in people, such as mesothelioma, the condition caused by asbestos,[25] or could contribute to neurodegenerative processes, such as Alzheimer's disease.[26] These studies establish that the FDA's presumption of bioequivalence is no longer scientifically supportable and that a new system for nanotech product regulation is required.

This Article discusses the public health, regulatory, legal, and ethical issues raised by the developing appreciation of the negative physical effects and potential health risks associated with nanotech products, and is arranged as follows. After this Introduction, this Article describes the present scientific understanding of the health risks associated with the consumption of nanoparticles. Next, a summary of the existing FDA regulatory structure that governs food, dietary supplements, cosmetics, and sunscreens is provided along with an explanation of why these regulations fail to protect public health when applied to regulate the nanotech versions of these products. The Article goes on to illustrate how the FDA's dated position on bioequivalence, coupled with preexisting regulations, lead to a lack of a labeling requirement which bars a consumer from engaging in self-protection. Compounding this situation is the tort system's inadequate response if a consumer is injured from this unavoidable exposure. This Article spells out how the insensitivity of the tort system to injuries from innovative technologies means that an injury from a nanotech product will be borne by the consumer and not the manufacturers who are profiting from product sales. This disconnect violates basic principles of distributive justice. Finally, this Article proposes alternative methods of regulating nanotech products that better protect public health while encouraging technical innovation. These proposals are based on lessons learned from past introductions of new chemicals and innovative technologies, such as asbestos, PCBs, DES, Thalidomide, medical X-rays, and Benzene which all had serious, long-term public health consequences.

It is important to note that, while the FDA has recently acknowledged in one paragraph on its website that nanoparticles "*can* have chemical, physical, and biological properties that differ from those of their larger counterparts,"[27] the acknowledgment of the possibility that 'nano can mean

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[24] Cristina Buzea et al., *Nanomaterials and Nanoparticles: Sources and Toxicity*, 2 BIOINTERPHASES MR17, MR23–25, MR47, MR59 (2007); *see also* Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 ENVTL. HEALTH PERSP. A740, A741 (2004); ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at 5.

[25] Andre E. Nel et al., *Understanding Biophysicochemical Interactions at the Nano-Bio Interface*, 8 NATURE MATERIALS 543, 550 (2009).

[26] *Id.* at 546.

[27] *Nanotechnology*, *supra* note 20 (emphasis added).

different' has yet to be given voice in any of the FDA's regulatory positions on safety. This Article will focus on the FDA's current regulatory positions on safety in order to explain how the FDA is currently regulating nanotech products and to explain what regulatory changes are necessary to better protect public health.

II. NANOTECHNOLOGY: BENEFITS AND RISKS

A. *Benefits*

Nanotechnology has been touted as the potential solution to global challenges, such as a cure for cancer, a source for renewable energy, and the answer to the provision of clean water.[28] More generally, nanotechnology offers economic benefits, improved materials, reduced use of resources, and new medical treatments.[29] Less compelling are the benefits associated with the use of nanoparticles in consumer products for direct and indirect human consumption. Nanotech cosmetics offer the opportunity for a more attractive appearance.[30] Nanotech sunscreens apply more smoothly and are clear instead of white and pasty.[31] Some nanotech dietary supplement manufacturers are currently claiming, without substantiation, that their products are more bioavailable or can be absorbed by the body more quickly.[32] Nanotech food and dietary supplement manufacturers hope that their products will, in the future, deliver nutrients directly to cells and block allergens and cholesterol.[33] Nanotech foods offer the possibility of "more potent food colourings, flavourings and nutritional additives, antibacterial ingredients for food packaging, and

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[28] Fabio Salamanca-Buentello et al., *Nanotechnology and the Developing World*, 2 PLOS MED. 0383, 0385 (2005). According to a study by the Canadian Program on Genomics and Global Health at the University of Toronto Joint Centre for Bioethics, the top ten applications of nanotechnology most likely to benefit developing countries, and which may contribute to the attainment of the United Nations Millennium Development Goals (MDGs) are as follows: energy storage; production and conversion; agricultural productivity enhancement; water treatment and remediation; disease diagnosis and screening; drug delivery systems; food processing and storage; air pollution and remediation; construction; health monitoring; vector and pest detection; and control. *Id.* at 0383, 0385.

[29] ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at viii–x.

[30] *See* Buzea et al., *supra* note 24, at MR36 (discussing how engineered nanomaterials in cosmetic products regenerate skin cells, help maintain a youthful appearance of the skin, and hide wrinkles and creases).

[31] Singer, *supra* note 12, at E1.

[32] SCHULTZ & BARCLAY, *supra* note 1, at 9 ("Examples of product claims that tout special properties due to the use of nanotechnology include: increased effectiveness in a calcium/magnesium product; more rapid, uniform and complete absorption of nutrients in a spray form; increased absorption of a B_{12} vitamin spray; supplements that pass through membranes directly into human cells; and increased absorption of gel supplements by transforming fat-soluble nutrients into water-soluble ones.").

[33] *See* MILLER & SENJEN, *supra* note 15, at 9.

more potent agrochemicals and fertilisers."[34]

In spite of these less than compelling benefits, these products are being freely marketed without undergoing any form of risk analysis by the FDA because, as more fully discussed below, the FDA has taken the position that, for safety purposes, nanoscale materials are bioequivalent to their normal size counterparts and, therefore, regulation is not needed.[35]

B. *Risks*

The FDA's presumption of bioequivalence results in nanotech food, dietary supplements, cosmetics, and sunscreens being regulated the same way as their non-nanotech counterparts. According to the FDA, if the normal size version of a substance is safe, the nanoscale version is also safe.[36] However, contrary to the FDA's presumption of bioequivalence, "nano" does not just mean that a particle is tiny or smaller, it means that the particle is fundamentally different. These differences manifest themselves on multiple levels as differences in optical, magnetic, bioaccumulation, toxicity, electrical, chemical, explosiveness, and persistence characteristics.[37]

As fully discussed in the next sections, numerous scientific studies over the past several years reveal that these unique properties actually create negative physical effects that may create unintended health risks such as mesothelioma, the condition caused by asbestos,[38] or could contribute to neurodegenerative processes, such as Alzheimer's disease.[39] In addition to consumer exposure to these health risks, workers handling nanomaterials are likely to be exposed at much higher levels than consumers during the manufacture, packaging, transportation, and use of nanotech materials.[40] In addition, there may be higher exposure levels during cleaning and maintenance of research, production, and handling

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[34] *Id*. at 4. Scientists have "developed several delivery systems not only for colorants, but also for vitamins, antioxidants, antifungals . . . with the goal of incorporating nanostructures in food systems for improved food quality and to promote human health." Stephen Daniells, *Nano Beta-carotene Entrapment Offers Natural Colour Options*, FOODNAVIGATOR.COM (Aug. 11, 2009), http://www.foodnavigator.com/Science-Nutrition/Nano-beta-carotene-entrapment-offers-natural-colour-options; *see also* Carlos E. Astete et al., *Ca2+ Cross-Linked Alginic Acid Nanoparticles for Solubilization of Lipophilic Natural Colorants*, 57 J. AGRIC. & FOOD CHEMISTRY 7505, 7505 (2009).

[35] *See Nanotechnology Task Force*, *supra* note 21, at 11 (noting that there is no available information suggesting that nanoscale materials are more hazardous than non-nanoscale materials).

[36] *See infra* Part III.

[37] ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at ix, 5, 7–9.

[38] Nel et al., *supra* note 25, at 550.

[39] *Id*. at 546.

[40] NIOSH BULLETIN, *supra* note 13, at 5, 18–19; Arthur Miller et al., *Characterizing Exposures to Airborne Metals and Nanoparticle Emissions in a Refinery*, 54 ANNALS OF OCCUPATIONAL HYGIENE 504, 511–12 (2010); RJ AITKEN ET AL., INST. OF OCCUPATIONAL MED. FOR HEALTH & SAFETY EXEC., NANOPARTICLES: AN OCCUPATIONAL HYGIENE REVIEW 2–3 (2004), *available at* http://www.hse.gov.uk/research/rrpdf/rr274.pdf.

facilities.[41] Currently, the levels at which workers can safely be exposed to nanoparticles in the workplace is unknown as the science on safe exposure levels and protective equipment is still evolving.[42] By 2015, it is estimated that over two million workers world-wide will be directly employed by nanotech industries.[43] And the numbers of individuals working indirectly in the supply chain will be much higher.[44]

Additional risks may result from nanopollution from manufacturing waste streams and accidental discharges.[45] Other nanopollutants include nanoparticles from washing off cosmetics and sunscreens into sinks and showers that flow into waste water, nanoparticles that wash off of swimmers into streams, lakes, and oceans, as well as nano-waste created as a by-product of the consumption of nanotech food and dietary supplements.[46] The environmental impact of these nanoparticles include brain damage in fish, damage to ecosystems, the opportunity for long range and wide-spread transport of pollutants in ground water, and the ability to bioaccumulate along the food chain.[47]

C. *What Makes Nanoparticles Different?*

Engineered nanoparticles differ significantly from their bulk counterparts[48] for two main reasons. First, the laws of classical physics do

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[41] NIOSH BULLETIN, *supra* note 13, at 19–20; MILLER ET AL., *supra* note 17, at 10.

[42] NIOSH BULLETIN, *supra* note 13, at 6, 8.

[43] Mihail C. Roco, *Converging Science and Technology at the Nanoscale: Opportunities for Education and Training*, 21 NATURE BIOTECH. 1247, 1248 (2003); *see also* NIOSH BULLETIN, *supra* note 13, at 19 ("[I]t has been projected that nanotechnology will employ millions of workers worldwide within the next decade.").

[44] *See* Roco, *supra* note 43, at 1248 (explaining that nanotechnology has the potential to create five million related jobs by 2015).

[45] *Nanotechnology in the Environment: Making Sure Wonder Materials Don't Become Wonder Pollutants*, SCIENCEDAILY (Apr. 12, 2008), http://www.sciencedaily.com/releases/2008/04/080408132129.htm (exploring the potential harm to the environment of nanoparticles); *see also* MILLER ET AL., *supra* note 17, at 10–11.

[46] MILLER ET AL., *supra* note 17, at 10–11.

[47] *See infra* notes 85–95 and accompanying text.

[48] Consistent with the nomenclature adopted by the literature, this Article will refer to particles that manifest these different properties as "nanoparticles" or "nanoscale" materials or versions and will refer to larger scale particles of the same chemical that do not have these unique properties as normal size materials or bulk materials. Buzea et al., *supra* note 24, at MR23–25; ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at 7. For example, the list of FDA approved active ingredients for use in sunscreens includes titanium dioxide for use up to a twenty-five percent concentration. Sunscreen Drug Products for Over-The-Counter Human Use: Final Monograph, 64 Fed. Reg. 27666, 27672 (May 21, 1999) (to be codified at 21 C.F.R. pt. 352) [hereinafter Final Monograph]. The FDA reviewed the safety and effectiveness of titanium dioxide in sunscreens prior to industry use of the engineered nanoparticle form of titanium dioxide pursuant to the normal process for over-the-counter (OTC) approval. *Small Business Assistance: Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069917.htm (last visited Sept 14, 2011) (describing the process for OTC

not apply to a particle that is smaller than approximately 100 nanometers (nm).[49] At this small size, the laws of quantum mechanics apply which affect the magnetic, optical, and electric behavior of materials.[50] Second, nanotech particles have an enormous surface to volume ratio resulting in a larger number of atoms found on the surface.[51] Compared to macro-particles, this provides a greater surface area per unit mass.

> In the size range of < 100 nm, the number of surface molecules (expressed as a % of the molecules in the particle) is inversely related to particle size. For instance, in a particle of 30 nm size, about 10% of its molecules are expressed on the surface, whereas at 10 and 3 nm size the ratios increase to 20% and 50%, respectively. Because the number of atoms or molecules on the surface of the particle may determine the material reactivity, this is key to defining the chemical and biological properties of nanoparticles.[52]

Thus, because chemical reactions occur at the particle surface, nanoparticles have a greater potential for biological interaction and are more reactive than larger particles.[53] As a consequence, the intrinsic toxicity of any given mass of nanoparticles is greater than the same mass of larger particles.[54]

Finally, it is important to point out that engineered nanoparticles are different from those found in nature.[55] People have always been exposed to "naturally" produced nanoparticles.[56] For example, nature produces some nanoparticles, such as ultrafine salt nanocrystals found in ocean air, and man has accidentally produced others, like carbon nanoparticles

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approval). The FDA stated that it is aware that sunscreen products use engineered nanoparticles but that it "does not consider micronized titanium dioxide to be a new ingredient but it considers it a specific grade of titanium dioxide originally reviewed by the Panel." Final Monograph, *supra*, at 27671–72.

[49] Buzea et al., *supra* note 24, at MR23; ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at 7.

[50] Buzea et al., *supra* note 24, at MR24–25; ROYAL SOC'Y & ROYAL ACAD. OF ENG'G, *supra* note 2, at 7.

[51] Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622, 622 (2006).

[52] *Id.* at 623 fig.1.

[53] *Id*. at 622.

[54] *Id.*; SCI. COMM. ON EMERGING & NEWLY IDENTIFIED HEALTH RISKS (SCENIHR), EUR. COMM'N., MODIFIED OPINION ON THE APPROPRIATENESS OF EXISTING METHODOLOGIES TO ASSESS THE POTENTIAL RISKS ASSOCIATED WITH ENGINEERED AND ADVENTITIOUS PRODUCTS OF NANOTECHNOLOGIES 13 (2005) [hereinafter SCENIHR], *available at* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf.

[55] Buzea et al., *supra* note 24, at MR21–43.

