

MERCURY'S TOXIC PROCESS: HOW BAD SCIENCE AND BAD DECISIONS CAUSED A PUBLIC HEALTH CRISIS

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Abstract: Since 1998, ethylmercury, a vaccine preservative, has often been confused with methylmercury, a dangerous neurotoxin, by the government and public. This confusion has led to a decrease in vaccination rates and an increase in the spread of preventable disease. Despite significant efforts to educate the public on the inaccuracy of studies linking ethylmercury to autism, the public health agencies have been unsuccessful in demonstrating to the public that the substance is safe. This Note analyzes the actions taken by the public health agencies responding to public concerns about ethylmercury's use in vaccines and recommends that the agencies undertake a comprehensive study of ethylmercury to determine its safety and resolve the growing public health crisis.

INTRODUCTION

Only a few decades ago, mercury was considered safe.¹ It was commonly used in many household products and industrial facilities with almost no regulation because there was little awareness of the dangers of mercury.² In the modern era the world's view of this once seemingly safe material has shifted dramatically, causing fear and misunderstanding of this substance.³

The saga began in the 1960s, when it was discovered that industrial emissions of one type of mercury—methylmercury—contaminated the surrounding

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¹ Gary Bigham et al., *Mercury—A Tale of Two Toxins*, NAT. RESOURCES & ENV'T, Spring 2005, at 26, 26 (“the toxicological significance of methylmercury and its behavior in the environment were not discovered until the twentieth century”).

² *Id.* at 29 (noting that mercury regulation did not begin in the United States until 1941, with the majority of regulation beginning in the 1960s and 1970s, following the discovery of the negative health effects of environmental mercury).

³ See Leila Barraza et al., *Denialism and Its Adverse Effect on Public Health*, JURIMETRICS J. L. SCI & TECH., Spring 2013, at 307, 308 (discussing the public health risks from public misperception of ethylmercury in vaccines); Bigham et al., *supra* note 1, at 29 (identifying the difficulties in regulating methylmercury); Mary Ann Chirba-Martin & Carolyn M. Welshhans, *An Uncertain Risk and an Uncertain Future: Assessing the Legal Implications of Mercury Amalgam Fillings*, HEALTH MATRIX J. L.-MED., Summer 2004, at 293, 293–94 (discussing the controversy behind the use of mercury amalgam dental fillings); Lauren L. Haertlein, *Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases*, LAW & CONTEMP. PROBS., no. 2, 2012, at 211, 230 (discussing the public health risk from the misinformation about ethylmercury in vaccines).

air, water, and land of a chemical company in Minimata, Japan, and caused mercury poisoning in nearby residents.⁴ Methylmercury is a neurotoxin that causes severe neurological damage to humans.⁵ The Environmental Protection Agency (EPA) quickly took charge to regulate the substance in the United States and, where contamination existed, initiated clean up efforts to prevent further harm to humans.⁶ In the ensuing decades, EPA made significant strides in the regulation of methylmercury; however, methylmercury continues to contaminate large bodies of water and the food supply.⁷

The negative effects of methylmercury quickly became publicly accepted, creating a general awareness of this environmental danger.⁸ The fear made it easy for Americans to accept industry regulation and even dietary recommendations to reduce the consumption of fish that were likely to be contaminated by methylmercury.⁹

Ethylmercury is another mercurial substance, but it does not pose the same health risks as methylmercury.¹⁰ Used as a key ingredient in the vaccine preservative thimerosal, ethylmercury existed for decades with little public awareness.¹¹ After a scientifically flawed study linked Autism Spectrum Dis-

⁴ ENVTL. PROT. AGENCY, EPA-HQ-OPPT-2005-0013, EPA'S ROADMAP FOR MERCURY 3 (July 2006) [hereinafter EPA MERCURY REPORT]; Bigham et al., *supra* note 1, at 29. Bigham describes the methylmercury contamination caused by a by-product of chemical production in Minimata, Japan and the neurotoxic symptoms presenting in residents.

⁵ EPA MERCURY REPORT, *supra* note 4, at 4, 7; Joëlle Anne Moreno, *Toxic Torts, Autism, and Bad Science: Why the Courts May Be Our Best Defense Against Scientific Relativism*, 40 NEW ENG. L. REV. 409, 410 (2006); *Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN. (Aug. 20, 2015), <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm#ref> [<https://perma.cc/LJ9S-95EE>]. Methylmercury is found in nature and is a common output of many industrial facilities and coal-fired power plants. EPA MERCURY REPORT, *supra* note 4, at 4, 7.

⁶ Bigham et al., *supra* note 1, at 29–31 (outlining the history of methylmercury regulation by EPA).

⁷ EPA MERCURY REPORT, *supra* note 4, at 3; Bigham et al., *supra* note 1, at 30; Thomas Sinks et al., *The Science and the Law of Toxics*, J. L. MED. & ETHICS, Winter 2007 Supp., at 63, 64; *Thimerosal in Vaccines*, *supra* note 5.

⁸ See Bigham et al., *supra* note 1, at 29 (crediting photos in *Life* magazine as the original source of the public's awareness of the ethylmercury contamination in Minimata, Japan).

⁹ *Id.*, at 27–28, 30–31 (describing various regulated products and industries); Moreno, *supra* note 5, at 410 (describing the broad acceptance of mercury's danger); see Mark Holden, *FDA-EPA Public Health Guidance on Fish Consumption: A Case Study on Informal Interagency Cooperation in "Shared Regulatory Space"*, 70 FOOD & DRUG L.J. 101, 119 (2015) (describing the initial broad authority under which the Food and Drug Administration (FDA) was able to regulate).

¹⁰ Barraza et al., *supra* note 3, at 321 (differentiating the toxicity of methylmercury from the toxicity of ethylmercury); Moreno, *supra* note 5, at 412–13 (differentiating the chemical structures of ethylmercury and methylmercury and explaining that these differences lead to different health outcomes in humans).

¹¹ See Moreno, *supra* note 5, at 410–11 (describing the early public reactions when ethylmercury's use became widely known in the early 2000s); Paul A. Offit, *Thimerosal and Vaccines—A Cautionary Tale*, 357 NEW ENG. J. MED. 1278, 1278 (2007) (outlining the history of ethylmercury as a preservative in vaccines since the 1930s); *Thimerosal in Vaccines*, *supra* note 5 (reviewing the initial introduction and purpose of thimerosal in vaccines).

order (autism or “ASD”) to the use of thimerosal in the Measles, Mumps, and Rubella (“MMR”) combined vaccine, parents across the United States and many other countries suddenly became aware of a covert source of mercury in their lives.¹² The public’s acceptance of methylmercury as a threat and limited public knowledge of ethylmercury created confusion and controversy that led to a temporary shift to regulate—then shift back to deregulate—ethylmercury.¹³ Shocked parents, who perceived the ethylmercury found in thimerosal to be the same as methylmercury, feared that they had unwittingly consented to injecting a neurotoxin into their infants.¹⁴

The government’s experts at the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), among others (collectively “Public Health Service,” “the PHS agencies,” or “the agencies”), quickly instituted a ban on the use of thimerosal in vaccines.¹⁵ The agencies used EPA’s regulatory standards for the environmental neurotoxin methylmercury to justify the dramatic prohibition of ethylmercury.¹⁶

¹² See Moreno, *supra* note 5, at 411 (sharing a grandparent’s story of surprise when grandson began showing symptoms of Autism Spectrum Disorder, (autism or “ASD”) shortly after vaccinations). See generally AJ Wakefield et al., *RETRACTED: Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 THE LANCET 637 (1998) (now-retracted study linking the Measles Mumps and Rubella (“MMR”) vaccine to symptoms of autism).

¹³ See Barraza et al., *supra* note 3, at 321 (identifying public awareness of thimerosal, a preservative containing ethylmercury, as a primary instigator of vaccination fears); Moreno, *supra* note 5, at 410–11 (sharing anecdotes of parent and grandparent reactions to the discovery that ethylmercury was present in vaccines); Offit, *supra* note 11, at 1278 (describing the initial ethylmercury calculations by the FDA and the subsequent public awareness).

¹⁴ *Statement on Thimerosal*, WORLD HEALTH ORG. (July 2006), http://www.who.int/vaccine_safety/committee/topics/thiomersal/statement_jul2006/en/ [<https://perma.cc/294M-GEAY>] [hereinafter *WHO Thimerosal Statement*] (identifying the source of vaccine fear in the United States as a confusion between ethylmercury and methylmercury); see Barraza et al., *supra* note 3, at 318 (describing the impact of the internet in helping “like-minded individuals” find support while ignoring scientific dissent); Moreno, *supra* note 5, at 410 (“I was outraged that I was not told that the most powerful neurotoxin was going to be injected into my new born [sic] child.”).

¹⁵ *Safety, Effectiveness, and Availability of Influenza and Other Vaccines: Hearing Before the Subcomm. on Lab., Health & Hum. Servs., Educ., & Related Agencies of the S. Comm. on Appropriations*, 108th Cong. (Oct. 4, 2004) (statement of William Egan, Ph.D., Acting Director, Office of Vaccines Research & Review, Center for Biologics Evaluation and Research), FOOD & DRUG ADMIN. (Oct. 5, 2004), <http://www.fda.gov/NewsEvents/Testimony/ucml13261.htm> [<https://perma.cc/QK9W-S6MS>] [hereinafter *Vaccine Testimony*] (describing the ban as precautionary); Offit, *supra* note 11, at 1278 (outlining the events leading to the prohibition); *Thimerosal in Vaccines*, *supra* note 5 (reviewing FDA actions leading to the ban); *Timeline: Thimerosal in Vaccines (1999–2010)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 28, 2015), <http://www.cdc.gov/vaccinesafety/concerns/thimerosal/timeline.html> [<https://perma.cc/AD8U-637A>] (providing the timeline of agency action leading to the ban as well as subsequent research milestones).