[56] *Id.* at MR17.

produced from fire.[57] However, the increased risk from exposure to intentionally engineered nanoparticles arises from the fact that engineered nanoparticles are being generated in larger and larger quantities with a uniform, monodispersed size compared to natural ultrafine particles that are more physically and chemically variable and polydispersed.[58]

Because of all of these different properties, an understanding of the characteristics of a substance at its normal size is not predictive of the behavior of that substance as it operates on a nanoscale.[59]

D. *The Unique Adverse Physical Effects and Human Health Risks Associated with Nanoparticles*

The unique features of nanoparticles—their size, high surface area to volume ratio, and high reactivity—are the same properties that give nanoparticles a higher possibility for risks to health.[60] Nanoparticles are more easily absorbed and have a higher level of interaction with biological tissues, giving them a greater potential for toxicity.[61]

1. *Routes of Exposure*

Products that contain "fixed" nanoparticles include sporting goods, cell phones, digital cameras, coatings for eyeglasses, paints, stain resistant clothing, and light emitting diodes used in computers.[62] Fixed nanoparticles are contained inside a solid matrix which makes them less likely to move into the environment or the human body from consumer products.[63] On the other hand, workers face heavy exposure to these engineered products during the manufacturing process.[64] Of much more concern to consumers are liquid products that contain "free" nanoparticles such as nanotech food, dietary supplements, cosmetics, and sunscreens. Free nanoparticles are highly mobile[65] and can be absorbed by the body

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[57] *Id.* at MR21–22.

[58] Hood, *supra* note 24, at A745; U.S. ENVTL. PROT. AGENCY, EPA 100/B-07/001, NANOTECHNOLOGY WHITE PAPER 52 (2007) [hereinafter NANOTECHNOLOGY WHITE PAPER], *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.

[59] Kenneth Chang, *Tiny is Beautiful: Translating 'Nano' into Practical*, N.Y. TIMES, Feb. 22, 2005, at F1; Shand & Wetter, *supra* note 11, at 83–86.

[60] Nel et al., *supra* note 51, at 622–23.

[61] *Id.* at 622–25.

[62] Buzea et al., *supra* note 24, at MR36; Shand & Wetter, *supra* note 11, at 80–82.

[63] *See supra* note 12 (noting that there is a clear possibility that "fixed" nanoparticles may be able to migrate into the environment or human body).

[64] NIOSH BULLETIN, *supra* note 13, at 6.

[65] David Rotman, *Measuring the Risks of Nanotechnology*, TECH. REV., Apr. 2003, at 71–73, (interviewing Dr. Vicki Colvin, Director of the Center for Biological and Environmental Nanotechnology at Rice University, about possibly unique health and environmental risks associated with nanotechnology); Buzea et al., *supra* note 24, at MR44–48, MR50–57.

through multiple routes of exposure.[66] Nanoparticles can enter the blood stream through the lungs,[67] skin,[68] and GI tract.[69] If nanoparticles are inhaled, they can travel to all areas of the respiratory tract.[70] Studies suggest that nanoparticles can enter the brain through the olfactory nerves[71] and can also cross the blood brain barrier.[72] In contrast to macro-particles that are caught and eliminated by the body's protective mechanisms,[73] once in the blood stream, nanoparticles can slip unhindered into bone marrow, muscles, the liver, brain, and spleen, and into cells themselves.[74] These tiny particles can bind to cellular structures, move through the cytoplasm[75] and lodge in the mitochondria.[76] Finally, during pregnancy, nanoparticles are capable of crossing the placenta to enter the fetus.[77]

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[66] Günter Oberdörster et al., *Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy*, 2 PARTICLE & FIBRE TOXICOLOGY 1, 2, 4 (2005).

[67] NIOSH BULLETIN, *supra* note 13, at 7.

[68] In the context of cosmetics, nanotech cosmetics that are rubbed onto the skin contain nanoparticles 1000 nm in size that are capable of absorption through intact skin. Jillian Rouse & Jianzhong Yang, *Repetitive Motion Speeds Nanoparticle Uptake: 'Bucky Amino Acid' Penetrates Faster, Deeper When Skin Is Flexed*, SCIENCEDAILY (Jan. 9, 2007), http://www.sciencedaily.com/releases/2007/01/070104144839.htm (discussing study by Rice University chemists and North Carolina State University toxicologists finding that repetitive movement can speed up the uptake of nanoparticles through the skin); Sally S. Tinkle et al., *Skin as a Route of Exposure and Sensitization in Chronic Beryllium Disease*, 111 ENVTL. HEALTH PERSP. 1202, 1204–05 (2003) (studying the penetration of nanoparticles into human skin). When the skin is damaged, for example through blemishes, sun burn, eczema, shaving cuts, or other trauma, nanoparticles up to 7000 nm can penetrate the skin. Günter Oberdörster et al., *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSP. 823, 834 (2005). In fact, many nanotech cosmetics and sunscreens are especially formulated to be used on damaged skin. And an as-yet-unanswered question is what impact the "penetration enhancers" that many cosmetic products use will have on this analysis. *Nanotechnology & Sunscreens*, ENVTL. WORKING GRP., http://www.ewg.org/nanotechnology-suncreens (last visited Sept. 13, 2011).

[69] Oberdörster et al., *supra* note 68, at 833–37; Peter HM Hoet et al., *Nanoparticles—Known and Unknown Health Risks*, 2 J. NANOBIOTECH., Dec. 2004, at 1, 2–10.

[70] Oberdörster et al., *supra* note 68, at 837; Hoet et al., *supra* note 69, at 1–4.

[71] Buzea et al., *supra* note 24, at MR50–51; Alex Kirby, *Tiny Particles 'Threaten Brain,'* BBC NEWS (Jan. 8, 2004), http://news.bbc.co.uk/2/hi/science/nature/3379759.stm; ANNABELLE HETT, SWISS REINS. CO., NANOTECHNOLOGY: SMALL MATTER, MANY UNKNOWNS 17 (2004), *available at* http://media.swissre.com/documents/nanotechnology_small_matter_many_unknowns_en.pdf.

[72] Rotman, *supra* note 65, at 73; Buzea et al., *supra* note 24, at MR51; Kirby, *supra* note 71.

[73] HETT, *supra* note 71, at 21.

[74] *Id.* at 22–23.

[75] Karen Florini et al., *Nanotechnology: Getting It Right the First Time*, 3 NANOTECH. L. & BUS. 39, 42 (2006).

[76] D. Maysinger et al., *Nanoparticles in Medicine*, *in* 3 OXFORD HANDBOOK OF NANOSCIENCE AND TECHNOLOGY: APPLICATIONS 503, 519 (A.V. Narlikar et al. eds., 2010); Buzea et al., *supra* note 24, at MR48.

[77] Karin S. Hougaard et al., *Effects of Prenatal Exposure to Surface-Coated Nanosized Titanium Dioxide (UV-Titan): A Study in Mice*, 7 PARTICLE & FIBRE TOXICOLOGY 16 (2010).

2. *Adverse Physical Effects and Associated Health Risks*

There are two major adverse physical effects that have been identified that may lead to human health risks associated with exposure to nanoparticles.[78] First, living tissue can be harmed from the usual (or expected) effect of nanoparticle reactivity.[79] Inside cells, nanoparticles interfere with cell signaling, causing structural damage and damage to DNA.[80] The smaller the particle, the more likely the toxicity.[81] Even if a material, like titanium dioxide, is safe at a normal size, studies have demonstrated that pulmonary toxicity increases when the particle shrinks to the nanoscale size.[82] Second, the scavenger cells that normally remove foreign substances, phagocytes, can be damaged by becoming overloaded with nanotech particles and cease to function.[83] Any foreign particles, including bacteria, that enter the body after the phagocytes are neutralized, can invade with impunity.[84]

It is not surprising, based on the relative amounts of investment in product development and investment in safety testing,[85] that there are very

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[78] *See* Jelena Kolosnjaj et al., *Toxicity Studies of Carbon Nanotubes*, *in* BIO-APPLICATIONS OF NANOPARTICLES 181 (Warren C.W. Chan ed., 2007) (presenting an excellent survey of toxicity studies). For a comprehensive and up to date summary of the most prominent experimental mechanisms of nanomaterial toxicity, see Nel et al., *supra* note 25, at 551 tbl.4.

[79] Nel et al., *supra* note 25, at 543.

[80] Jirasak Wong-Ekkabut et al., *Computer Simulation Study of Fullerene Translocation Through Lipid Membranes*, 3 NATURE NANOTECH. 363, 363, 367 (2008); CL TRAN ET AL., INST. OF OCCUPATIONAL MED., A SCOPING STUDY TO IDENTIFY HAZARD DATA NEEDS FOR ADDRESSING THE RISKS PRESENTED BY NANOPARTICLES AND NANOTUBES 15 (2005); Hisao Hidaka et al., *In Vitro Photochemical Damage to DNA, RNA and Their Bases by an Inorganic Sunscreen Agent on Exposure to UVA and UVB Radiation*, 111 J. PHOTOCHEMISTRY & PHOTOBIOLOGY 205, 212 (1997); Rosemary Dunford et al., *Chemical Oxidation and DNA Damage Catalysed by Inorganic Sunscreen Ingredients*, 418 FEBS LETTERS 87, 87–90 (1997).

[81] Qamar Rahman et al., *Evidence That Ultrafine Titanium Dioxide Induces Micronuclei and Apoptosis in Syrian Hamster Embryo Fibroblasts*, 110 ENVTL. HEALTH PERSP. 797, 797, 799 (2002); T. Uchino et al., *Quantitative Determination of OH Radical Generation and its Cytotoxicity Induced by TiO_2-UVA Treatment*, 16 TOXICOLOGY IN VITRO 629, 634 (2002); Nel et al., *supra* note 51, at 622.

[82] TRAN ET AL., *supra* note 80, at 21–23; Nel et al., *supra* note 51, at 622.

[83] Nel et al., *supra* note 25, at 550–52; Margot Lundborg et al., *Human Alveolar Macrophage Phagocytic Function is Impaired by Aggregates of Ultrafine Carbon Particles*, 86 ENVTL. RES. SEC. A 244, 252 (2001); Peter G. Barlow et al., *Reduced Alveolar Macrophage Migration Induced by Acute Ambient Particle (PM_{10}) Exposure*, 24 CELL BIOLOGY & TOXICOLOGY 243, 248–51 (2008); Buzea et al., *supra* note 24, at MR45–46.

[84] Lundborg et al., *supra* note 83, at 252; Barlow et al., *supra* note 83, at 251; Buzea et al., *supra* note 24, at MR45–46.

[85] Compared to the amount of funding for nanotech commercial applications, the amount of money spent on health and environmental risks associated with nanotech products is very small. For example, only four percent of the NNI's budget is dedicated to the health and environmental implications of this new technology. Letter from Joseph Mendelson III, Legal Dir., Int'l Ctr. for Tech. Assessment, to a Senator (Feb. 15, 2006), *available at* http://www.icta.org/doc/nano%20approp%20letter_Feb_2006.pdf.

few animal studies of the physical effects of exposure to nanoparticles.[86] One well-known study examines the effects of one form of nanoparticles called buckyballs[87] on fish.[88] Buckyballs are spherical, soccer-ball-shaped molecules containing sixty carbon molecules and are the smallest of the fullerene family.[89] Fullerenes are molecules made entirely of carbon.[90] Buckyballs are commonly used in food packaging, dietary supplements,[91] and cosmetics.[92] The exposure of the fish, here largemouth bass, caused toxic effects on the brain in the form of significant lipid peroxidation.[93] The buckyballs also killed off all the water fleas and bacteria in the water habitat containing the fish, thus negatively affecting the natural habitat.[94] Similarly, in a separate study, nanoparticles in small amounts were found to be toxic to soil bacteria.[95]

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[86] *Id.*

[87] Buckminsterfullerene (C60), called "buckyballs," was named after Richard Buckminster Fuller, the famous engineer known for the creation of the geodesic dome. *Buckyballs Could Keep Water Systems Flowing*, SCIENCEDAILY (Mar. 12, 2009), http://www.sciencedaily.com/releases/2009/03/090305080139.htm.

[88] Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C_{60}) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENVTL. HEALTH PERSP. 1058, 1058 (2004).

[89] T. Csörgő et al., Letter to the Editor, *Buckyballs and Gluon Junction Networks on the Femtometre Scale*, 30 J. PHYSICS G: NUCLEAR & PARTICLE PHYSICS L17, L17–18 (2004); H.W. Kroto et al., Letters to Nature, *C_{60} Buckminsterfullerene*, 318 NATURE 162, 162–63 (1985).

[90] Csörgő et al., *supra* note 89, at L17.

[91] LESLIE PRAY & ANN YAKTINE, INST. OF MED., NANOTECHNOLOGY IN FOOD PRODUCTS: WORKSHOP SUMMARY 739 (2009), *available at* http://www.nap.edu/catalog.php?record_id=12633; SCHULTZ & BARCLAY, *supra* note 1, at 9; Walter Derzko, *Novel, Safe Natural Food Supplement, Hydrated Fullerenes (C60-HyFn) or Water-Soluble Buckyballs Could Make 50–60% of the Riskier Synthetic Drugs and Pharmaceuticals Obsolete by 2025–30*, SMART ECONOMY (May 17, 2010), http://smarteconomy.typepad.com/smart_economy/2010/05/novel-safe-natural-food-supplement-hydrated-fullerenes-c60hyfn-or-watersoluble-buckyballs-could-make.html; *Questioning Safety Of Nanotechnology in Your Vitamins*, SCIENCEDAILY (Jan. 15, 2009), http://www.sciencedaily.com/releases/2009/01/090114114936.htm; *Nanoparticles in Dietary Supplements Cause Health Concerns, Regulatory Challenges*, SCIENCEDAILY (Feb. 10, 2009), http://www.sciencedaily.com/releases/2009/02/090209075633.htm.