¹⁶ See *Vaccine Testimony*, *supra* note 15; Offit, *supra* note 11, at 1278. Acting Director of the Office of Vaccines Research and Review, William Egan, Ph.D., identified EPA’s methylmercury standard as an original reference standard for the review of thimerosal. *Vaccine Testimony*, *supra* note 15.

Shortly after these prohibitions were put into place, scientists around the world disproved the MMR combined vaccine study that had incited this panic and the PHS agencies lifted the ban on thimerosal.¹⁷ Once again, ethylmercury was classified as a safe substance.¹⁸ Because the agencies based this classification only on studies absolving thimerosal of any autism risk, there was no comprehensive safety assessment that could fully allay public fears.¹⁹ Mixed messages, including a federal recommendation to develop thimerosal-free vaccines and state-level prohibitions on the use of thimerosal, left some parents fearful of vaccines and generally distrusting of the agencies' recommendations.²⁰ This widespread fear and skepticism led to serious public health consequences as the rate of vaccinated infants decreased.²¹

Critics have since questioned the agencies' precautionary ban in light of the virulent public reaction and negative long-term effects on public health.²² Under these circumstances, the agencies failed to utilize the relevant available information and therefore could not adequately judge and implement an appropriate strategy.²³ The agencies' decision to reverse the prohibition of ethylmercury was dangerous because it ignored the public health risk the ban had already created.²⁴ Absent additional research into the safety of ethylmercury outside the scope of ASD, the agencies are in the same position where they

¹⁷ Vaccine Testimony, *supra* note 15; Barraza et al., *supra* note 3, at 317; Moreno, *supra* note 5, at 414; WHO *Thimerosal Statement*, *supra* note 14.

¹⁸ Vaccine Testimony, *supra* note 15; Barraza et al., *supra* note 3, at 317; Moreno, *supra*, note 5 at 414; *Timeline: Thimerosal in Vaccines (1999–2010)*, *supra* note 15; WHO *Thimerosal Statement*, *supra* note 14. Agency testimony indicates that the results of reviewing the autism-related research as demonstrating the causal link was only theoretical, a conclusion supported by WHO statements. Vaccine Testimony, *supra* note 15; WHO *Thimerosal Statement*, *supra* note 14.

¹⁹ See Barraza et al., *supra* note 3, at 319 (suggesting that additional investigation into the risks of thimerosal may be appropriate to combat concerns about vaccinations).

²⁰ See *id.* at 317–18 (describing the evolution of the anti-vaccine movement); Moreno, *supra* note 5, at 414–15 (highlighting two anti-vaccine leaders fueling this fear and distrust); Offit, *supra* note 11, at 1278–79 (discussing the growth of the anti-vaccine movement).

²¹ STATE OF THE WORLD'S VACCINE AND IMMUNIZATION 66 (World Health Org. et al. eds., 3d ed. 2009) (linking decreased infant vaccination rates to public awareness of the MMR vaccine study); Barraza et al., *supra* note 3, at 321–22 (discussing the impact of decreased vaccination rates concentrated in communities, including specific outbreaks caused by unvaccinated individuals); Offit, *supra* note 11, at 1279 (identifying a specific example of overreaction by medical institutions resulting in lower vaccination rates causing one fatality from preventable illness).

²² See Offit, *supra* note 11, at 1279 (suggesting that the use of the precautionary principle in this instance caused harm to public health).

²³ See Moreno, *supra* note 5, at 415–16 (noting the prevalent conspiracy theories and highlighting the non-governmental actors seeking to fill this education role where the agencies failed); Offit, *supra* note 11, at 1278 (describing the limited data used to make the decision); *Thimerosal in Vaccines*, *supra* note 5 (identifying several reports and toxicity studies available at the time of the precautionary ban indicating that thimerosal was safe, even at doses significantly higher than the immunization schedule total).

²⁴ See Offit, *supra* note 11, at 1279.

began—without a comprehensive scientific basis of ethylmercury's safety.²⁵ The agencies must regulate ethylmercury because the environment of fear and distrust caused by the public misunderstanding is a negative health effect under their authority.²⁶

This Note argues that the PHS agencies failed, and continue to fail, to respond to the public's fear of the use of thimerosal in vaccines and recommends a comprehensive approach to resolving the public health crisis through research, transparency, and a clear structure of agency accountability.²⁷ Part I of this Note outlines the history of mercury regulation in the environmental and public health contexts and offers a review of the autism vaccine controversy.²⁸ Part II analyzes the reasonableness of the agency actions following the controversy and discusses the negative impact these actions had on public health.²⁹ Finally, Part III recommends a methodology to resolve the current flaws in the Public Health Agencies' process of ethylmercury and vaccine regulation and increase public trust and immunization rates.³⁰

I. THE HISTORY OF MERCURY REGULATION—FROM IGNORANCE TO FEAR

The Food and Drug Administration and the Environmental Protection Agency regulate mercury-based substances.³¹ In spite of their broad regulatory power, agencies have historically been hesitant to assert the full breadth of their authority because of the lack of scientific data on the toxicity levels of all mercurial substances.³² Without clear data about the dangers posed to humans, the agencies generally categorize substances as safe and, therefore, do not regulate them.³³ This presumption of safety allows mercury to remain common-

²⁵ See Barraza et al., *supra* note 3, at 319.

²⁶ See *id.* at 321–22; Moreno, *supra* note 5, at 415; Offit, *supra* note 11, at 1279. The risks of vaccine misinformation include international public health because manufacturers may remove preservatives, which continue to be essential in developing countries, from all vaccines to satisfy demand in the American market. Moreno, *supra* note 5, at 415.

²⁷ See *infra* notes 134–247 and accompanying text.

²⁸ See *infra* notes 31–133 and accompanying text.

²⁹ See *infra* notes 134–186 and accompanying text.

³⁰ See *infra* notes 187–247 and accompanying text.

³¹ See Bigham et al., *supra* note 1, at 27–31.

³² See *id.* at 27 (noting that, historically, the United States has been slow to regulate, even compared to other western countries); Sinks et al., *supra* note 7, at 64 (discussing conflicting studies on maximum safety levels for methylmercury exposure and the lack of data available on ethylmercury).

³³ See Kimberly M. Baga, *Taking a Bite Out of the Harmful Effects of Mercury in Dental Fillings: Advocating for National Legislation for Mercury Amalgams*, 20 J. L. & HEALTH 169, 180 (2007) (describing the FDA's decision not to regulate after finding that "the evidence is not persuasive that the potential for toxicity at the levels attributable to dental amalgams should be totally disregarded," even though it admitted there was insufficient evidence to determine the amalgams are in fact safe); Elizabeth Fisher, *Framing Risk Regulation: A Critical Reflection*, 4 EUR. J. RISK REG. 125, 131–32 (arguing that the linear risk assessment model often leads to "conventional assumptions" in the face of uncertainty); see also *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120,

place in household products, like thermometers, and as a preservative for medical products.³⁴

The public's misunderstanding of the different types of mercury is best exemplified by the confusion and controversy surrounding methylmercury and ethylmercury—one a dangerous neurotoxin, the other a non-toxic preservative.³⁵ Agencies broadly regulate methylmercury based on substantial evidence that it is harmful to human health, but have faced challenges in regulating ethylmercury due to lack of scientific knowledge.³⁶ Recent attempts to regulate the use of ethylmercury in vaccines have faltered from inconsistent decision-making, despite clear direction from past agency procedure, Congress, and the United States Supreme Court.³⁷

A. Methylmercury: A Dangerous Environmental Neurotoxin

Methylmercury is a neurotoxin proven to cause significant damage to human health and has been linked to impaired neurological development in infants and fetuses.³⁸ Methylmercury is most commonly found as a byproduct of industrial plant operations.³⁹ For example, coal-fired power plants release this toxic substance into the surrounding air, water, and land.⁴⁰ In order to inhibit this release, agencies have issued containment regulations that require power plants to reduce or eliminate the amount of methylmercury used and the amount emitted by the plant.⁴¹ EPA utilizes its regulatory powers primarily to monitor, decrease, clean, and ultimately prohibit emissions of methylmercury.⁴² EPA also works with the FDA to promulgate dietary recommendations for food products, such as fish, that are likely to have a high methylmercury content.⁴³

125–29 (2000) (noting the preference to categorize tobacco products as safe before conclusive evidence of a link to lung cancer and other diseases was demonstrated).

³⁴ Barraza et al., *supra* note 3, at 321; Bigham et al., *supra* note 1, at 27.

³⁵ See *infra* notes 76–111 and accompanying text.

³⁶ See *infra* notes 58–111 and accompanying text.

³⁷ See *infra* notes 76–133 and accompanying text.

³⁸ EPA MERCURY REPORT, *supra* note 4, at 4, 7 (defining the sources of contamination and the neurotoxic effects of methylmercury on human health); *Thimerosal in Vaccines*, *supra* note 5 (describing the neurotoxic effects of methylmercury in fetuses).

³⁹ EPA MERCURY REPORT, *supra* note 4, at 3.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² See Clean Water Act of 1977, 33 U.S.C. §§ 1251–1387 (2012); Clean Air Act (Air Pollution Control Act), 42 U.S.C. §§ 7401–7671q (2012); EPA MERCURY REPORT, *supra* note 4, at 8–9.

⁴³ Press Release, Food & Drug Admin, FDA and EPA Issue Draft Updated Advice for Fish Consumption (June 10, 2014) (available on WestLaw, 2014 WL 2749498) [hereinafter Fish Advisory]; see *infra* notes 67–75 and accompanying text.

B. Regulatory Basics: Standards of Causation

Although government regulation of many mercurial substances is limited, agencies take a broad approach to methylmercury regulation based on concrete scientific evidence that proves this substance causes neurological damage.⁴⁴ To regulate a substance, an agency must show that the substance actually causes harm under one of three standards of causation: (1) the necessary and sufficient approach; (2) the public health approach; and (3) the risk assessment approach.⁴⁵ EPA regulates methylmercury under the risk assessment approach, with elements of the public health approach blended in.⁴⁶

The necessary and sufficient approach requires the substance subject to regulation be necessary to cause the negative health consequence and that exposure to the substance be sufficient to trigger it.⁴⁷ This strict standard requires direct scientific evidence that the negative health effect never occurs in the substance's absence.⁴⁸ Necessary and sufficient causation is difficult to show.⁴⁹

The inherent difficulty in the necessary and sufficient approach has led environmental and public health agencies to more often regulate using the public health approach.⁵⁰ The public health approach looks to health trends that correlate exposure to a substance with an increased risk of disease.⁵¹ Here, a body of etiologic research must show that the substance is a cause, but not the only cause of the disease.⁵²

The risk assessment approach works best when there is scientific uncertainty about the link between the toxic substance and negative health consequences.⁵³ An agency must determine the level of exposure of the specific substance, or the "critical value," required to cause the disease based on the best available research.⁵⁴ The critical value must be sufficiently based in scientific

⁴⁴ See *Thimerosal in Vaccines*, *supra* note 5 (outlining the scientific data used by EPA as authority to regulate emissions and make dietary recommendations).

⁴⁵ Sinks et al., *supra* note 7, at 64 (defining the three types of causation).

⁴⁶ See *id.* (illustrating the application of the risk assessment and public health approaches to the regulatory efforts of methylmercury and fish consumption).

⁴⁷ *Id.* The approach may be applied to a specific exposure dosage at which the agency is setting the regulatory standard and does not require causation at levels lower than the standard. *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.* (defining component causes as those that are linked to the disease but not necessary or sufficient).

⁵⁰ See Fisher, *supra* note 33, at 131; Sinks et al., *supra* note 7, at 64. There are inherent difficulties of following a strict risk assessment model for policy-making. See Fisher, *supra* note 33, at 131.

⁵¹ Sinks et al., *supra* note 7, at 64.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ See *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst. (Benzene Case)*, 448 U.S. 607, 656 (1980); Sinks et al., *supra* note 7, at 64.

evidence so as to give the agency the authority to regulate the substance in question.⁵⁵

In 1980, in *Industrial Union Department, AFL-CIO v. American Petroleum Institute (Benzene Case)*, the United States Supreme Court overturned the benzene exposure standard promulgated by the Occupational Safety and Health Administration (“OSHA”) because OSHA’s supporting evidence only linked leukemia to levels of benzene above the promulgated standard, but could not provide scientific explanation for the standard itself.⁵⁶ This holding does not mandate absolute scientific certainty, but requires agencies to provide substantial evidence to support regulatory standards and reduce uncertainty.⁵⁷

C. Regulating Methylmercury: Developing a Safety Standard and Navigating Regulations for Environmental and Dietary Concerns

Early regulation of mercury began when the neurotoxic effects of methylmercury became known.⁵⁸ Findings of methylmercury’s neurotoxicity inspired regulation of the dangerous substance at all levels of government.⁵⁹ EPA’s effort began with, and continues to focus on, controlling and prohibiting the release of methylmercury into the environment.⁶⁰

Methylmercury is safe for human exposure at very low levels, which requires EPA to determine and set a maximum safety standard, or critical value.⁶¹ In an effort that blends the public health and risk assessment approaches, EPA has conducted comprehensive reviews of the research on methylmercury in coordination with the public health agencies.⁶² The research demonstrates the effects of methylmercury exposure at various levels and forms the scientific basis for the maximum exposure standard.⁶³

EPA has broad authority to regulate methylmercury emissions but must balance the risk of harm against relevant factors.⁶⁴ In 2015, in *Michigan v. Environmental Protection Agency*, the United States Supreme Court held that EPA must take cost into consideration when instituting new guidelines for

⁵⁵ See 448 U.S. at 656; Sinks et al., *supra* note 7, at 64.

⁵⁶ 448 U.S. at 611, 656–62 (requiring the agency’s standard be “supported by substantial evidence”).

⁵⁷ See *id.* at 656; Brian D. Israel, *An Environmental Justice Critique of Risk Assessment*, 3 N.Y.U. ENVTL. L.J. 469, 477 (1995).

⁵⁸ Bigham et al., *supra* note 1, at 29; *Thimerosal in Vaccines*, *supra* note 5.

⁵⁹ Bigham et al., *supra* note 1, at 28.

⁶⁰ See *id.* at 29–30 (describing methylmercury regulation).

⁶¹ Sinks et al., *supra* note 7, at 64.

⁶² EPA MERCURY REPORT, *supra* note 4, at 3–12.

⁶³ See *id.* (providing an executive summary of the comprehensive methylmercury report).

⁶⁴ *Bowen v. Am. Hosp. Ass’n*, 476 U.S. 610, 626–27 (1986) (requiring administrative agencies to set standards that are rationally connected to the facts); see *Michigan v. Env’tl. Prot. Agency*, 135 S. Ct. 2699, 2706 (2015) (requiring that EPA take relevant factors as defined by statute into account in decision-making).

methylmercury emissions from power plants.⁶⁵ Agencies are not bound to make the final decision based on cost, though, and may find that other factors reasonably outweigh the financial burden.⁶⁶

Human exposure to methylmercury has been linked not just to industrial emissions, but also to certain dietary choices.⁶⁷ Fish consumption has posed an interesting challenge to agencies because although EPA can create a safety standard for new emissions, it is more difficult to regulate the amount of contaminants already present in the environment.⁶⁸ High levels of individual consumption of certain types of fish may result in levels of methylmercury within the human body that exceed the levels the EPA has determined to be safe because mercury can accumulate in fish living in contaminated environments pass to humans through the food chain.⁶⁹ Widespread concern about the possible health risks associated with consumption of methylmercury-contaminated fish has led the PHS agencies to set regulatory standards despite the scientific uncertainty created by the variable contamination level of individual fish.⁷⁰

To limit the risks posed by individual consumption of contaminated fish, the agencies developed dietary recommendations that suggested limited amounts of fish with high levels of methyl-mercury for high-risk groups, including children and pregnant women.⁷¹ Unlike emissions regulations, this approach is less rigid and requires public education and acceptance to be successful.⁷² Frightened by EPA's education campaign extolling the dangers of methylmercury, many individuals misunderstood the recommendations and interpreted the guidelines to prohibit the consumption of all fish.⁷³ In choosing to avoid all fish, these groups miss out on critical nutrients, including those that promote chil-

⁶⁵ *Michigan v. Envtl. Prot. Agency*, 135 S. Ct. at 2712 (interpreting cost as within the scope EPA's statutorily mandated "appropriate and necessary" balancing test).

⁶⁶ *See id.* at 2711.

⁶⁷ *See* Bigham et al., *supra* note 1, at 31 (describing the complex challenge of regulating emissions of methylmercury in the food supply because of lack of predictability and scientific knowledge); Holden, *supra* note 9, at 129 (describing the challenges of balancing the two agencies perspectives); Sinks et al., *supra* note 7, at 64 (describing the public health risks that stem from overregulating methylmercury in the food supply).

⁶⁸ *See* Bigham et al., *supra* note 1, at 31; *Mercury in Aquatic Ecosystems*, U.S. GEOLOGICAL SURVEY (June 3, 2010), <http://water.usgs.gov/nawqa/mercury/MercuryFAQ.html> [<https://perma.cc/Q2YG-NV4Q>].

⁶⁹ Holden, *supra* note 9, at 116 (explaining the bioaccumulation process through which mercury accumulates in higher concentrations in fish tissue than in air or water and the neurotoxic effects on fetuses and young children).

⁷⁰ *See* Bigham et al., *supra* note 1, at 31 (describing the challenges of balancing the health risks and benefits of fish consumption).

⁷¹ Holden, *supra* note 9, at 129.

⁷² *Id.* at 125.