[92] Bethany Halford, *Fullerene for the Face: Cosmetics Containing C60 Nanoparticles are Entering the Market even if Their Safety is Unclear*, 84 CHEM. & ENG'G NEWS 47, 47 (2006); MILLER ET AL., *supra* note 17, at 7.

[93] Oberdörster, *supra* note 88, at 1060; *see also* Emil Venere, *'Buckyballs' Have a High Potential to Accumulate in Living Tissue*, PURDUE NEWS (Sept. 18, 2008), http://news.uns.purdue.edu/x/2008b/080918JafvertBuckyballs.html (interviewing author Chad T. Jafvert who states that his recent research indicates that buckyballs have a greater chance of partitioning into fatty tissue than the banned pesticide DDT and referring to Chad T. Jafvert & Pradnya P. Kulkarni, *Buckminsterfullerene's (C_{60}) Octanol—Water Partition Coefficient (K_{ow}) and Aqueous Solubility*, 42 ENVTL. SCI. & TECH. 5945, 5946–49 (2008)).

[94] Oberdörster, *supra* note 88, at 1059.

[95] J. D. Fortner et al., *C_{60} in Water: Nanocrystal Formation and Microbial Response*, 39 ENVTL. SCI. & TECH. 4307 (2005); *Buckyballs Could Keep Water Systems Flowing*, SCIENCEDAILY (Mar. 12, 2009), http://www.sciencedaily.com/releases/2009/03/090305080139.htm; *Silver Nanoparticles May Be Killing Beneficial Bacteria in Wastewater Treatment*, *supra* note 87.

Another set of very recent, major studies[96] suggests that another form of nanoparticles, called multi-walled carbon nanotubes,[97] could be as

> For years, scientists have known about silver's ability to kill harmful bacteria and, recently, have used this knowledge to create consumer products containing silver nanoparticles. Now, a University of Missouri researcher has found that silver nanoparticles also may destroy benign bacteria that are used to remove ammonia from wastewater treatment systems.
>
> Several products containing silver nanoparticles already are on the market, including socks containing silver nanoparticles designed to inhibit odor-causing bacteria and high-tech, energy-efficient washing machines that disinfect clothes by generating the tiny particles. The positive effects of that technology may be overshadowed by the potential negative environmental impact.
>
> "Because of the increasing use of silver nanoparticles in consumer products, the risk that this material will be released into sewage lines, wastewater treatment facilities, and, eventually, to rivers, streams and lakes is of concern," said Zhiqiang Hu, assistant professor of civil and environmental engineering in MU's College of Engineering.
>
> "We found that silver nanoparticles are extremely toxic. The nanoparticles destroy the benign species of bacteria that are used for wastewater treatment. It basically halts the reproduction activity of the good bacteria."
>
> Hu said silver nanoparticles generate more unique chemicals, known as highly reactive oxygen species, than do larger forms of silver. These oxygen species chemicals likely inhibit bacterial growth. For example, the use of wastewater treatment "sludge" as land-application fertilizer is a common practice, according to Hu. If high levels of silver nanoparticles are present in the sludge, soil used to grow food crops may be harmed.

Too Much Nanotechnology May Be Killing Beneficial Bacteria, PHYSORG.COM (Apr. 29, 2008), http://www.physorg.com/news128694288.html.

[96] Vincent Castranova et al., *Persistent Pulmonary Fibrosis, Migration to the Pleura, and Other Preliminary New Findings After Subchronic Exposure to Multi-Walled Carbon Nanotubes*, NIOSH SCIENCE BLOG (Mar. 19, 2009, 10:24 AM) [hereinafter NIOSH Study], http://www.cdc.gov/niosh/blog/nsb031909_mwcnt.html (abstract published in 108 TOXICOLOGIST 457 (2009)); Craig A. Poland et al., Letters, *Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-Like Pathogenicity in a Pilot Study*, 3 NATURE NANOTECH. 423, 423–28 (2008); *Carbon Nanotubes that Look like Asbestos, Behave like Asbestos, Could Lead to Asbestos-Related Disease*, SCIENCEDAILY (May 22, 2008) [hereinafter *Carbon Nanotubes that Look Like Asbestos*], http://www.sciencedaily.com/releases/2008/05/080520144004.htm.

[97] "Discovered nearly 20 years ago, carbon nanotubes have been described as the wonder material of the 21st Century. Light as plastic and stronger that [sic] steel, they are being developed for use in new drugs, energy-efficient batteries and futuristic electronics." *Carbon Nanotubes that Look Like Asbestos*, *supra* note 96.

> Carbon nanotubes are atom-thick sheets of graphite formed into cylinders. They may be formed from a single layer of graphite or they may consist of multiple concentric layers of graphite, resulting in multi-walled carbon nanotubes. While the diameter of a nanotube can vary from a few nanometers up to tens of nanometers, they can be hundreds or even thousands of nanometers long. Carbon nanotubes come in many forms, with different shapes, different atomic

harmful as asbestos.[98] Like buckyballs, nanotubes are also part of the fullerene family as they are made entirely of carbon molecules. However, instead of being shaped like a ball, nanotubes consist of carbon atoms bonded into a tube shape, sometimes with a single wall—called single-wall carbon nanotubes ("SWCN"), or multiple walls—called multi-wall carbon nanotubes ("MWCN"). In fact, carbon nanotubes are sometimes called "buckytubes" because their ends, when closed, take the form of buckyballs.[99]

This second set of studies focused on whether carbon nanotubes have the potential to cause mesothelioma—a cancer of the lung lining that can take thirty to forty years to appear following exposure.[100] In one of these studies, published in 2008, nanoparticle material was injected into the abdominal cavity of mice—a sensitive predictor of long fiber response in the lung lining. The results showed that long, thin, multi-walled carbon nanotubes that look like asbestos fibers, behave like asbestos fibers, creating the chance that people who breathe in nanotubes could develop cancer years after exposure.[101]

> arrangements, and varying amounts and types of added chemicals—all of which affect their properties and might influence their impact on human health and the environment.

Id.

[98]

> Asbestos fibers are harmful because they are thin enough to penetrate deep into the lungs, but sufficiently long to confound the lungs' built-in clearance mechanisms for getting rid of particles. Widespread exposure to asbestos has been described as the worst occupational health disaster in U.S. history and the cost of asbestos-related disease is expected to exceed $200 billion.

Id.

> The toll of asbestos-related cancer, first noticed in the 1950s and 1960s, is likely to continue for several more decades even though usage reduced rapidly some 25 years ago. While there are reasons to suppose that nanotubes can be used safely, this will depend on appropriate steps being taken to prevent them from being inhaled in the places they are manufactured, used and ultimately disposed of. Such steps should be based on research into exposure and risk prevention, leading to regulation of their use.

Id. (quoting Anthony Seaton, professor emeritus at the University of Aberdeen, UK).

[99] *Nanotubes and Buckyballs*, NANOTECHNOLOGYNOW.COM, http://www.nanotech-now.com/nanotube-buckyball-sites.htm (last visited Nov. 5, 2011).

[100] *Id.*

[101] Poland et al., *supra* note 96, at 426–27. The lead author of the study cautions that, if nanotubes get into the sensitive outer lining of the lungs "in sufficient quantity, there is a chance that some people will develop cancer—perhaps decades after breathing the stuff." *Carbon Nanotubes that Look Like Asbestos*, *supra* note 96 (quoting Ken Donaldson).

One year later, in 2009, NIOSH completed a ground-breaking study involving mice that inhaled a small drop of liquid containing the multi-walled carbon nanotubes in a manner that closely resembles inhalation of the same material suspended in the air—similar to the exposure that a worker might encounter.[102] This study was the first to demonstrate that multi-walled carbon nanotubes aspirated by laboratory mice can actually migrate from the tiny structures in the lung called alveoli (the air sacks), which are critical for gas exchange, through the lungs to the pleura (the membrane that goes around the lungs).[103] The lungs of the mice showed persistent inflammation and fibrosis (scarring).[104] These findings are important as mesothelioma (a form of cancer) develops in the pleura after asbestos exposure and multi-walled carbon nanotubes share many of the same characteristics as asbestos.[105] This study linked up prior studies in that it showed that multi-walled carbon nanotubes can migrate from workers' lungs to the pleura.[106] The question remains whether this type of nanotube, like asbestos, will cause mesothelioma.[107] The authors of the study concluded:

> This is of considerable importance, because research and business communities continue to invest heavily in carbon nanotubes for a wide range of products under the assumption that they are no more hazardous than graphite. Our results suggest the need for further research and great caution before introducing such products into the market if long-term harm is to be avoided.[108]

According to Dr. Andrew Maynard, who is a co-author of the NIOSH study:

> This study is exactly the kind of strategic, highly focused research needed to ensure the safe and responsible development of nanotechnology . . . . It looks at a specific

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[102] NIOSH Study, *supra* note 96.

[103] *Id*.; *see also* L.M. Sargent et al., *Induction of Aneuploidy by Single-Walled Carbon Nanotubes*, 50 ENVTL. MOLECULAR MUTAGENESIS 708, 713–15 (2009) (discussing *in vitro* cell studies showing that single-walled carbon nanotubes can cause genotoxicity and abnormal chromosome number due to interference with cell division (mitosis)); Atsuya Takagi et al., *Induction of Mesothelioma in p53+/- Mouse by Intraperitoneal Application of Multi-Walled Carbon Nanotube*, 33 J. TOXICOLOGY SCI. 105, 110–14 (2008) (finding mesothelial tumors in mice after intraperitoneal injection of multi-walled carbon nanotubes).

[104] NIOSH Study, *supra* note 96.

[105] *Id*.

[106] *Id*.

[107] *Id*.

[108] Poland et al., *supra* note 96, at 423 (footnote omitted).

> nanoscale material expected to have widespread commercial applications and asks specific questions about a specific health hazard. Even though scientists have been raising concerns about the safety of long, thin carbon nanotubes for over a decade, none of the research needs in the current U.S. federal nanotechnology environment, health and safety risk research strategy address this question.[109]

Although further research is required, results presented today clearly demonstrate that, under certain conditions, especially those involving chronic exposure, carbon nanotubes can pose a serious risk to human health.[110]

As manufacturers are not required to identify the use of nanoparticles on product labels, and as it appears that manufacturers are reluctant to reveal this use voluntarily,[111] it is unknown whether carbon nanotubes are currently being used in particular food, food packaging, cosmetics, dietary supplements, or other products that are marketed for direct or indirect human consumption. However, like the buckyball, the nanotube can carry

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[109] *Carbon Nanotubes that Look Like Asbestos*, *supra* note 96 (internal quotation marks omitted).

[110] *See, e.g.*, Kolosnjaj et al., *supra* note 78, at 181 (concluding that "available data clearly show that, under some conditions, nanotubes can cross the membrane barriers and suggests that if raw materials reach the organs they can induce harmful effects as inflammatory and fibrotic reactions"); Alexandra E. Porter et al., *Direct Imaging of Single-Walled Carbon Nanotubes in Cells*, 2 NATURE NANOTECH. 713, 713, 716 (2007) (demonstrating that nanotubes can enter into cell "cytoplasm and localize within the cell nucleus, causing cell mortality in a dose-dependent manner"); Chiu-Wing Lam et al., *A Review of Carbon Nanotube Toxicity and Assessment of Potential Occupational and Environmental Health Risks*, 36 CRITICAL REV. IN TOXICOLOGY 189, 207 (2006); *see also* A. Hubbs et al., *Persistent Pulmonary Inflammation, Airway Mucous Metaplasia and Migration of Multi-Walled Carbon Nanotubes from the Lung After Subchronic Exposure*, 108 TOXICOLOGIST 457 (2009) (explaining that the fiber-like dimensions and durability of MWCNTs, as well as their ability to cause peritoneal inflammation, are reminiscent of asbestos); E. Kisin et al., *Pulmonary Response, Oxidative Stress and Genotoxicity Induced by Carbon Nanotubes*, 114 TOXICOLOGIST A793 (2010) (finding acute inflammation and interstitial fibrosis in mice exposed to carbon nanofibers); Robert R. Mercer et al., *Distribution and Persistence of Pleural Penetrations by Multi-Walled Carbon Nanotubes*, 7 PARTICLE & FIBRE TOXICOLOGY 1, 5–6 (2010) (showing that MWCNTs can have toxic effects as they frequently penetrate into both the alveollar epithelium and visceral pleura); Jürgen Pauluhn et al., *Subchronic 13-Week Inhalation Exposure of Rats to Multi-Walled Carbon Nanotubes: Toxic Effects are Determined by Density of Agglomerate Structures, not Fibrillan Structures*, 113 TOXICOLOGY SCI. 226, 226 (2010) (demonstrating reduced lung clearance in rats exposed to low mass concentrations of carbon nanotubes); Dale W. Porter et al., *Mouse Pulmonary Dose—and Time Course—Responses Induced by Exposure to Multi-Walled Carbon Nanotubes*, 269 TOXICOLOGY 136, 136–47 (2010) (observing that the long and thin structures of common carbon nanotubes and carbon nanofibres resemble asbestos fibres and migrate from pulmonary alveoli to pleural tissue which is the same site where malignant mesothelioma develops triggered by asbestos exposure).

[111] Caroline Scott-Thomas, *Food Companies Go Quiet on Nanotech Research Activity*, FOODNAVIGATOR-USA.COM (July 19, 2010), http://www.foodnavigator-usa.com/Financial-Industry/Food-companies-go-quiet-on-nanotech-research-activity.

a substance inside. Consequently, it appears possible that nanotubes may be being used in food packaging, dietary supplements, cosmetics, and sunscreens, in a similar fashion to the use of buckyballs. What is known is that carbon nanotubes have been proposed as a drug delivery device,[112] as a possible gene delivery vehicle,[113] and for use in combination with radiofrequency fields to destroy cancer cells.[114] In addition, at least one cosmetic company is exploring the use of nanotubes for cosmetics[115] and various uses for nanotubes in food and food packaging have been proposed.[116] Finally, researchers have developed a method for large-scale production of carbon nanotube filters for use in water quality improvement.[117]

3. *Presumptions of Safety*

According to toxicological principles, health risks normally correlate to the amount (or doses) to which an individual is exposed. In contrast, when evaluating health risks from exposure to nanoparticles, the concentration number and resulting total surface area predominately influence their interactions with biological systems, and are more reasonable parameters for doses of exposure.[118]

According to the EPA:

> [I]t is generally believed that nanoparticles can have toxicological properties that differ from their bulk material. A number of studies have demonstrated that

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[112] *Carbon Nanotubes that Look like Asbestos*, *supra* note 96.

[113] Ravi Singh et al., *Binding and Condensation of Plasmid DNA onto Functionalized Carbon Nanotubes: Toward the Construction of Nanotube-Based Gene Delivery Vectors*, 127 J. AM. CHEM. SOC. 4388, 4389 (2005).

[114] Christopher J. Gannon et al., *Carbon Nanotube-Enhanced Thermal Destruction of Cancer Cells in a Noninvasive Radiofrequency Field*, 110 CANCER 2654, 2654–55 (2007).

[115] Katie Schaefer, *Special Delivery: Clay Nanotubes for Skin*, COSMETICS & TOILETRIES (March 2008), http://www.cosmeticsandtoiletries.com/research/techtransfer/16119562.html.

[116] NANOBIO-RAISE, NANOTECHNOLOGY AND FOOD, *available at* http://files.nanobio-raise.org/Downloads/Nanotechnology-and-Food-fullweb.pdf (last visited Dec. 16, 2011); *see also Nanobiology: Responsible Action on Issues in Society and Ethics*, NANOBIO-RAISE, http://nanobio-riase.org (last visited Sept. 11, 2011) ("NanoBio-RAISE combines ethics research in nanobiotechnology with science communication. This interdisciplinary project brings together nanobiotechnologists, ethicists and communication specialists with the aims to anticipate the societal and ethical issues likely to arise as nanobiotechnologies develop and to use the lessons from the GM debate to respond to the probable public concerns. NanoBio-RAISE is a 6th Framework Programme Science & Society Co-ordination Action funded by the European Commission."); J.F. Graveland-Bikker & C.G. de Kruif, Review, *Unique Milk Protein Based Nanotubes: Food and Nanotechnology Meet*, 17 TRENDS FOOD SCI. & TECH. 196, 200–01 (2006) (providing an overview of potential applications of alpha-lactalbumin nanotubes in food and pharmaceuticals).

[117] *Nanotechnology's Miniature Answers to Developing World's Biggest Problems*, SCIENCEDAILY (May 12, 2005), http://www.sciencedaily.com/releases/2005/05/050512120050.

[118] *See* SCENIHR, *supra* note 54, at 22 (illustrating the importance of particle size).

> nanoparticle toxicity is complex and multifactorial, potentially being regulated by a variety of physiochemical properties such as size, chemical composition, and shape, as well as surface properties such as charge, area and reactivity. As the size of the particles decreases, a resulting larger surface-to-volume ratio per unit weight for nanoparticles correlates with increased toxicity as compared with bulk material toxicity.[119]

4. *Toxicological Screening*

To properly identify the safety risks of nanotech particles, established methods for testing normal size materials must be modified to address the unique properties of nanomaterials. Thus, the additional factors of size, shape, and surface properties will need to be examined.[120] As Günter Oberdörster explained,

> [t]here is a strong likelihood that the biological activity of nanoparticles will depend on physiochemical properties not routinely considered in toxicity screening studies. Physiochemical properties that may be important in understanding the toxic effects of test materials include particle size and size distribution, agglomeration state, shape, crystal structure, chemical composition, surface area, surface chemistry, surface charge, and porosity.[121]

A suggested strategy for screening for potential health effects is to use predictive toxicology. This method exposes cells in a culture to nanoparticles and then watches for subtle signs that the cells are starting to defend themselves.[122] A series of toxicity assays could be developed using this method that would include three key elements: "physiochemical characterization of [engineered nanomaterials], in vitro assays (cellular and noncellular), and in vivo studies."[123] According to scientists, there is a "strong likelihood that biological activity will depend on physiochemical characteristics that are not usually considered in toxicity screening

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[119] NANOTECHNOLOGY WHITE PAPER, *supra* note 58, at 78.

[120] *See* Nel et al., *supra* note 51, at 622 ("Particle size and surface area are important material characteristics from a toxicological perspective . . . . The change in the physiochemical and structural properties of engineered NM with a decrease in size could be responsible for a number of material interactions that could lead to toxicological effects.").

[121] Oberdörster et al., *supra* note 66, at 2.

[122] Nel et al., *supra* note 51, at 626 ("[P]redictive scientific model . . . focuses on target-specific, mechanism-based biological observations, rather than a descriptive approach.").

[123] *Id.*

studies."[124] Consequently,

> any test paradigm must attempt to characterize the test material with respect to size (surface area, size distribution), chemical composition (purity, crystalinity, electronic properties, etc.), surface structure (surface reactivity, surface groups, inorganic/organic coatings, etc.), solubility, shape and aggregation. This should be done at the time of [engineered nanomaterial] administration as well as at the conclusion, if possible.[125]

It is important to note that even this method could miss significant risks to health because it is very possible that, as scientific understanding grows and as new types of nanoparticles are created, new properties will be discovered that can lead to novel mechanisms of toxicity.[126] Moreover, not only should assays reflect portal-of-entry toxicity in skin, mucous membranes, and lungs, but, because of the mobility of nanoparticles, systemic responses must also be considered.

III. FDA REGULATION OF NANOTECH PRODUCTS FOR HUMAN CONSUMPTION AND THE PRESUMPTION OF BIOEQUIVALENCE

Ignoring a rapidly developing body of science to the contrary, the FDA opines that there is no scientific basis on which to conclude that "nanoscale" materials as a class are inherently more hazardous than "non-nanoscale" materials.[127] Its opinion that if the normal size material is safe, then its nanoscale counterpart is also safe is based on a now dated presumption of bioequivalence. Perhaps of even more concern, the FDA has also announced that the existing health and safety tests that it uses to assess the safety of normal size materials are "probably adequate" to assess the health effects of nanoparticles.[128] Consequently, nanotech products are being regulated exactly like their non-nanotech counterparts. The result is that manufacturers of nanotech food, dietary supplements, sunscreens, and cosmetics are not required to test their products for safety and are not required to obtain premarket approval from the FDA. The following sections describe the FDA regulation of each separate product category and explain why these regulations fail to protect public health when applied to

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[124] *Id.*

[125] *Id.*

[126] *See* SCENIHR, *supra* note 54, at 54–57 (emphasizing that critical gaps remain in the knowledge required for risk assessment purposes).

[127] U.S. FOOD & DRUG ADMIN., NANOTECHNOLOGY 11 (2007).

[128] *FDA Regulation of Nanotechnology Products*, *supra* note 23 (addressing FDA regulation of all nanoproducts).

nanotech products.

A. *Nanotech Drugs*

Under the current regulatory structure created by the Food, Drug and Cosmetic Act ("FDCA"), the FDA regulates products according to their intended use.[129] For example, products intended to treat diseases (referred to as "disease claims") or products intended to alter the structure and function of the body ("structure and function claims") are considered to be either drugs[130] or devices.[131]

> For drugs and devices, the modern FDA relies on a premarket enforcement process that places the majority of the cost and burden on the product manufacturer to establish safety and efficacy through the clinical trial process prior to distribution to the public. Without premarket approval from the FDA, these products will be deemed both adulterated and misbranded as a matter of law.[132]

The current regulatory scheme for drugs appears to be adequate to protect public health as the manufacturers bear the burden of proving that each new drug is both safe and effective for its intended use.[133] The FDA's

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[129] 21 U.S.C. § 321(g)(1)(B) (2006) (drugs); *id.* § 321(h)(2) (devices); *id.* § 321(i)(1) (cosmetics); United States v. Lane Labs-USA, Inc., 324 F. Supp. 2d 547, 567 (D.N.J. 2004) ("[T]he 'intended use' referred to within the FDCA framework contemplates 'the [objective] intent of those persons legally responsible for the labeling of drugs. . . . The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article.'") (quoting 21 C.F.R. § 201.128); *see also* United States v. Storage Spaces Designated Nos. "8" & "49," 777 F.2d 1363, 1366 (9th Cir. 1985) ("[I]ntent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source."); Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 229–30 (2009).

[130] *See* 21 U.S.C. § 321(g)(1)(B) (defining "drug" as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"); *id.* § 321(g)(1)(C) (defining "drug" also as an "article[] (other than food) intended to affect the structure or any function of the body of man or other animals"); Van Tassel, *supra* note 129, at 229–30.

[131] 21 U.S.C. § 321(h)(2); Van Tassel, *supra* note 129, at 229–31.

[132] Van Tassel, *supra* note 129, at 230 (citing 21 U.S.C. §§ 355(a) & 360e(c) (regulating drugs and devices, respectively), and Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761–76 (1996)).

[133] One new ingredient is sufficient to trigger "new drug" status. "The newness of a drug may arise by reason (among other reasons) of: (1) The newness for drug use of any substance which composes such drug, in whole or part, whether it be active substance . . . or other component." 21 C.F.R. § 310.3(h)(1) (2010). The FDA's position that "particle size does not matter" and that the safety of the large particle version of an active ingredient can be used to predict the safety of the nanoparticle version of the same ingredient appears to lead to the conclusion that the nanotech version of a preapproved bulk component is not a "new substance." This renders this section inapplicable. Section

position that "particle size does not matter" and that the safety of the large particle version of an active ingredient can be used to predict the safety of the nanoparticle version of the same ingredient is less important in this context. A drug with an entirely new normal size ingredient must go through the premarket approval process. Similarly, if a drug that already has FDA approval is modified to add nanoparticles, even if the modified drug is being marketed to treat the same condition or disease, it will become a "new drug" because the proportion of the ingredients to each other will change.[134] In other words, the formula for the amount of each ingredient used to make the drug will change. Any change in the formula will cause the drug to be labeled a "new drug" which will trigger the pre-market approval process. All "new drugs" require testing for safety and effectiveness and premarket approval[135] from the FDA.[136] In addition, as the status of the nanotech version of the drug will change to that of a "new drug," notice of the fact that the drug is using a new formula will be provided to the physicians who are prescribing the new drug to their patients. The physicians must disclose any material health risks associated with the new drug.

On the other hand, the FDA's position that "particle size does not matter" is outcome determinative when it comes to devices. A pacemaker

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310.3 should be modified to include a section that renders a drug "new" if the mechanism of action of the drug is different. This would then trigger "new drug" status as the addition of nanoparticles to a drug is likely to change its mechanism of action.

[134] "New drug substance means any substance that when used in the manufacture, processing, or packing of a drug, causes the drug to be a new drug." *Id.* § 310.3(g). A substance can cause a drug to be considered a "new drug" if the proportion of one of the substances that is used in relation to the other ingredients, is new. *Id.* § 310.3(h)(3) ("The newness of a drug may arise by reason (among other reasons) of: . . . (3) The newness for drug use of the proportion of the substance in a combination, even though such combination containing such substance in other proportion is not a new drug."). Even if the FDA opines that the nanotech version of a preapproved bulk component is not a different component as they are bioequivalent, the proportion of the nanotech component to the other components of the drug will be different rendering it a "new drug" and triggering the pre-market approval process. *See id.*

[135] "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the FDA] is effective with respect to such drug." 21 U.S.C. § 355(a).

[136] A "new drug" is

> [a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . or . . . [a]ny drug . . . as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used in a material extent or for a material time under such conditions.

Id. § 321(p)(1)–(2).

that already has undergone testing for safety and effectiveness will not need to be retested and undergo the FDA approval process again if it is modified to use nanoparticles in its design. This is because, unlike nanotech drugs, the nanotech device is likely to perform in the same way as the preapproved non-nanotech version. The FDA's position is that the two versions of the pacemaker are bioequivalent. On the other hand, devices are of less concern to public health than products that use free nanoparticles because devices are likely to contain nanoparticles that are fixed inside a solid matrix, which makes them less likely to move into the environment or the human body.

B. *Nanotech Food*

Unlike drugs and devices, traditional food products have their own special place in the FDA's regulatory structure as they can be placed directly upon the market without undergoing any testing for safety.[137] Government has little need to provide regulatory protection for consumers, "as thousands of years of use of traditional food provides consumers with the common knowledge, and thus the ability, to protect themselves from the ordinary risks associated with different traditional food products."[138] This common knowledge and ability to self-protect supports the presumption of safety that is granted to traditional food under the FDCA. If a particular food poses a safety risk over and above those which are normally associated with a food product, such as salmonella in peanut butter, the FDA carries the burden of proving that the food is adulterated or misbranded before it can be removed from the market.[139]

With the introduction of free nanoparticles to food, this rationale for minimal FDA regulation no longer holds true. Food and agricultural industries see opportunities to use nanoparticles for "more potent food colourings, flavourings and nutritional additives, antibacterial ingredients for food packaging, and more potent agrochemicals and fertilisers."[140] Nanoparticle additives are now found in sodas, dairy products, margarine, and sausages.[141] There is also wide use in food and beverage packaging of "nanoclay composites—plastics to which nanoscale clay platelets have been added . . . ."[142] These nanoclay composites are also being used "in agriculture pipes and plastics to allow controlled release of

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[137] Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1651 (2004).

[138] Van Tassel, *supra* note 129, at 230.