⁷³ *Id.* at 131 (describing the confusion caused by the recommendation and the position supported by David Martosko, research director at the Center for Consumer Freedom, to withdraw the recommendation).

dren's growth and fetal development.⁷⁴ To resolve this issue, the agencies implemented a campaign to educate people about a more balanced approach, starting with a revised set of guidelines that provide a maximum as well as a minimum recommended level for fish consumption.⁷⁵

D. Regulating Ethylmercury: Vaccines, Autism, and Public Panic

When it comes to mercury, public overreactions have ranged from calls to ban specific products to claims of government conspiracy; the agencies have failed to address these public outcries.⁷⁶ Following research linking the use of mercury in dental fillings to neurological disorders in patients and dentists, government agencies continued to treat the substance as safe and ignored the controversy.⁷⁷ This head-in-the-sand approach—which mirrors the government's recent approach to vaccines—failed to allay fears.⁷⁸ Recent polls indicate the public remains distrustful of the government's refusal to regulate the components of these fillings.⁷⁹

Arguably no movement better demonstrates the risk that comes with failing to adequately address public concerns about mercury more clearly than the debate on the connection between vaccines and Autism Spectrum Disorder.⁸⁰ The substance at the heart of the controversy is thimerosal—an ethylmercury-

⁷⁴ Fish Advisory, *supra* note 43.

⁷⁵ *Id.*; Holden, *supra* note 9, at 132. Although the agencies continue to approach the issue differently, EPA and the FDA are publicly supporting the FDA net effects recommendation. Holden, *supra* note 9, at 132.

⁷⁶ See Baga, *supra* note 33, at 178 (describing the FDA's inaction with respect to mercury amalgam in dental fillings); Barraza et al., *supra* note 3, at 319 (noting that governmental action in support of misunderstandings about mercury entrench the inaccurate information further); Moreno, *supra* note 5, at 414–15 (discussing Robert F. Kennedy, Jr.'s pharmaceutical industry conspiracy theory); Offit, *supra* note 11, at 1278–79 (highlighting the extreme and public response to claims that thimerosal in vaccines caused autism).

⁷⁷ Baga, *supra* note 33, at 178.

⁷⁸ *Id.* at 180 (noting that the FDA recognized evidence of harm but found that there was not enough research to support regulation); Chirba-Martin & Welshhans, *supra* note 3, at 293–94, 298 (sharing results of a survey of one thousand people finding that fifty percent of respondents believed dental mercury has health risks).

⁷⁹ See Barraza et al., *supra* note 3, at 319 (sharing the results of a 2011 Harris Interactive-HealthDay poll: 18% of those surveyed believed autism was linked to vaccines and, of the 69% of respondents aware of the Wakefield study, only 47% knew of the study's retraction); Offit, *supra* note 11, at 1279 (describing the actions taken by those distrustful of the government's position, including harassment and physical attacks of those supporting the government's position that thimerosal is a safe substance).

⁸⁰ See Barraza et al., *supra* note 3, at 320; Haertlein, *supra* note 3, at 226; Offit, *supra* note 11, at 1278–79. See Offit, *supra* note 11, at 1278–79, for a review of the events leading to and following the debate on thimerosal in vaccines in the United States.

based preservative.⁸¹ Ethylmercury is a different substance from methylmercury, despite the common mercurial base and similar name.⁸²

In the 1930s, manufacturers added the preservative thimerosal to immunizations to minimize vaccine injuries resulting from bacterial and fungal growth in the vaccines.⁸³ Economic efficiency was critical to achieving herd immunity in the Depression era and to maintain such efficiency manufacturers stored the vaccines in multi-use vials.⁸⁴ Because the vials would often need to be stored between uses, a preservative agent was necessary to prevent bacterial contamination.⁸⁵ Early reports showed the use of thimerosal reduced the risk of bacterial contamination with no apparent side effects.⁸⁶ The modern advent of single-use vaccination vials in the early 2000s made the need for thimerosal practically nonexistent in the United States and the substance has since been removed from almost all vaccines today.⁸⁷

The use of thimerosal was called in to question and its public perception as safe was destroyed in 1998 when a British scientist, Andrew Wakefield, announced research (“the Wakefield study” or “the study”) linking the thimero-

⁸¹ Vaccine Testimony, *supra* note 15; Barraza et al., *supra* note 3, at 321; *Thimerosal in Vaccines*, *supra* note 5.

⁸² Barraza et al., *supra* note 3, at 321 (explaining that ethylmercury does not have the health impact of methylmercury because of the way the human body processes and excretes the substance); Moreno, *supra* note 5, at 412–13 (noting that the amount of ethylmercury used in vaccines has never been shown to cause mercury toxicity); Offit, *supra* note 11, at 1278 (“Although these two molecules differ by only one carbon atom, the difference isn’t trivial.”); *WHO Thimerosal Statement*, *supra* note 14 (outlining the scientific data distinguishing methylmercury and ethylmercury).

⁸³ Barraza et al., *supra* note 3, at 321; Michael J. Donovan, Note, *The Impact of “Hurricane” Hannah: The Government’s Decision to Compensate in One Girl’s Vaccine Injury Case Could Drastically Alter the Face of Public Health*, 50 *JURIMETRICS J.* 229, 241 (2010); Offit, *supra* note 11, at 1278; *Thimerosal in Vaccines*, *supra* note 5.

⁸⁴ Barraza et al., *supra* note 3, at 321–22 (noting the critical role childhood vaccinations play in herd immunity); Donovan, *supra* note 83, at 236 (defining herd immunity as the idea that, by vaccinating eighty to ninety percent of the population, the spread of disease is contained); Moreno, *supra* note 5, at 415–16 (commenting that the economic and public health concerns that existed in the United States during the Depression still exist today in many countries around the world); *Thimerosal in Vaccines*, *supra* note 5 (discussing the “tragic consequences” that led to thimerosal’s use); see *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1277 (D.C. Cir. 2012) (noting that this condition exists today with the influenza vaccine because thimerosal is necessary to provide adequate supply at a price consumers can afford).

⁸⁵ *Thimerosal in Vaccines*, *supra* note 5; see also 42 U.S.C. § 300aa-2 (2012). Statute defines a vaccine injury as any adverse reaction caused by a vaccine. 42 U.S.C. § 300aa-2.

⁸⁶ Moreno, *supra* note 5, at 413; *Thimerosal in Vaccines*, *supra* note 5. FDA.gov outlines the animal and human studies of ethylmercury prior to its use in vaccines demonstrating safety and effectiveness. *Thimerosal in Vaccines*, *supra* note 5.

⁸⁷ Barraza et al., *supra* note 3, at 321; Haertlein, *supra* note 3, at 218; Moreno, *supra* note 5, at 415–16; *Thimerosal in Vaccines*, *supra* note 5. Although thimerosal is mostly obsolete in the United States, it continues to play an important role in continuing international vaccination programs. Moreno, *supra* note 5, at 415–16.

sal-containing MMR combined vaccine to ASD.⁸⁸ In the years immediately preceding the study, the prevalence rate of ASD grew dramatically, causing fears of an epidemic and leading to new research into the cause of ASD.⁸⁹ The Wakefield study bolstered the fears of epidemic and, coupled with PHS agencies' recommendation for an increase in early childhood vaccinations, led to widespread public alarm.⁹⁰

In 1999 and 2000, the public health agencies responded to this panic by instituting a ban on vaccinations containing thimerosal for children.⁹¹ The precautionary ban resulted from what the agencies saw as a complete lack of research to determine a safe level of thimerosal exposure because, until this time, the agencies had categorized thimerosal as a safe product.⁹² Instead, the agencies looked to what they believed to be the best available data—EPA's regulatory standards for methylmercury.⁹³

When the agencies sought reference standards for thimerosal, they failed to take into account the difference between methylmercury and ethylmercury—the mercurial compound present in thimerosal.⁹⁴ EPA's standards indicated the levels at which water, air, and land become toxic due to methylmercury contamination, but the standards did not apply to any other type of mercury or mer-

⁸⁸ Donovan, *supra* note 83, at 231; Moreno, *supra* note 5, at 409–10; Wakefield et al., *supra* note 12, at 641. The Wakefield study was the first to provoke the public awareness that launched the debate concerning autism and vaccines, but some publications focus on the FDA's 1999 review of mercury in consumer products as the beginning of the timeline. See Donovan, *supra* note 83, at 231; Offit, *supra* note 11, at 1278; Wakefield et al., *supra* note 12, at 641.

⁸⁹ Stefan N. Hansen et al., *Explaining the Increase in the Prevalence of Autism Spectrum Disorders: The Proportion Attributable to Changes in Reporting Practices*, J. AM. MED. ASS'N PEDIATRICS, Jan. 2015, at 56, 57; Moreno, *supra* note 5, at 411. "[R]eported autism diagnoses have increased from approximately 1 in 10,000 in the 1980s to 1 in 166 in 2003." Moreno, *supra* note 5, at 411.

⁹⁰ See Moreno, *supra* note 5, at 411. Most medical professionals and researchers now point to the 1994 update to the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-IV"), making diagnostic criteria more inclusive, and a heightened awareness of ASD as reasons for the increased rate of diagnosis. Hansen, *supra* note 89, at 57, 60–61; see AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-IV) § 299.00, 66–71 (4th ed. 2000) [hereinafter DSM-IV]. This edition broadened the diagnostic criteria for autism from the previously strict criteria that only recognized the most pervasive form. *Autism at 70—from Kanner to DSM-5*, AUTISM SPEAKS (Sept. 19, 2013), <https://www.autismspeaks.org/science/science-news/autism-70—kanner-dsm-5> [<https://perma.cc/ZXG7-E4ZL>]; see DSM-IV, *supra*. Recent research found a link between the increase in ASD prevalence and the change in diagnostic criteria, "most (60%) of the increase in ASD prevalence in children born from 1980 through 1991 in Denmark based on registry-reported diagnoses can be explained by the change in diagnostic criteria in 1994 and the inclusion of outpatient data to the DPR in 1995." Hansen, *supra* note 89, at 57, 60–61.

⁹¹ Vaccine Testimony, *supra* note 15; *Thimerosal in Vaccines*, *supra* note 5.

⁹² 21 C.F.R. § 310.545(27)(i) (1990); Offit, *supra* note 11, at 1278; *Thimerosal in Vaccines*, *supra* note 5. Regulations categorize thimerosal as safe in over-the-counter drugs. 21 C.F.R. § 310.545(27)(i).

⁹³ Vaccine Testimony, *supra* note 15; Offit, *supra* note 11, at 1278; see Moreno, *supra* note 5, at 413 ("Advocates of the vaccine-autism link add to the public confusion by ignoring the evidence of the different health risks associated with methyl and ethyl mercury.")

⁹⁴ See Offit, *supra* note 11, at 1278; see also WHO *Thimerosal Statement*, *supra* note 14.

cury derivative.⁹⁵ At the time of investigation, EPA's standard for a safe methylmercury level in humans was 0.1 microgram per kilogram body weight per day.⁹⁶ The agencies calculated the amount of ethylmercury under the recommended vaccine schedule and found that during the first six months of life, children could receive up to 187.5 micrograms of ethylmercury through vaccinations.⁹⁷ Comparing the numbers at face value, the agencies determined that the amount of ethylmercury was far above EPA's limit for methylmercury and was therefore unsafe.⁹⁸

After lawsuits and widespread fear, spurred on in part by celebrities and politicians, the Wakefield study was roundly and decisively discredited as the result of bad science and bad ethics.⁹⁹ This criticism ultimately led to the study's retraction.¹⁰⁰ The Wakefield study employed poor scientific protocols, false readings from medical devices, and unethically interpreted results.¹⁰¹ Subsequent studies funded by private and government entities were unable to replicate the results, casting doubt on the findings and disproving the original hypothesis.¹⁰² Substantiating the weight of research against the Wakefield study, data showed that states and countries with a ban on thimerosal continued to see a rise in rates of ASD diagnosis.¹⁰³

Based on this new evidence, the agencies reversed their position and reinstated their support for all vaccine recommendations with thimerosal, but it

⁹⁵ Bigham et al., *supra* note 1, at 29–31; *see* Offit, *supra* note 11, at 1278.

⁹⁶ *Thimerosal in Vaccines*, *supra* note 5.

⁹⁷ Vaccine Testimony, *supra* note 15; Offit, *supra* note 11, at 1278.

⁹⁸ Vaccine Testimony, *supra* note 15; *Thimerosal in Vaccines*, *supra* note 5 (“The Committee believed that the effort to remove thimerosal from vaccines was ‘a prudent measure in support of the public health goal to reduce mercury exposure of infants and children as much as possible.’”).

⁹⁹ Barraza et al., *supra* note 3, at 317; Donovan, *supra* note 83, at 231; Haertlein, *supra* note 3, at 218; Moreno, *supra* note 5, at 414; Offit, *supra* note 11, at 1279; Gardiner Harris, *Journal Retracts 1998 Paper Linking Autism to Vaccines*, N.Y. TIMES (Feb. 2, 2010), <http://www.nytimes.com/2010/02/03/health/research/03lancet.html> [<https://perma.cc/AHC6-YT7L>].

¹⁰⁰ Barraza et al., *supra* note 3, at 317; Donovan, *supra* note 83, at 231; Haertlein, *supra* note 3, at 218; Moreno, *supra* note 5, at 414; Offit, *supra* note 11, at 1279; Harris, *supra* note 99. For an explanation of the widespread criticisms and the ethical concerns leading to the study's retraction and the revocation of Wakefield's medical license, *see* Donovan, *supra* note 83, at 231 and Haertlein, *supra* note 3, at 218.

¹⁰¹ Donovan, *supra* note 83, at 231; Haertlein, *supra* note 3, at 218; Harris, *supra* note 99.

¹⁰² Barraza et al., *supra* note 3, at 317 (noting that the controversy did not end in the face of a lack of scientific support); Moreno, *supra* note 5, at 414 (highlighting relevant research disproving the causal link as well as the scientific challenges to principal anti-vaccine research by Dr. Mark Geier); Harris, *supra* note 99 (announcing the retraction); *Thimerosal in Vaccines*, *supra* note 5 (discussing two key studies finding no causal link between thimerosal and autism); *Timeline: Thimerosal in Vaccines (1999–2010)*, *supra* note 15 (identifying key studies finding no causal link between thimerosal and autism).

¹⁰³ Barraza et al., *supra* note 3, at 321; Harris, *supra* note 99. There is evidence that ASD prevalence rates have increased after thimerosal bans went into effect in some states and other countries. Barraza et al., *supra* note 3, at 321.

was all too little, too late.¹⁰⁴ Families brought more than five thousand legal claims to the National Vaccine Injury Compensation Program (“NVICP”) on behalf of children diagnosed with ASD after receiving the MMR combined vaccine.¹⁰⁵ In the special Omnibus Autism Proceeding (“OAP”), the Special Master of the United States Court of Federal Claims dismissed all claims for failure to prove causation, but this made little difference in the growing public panic and misinformation campaigns.¹⁰⁶ Parent advocacy groups fought to ban all vaccines and the resulting fear-mongering left many children unvaccinated, leading to outbreaks of preventable—and fatal—diseases.¹⁰⁷ The agencies attempted to quell these fears by requiring all vaccines be available in a thimerosal-free version and encouraged manufacturers to remove thimerosal from all vaccines.¹⁰⁸

Many people still firmly believed that the discredited Wakefield study was correct and the public outrage and fear quickly spread beyond the Wakefield-implicated MMR combined vaccine to a fear of all vaccines.¹⁰⁹ These individuals responded to the research, agency reversal, and court decision by arguing that a conspiracy existed between the government and vaccine manufacturers.¹¹⁰ No amount of research disproving the autism theory could change minds.¹¹¹

¹⁰⁴ See Vaccine Testimony, *supra* note 15; *Timeline: Thimerosal in Vaccines (1999–2010)*, *supra* note 15.

¹⁰⁵ Barraza et al., *supra* note 3, at 320; Haertlein, *supra* note 3, at 219; Moreno, *supra* note 5, at 411. The National Vaccine Injury Compensation Program (“NVICP”) claims offered three theories of causation: “(1) MMR vaccines and thimerosal-containing vaccines together cause autism; (2) thimerosal-containing vaccines cause autism; and (3) MMR vaccine causes autism.” Barraza et al., *supra* note 3, at 320; see also Haertlein, *supra* note 3, at 219.

¹⁰⁶ *Cedillo v. Sec’y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *134 (Fed. Cl. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); Barraza et al., *supra* note 3, at 320–21; Haertlein, *supra* note 3, at 212. *Cedillo* held that “the overall weight of the evidence is *overwhelmingly contrary to*” the theories of causation presented. 2009 WL 331968, at *134.

¹⁰⁷ Barraza et al., *supra* note 3, at 317–18; Haertlein, *supra* note 3, at 225; Offit, *supra* note 11, at 1279.

¹⁰⁸ Vaccine Testimony, *supra* note 15; Barraza et al., *supra* note 3, at 321; *Timeline: Thimerosal in Vaccines (1999–2010)*, *supra* note 15.

¹⁰⁹ Barraza et al., *supra* note 3, at 318–19 (noting that MMR vaccine fears have affected public perception of all vaccines and providing example of then presidential-candidate Michelle Bachmann’s comments on the risks of the human papillomavirus vaccine, Gardasil, during a presidential debate); Offit, *supra* note 11, at 1279 (noting that MMR vaccine fears have not stopped the use of thimerosal in the influenza vaccine).

¹¹⁰ Haertlein, *supra* note 3, at 226 (observing that the vaccine concerns have grown into a belief of government and industry conspiracy); Moreno, *supra* note 5, at 414–15 (discussing Robert F. Kennedy, Jr.’s support of the governmental and industry conspiracy theory).

¹¹¹ Barraza et al., *supra* note 3, at 317–19 (“Studies finding no unexpected ill health effects rarely receive comparable attention.”); Haertlein, *supra* note 3, at 225 (explaining why the OAP judgment did not end the debate of whether there is a causal relationship between autism and vaccines); Moreno, *supra* note 5, at 415 (“Unfortunately, dangerous beliefs that lack a scientific basis and should be

E. Regulating Vaccines: The Administrative Complex

Federal regulation of vaccinations is conducted by the United States Department of Health and Human Services (“HHS”).¹¹² State and local governments also have the power to adopt and implement compulsory vaccination laws.¹¹³ HHS, though, takes a lead role in policy-making and industry oversight.¹¹⁴ HHS develops and enacts public health goals and authorizes the public health agencies to take action.¹¹⁵ In the case of immunizations, these public health goals require a broad range of activities executed by agencies that are subsidiaries of HHS, including the FDA and CDC.¹¹⁶ The FDA has primary authority over the approval process for vaccine compounds and inoculation devices and the CDC leads research and makes vaccination recommendations.¹¹⁷ Although each agency has a specific role, the agencies also work together for larger policy decisions, such as the initial ban and study of thimerosal, wherein each agency offers unique expertise and the perspective needed to make a final decision.¹¹⁸

The FDA regulates the active ingredients in vaccines necessary for the prevention of disease as well as the inactive substances in the vaccine under the Food, Drug, and Cosmetic Act (“FDCA”).¹¹⁹ The FDA’s authority to regulate any substance within its scope is plenary.¹²⁰ If a substance is found to be safe, the FDA has significant discretionary authority to regulate it through the FDCA, even going so far as to allow the FDA to prohibit the manufacture of any regulated product it deems unsafe.¹²¹

further discredited by this type of flagrant conspiracy-mongering can survive and flourish.”); *see* Offit, *supra* note 11, at 1279 (sharing that the perceived link between thimerosal and ASD is so firmly held that many children undergo a dangerous mercury poisoning treatment known as chelation in an attempt to cure their autism).