[139] Van Tassel, *supra* note 137, at 1651.

[140] MILLER & SENJEN, *supra* note 15, at 4.

[141] *Id.* at 9.

[142] *Id.* at 4.

herbicides . . . ."[143] Analysts of the uses of nanotechnology in food estimate that more than six hundred food products contain nanoparticle additives.[144] In addition, between four hundred and five hundred foods have nanoparticle packaging, raising concerns regarding the migration of nanoparticles from the packaging into the food.[145]

1. *Nanotech Food Additives*

In the mid-twentieth century, there was an explosion in the growth of the food processing industry with a parallel increase in the number and variety of chemicals added to food.[146] In response to consumer concern over this increase in the number of new chemicals introduced into the food supply and an enhanced concern over rising cancer rates, Congress passed the Food Additives Amendment Act of 1958 ("FAAA").[147] The FAAA places the burden of proof on the manufacturers, rather than on the FDA, to show that a newly discovered substance added to food is safe if used within specified quantities.[148] This change fixed a major flaw in the 1938 FDCA that had originally placed the burden of proof on the FDA to prove that a food additive was unsafe.[149] Until the passage of the FAAA, the food industry could market potentially injurious chemical additions to the consuming public without interference from the FDA.[150] According to current FDA regulations, if substances added to food are "food additives," premarket testing for safety is required.[151] If a normal size version of a food additive has premarket approval, a modification using nanoparticles will also have approval as the FDA states that these two versions are bioequivalent.

The exception to this rule is when a food additive is generally regarded

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[143] *Id*.

[144] Stephen Daniells, *Think Big, Think Nano*, FOODNAVIGATOR.COM (Dec. 19, 2007), http://www.foodnavigator.com/Science-Nutrition/Think-big-think-nano.

[145] MILLER & SENJEN, *supra* note 15, at 10.

[146] Van Tassel, *supra* note 129, at 213–15.

[147] Joseph A. Levitt, *Keeping America's Food Supply Safe*, *in* FDA: A CENTURY OF CONSUMER PROTECTION 135, 140 (Wayne L. Pines ed., 2006).

[148] *Id.*

[149] *Id.*

[150] *Id.*

[151] A "food additive" is "any substance the intended use of which results . . . in it becoming a component or . . . affecting the characteristics of . . . food," unless the substance is generally regarded as safe (GRAS). 21 U.S.C. § 321(s) (2006). In response to the public's concern over the steadily increasing amounts of chemicals added to food as food processing technology developed, Congress enacted the Food Additives Amendment of 1958. Pub. L. No. 85-929, 72 Stat. 1784. The Food Additives Amendment established a pre-market approval requirement for "food additives." This placed the burden on the food processor to establish, through scientific methodology, that the additive was safe for its intended use before placing the food additive on the market. *Id.* This is referred to as the pre-market approval process.

as safe or "GRAS."[152] A substance is considered to be GRAS if there is a general consensus among informed experts that a substance is safe for human consumption.[153] If a substance added to food is considered to be GRAS, it will not require pre-market approval.[154] Examples are salt and sugar. The nanoparticle version of an already approved food additive also falls into this exception as the FDA's position on bioequivalency means that the safety of the normal size version is predictive of the safety of the nano scale version.

C. *Nanotech Dietary Supplements*

Congress passed the Dietary Supplement Health Education Act ("DSHEA") in 1994.[155] DSHEA was a victory to dietary supplement manufacturers who have claimed for decades that their products should be regulated like food.[156] By virtue of DSHEA, like traditional food, dietary supplements can now be placed directly on the market without any testing under a completely unsupported presumption of safety.[157] The term

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[152] 21 U.S.C. § 321(s).

[153] *Id.*

[154] A substance added to food is not a food additive and, therefore, does not require pre-market approval if it is "GRAS." *Id.* A substance that is "GRAS" is defined as a substance that is

> generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

Id.

[155] Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U.S.C.). Under DSHEA, a dietary supplement is,

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E) . . . .

21 U.S.C. § 321(ff)(1); *see also* Van Tassel, *supra* note 129, at 239–41.

[156] Van Tassel, *supra* note 129, at 231–41.

[157] 21 U.S.C. § 321(s) (detailing the exemption from food additive provisions); Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1035 (10th Cir. 2006). This exemption covers dietary supplements that carry labels with "statements of nutritional support" and statements explaining how a supplement may *maintain* or *improve* the "structure and function" of the body. 21 U.S.C. § 321(g); *see also id.* § 343(r)(6) (allowing substantiation and disclaimer for structure and function claims); 27 C.F.R. § 101 (2010). A dietary supplement can also include on its label a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(r)(6)(A). Not only are dietary supplements cloaked with a

"dietary supplement" now encompasses both nutritional and non-nutritional substances by including not only vitamins, minerals, and amino acids, but also herbs or other botanicals which have no nutritional value.[158] Under the FDCA, the only way that the FDA can remove a dietary supplement from the market is to prove that it is adulterated by demonstrating that the product poses a "significant or unreasonable risk of illness or injury."[159]

1. *New Ingredients in Dietary Supplements*

DSHEA does provide the FDA with very limited premarket review power for a "new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."[160] A dietary ingredient is defined as "new" if it was not on the market before October 15, 1994 when DSHEA was passed.[161] A new ingredient will be deemed to be adulterated if there is no history of use or "other evidence of safety."[162] The manufacturer must give the FDA seventy-five days notice prior to marketing and must provide the FDA with information indicating that the ingredient is reasonably expected to be safe.[163] Alternatively, the manufacturer may file a petition seeking an order from the FDA detailing the conditions under which the dietary ingredient will reasonably be expected to be safe.[164]

Under this system, if the FDA announces that all nanoparticles used in dietary supplements are "new" ingredients, the manufacturers who are currently distributing nanotech products must halt distribution for seventy-five days, must give the FDA seventy-five days notice that they plan to place their dietary supplement on the market, and must provide the FDA

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baseless presumption of safety, as if they were similar to traditional food, but DSHEA (as applied by the FDA) also grants an equally unwarranted presumption that dietary supplements for weight loss are effective as claimed. *See Nutraceutical Corp.*, 459 F.3d at 1039 n.5 ("The district court compared the language of DSHEA to the statutory language governing medical devices and drugs and concluded that, unlike manufacturers of medical devices and drugs, manufacturers of dietary supplements do not need to prove effectiveness prior to taking their product to market."); Van Tassel, *supra* note 129, at 240.

[158] However, dietary supplements do not include products that contain any other active ingredients such as synthetic ingredients that are regulated as over-the-counter medications or prescription drugs. Dietary Weight Loss Supplements: Limited Federal Oversight has Focused more on Marketing than on Safety: Before the Subcomm. on Oversight of Gov. Management, Restructuring, and the Dist. of Columbia, Comm. on Gov. Affairs, U.S. Senate, 1 (July 31, 2002) (statement of Janet Heinrich, Director, Health Care—Public Health Issues, U.S. Gen. Accounting Office); Van Tassel, *supra* note 129, at 239–41.

[159] *Nutraceutical Corp.*, 459 F.3d at 1035 (quoting 21 U.S.C. § 342(f)(1)).

[160] 21 U.S.C. § 342 (f)(1)(B).

[161] *Id.* § 350b(c).

[162] *Id.* § 350b(a).

[163] *Id.*

[164] *Id.* § 350b(b).

with the information that supports their position that the nanotech ingredient is reasonably safe.[165] However, unless the FDA can meet its burden of proof that "there is inadequate information to provide a reasonable assurance that such ingredient does not provide a significant or unreasonable risk of illness or injury," the manufacturer may automatically start to market its nanotech product seventy-five days after it provided the FDA with notice.[166] As the Ephedra case, discussed *infra* in Section IV.B, demonstrates, it is unlikely that the FDA will be able to meet this burden of proof until the risks associated with nanoparticles can be quantified using classic probability analysis.

D. *Nanotech Cosmetics*

Cosmetics[167] should be considered to be products that are marketed for human consumption as they are absorbed into the body indirectly through the skin when applied and are absorbed through the lungs as a result of the aspiration of aerosolized particles when washing off the cosmetic. Nanoparticles can be found in most personal care products including soap, deodorant, shampoo, hair conditioner, toothpaste, moisturizer, foundation, blush, lipstick, eyeshadow, perfume, nail polish, and after-shave lotion.[168] Manufacturers who use nanoparticles in their products include L'Oréal, Revlon, Estée Lauder, Chanel, Procter and Gamble, Beyond Skin Science LLC, SkinCeuticals, Dr. Brandt, Dermazone Solutions, and Shiseido, among many others.[169] Nanotech cosmetics that are rubbed onto the skin contain nanoparticles 1000 nm in size that are capable of absorption through intact skin.[170] When the skin is damaged, for example through blemishes, sun burn, eczema, shaving cuts, or other trauma, nanoparticles up to 7000 nm can penetrate the skin.[171] In fact, many nanotech cosmetics and sunscreens are especially formulated to be used on damaged skin. And an as yet unanswered question is what impact the "penetration enhancers"

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[165] SCHULTZ & BARCLAY, *supra* note 1, at 17.

[166] *Id.*

[167] The term "cosmetic" means

> articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and . . . articles intended for use as a component of any such articles; except that such term shall not include soap.

21 U.S.C. § 321(i).

[168] *See* MILLER ET AL., *supra* note 17, at 18–26 (listing 116 products that contain nanoparticles).

[169] *Id.* at 14.

[170] Rouse & Yang, *supra* note 68; Tinkle et al., *supra* note 68, at 1202–03.

[171] Oberdörster et al., *supra* note 68, at 834.

that many cosmetic products use will have on this analysis.[172]

However, nanotech cosmetics are not required to be tested for safety because products that are intended to be used as cosmetics do not require premarket testing under the FDCA.[173] This treatment is a result of the belief held when the FDCA was first enacted that cosmetics were low-risk products because they are only spread onto the surface of the skin to improve attractiveness. That incorrect regulatory assumption persists today. In fact, Friends of the Earth has noted that "[a]lthough the FDCA has a lot of language devoted to cosmetics, it is not too much of an exaggeration to say that cosmetics in the USA are essentially unregulated."[174] Of the 10,500 normal size ingredients used in cosmetic products, only thirteen percent have been assessed for safety by the industry-funded Cosmetics Industry Review Panel.[175] The FDA can only remove an unsafe cosmetic from the market if the FDA can prove that the cosmetic is adulterated because "it bears or contains a poisonous or deleterious substance which may render it injurious" to users.[176]

E. *Nanotech Sunscreens*

Sunscreens fall into the "drug"[177] category as their intended use is to protect the skin from harm from the sun.[178] As a result, sunscreens, like other drugs, require pre-market testing for safety and effectiveness.[179] Consequently, sunscreens that are currently on the market have obtained FDA approval for human use.[180] The chemicals zinc oxide and titanium oxide have been major components in sunscreens for a long period of time.[181] The use of these chemicals in sunscreens has been screened for safety by the FDA and subsequently approved for use.[182]

The FDA has gone one step further and approved the use of sunscreens

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[172] *Nanotechnology & Sunscreens*, *supra* note 68, at 8.

[173] *Nanotechnology Consumer Products Inventory*, *supra* note 11, at 15.

[174] *Id.*

[175] *Frequently Asked Questions: Why Should I Be Concerned About the Safety of Personal Care Products? Doesn't the Government Regulate Them?*, ENVTL. WORKING GRP., http://www.ewg.org/skindeep/faq/ (last visited Nov. 26, 2011) ("On average, consumers use about 10 personal care products containing 126 ingredients per day. The Cosmetics Ingredients Review (CIR), the industry's self-policing safety panel, does not make up for FDA inaction. In 2007 EWG analysis found that over 30 years, the industry panel has reviewed the safety of just 13% of the 10,500 ingredients in personal care products.").

[176] 21 U.S.C. § 342(a)(1) (2006).

[177] *Id.* § 321(g)(1)(B).

[178] Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 58 Fed. Reg. 28194, 28195 (May 12, 1993).

[179] *See supra* Section III.A.

[180] *See* Final Monograph, *supra* note 48.

[181] *Id.*

[182] *Id.*

with these chemicals without a doctor's prescription so that consumers can purchase them over-the-counter without a doctor's prescription.[183] This over-the-counter ("OTC") status is achieved by giving each active component of the sunscreen "monograph" status.[184] In order to be placed in the OTC category, each active component is reviewed for use for safety and effectiveness by the FDA. The successful outcome of this review results in a regulation for each substance that is called a "monograph."[185] Sixteen active ingredients in sunscreens have monograph status, including zinc oxide and titanium oxide.[186]

A short-coming of zinc oxide and titanium oxide for the image-conscious user is that they make the sunscreen appear white and pasty due to a large amount of scattering of light from the particles.[187] The use of the engineered nanoparticle version of zinc oxide and titanium oxide has resolved these problems as they make the sunscreen "cosmetically clear" and easy to smooth onto the skin.[188] Seventy percent of the sunscreens that use titanium dioxide use engineered nanoparticles.[189] Thirty percent of sunscreens that use zinc oxide use engineered nanoparticles.[190]

The monograph that approves of the use of zinc oxide and titanium oxide does not expressly address sunscreen drug products that contain the nanoparticle version of these chemicals. However, the FDA states that it is aware that sunscreens are being marketed with nanoparticles.[191] In addition, in the sunscreen monograph, the FDA explains that:

> The agency is aware that sunscreen manufacturers are using micronized titanium dioxide to create high SPF products that are transparent and esthetically pleasing on the skin. The agency does not consider micronized titanium dioxide to be a new ingredient but considers it a

[183] *See* 21 C.F.R. § 330.10(a)(7)–(10) (2011) (allowing these sunscreens to be sold over-the-counter).