¹¹² Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

¹¹³ Barraza et al., *supra* note 3, at 316; Donovan, *supra* note 83, at 230.

¹¹⁴ 42 U.S.C. § 242k (2012) (authorizing the agencies under the Department of Health and Human Services (“HHS”) to take the regulatory actions necessary to protect public health).

¹¹⁵ *Id.* § 242k(b) (outlining the responsibilities of HHS).

¹¹⁶ *See Thimerosal in Vaccines*, *supra* note 5 (indicating the lead agencies are the FDA and the Centers for Disease Control and Prevention (CDC)).

¹¹⁷ 42 U.S.C. §§ 262–264. (designating HHS authority of “biological products,” including immunizations, and authority to regulate the “communicable diseases”).

¹¹⁸ *See Vaccine Testimony*, *supra* note 15; *Thimerosal in Vaccines*, *supra* note 5. The testimony provides an overview of the roles of the FDA and CDC in vaccine regulation. *Vaccine Testimony*, *supra* note 15.

¹¹⁹ 42 U.S.C. § 262 (granting the authority to regulate biologics to the Secretary of HHS); *Vaccine Testimony*, *supra* note 15 (summarizing the FDA’s pre- and post-licensure role in vaccine regulation).

¹²⁰ *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000).

¹²¹ 21 U.S.C. § 321(u) (2012); *See id.* § 355; *Brown & Williamson Tobacco Corp.*, 529 U.S. at 137 (“Congress, however, has foreclosed the removal of tobacco products from the market.”).

In 2000, the United States Supreme Court in *Food & Drug Administration v. Brown & Williamson Tobacco Corp.* held that this discretion is only limited in the case of preemption by Congress.¹²² Rejecting the FDA attempt to assert regulatory authority over tobacco products, the Court held that Congress preempted tobacco regulation from FDA authority by granting these powers to other agencies.¹²³ The Court's discussion of the agency's power establishes that so long as a regulated substance falls within the scope of the FDCA, and Congress has not granted authority to another agency, a court conducting judicial review of an agency decision will give deference to the agency's action.¹²⁴

Vaccinations are considered "biological products" under the FDCA, therefore, the FDA has the statutory authority to conduct thorough review and approval for all new vaccines and to promulgate general standards of safety.¹²⁵ Because vaccines are commonly employed to tackle existent or imminent public health threats, such as the flu vaccine that is modified annually to target the expected strains, these substances typically experience an expedited review.¹²⁶ The FDCA and implementing regulations set requirements for all vaccines so that the agency need only approve the active ingredient.¹²⁷ These requirements mandate the use of a "sufficiently nontoxic" preservative.¹²⁸ The FDA may also conduct a post-approval safety review even when it had no requirement of a risk evaluation at the time the vaccine was approved.¹²⁹

The CDC's role in vaccinations focuses on the study of communicable diseases and the use of approved vaccines.¹³⁰ The CDC recommends vaccination standards, such as which vaccines states should mandate for school-age children and high-risk groups, by tracking and developing prevention strategies for communicable diseases.¹³¹ The agency then evaluates these recom-

¹²² 529 U.S. at 161.

¹²³ *Id.* at 137–39 (explaining the pattern of congressional intent to limit the FDA's authority for tobacco regulation).

¹²⁴ *See id.* at 126, 137–38, 159–60.

¹²⁵ 42 U.S.C. § 262(i) (2012).

¹²⁶ *See Vaccine Testimony*, *supra* note 15 (describing the unique timeline of the annual influenza vaccine).

¹²⁷ 42 U.S.C. § 262 (granting the FDA the authority to approve active ingredients); 21 C.F.R. § 310.545(27)(i) (2016) (defining thimerosal as an ingredient not regulated despite "inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses").

¹²⁸ *See* 21 C.F.R. § 610.15(a) (2016).

¹²⁹ 42 U.S.C. § 262(a)(2)(A).

¹³⁰ *Id.* § 300aa-2 (mandating safe childhood vaccinations); *see also id.* § 242k (describing broader HHS powers that may be delegated to the CDC).

¹³¹ *Id.* § 300aa-2(a)(1) (mandate requires CDC participation in the safety assessment of childhood vaccinations); *see also id.* § 264 (outlining HHS's responsibilities to "control communicable diseases" that may be delegated to CDC); *Vaccination Strategies for High-Risk Adults*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 2, 2016), <http://www.cdc.gov/vaccines/hcp/adults/for-practice/highrisk-strat.html> [<https://perma.cc/W3L9-VSR3>] (defining high-risk groups as adults with specific medical conditions, healthcare workers, and individuals with high-risk behaviors).

mendations based on the rate that the disease occurs without vaccination, also known as its incidence rate.¹³² Additionally, the CDC works with the FDA's Center for Biologics Evaluation and Research program to track vaccine injury reports on the Vaccine Adverse Event Reporting System ("VAERS"), a consumer tool for incident reporting.¹³³

II. CENTERS FOR DISEASE CONTROL AND PREVENTION RESPONSE TO THE VACCINE CONTROVERSY: REASONABLE PROCESS TO PROTECT THE PUBLIC HEALTH OR A POLITICALLY MOTIVATED OVERREACTION CAUSING MORE HARM?

When faced with a critical decision on public health, the default position for vaccine regulation is to proceed under the precautionary principle.¹³⁴ In the case of ethylmercury, caution bred fear and created a greater public health risk—the loss of herd immunity due to decreasing vaccination rates.¹³⁵ The decision by the public health agencies (collectively the CDC, FDA and others, "Public Health Service," "the PHS agencies," or "the agencies") to ban thimerosal based on a flawed comparison to the methylmercury standard used by the Environmental Protection Agency (EPA) was not based on a thorough assessment of the scientific data available.¹³⁶ The subsequent decision to reverse the ban without a comprehensive understanding of thimerosal's safety and without regard to the public's confusion failed to rebuild confidence in vaccinations.¹³⁷

A. The Precautionary Ban on the Use of Thimerosal in Vaccines Ignored the Substantial Evidence Standard Required in Substance Regulation

In 2015, the United States Supreme Court held in *Industrial Union Department, AFL-CIO v. American Petroleum Institute (Benzene Case)* that agen-

¹³² 42 U.S.C. § 300aa-2(a)(7); *see also id.* § 242k. Section 242k (outlining the HHS public health research responsibilities that may be delegated to CDC).

¹³³ Vaccine Testimony, *supra* note 15.

¹³⁴ *See id.*; Fisher, *supra* note 33, at 127–28; Israel, *supra* note 57, at 480; Offit, *supra* note 11, at 1279. Agency testimony describes the reasoning behind the precautionary response of the public health agencies. *See* Vaccine Testimony, *supra* note 15. The scientific community challenges this reasoning, noting that "the precautionary principle *assumes that there is no harm in exercising caution.*" Offit, *supra* note 11, at 1279 (emphasis added).

¹³⁵ *See* Barraza et al., *supra* note 3, at 319; Haertlein, *supra* note 3, at 230; Moreno, *supra* note 5, at 412, 414–25; Offit, *supra* note 11, at 1279. Offit identifies several other predictable legal, political, and public health outcomes that should have been considered in the decision-making process. Offit, *supra* note 11, at 1279.

¹³⁶ *See infra* notes 138–167 and accompanying text.

¹³⁷ *See* Barraza et al., *supra* note 3, at 319; Moreno, *supra* note 5, at 412–13; Offit, *supra* note 11, at 1279. Moreno argues by analogy to the courts that a review of medical literature and statistical data should guide mercury regulation. Moreno, *supra* note 5, at 412–13.

cies may only regulate exposure to a substance by setting a standard level of exposure based on relevant factors, such as “substantial evidence” and cost.¹³⁸ Complete elimination is rarely possible, or even necessary, and the standard must be the highest level of exposure, based on “substantial evidence,” at which the substance is safe.¹³⁹ Evidence of harm may be available before there is substantial evidence supporting an appropriate standard of exposure, therefore the Court found that an agency may set a precautionary standard so long as it is based on “reputable scientific thought.”¹⁴⁰ The Court’s holding in *Michigan v. Environmental Protection Agency* defines the required process to determine an appropriate standard level of exposure as “reasoned decision making” that must be based on pertinent information.¹⁴¹

In an attempt to quell public panic, the agencies improperly relied on the precautionary principle during the Autism Spectrum Disorder (autism or “ASD”) controversy by ignoring the vast amount of available relevant scientific and vaccine tracking data.¹⁴² Several human and animal studies available at the time indicated that there was no mercury toxicity risk related to vaccines except in doses of more than one thousand times the standard thimerosal dose.¹⁴³ These studies indicate that ethylmercury may have a critical value that requires the agencies to set a standard level of exposure, but the agencies did not rely on these studies.¹⁴⁴

The ethylmercury toxicity studies do not support use of the EPA’s methylmercury standard because these studies suggest a safe level of exposure for ethylmercury that is much higher than the critical value for methylmercury.¹⁴⁵ Even with access to evidence that the substances had vastly different tox-

¹³⁸ See *Indus. Union Dept’t, AFL-CIO v. Am. Petroleum Inst. (Benzene Case)*, 448 U.S. 607, 656 (1980); see *Michigan v. Env’tl. Prot. Agency*, 135 S. Ct. 2699, 2706 (2015). *Michigan v. Environmental Protection Agency* held that “agency action is lawful only if it rests ‘on a consideration of the relevant factors.’” 135 S. Ct. at 2706.

¹³⁹ See *Benzene Case*, 448 U.S. at 656.

¹⁴⁰ See *id.*

¹⁴¹ *Michigan v. Env’tl. Prot. Agency*, 135 S. Ct. at 2706 (requiring agencies to use “reasoned decisionmaking” when setting exposure standards).

¹⁴² See *Offit*, *supra* note 11, at 1279 (challenging the agencies’ precautionary response); Vaccine Testimony, *supra* note 15 (sharing the initial review of data showed no risk of toxicity from thimerosal from the amount of vaccinations recommended in the current immunization schedule); *Thimerosal in Vaccines*, *supra* note 5 (identifying the specific relevant studies).

¹⁴³ Vaccine Testimony, *supra* note 15 (showing that the agencies relied on EPA’s methylmercury standard instead of the ethylmercury data); *Thimerosal in Vaccines*, *supra* note 5 (compiling the results of several studies and reports of thimerosal safety, including: a 1931 human study finding no toxicity with exposure levels “up to [twenty-six] milligrams thimerosal/kg” and the only cases of acute mercury poisoning from thimerosal at exposure of “approximately [three] mg/kg to several hundred mg/kg . . . 1000 times the proper dose of thimerosal as a preservative”).

¹⁴⁴ *Thimerosal in Vaccines*, *supra* note 5.

¹⁴⁵ *Id.* (noting that the data offers doses higher than the total in the immunization schedule that showed with no toxicity and significantly higher doses with toxicity, indicating that there may be a threshold amount that is safe for human health); see *Benzene Case*, 448 U.S. at 655 (requiring con-

icity levels, the agencies' use of EPA's methylmercury standard made the same error overturned under the *Benzene Case*—setting an exposure standard at a level far below the level the “substantial evidence” suggested without any “reputable scientific thought” to support such a deviation.¹⁴⁶ The agencies failed to apply substantial evidence to make their decision properly.¹⁴⁷

The agencies also ignored the National Vaccine Injury Compensation Program (“NVICP”) in favor of the consumer-sourced Vaccine Adverse Event Reporting System (“VAERS”) data; however the proper methodology for the agencies was to review both sources in order to ascertain a comprehensive picture of the risks not demonstrated by other research.¹⁴⁸ The VAERS resource relies on voluntary submissions that are not verified and are intended only as a rough estimate of incidence rates, these characteristics have caused scholars to question the reliability of the data set.¹⁴⁹ NVICP provides data on the injury and symptoms for review by medical staff at the United States Department of Health and Human Services (“HHS”).¹⁵⁰ This review process makes the data statistically more reliable.¹⁵¹ Reviewing both sources for indications of a causal link to autism is the most thorough methodology because, taken together, the data sets provide data that is both quantitatively and qualitatively significant.¹⁵²

servative standards be based on “reputable scientific thought”); Moreno, *supra* note 5, at 412–13 (reviewing the scientific research distinguishing the health effects of methylmercury from ethylmercury, particularly with respect to the human body's ability to process and excrete each compound); Sinks et al., *supra* note 7, at 65–66 (describing the challenges of regulating based on uncertain or unknown scientific data).

¹⁴⁶ See *Benzene Case*, 448 U.S. at 656, 662 (requiring agencies to base exposure levels on “substantial evidence,” which requires the “best available evidence” and may be based on “conservative assumptions . . . supported by a body of reputable scientific thought” where concrete evidence is unavailable); *Thimerosal in Vaccines*, *supra* note 5 (EPA's methylmercury standard: 0.1 micrograms/kilograms/day; lowest dose from which ethylmercury caused toxicity: approximately 3 milligrams/kilogram or 3,000 micrograms/kilogram).

¹⁴⁷ See *Benzene Case*, 448 U.S. at 656, 662; *Thimerosal in Vaccines*, *supra* note 5.

¹⁴⁸ See Fisher, *supra* note 33, at 128; Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480, 531 (2011). Holland argues that the NVICP claims are a valuable resource in the autism/vaccine link. Holland et al., *supra*, at 531.

¹⁴⁹ VAERS Data, VACCINE ADVERSE EVENT REPORTING SYS., <https://vaers.hhs.gov/data/index> [<https://perma.cc/LVZ3-4GTJ>] (disclosing the limitations of Vaccine Adverse Event Reporting System (“VAERS”) data, including voluntary sources and frequency of missing details and errors).

¹⁵⁰ See Haertlein, *supra* note 3, at 230; Holland et al., *supra* note 148, at 503–27; *National Vaccine Injury Compensation Program*, U.S. DEP'T OF HEALTH & HUMAN SERVS.: HEALTH RES. & SERVS. ADMIN. (Mar. 2017), <https://www.hrsa.gov/vaccinecompensation> [<https://perma.cc/FTN7-VKX2>].

¹⁵¹ See Haertlein, *supra* note 3, at 230 (arguing that the NVICP allows for a more flexible standard of causation appropriate for the unique cases of vaccine injury); Holland et al., *supra* note 148, at 503–27 (describing study of the NVICP compensated claims for autism-like symptoms conducted by Pace Law School); *National Vaccine Injury Compensation Program*, *supra* note 150 (explaining the process for NVICP claims).

¹⁵² See Haertlein, *supra* note 3, at 230 (illustrating that the NVICP claims provide a more flexible evidentiary standard that indicates claims may have been brought for ASD symptoms in the past);

B. The Agencies' Reliance on the Wakefield Study Is Contrary to the Legal Requirements of Causation and the Scientific Method

The legal elements of causation and the scientific method were ignored when the agencies issued a ban on thimerosal in vaccines based on a single study with an uncorroborated result.¹⁵³ Scientific causation requires results in multiple studies, relevant dose-response evidence, and specificity.¹⁵⁴ Regulators must apply these factors to new data before imposing new standards because, even with a full understanding of the data, there would still be gaps between the law and scientific reality.¹⁵⁵

The basic principles of scientific research require that a study's results prove true upon replication by other scientists in order to ensure the study's reliability.¹⁵⁶ Without consistent results in multiple studies, which did not exist at the time of the precautionary ban, the 1998 study conducted by British scientist Andrew Wakefield ("the Wakefield study" or "the study") is not sufficiently reliable to show causation and should not be used to support regulation.¹⁵⁷ The Wakefield study also lacked dose-response data, leaving the agencies to fill in the gaps with the irrelevant methylmercury standard.¹⁵⁸

The immediate reaction to concerns about ethylmercury shows the rash nature of the public health agencies' decision.¹⁵⁹ Regulating a substance based on a lower standard of causation was intended to be overly protective but effectively removed the causation requirement from public health regulation.¹⁶⁰ In contrast, EPA did not impose its methylmercury regulations until the agency could prove the substance caused neurological impairments.¹⁶¹

Holland et al., *supra* note 148, at 494–95 (noting that, although autism was not listed as a disorder until the 1980 publication of the third edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, relevant symptoms were indicated as early as the 1940s and attributed to other disorders).

¹⁵³ See Sinks et al., *supra* note 7, at 63.

¹⁵⁴ Bigham et al., *supra* note 1, at 26; Sinks et al., *supra* note 7, at 63.

¹⁵⁵ See Sinks et al., *supra* note 7, at 66 (discussing the difficulties of legislating with limited scientific knowledge in an area of scientific uncertainty).

¹⁵⁶ See Joe G. Hollingsworth & Eric G. Lasker, *The Case Against Differential Diagnosis: Daubert, Medical Causation Testimony, and the Scientific Method*, 37 J. HEALTH L. 85, 90 (2004); Sinks et al., *supra* note 7, at 63.

¹⁵⁷ Hollingsworth & Lasker, *supra* note 156, at 103; Sinks et al., *supra* note 7, at 63; see *Thimerosal in Vaccines*, *supra* note 5. Subsequent actions by the agency indicate that these elements were fulfilled. See *Thimerosal in Vaccines*, *supra* note 5.

¹⁵⁸ Sinks et al., *supra* note 7, at 63; *Thimerosal in Vaccines*, *supra* note 5.

¹⁵⁹ See Fisher, *supra* note 33, at 128; Sinks et al., *supra* note 7, at 64. In contrast, some favor cautious regulation to balance all relevant parties and information as a general preference. See Sinks et al., *supra* note 7, at 64.

¹⁶⁰ See Fisher, *supra* note 33, at 127–28; Sinks et al., *supra* note 7, at 64. There is a critical need for causation before regulating. See Sinks et al., *supra* note 7, at 64.

¹⁶¹ See Bigham et al., *supra* note 1, at 26–27 (noting that the United States has been slow to regulate mercury, even in comparison to the United Kingdom or France).