[184] Sunscreen Drug Products for Over-the-Counter Human Use, 43 Fed. Reg. 38206–07 (Aug. 25, 1978).

[185] *Id*. at 38207.

[186] *See* Final Monograph, *supra* note 48, at 27673.

[187] *Nanotechnology & Sunscreens*, *supra* note 68, at 3.

[188] *Id.* at 2.

[189] DEP'T OF HEALTH & AGEING, AUSTL. GOV'T, SAFETY OF SUNSCREENS CONTAINING NANOPARTICLES OF ZINC OXIDE OR TITANIUM OXIDE (2006), *available at* http://www.benev.com.tr/page/downloadfile.php?file=13.

[190] *Id*.

[191] Final Monograph, *supra* note 48, at 27676.

> specific grade of the titanium dioxide originally reviewed by the Panel.[192]

While it is not clear whether the FDA intended to include nanoparticles in its definition of "micronized," these monograph statements parallel the more general statements that the FDA has made in the context of nanoparticles that "particle size is not the issue."[193]

IV. FLAWS IN THE CURRENT FDA REGULATION OF NANOTECH PRODUCTS FOR HUMAN CONSUMPTION

A. *FDA Regulations on Ingredient Labeling*

The FDA takes the position that there is no need for labeling on products for human consumption that contain nanomaterials. Under the FDCA, a drug, device, food, dietary supplement, cosmetic, or sunscreen is deemed misbranded if its labeling is "false or misleading in any particular."[194]

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading . . . there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, *but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations* or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising relates under the conditions

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[192] *Id.* at 27671. The FDA explains that "micronized" simply refers to "a refinement of particle size distribution." *Id*. And that its position on bioequivalence is based on the fact that "fines" have been a part of titanium dioxide powders for decades. *Id.*; *see also Frequently Asked Questions on OTC Drugs*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069917.htm The FDA goes on to state that it was not "aware of any evidence at this time that demonstrates a safety concern from the use of micronized titanium dioxide in sunscreen products." Final Monograph, *supra* note 48, at 27671.

[193] *See supra* notes 127–28 and accompanying text (discussing the fact that the FDA does not see a scientific basis for the conclusion that nanoscale materials are any more inherently hazardous than non-nanoscale materials as well as the fact that the FDA announced that its existing health and safety tests are adequate assessors of health effects of nanoparticles).

[194] 21 U.S.C. § 362(a) (2006); *see also* 21 C.F.R. § 701.1 (2011).

> of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.[195]

The FDA opines that product ingredient lists that refer to nanomaterial content by the same name as the normal size material counterpart are not false and misleading as there is no scientific basis on which to conclude that nanoscale materials as a class are inherently more hazardous than non-nanoscale materials. Thus, the FDA has taken the position that the fact that a product marketed for direct and indirect human consumption contains nanomaterials is not material and need not be disclosed on labels.

1. *Labeling, Notice, Distributional Justice, and Accountability*

Because nanotech ingredients are not listed on food, dietary supplements, cosmetic, or sunscreen labels, a consumer cannot choose to avoid products that contain nanotech ingredients. And yet, if there is an injury, who will bear the cost of the loss? Decision Analysis teaches that there are two significant types of error that can be made when dealing with scientific uncertainty. A type I error, also called an α error or an error of the first kind, occurs "if society regulates an activity that appears to be hazardous, but turns out later to be harmless (a 'false positive' in the parlance of experimental findings) and resources are needlessly expended."[196] A type II error, also referred to as a β error or an error of the second kind, occurs "if society fails to regulate an activity because the evidence is not initially thought to be strong enough, but that finally turns out to be harmful (a 'false negative')."[197] In the case of nanotech food, dietary supplements, cosmetics, and sunscreens, when a type I error occurs, the cost of that error is absorbed by the companies who produce the nanotech products. That cost, in turn, is shifted onto those consumers who purchase the products.

In contrast, when a type II error occurs, the cost is left squarely on the shoulders of those consumers who suffer a toxic injury from the consumption of a nanotech food, dietary supplement, cosmetic, or sunscreen. This result follows from the inability of the consumer to recover for those injuries under the tort system. The principle reasons for

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[195] 21 U.S.C. § 321(n) (emphasis added); *see also id.* § 331(a) (prohibiting the introduction into commerce of any food, device, or cosmetic that is misbranded); *id.* § 343(a) (stating that foods are misbranded if their labeling is "false or misleading in any particular"); *id.* § 352(a) (stating that drugs and devices are misbranded if their labeling is "false or misleading in any particular"); *id.* § 362(a) (stating that cosmetics are misbranded if their labeling is "false or misleading in any particular").

[196] Nicholas A. Ashford, *The Legacy of the Precautionary Principle in US Law: The Rise of Cost-Benefit Analysis and Risk Assessment as Undermining Factors in Health, Safety and Environmental Protection*, *in* IMPLEMENTING THE PRECAUTIONARY PRINCIPLE: APPROACHES FROM THE NORDIC COUNTRIES, EU AND USA 352, 369 (Nicolas de Sadeleer ed., 2007).

[197] *Id.*

this result are three-fold. First, as nanotech ingredients are not required to be listed on product labels, the consumer will not know that she was exposed to a nanotech ingredient. Thus, the consumer is unlikely to suspect that her injuries were caused by a novel substance.[198] Moreover, many of the health effects from toxic exposures are cumulative and generally do not appear for decades. Second, if the consumer learns that a nanotech ingredient was the cause of her injury, she will be required to establish fault under tort law by showing that the manufacturer could have foreseen the risk of harm.[199] As with many new technologies, the rate of the introduction of nanotech products into the market has far out-paced the science needed to demonstrate its associated risks. Under either the *Daubert* or *Frye* tests, this research lag acts to insulate a manufacturer from liability based on a lack of causation[200] and foreseeability.[201]

The final hurdle arises in the context of both negligence and strict liability claims. Unless the consumer can establish that she is a member of a substantial class of people who are at risk for the same type of adverse reaction, the case is likely to be dismissed under what is commonly referred to as the "idiosyncratic plaintiff defense."[202] This "*de minimus* harm" liability threshold can range from tens of thousands to millions of people.[203] Compounding this problem, as nanotech ingredients in food, dietary supplements, cosmetics, and sunscreens are unlabeled, injured consumers are unlikely to recognize what actually caused their injuries. As a result, these injuries will go unreported. Without this data, a consumer will be unable to establish that she is a member of a substantial class, creating an almost impassable barrier to recovery.[204] Even if the products were labeled, and a data collection system was established, it could be years before enough people were injured to reach the large threshold numbers expected under the burden of production created by this defense.[205]

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[198] Van Tassel, *supra* note 137, at 1681.

[199] *Id.* at 1683–84.

[200] Under the *Daubert* and *Frye* standards, evidentiary principles are likely to bar any introduction of scientific evidence to meet the burden of proof on causation as long as there is scientific uncertainty. Daubert v. Merrell Dow Pharm., Inc. 509 U.S. 579, 589 (1993); Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923). The *Daubert* factors counsel judges to ask the following questions in making decisions on the admissibility of scientific evidence: (1) Has the technique been tested in actual field conditions (and not just in a laboratory)?; (2) Has the technique been subject to peer review and publication?; (3) What is the known or potential rate of error? Is it zero, or low enough to be close to zero?; (4) Do standards exist for the control of the technique's operation?; and, (5) Has the technique been generally accepted within the relevant scientific community? *Daubert*, 509 U.S. at 580.

[201] Van Tassel, *supra* note 137, at 1683–84.

[202] *Id.* at 1680, 1683–84. This defense is basically a contention that a reasonable consumer would not have had the reaction and that the defect is in the consumer, not the product. *Id.*

[203] *Id.*

[204] *Id.*

[205] *Id.* at 1682–84.

The bottom line under the current system is that the personal injury costs associated with a type II error will be borne by innocent consumers and not the food, dietary supplements, cosmetics, and sunscreen manufacturers who reap the profits from product sales. This disconnect results in a morally suspect outcome under principles of distributive justice that counsel that one ought to act in such a manner that no one person or group bears a disproportionate share of benefits or burdens.

B. *Placing the Burden of Proof on the FDA*

An example of the implications of placing the burden of proof for safety on the FDA to prove that nanotech food, dietary supplements, and cosmetics are unsafe and ineffective is the case of a product called Ephedra, a dietary supplement which contained ephedrine-alkaloid ingredients.[206] Ephedrine alkaloids occur naturally in some plants, work as stimulants and fall into the same category as the street drug referred to as "Speed."[207] Products containing ephedrine alkaloids were marketed as dietary supplements for weight loss and to enhance sports performance.[208] Over time, the FDA began receiving adverse event reports ("AERs") from consumers which included numerous complaints of heart attacks, strokes, seizures, and deaths associated with the consumption of products containing ephedrine alkaloids.[209] One of the most highly-publicized cases of a fatal consequence from the use of ephedrine alkaloids in a dietary supplement was the death of Steve Belcher, a twenty-three-year-old baseball player with the Baltimore Orioles.[210]

In order to meet its burden of proof, the FDA took seven years to gather sufficient evidence on the safety of ephedrine alkaloids. The FDA compiled an administrative record of 130,000 pages, 19,000 AERs, and engaged in extensive notice and comment before it passed a regulation banning the sale of products containing ephedrine alkaloids in 2004.[211] In this final rule, the FDA stated that "[t]he best clinical evidence for a benefit . . . supports only a modest short-term weight loss, insufficient to positively affect cardiovascular risk factors or health conditions associated

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[206] Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1036 (10th Cir. 2006).

[207] Barry A. Palevitz, *Harmless Energizers or Dangerous Drugs?*, SCIENTIST, Dec. 9, 2002, at 18, 18–19 ("Ephedrine is a close relative of amphetamine, sometimes called benzedrene. A little chemical tinkering creates the street drugs methamphetamine and Ecstasy.").

[208] *Nutraceutical Corp.*, 459 F.3d at 1036.

[209] *Id.*

[210] FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 57 (2005).

[211] *Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk*, 69 Fed. Reg. 6788 (Feb. 11, 2004) [hereinafter *Final Rule*]; *Nutraceutical Corp.*, 459 F.3d at 1036.

with being overweight or obese."[212] The manufacturer of Ephedra filed suit, arguing that the FDA had failed to meet its burden of proof of showing that products containing ephedrine alkaloids were unsafe.[213] The district court found for the manufacturer; however, in 2006, the FDA prevailed on appeal.[214] The total time and expense involved in this process, including the cost of the harm suffered by consumers, was tremendous.[215]

The rising concern that the FDA has been unable to keep pace with emerging science and technology magnifies the problem of placing the burden of proof for safety on the FDA. In 2006, the Commissioner of the FDA requested that the FDA's Science Board appoint a Subcommittee on Science and Technology. The assigned task of this thirty-three-member subcommittee was to evaluate "whether [the] FDA's scientific and technological infrastructure could support current and future regulatory needs."[216] In November of 2007, the subcommittee issued its report with the unanimous approval of the panel members.[217] The report "identified serious deficiencies in the present system, including too few scientists who understand emerging science and technology, a flawed system for regulating imports into the United States and an information infrastructure that was deeply flawed and unable to support various areas in the agency."[218] In its 2008 report in response to the request of Representatives Dingell, Waxman, Stupak, and Pallone, the subcommittee noted that

> the capacity of science to support the FDA mission is dangerously constrained from the effects of a long period of expanding Agency mandates and responsibilities, chronic under funding, the extraordinary advance of scientific discoveries, the complexity of new products and claims submitted to the FDA for premarket approval, the emergence of challenging safety problems, and the globalization of the industries that the FDA regulates.[219]

The report noted that "there is insufficient capacity in modeling, risk

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[212] *Nutraceutical Corp.*, 459 F.3d at 1036–37.

[213] *Id.* at 1043–44.

[214] *Id.* at 1038–39.

[215] *Final Rule*, *supra* note 211.

[216] SCHULTZ & BARCLAY, *supra* note 1, at 20.

[217] U.S. FOOD & DRUG ADMIN., FDA SCIENCE AND MISSION AT RISK; REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY 7 (Nov. 2007) [hereinafter FDA SCIENCE AND MISSION AT RISK], *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

[218] SCHULTZ & BARCLAY, *supra* note 1, at 20.

[219] SCHULZ & BARCLAY, *supra* note 1, at 20 (referencing FDA SCIENCE AND MISSION AT RISK, *supra* note 217).

assessment and analysis" and that the "FDA['s] science agenda lacks a coherent structure and vision, as well as effective coordination and prioritization."[220] The report concluded that the FDA "cannot fulfill its mission because its scientific base has eroded, its scientific workforce does not have sufficient capacity and capability and its information technology infrastructure is inadequate."[221]

C. *Testing For Safety*

The past decade has elevated the level of scientific understanding of the health risks associated with nanoparticles from ignorance to indeterminacy. Scientists now know what they do not know about health risks and are able to plan the tests to discover those risks. The FDA can no longer ignore this large body of science and should begin the process of toxicological screening using predictive toxicology. Only then will the FDA have the body of evidence that it needs to meet its burden of proof under the current system to show that the nanotech products marketed for direct and indirect human consumption are unsafe and should be removed from the market.

D. *Ingredient Labeling and the Discovery of New Toxicants*

As a public health matter, the reality is that scaling up testing to a reasonable level, even with the use of predictive toxicology, will only detect a portion of all the potential toxicants associated with nanoparticles. There are two basic reasons for this conclusion. First, the science for testing for health risks of nanoparticles is in its infancy.[222] Second, additional significant risks to health may materialize because it is probable that, as scientific understanding grows and as new types of nanoparticles are created, new properties will be discovered that can lead to novel mechanisms of toxicity.[223]

As a result, many toxicants created by nanotech products will not be identified until after the product is introduced into the market and is exposed to the vast genetic diversity of the population. Over time, this exposure will reveal the type, severity, and statistical probability of any associated adverse reactions. For example, the drug industry regularly introduces novel substances into the general population recognizing that this is the only method that can fully identify the statistical probability of

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[220] SCHULZ & BARCLAY, *supra* note 1, at 20 (referencing FDA SCIENCE AND MISSION AT RISK, *supra* note 217, at 30, 33).

[221] SCHULZ & BARCLAY, *supra* note 1, at 20 (referencing FDA SCIENCE AND MISSION AT RISK, *supra* note 217, at i).

[222] Nel et al., *supra* note 51, at 626–27.

[223] SCENIHR, *supra* note 54, at 4.

adverse reactions.[224] This is because the clinical trials mandated by the FDA to establish premarket safety are fairly small and can have relatively low statistical power.[225] Consequently, even after FDA testing, serious adverse effects were not detected for approximately one-half of drugs on the market until after the drugs received regulatory approval and were made available to the general population.[226]

Thus, there is a regulatory recognition that premarket testing will not detect many adverse reactions when novel substances are distributed to the general population for use as drugs. For this reason, a very limited post-market surveillance system is in place to collect at least some data from some portions of the general population on their negative experiences with new drugs.[227] After the spate of highly-publicized drug withdrawals,[228] including Vioxx, this tracking system is being updated and strengthened.[229] Comparably, a system that pairs premarket safety testing with a post-market surveillance should be created as a pre-condition for the introduction of other novel, man-made substances into the market, such as nanotechnology used in consumer products that are absorbed by the body.

As the system exists today, there is no mechanism for public health officials to monitor whether nanotech products marketed for direct and indirect human consumption are triggering toxic reactions. The vast majority of consumers are unaware of the extent of their exposure to novel nanotech substances in spite of the extraordinary yearly growth in the national and global production of nanotech products. Consequently, it is currently highly unlikely that many of the health risks from this exposure can be identified and eliminated. For example, if a consumer uses a nanotech product and has a toxic reaction, the consumer will assume that the reaction is to the product itself, not an exposure to the nanoparticle ingredient. The only result is that the consumer will avoid that particular product in the future. A mild reaction will not merit a visit to a physician and will go unreported. If the reaction is moderate to severe, a physician may be consulted. However, there is no mandatory physician reporting of adverse effects to this type of product. And even if the physician has the time and inclination to report the adverse reaction, it will be incorrectly

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[224] Kevin Bullis, *Screening for Toxic Nanoparticles: Researchers Suggest a Strategy That Could Weed Out Dangerous Nanoparticles*, TECH. REV. (Feb. 7, 2006), http://www.technologyreview.com/NanoTech-Devices/wtr_16296,303,pl.html.

[225] Shelby D. Reed et al., *Use of Larger Versus Smaller Drug-Safety Databases Before Regulatory Approval: The Trade-Offs*, 27 HEALTH AFF. 360, 360–61 (2008).

[226] *Id.* at 366–67.

[227] Rena Steinzor & Margaret Clune, *The Hidden Lesson of the Vioxx Fiasco: Reviving a Hollow FDA*, CPR WHITE PAPER #514 (Center for Progressive Reform, Washington, D.C.), Oct. 2005, at 19, *available at* http://www.progressivereform.org/articles/Vioxx_514.pdf.

[228] Henry A. Waxman, *The Lessons of Vioxx—Drug Safety and Sales*, 352 NEW ENG. J. MED. 2576, 2576–78 (2005); Steinzor & Clune, *supra* note 227, at 1.

[229] Steinzor & Clune, *supra* note 227, at 19.

reported as a reaction to the particular product based on the information given by the patient, not to its nanotech content. And even if there was mandatory reporting, who would collect the report? The Centers for Disease Control and Prevention ("CDC") is neither required nor is set up to collect or monitor this type of data. Finally, some of the adverse health effects to nanotech toxicants may be delayed or latent (such as an increased occurrence of cancer). This lag time means that some long-term, serious adverse effects may not be connected to the nanoparticle exposures until a considerable period of time has passed.

Overall, as a public health matter, it appears that data collection for nanoparticle exposure should proceed in a manner that is similar to that which is used for other types of biologically active novel chemicals introduced into the market for absorption into the human body, such as drugs.

V. PROPOSALS FOR RESTRUCTURING THE REGULATION OF NANOTECH PRODUCTS FOR HUMAN CONSUMPTION

There are several steps that must be taken in order to update the FDA's regulation of nanotech products intended for human consumption to protect human health while supporting innovation. Drugs, food additives, and sunscreens already require premarket testing for all new chemicals. Consequently, the regulatory changes necessary to protect public safety will take less effort overall with these categories of products than the work that will be necessary in order to pass the new legislation that will be required in cases of dietary supplements and cosmetics.

A. *Drugs, Food Additives, and Sunscreens*

1. *FDA Acknowledgment That Nano Means Fundamentally Different*

Drugs, food additives, and sunscreens already require premarket testing for all new chemicals.[230] Consequently, if the FDA acknowledges that nano does not just mean small, it means fundamentally different as well, most of the rest of the needed changes will automatically fall into place. Under current regulations, this acknowledgment that nanotech versions of active ingredients are new chemicals will ensure that drugs, food additives, and sunscreens that have already been approved by the FDA, but are later modified to add nanotech particles, will undergo a new and complete round of safety testing in order to obtain premarket approval from the FDA.

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[230] *See supra* notes 129–36, 147–54, 177–93 and accompanying text.

2. *Nanotech Ingredient Labeling*

Under the current consumer product safety system, there is no mechanism in place for public health officials to monitor whether the heavy exposure of U.S. consumers to nanotech products marketed for direct and indirect human consumption is causing acute or latent toxic reactions. The new understanding that nanotech particles create novel, biologically active ingredients, in conjunction with the lack of definitive testing for toxicological effects of new nanoparticles, counsels for the establishment of a post-market surveillance system for monitoring for any unintended effects of nanotech food, dietary supplements, cosmetics, and sunscreens. Once the FDA acknowledges that nanotech particles are new chemicals, ingredient labeling will be required, removing the major obstacle to gathering data on toxicity.[231] Referring to nanomaterial content by the same name as the normal size material counterpart will then be false and misleading since nanoscale materials as a class will be recognized as inherently more hazardous than non-nanoscale materials. Thus, the fact that a product marketed for direct and indirect human consumption contains nanomaterials would become "material" and would have to be disclosed on labels.[232]

3. *Post-Market Surveillance*

As discussed above, requiring premarket testing is only a partial solution. Based on the current immature level of the science for health risk detection, many toxicants are unlikely to be identified until the general population is using these novel nanoproducts and adverse reactions begin to appear as a result of the exposure of the product to the enormously diverse U.S. gene pool. A post-market surveillance system, created through new legislation, will allow public health officials to monitor this data, thereby providing an early warning system to alert public health officials if there are toxic reactions to a particular nanotech product. This will allow a quick recall of the product preventing needless injuries to consumers. The proposed Food Safety Enhancement Act of 2009,[233] which

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[231] 21 C.F.R. § 101.18 (2011) (addressing the misbranding of food); *id.* § 201.6 (2010) (addressing drugs and misleading statements); *id.* § 701.1 (2011) (addressing cosmetics, labeling, and misbranding).

[232] *See supra* notes 194–95 and accompanying text.

[233] Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. Introduced in early June, the Act would amend the Federal Food, Drug, and Cosmetic Act to require each food facility to: "(1) conduct a hazard analysis (or more than one if appropriate); (2) identify and implement effective preventive controls"; and (3) implement a food safety plan. *Id.* §§ 418(a), 418A. The Act would require the Secretary of Health and Human Services ("HHS") to: (1) "issue guidance or promulgate regulations to establish science based standards" to minimize the hazards from food borne contaminants, *id.* §§ 418A(b)(3)(A), 419(a); (2) "establish by regulation scientific and risk-based food safety standards for . . . raw agricultural commodities," *id.* § 419A(a); (3) inspect facilities at a

was passed by the House of Representatives in August of 2009, includes a requirement for the creation of a food tracking system[234] in order to quickly locate the source of any outbreak of food-borne illness.[235] A tracking system for all nanoparticle products marketed for human consumption could easily be grafted onto this food safety system.

B. *Dietary Supplements and Cosmetics*

1. *Switching the Burden of Proof for Safety, Labeling, and Post-Market Surveillance*

In order to remedy the regulation of nanotech dietary supplements and cosmetics, new legislation will be required that will place the burden of proof for safety onto the manufacturers by requiring that these products undergo the FDA premarket approval process. In the case of dietary supplements, this means a revision to the current legislation that places the burden of proof on the FDA to show that "new" ingredients are unsafe. This revision must switch the burden of proof from the FDA to manufacturers. In the case of cosmetics, it means creating entirely new legislation that requires that nanotech cosmetics undergo the FDA premarket approval process. Active ingredients are already required to be placed on dietary supplement and cosmetic labels.[236] A policy change by the FDA acknowledging nanotech ingredients as new chemicals, as recommended above, will result in nanotech ingredient labeling under current regulations. A post-market surveillance system for all nanotech products marketed for human consumption, as outlined above, should also be included in any new legislation.

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frequency determined pursuant to a risk-based schedule, *id.* § 105(a)(4)(A); (4) establish a food tracing system, *id.* § 107(c)(2); (5) assess fees relating to food facility re-inspection and food recall *id.* § 743A(a)–(b); and (6) establish a program for accreditation of laboratories that perform analytical testing of food for import or export, *id*. § 714(b). The proposed Act goes on to authorize the Secretary to: (1) order an immediate cessation of distribution, or a recall, of food, *id.* § 420(f)(1); (2) develop "safety and security guidelines applicable to the importation of food," *id.* § 805(b)(1); and (3) quarantine food in any geographic area within the United States, *id*. § 133(b)(i)(1).

[234] The HHS Secretary "shall by regulation establish a tracing system for food that is located in the United States or is for import into the United States." *Id.* § 107(c)(2). Direct sales by farms, restaurants, or grocery stores to consumers are exempted from the Act. *Id*. § 101(a)(1)(A)–(B). A facility shall recall an article of food or ingredient that presents a reasonable probability that it is a threat to human health. The HHS Secretary may request a recall if the Secretary "has reason to believe [the food] is adulterated, misbranded, or otherwise in violation of [the] Act." *Id.* § 420(a)(1). The HHS Secretary may order a facility to cease distribution of a food product "[i]f the Secretary ha[s] reason to believe that the use, consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals." *Id.* at § 420(b)(1). Similarly, the HHS Secretary may order a recall. *Id.* at § 420(e).

[235] The CDC "shall enhance food-borne illness surveillance . . . by coordinating Federal, State and local food-borne illness surveillance systems . . . ." *Id.* § 121(b).

[236] *See supra* note 231.

C. *Revisions to Analytical Tools Used to Evaluate the Need for Regulation of Innovative Technologies*

There are two hurdles that must be addressed in order for new legislation for the regulation of all nanotech products marketed for human consumption to be successfully adopted. First, the risk-benefit analysis used by the FDA to evaluate health risks must be revised. Second, the recent reliance by administrative agencies and legislators on cost-benefit analysis must be abandoned.

1. *Risk-Benefit Analysis*

As discussed in the following sections, the FDA conclusions to date with regard to nanotech particles are a function of its reliance on risk-benefit analysis in order to make regulatory decisions about innovative technologies. The problem with this reliance, as demonstrated clearly with the marketing of nanotech food, dietary supplements, cosmetics, and sunscreens, is that there is invariably a lag time between the production of the innovative technology and the development of the science necessary to identify the risks associated with that technology. Thus, the FDA has to wait to use its risk-benefit tool to regulate to protect public health until the state of the science on health risks catches up to the innovation itself. During this scientific lag time, manufacturers are free to market their products with no interference and no notice to unsuspecting consumers.

The FDA's regulatory reliance on risk-benefit analysis when there is insufficient evidence to actually quantify health risks—in other words, when there is uncertainty—results in several serious consequences for public health. First, the number of products containing nanotech particles that are marketed for direct and indirect human consumption grows daily. The FDA is not taking any steps to protect consumers by ensuring that these nanotech products are safe for direct or indirect human consumption. Second, the FDA is thwarting consumers' ability to protect themselves against any additional risks of harm by finding that manufacturers have no obligation to identify nanotech ingredients on product labels. Thus, consumers are not aware that they are being exposed to a novel substance with unique health risks. Finally, the FDA is failing to conduct the appropriate scientific testing in order to resolve the question of nanotech product safety. As long as the FDA relies on the tests for health risks created for and utilized on bulk materials to make determinations on the safety of nanoparticles, the data necessary to show that a nanotech product marketed for direct and indirect human consumption is unsafe and should be pulled from the market will never be developed.

a. Lessons Learned from History

There are numerous examples of the serious health consequences of this lag time between the introduction of new chemicals and technologies

into the market and the development of the science that defines the associated human health risks. The list includes the evolving understanding of endocrine disruption caused by tributylin ("TBT"), polychlorinated biphenyls ("PCBs"), diethylstilbestrol ("DES"), the Great Lakes pollution, and Thalidomide.[237] Illustratively, evidence existed in the 1930s that PCBs could cause serious harm to human health.[238] However, it was not until the 1970s that the first action was taken by Sweden to ban these chemicals; the European Union followed suit in 1996, implementing a phase-out to be completed by 2010.[239] Scientists are still grappling to understand the devastating consequences of a fifty year period of human and environmental exposure to organochlorine compounds used as pesticides in the Great Lakes area.[240] The marketing of these chemicals occurred in spite of the publication of the book *Silent Spring* in 1962 that warned of the negative health effects on humans and wildlife of this exposure.[241]

The time lag between the first scientific warnings over medical x-rays (1896), benzene (1897), and asbestos (1898), and when policy makers finally took action to reduce damage was between thirty and one hundred years.[242] The consequences of failure to act in time can have a "long tail" when there is a long latent period between exposure and negative health consequences. For example, the introduction of CFCs and the creation of the ozone hole are resulting in thousands of additional skin cancers that will only peak in number in the middle of this century. Another example is the introduction onto the market of DES to prevent miscarriages.[243] DES was introduced in 1947 and was widely distributed until 1970 when the first evidence that it produced human cancer appeared.[244] The fact that DES was an animal carcinogen was identified in 1938.[245] These are just a few examples[246] of the long lag time that can occur between the identification of an association between exposures to new technologies and negative health consequences, and the eventual understanding of how the

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[237] David Gee, *Late Lessons from Early Warnings: Toward Realism and Precaution with Endocrine-Disrupting Substances*, 114 ENVTL. HEALTH PERSP. 152, 156 (2006); *see also* Van Tassel, *supra* note 129, at 228–29 (discussing the case of Thalidomide).

[238] EUROPEAN ENV'T AGENCY, ENVTL. ISSUE REP. NO. 22, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000 66–69 (2001).

[239] *Id.*

[240] EUROPEAN ENV'T AGENCY, *supra* note 238, at 126.

[241] *Id.*

[242] Gee, *supra* note 237, at 155.

[243] *Id.* at 155–56.

[244] EUROPEAN ENV'T AGENCY, *supra* note 238, at 153.

[245] *Id.* at 152–53.

[246] For a comprehensive analysis of fourteen case studies of these types of scenarios, see generally EUROPEAN ENV'T AGENCY, *supra* note 238.

new technology actually causes the negative health effects.

2. *Dealing With Uncertainty in the Face of Clear Warnings*

While the use of engineered nanoparticles in products marketed for direct and indirect human consumption and the resultant exposure of consumers is growing daily, the body of science necessary to identify the health risks associated with engineered nanoparticles is still in its infancy. As has occurred so often in the past, this scientific lag time creates a period when there is an information void with regard to the risks to human health. As this information void is slowly filled through scientific experimentation, the level of uncertainty over health risks commonly progresses from ignorance (where scientists *don't know* what they don't know) to indeterminacy (where scientists *know* what they don't know but can plan the scientific experiments necessary to find out) to, finally, a tipping point in the state of knowledge when classic probability analysis can be applied to predict, or quantify, risk levels to human health.

When the FDA first made its decisions on how to regulate nanotech products, far less was known about the distinctive properties of nanoparticles, their uniquely high level of bioreactivity, and the resultant heightened potential for adverse health effects. Scientists simply "did not know what they did not know" about the health risks associated with nanotech particles. At that point in time, the FDA made its regulatory choices in an environment of ignorance, choosing to regulate based on what scientists now know to be a false assumption of bioequivalence. Over the past several years, a parade of major scientific discoveries has shifted the nature of the uncertainty over the public health risks of nanotech particles from ignorance to indeterminacy. In other words, scientists have progressed from *not knowing* what they do not know, to *knowing* what they do not know.

Scientists now understand that engineered nanoparticles may create novel health risks caused by powerful nano-bio interactions that have never before existed in nature. In order to move from indeterminacy to classic risk analysis, scientists must determine the nature and extent of the harm that occurs as a result of these nano-bio interactions. Then, using classic uncertainty principles, scientists must quantify the probability and degree of those harms. Thus, the new awareness on the part of scientists that nanoparticles can cause serious physical harm, and the identification of some of the potential mechanisms for causation, opens the door to the ability to plan out the systematic study of each new type of engineered nanoparticle in order to eliminate or confirm the associated health risks.

In spite of the fact that the state of the science has now moved into indeterminacy, the FDA's reliance on classic risk/benefit analysis in making decisions over whether to regulate for safety means that, until the science on the health risks associated with nanoparticles has matured to the

point that the risks can be quantified, the FDA will proceed as if this growing body of science did not exist. Taking note of lessons from past introductions of new technologies which involved clear warning signals, but also uncertainties over health risks, the FDA should modify its analysis to incorporate trade-off analysis.

3. *The Use of Trade-Off Analysis*

Applying trade-off analysis allows for the consideration of new kinds of uncertainties, as well as attendant risk mitigation strategies and factors into the analysis of the societal distribution of possible costs and benefits of policies and innovative technologies. Elements of trade-off analysis include:

- the seriousness and irreversibility of the harm addressed;
- the social distribution of possible costs and benefits of policies and technologies;
- the technological options for preventing, arresting, reversing or mitigating possible harm and the opportunity costs of selecting a given policy option;
- society's inclinations regarding erring on the side of caution and erring on the side of laxity; and
- the nature of uncertainty encountered: classical uncertainty, indeterminacy, or ignorance.[247]

Application of the above factors to nanotech products marketed for direct and indirect human consumption reveals the following: the harm is cumulative and causes irreversible damage to multiple different bodily functions that may, in the long run, be life threatening; the cost of the loss associated with any harm will be borne by the factory workers who handle the nanoparticles during the manufacturing process and consumers, while the nanotech product manufacturers reap the profits; the cost of identifying nanotech ingredients on product labels is very, very small and the cost of setting up a web based reporting system modeled on systems already in place at the FDA is even smaller; surveys indicate that consumers are tentatively supportive of nanotech products that have important benefits

[247] Ashford, *supra* note 196, at 371.

but have a clear preference for labeling and notice;[248] and, finally, scientists are no longer operating in ignorance as the state of the science has moved into indeterminacy and the possibility of serious health risks are no longer based on mere speculation. Therefore, as the risk of harm is serious, maybe even life threatening, and is cumulative and irreversible, the cost of the risk mitigation strategy of ingredient labeling and post market surveillance is small, the public will is to err on the side of caution, and the state of the science is indeterminacy not ignorance, trade-off analysis counsels for the implementation of the risk mitigation strategies of premarket testing, labeling, and post-market surveillance.

These risk mitigation strategies will allow for the creation of systems for the collection of data that will allow injured consumers to meet the *Daubert* and *Frye* admissibility standards necessary to establish causation.[249] In addition, the data will be available to allow an injured consumer to surmount the idiosyncratic plaintiff defense and the foreseeability pre-condition to tort recovery. These strategies will also encourage a more appropriate level of private investment into research to test for public health effects of this innovative technology. This investment will be passed on to increase the price of the use of nanotechnology in products, putting the brakes on the current free-for-all and allowing for a more measured growth of the type of products that use nanotechnology during this period of scientific uncertainty regarding the risks to public health.

4. *Abandonment of the Cost-Benefit Analysis*

A risk-benefit analysis performed today, that factors in different levels of uncertainty as reflected in trade-off analysis, suggests that the benefits of nanotech products for human consumption only outweigh human health risks if risk mitigation strategies, such as premarket testing, nanoparticle ingredient labeling, and post-market surveillance, are employed. Unfortunately, even if a trade-off analysis is adopted by the FDA, modern day risk assessment used to evaluate public health regulations has been functionally co-opted and has become a two-step process. The first step is the risk-benefit step discussed above. The second step entails the performance of a cost-benefit analysis of all new legislation. The use of cost-benefit analysis is both inappropriate and destructive in the context of evaluating the impact of new technologies on public health, discourages

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[248] *Study Points Way to Communicating Nanotech*, SCIENCEDAILY (Feb. 3, 2007), http://www.sciencedaily.com/releases/2007/01/070131211717.htm. *But see Nanotechnology: To Know it is not Necessarily to Love it*, SCIENCEDAILY (Dec. 8, 2008), http://www.sciencedaily.com/releases/2008/12/081208114302.htm (reporting the findings of a study indicating that consumer support may be tied to cultural predispositions).

[249] *See supra* notes 200–01 and accompanying text.

investment into health risk research, and short circuits the injury recovery system.

Triggered in 1994 by then Speaker of the House Newt Gingrich's "Contract with America,"[250] a series of legislative and executive orders mandated that all new federal regulatory proposals include a cost-benefit analysis[251] justifying the cost of regulation.[252] Lessons from the past demonstrate that this cost-benefit hurdle has undermined public health and safety as it is common for the development of new technologies to far outpace the development of the science necessary to test for the risks associated with those technologies.[253] Health risks take time to quantify. Until they are quantified, risk mitigation strategies have no measurable benefit to out-balance the associated costs. Thus, the result of a cost-benefit analysis for any proposed public health measure to monitor the health effects of new technologies is a non-starter when many new technologies first enter the market.[254]

As the type of uncertainty over public health risks of nanotech products marketed for direct and indirect human consumption is indeterminacy, the FDA and Congress should avoid the application of

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[250] Ashford, *supra* note 196, at 356–57 (internal quotation marks omitted).

[251]

> In theory, cost-benefit analysis of a policy option enumerates all possible consequences, both positive and negative; estimates the probability of each; estimates the benefit or loss to society should each occur, expressed in monetary terms; computes the expected social benefit or loss from each consequence by multiplying the amount of the associated benefit or loss by its probability of occurrence; and computes the net expected social benefit or loss associated with the government policy by summing over the various possible consequences. The reference point for these calculations is the state of the economy in the absence of the government policy, termed the 'baseline.'

Id. at 366.

[252] Cost-benefit analysis attempts to describe the consequences of a candidate regulation in monetary terms.

> This poses two problems. One is the difficulty, even arbitrariness, of placing a monetary value on human life, health and safety and a healthy environment. Another is that by translating all of these consequences into equivalent monetary units, discounting each to current value (since a US$/Euro invested now is expected to earn interest over time), and aggregating them into a single US$/Euro value intended to express the net social effect of the government policy, the effects on the economy from investing now in future health, safety and environmental benefits are weighted far more heavily than those benefits that occur in the future, including those to future generations.

Id. at 367.

[253] EUROPEAN ENV'T AGENCY, *supra* note 238, at 194.

[254] Steffen Foss Hansen et al., Commentary, *Late Lessons from Early Warnings for Nanotechnology*, 3 NATURE NANOTECHNOLOGY 444, 444–47 (2008).

formulaic cost-benefit analysis when performing a risk assessment to decide whether such a system is warranted. In addition to other shortcomings,[255] cost-benefit analysis leads to a quick and dirty "if you cannot quantify it, it does not exist" conclusion and produces a single number that fails to reveal who benefits and who pays.[256] The FDA should uncouple cost-benefit analysis from risk assessment to avoid being in the position of reacting to public health crises rather than preventing them. Instead, regulators should apply a risk assessment that uses trade-off analysis.

The mistakes made with prior introductions of new chemicals and technologies into society are looking progressively more similar to the concerns now being raised regarding various forms of nanotechnologies, including nanotech food, dietary supplements, cosmetics, and sunscreens. Until recently, even a pure risk assessment coupled with trade-off analysis has counseled against the need for premarket testing, labeling, and post-market surveillance. The risks to public health appeared to be based on little more than speculation. The past decade has brought a dramatic change in this picture in the form of the new scientific understanding of the health effects of nanotech particles. The FDA is now faced with more than just speculation over the possible health risks associated with nanoparticles used in products marketed for human consumption. While still not quantified, the level and extent of the risk of unintended health consequences from nanoparticle exposure is now quantifiable. When regulating new technologies, such as engineered nanoparticles,[257] if the FDA continues to rely on rigid cost-benefit analysis when the risk is not yet quantified, but is quantifiable through scientific testing, the FDA will be continuously operating behind the curve, reacting to public health crises rather than preventing them. Instead, the FDA should learn from the lessons of past technologies, abandon the use of cost-benefit analysis and apply trade-off analysis when engaging in risk assessment to evaluate new technology regulations designed to protect public health.

IX. CONCLUSION

The number of nanotech products marketed for direct and indirect human consumption is increasing yearly. This growth is paralleled by steadily increasing human exposure to these novel, highly bioreactive substances. At the same time, the current regulatory system discourages the proper level of investment into research for public health risk

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[255] *See supra* note 253 and accompanying text.

[256] *Id.*

[257] *See* Katharine A. Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U. J. SCI. & TECH. L. 220 (2007) (evaluating the FDA's regulation of genetically modified food in light of the new scientific understanding of the networked gene).

identification and avoidance leaving the true cost of nanotech products artificially low and creating an overuse of this potentially high risk nanotechnology. While the present regulatory scheme has created a health risk information void, collectively, the public health protection systems simultaneously act to defeat the consumer's ability to engage in self-protection, a current requirement of the tort system. Ironically, this inability to self-protect runs directly contrary to the movement by tort reformers to require even more individual responsibility.

Now that the nature of the uncertainty over the public health risks associated with these nanoparticles is indeterminacy rather than ignorance, premarket testing of nanotech products for human consumption, nanotech ingredient labeling, and post-market surveillance should be required in order to provide for both the transparency and accountability necessary to protect public health. In order to achieve this result, risk assessments should be modified to use trade-off analysis and the use of cost-benefit analysis should be abandoned altogether.

Revising the legislative decision-making process in these ways will permit consumers to engage in self-protection and will open the door to the creation of systems for the collection of data that will allow any injured consumers to meet the *Daubert* and *Frye* admissibility standards necessary to establish causation. In addition, this data will be available to any injured consumers to use to meet the idiosyncratic plaintiff defense and the foreseeability pre-condition to tort recovery. These strategies will also encourage a more appropriate level of private investment into research to test for the public health effects of this innovative technology. This investment will be passed on to increase the price of the use of nanotechnology in products, putting the brakes on the current "free-for-all" and allowing for a more measured growth of the type of products that use nanotechnology during this period of scientific uncertainty over the risks to public health.

In conclusion, the application of trade-off analysis results in a recognition that these risk mitigation strategies will fill the critical gaps in our public health system and will supply the accountability that is necessary to maintaining safe consumer products as each new nanotech product is introduced into the market.