*C. The Decision to Support a Precautionary Ban Failed to
Balanced the Relevant Factors*

In addition to this flawed risk assessment, the agencies' public health approach failed when its balancing test used irrelevant factors and weighed the wrong risks.¹⁶² A reasonable and precautionary test would have examined the consequences of the ban against the risk defined in the Wakefield study.¹⁶³ This type of analysis is the standard protocol when determining vaccine regulations.¹⁶⁴ In this test, the consequences of not vaccinating children, specifically an increased risk of outbreak and fatality and a decrease in the ability to ensure herd immunity, are weighed against the risk of increased prevalence of ASD.¹⁶⁵ Although an ASD diagnosis has pervasive consequences on an individual's life, it is not fatal and does not present a contagious risk to public health like the diseases prevented by vaccinations.¹⁶⁶ The agencies nonetheless merely weighed the risk of an increased incidence of ASD against the hope of decreasing the incidence rate of ASD and ignored the public health risks entirely.¹⁶⁷

*D. The Decision to Reverse the Ban Failed to Meet the Critical
Public Health Needs of Vaccination Policy*

The public reaction—and overreaction—to the Wakefield study and the government's subsequent actions should serve as a cautionary tale not simply for future regulatory actions, but also for resolution of the broader vaccine de-

¹⁶² See *Michigan v. Env'tl. Prot. Agency*, 135 S. Ct. at 2706; Offit, *supra* note 11, at 1279. For a suggestion of the correct risks for consideration, see Offit, *supra* note 11, at 1279.

¹⁶³ See Barraza et al., *supra* note 3, at 316 (providing an analogous balancing test for water fluoridation where potential cosmetic risks were outweighed by benefits to public health); Offit, *supra* note 11, at 1279 (identifying predictable harms caused by the precautionary ban).

¹⁶⁴ See Vaccine Testimony, *supra* note 15 (describing the balancing test for the influenza vaccine as the public and individual health benefits against "the theoretical risk" from thimerosal); Medicare and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities, 70 Fed. Reg. 58,834, 58,839 (Oct. 7, 2005) (to be codified at 42 C.F.R. pt. 483) (speaking to concerns about vaccine injury associated with the influenza vaccine, the FDA responded to public comment balancing the risk associated with failure to vaccinate against the risk of vaccine injury).

¹⁶⁵ Vaccine Testimony, *supra* note 15 (explaining that the decision-making process leading to the ban weighed the risks of autism against the benefits of vaccination); Barraza et al., *supra* note 3, at 309 (identifying the potential public health risk from decreased vaccination rates); see Offit, *supra* note 11, at 1279 (describing the factors and public health risks that should be weighed against "a theoretical (and now disproved) risk").

¹⁶⁶ Barraza et al., *supra* note 3, at 308–09, 321–22 (discussing the wide spread and potentially fatal risk of losing herd immunity); Moreno, *supra* note 5, at 409 (describing the parental fears associated with an ASD diagnosis); Offit, *supra* note 11, at 1279 (explaining the real public health risk through examples of overreaction and fatal failure to vaccinate).

¹⁶⁷ See Offit, *supra* note 11, at 1278.

bate.¹⁶⁸ When the Wakefield study was announced, it revealed a massive knowledge gap in the agencies that were charged with regulation because there was so little research on ethylmercury that might give the agencies a reference point to determine a safety standard.¹⁶⁹ This information gap showed a need for research on ethylmercury's critical value and its potential negative effects, as well as a lack of understanding of how public reaction could morph into a much more significant public health problem.¹⁷⁰

The knowledge gap regarding the safety of ethylmercury exists even today.¹⁷¹ Although there is a breadth of scientific evidence disproving the claim of ASD causation, no recent evidence proves that ethylmercury is safe or what level of exposure causes mercury toxicity.¹⁷² In the face of public panic and decreasing vaccination rates, merely disproving a single harm is insufficient to change perception.¹⁷³ Therefore, the decision to categorize ethylmercury as safe at any level of exposure after disproving only one harm was unreasonable and dangerous.¹⁷⁴ Although acting based on insufficient data may have felt necessary in the face of public panic, it is time for the agencies to study ethylmercury in depth.¹⁷⁵

The misunderstanding of how the public would react to a rapid and substantial policy shift was underestimated in the ASD controversy.¹⁷⁶ In an effort

¹⁶⁸ Barraza et al., *supra* note 3, at 317–19; Moreno, *supra* note 5, at 415–16; Offit, *supra* note 11, at 1279. For a discussion of the international public health ripple effects that should be considered in any balancing test, see Moreno, *supra* note 5, at 415–16.

¹⁶⁹ *Thimerosal in Vaccines*, *supra* note 5 (describing available data); see Sinks et al., *supra* note 7, at 66 (describing problems when regulators are charged with scientific decisions).

¹⁷⁰ See *Benzene Case*, 448 U.S. at 656 (holding that agencies may use “conservative assumptions” only if “they are supported by a body of reputable scientific thought”); Barraza et al., *supra* note 3, at 319 (highlighting public opinion polls showing the prevalence of the controversy as evidence that the public does not view risk through scientific principles); Offit, *supra* note 11, at 1279 (emphasizing the need for clearly understanding the potential public reaction).

¹⁷¹ See Vaccine Testimony, *supra* note 15; Offit, *supra* note 11, at 1279.

¹⁷² See 21 C.F.R. § 310.545(27)(i) (1990) (identifying thimerosal among ingredients with “inadequate data to establish general recognition of the safety and effectiveness”); *Thimerosal in Vaccines*, *supra* note 5 (reporting that no research into other toxicity risks was published since 1996).

¹⁷³ See Barraza et al., *supra* note 3, at 317–18, 320 (describing the various challenges to vaccinations not directly associated with autism claims, including “immune system overload” and the belief that it is unnecessary to vaccinate for diseases with low occurrence); Offit, *supra* note 11, at 1279 (stating the negative impact of failure to concretely prove safety); *Thimerosal in Vaccines*, *supra* note 5 (stating that past data indicates safety except at high doses).

¹⁷⁴ See *Michigan v. Env'tl. Prot. Agency*, 135 S. Ct. at 2707–08; Barraza et al., *supra* note 3, at 319; Offit, *supra* note 11, at 1278. The reaction to the initial ban is credited with spawning the current distrust, “[c]ritics wondered how removing something that hadn't been found to be unsafe could make vaccines safer.” See Offit, *supra* note 11, at 1278.

¹⁷⁵ See Barraza et al., *supra* note 3, at 319; Offit, *supra* note 11, at 1279.

¹⁷⁶ See Vaccine Testimony, *supra* note 15; Barraza et al., *supra* note 3, at 319; Offit, *supra* note 11, at 1278. The Acting Director's 2004 testimony demonstrates the continued confusion by agencies on how to deal with public perception. See Vaccine Testimony, *supra* note 15. The testimony priori-

to respond quickly and to quell public fears, the agencies inadvertently fanned the flames of distrust by validating a study that had not yet been reviewed by the scientific community.¹⁷⁷ In subsequently reversing their position, the agencies took for granted that the public's blind trust would continue.¹⁷⁸ Instead, communities became skeptical upon receiving mixed messages from agencies.¹⁷⁹

The agencies worked hard over the past decade to ensure that there is public awareness regarding the inaccuracy of the Wakefield study but they have continued to put out mixed messages on the safety of thimerosal and failed to conduct research to determine ethylmercury's critical value.¹⁸⁰ The decision to deregulate thimerosal was undermined by the PHS agencies' simultaneous recommendation that manufacturers remove the substance from vaccines.¹⁸¹ Furthermore, the Omnibus Autism Proceeding ("OAP") dismissal, which held that plaintiffs could not support a claim because the research did not prove causation, was intended to provide uniformity but was contradicted by at least one NVICP claim, granting damages for vaccine injuries that included ASD.¹⁸² Focusing on discrediting one study, while ignoring the broader question of whether ethylmercury is safe, is the reason the agencies' efforts to calm public fear have failed to resolve, and may even be fueling, the growing public health concern.¹⁸³

Federal agencies are aware that their recommendations have weight and can often be taken to an extreme.¹⁸⁴ The fish consumption recommendation regarding methylmercury demonstrates that such a reaction to thimerosal was foreseeable to the public health agencies.¹⁸⁵ Therefore, the agencies must restructure their decision-making process and begin comprehensive research in

tizes calming public fears over educating on vaccine safety. *See id.* This is especially confusing because the testimony is intended to defend the safety of thimerosal in the influenza vaccine. *See id.*

¹⁷⁷ *See Vaccine Testimony, supra* note 15; Barraza et al., *supra* note 3, at 319.

¹⁷⁸ *See Barraza et al., supra* note 3, at 319; Offit, *supra* note 11, at 1279.

¹⁷⁹ *See Barraza et al., supra* note 3, at 317–18; Haertlein, *supra* note 3, at 226; Moreno, *supra* note 5, at 414–15; Offit, *supra* note 11, at 1279. Such skepticism is linked to the rampant public push to utilize a philosophical exemption after the ban on thimerosal was lifted. *See Barraza et al., supra* note 3, at 317–18.

¹⁸⁰ *See Vaccine Testimony, supra* note 15; Barraza et al., *supra* note 3, at 319, 321. For instance, testimony from the Acting Director of the Office of Vaccines Research and Review supported thimerosal's safety, but also touted the removal of thimerosal. *Vaccine Testimony, supra* note 15.

¹⁸¹ *See Vaccine Testimony, supra* note 15; Barraza et al., *supra* note 3, at 321; *Thimerosal in Vaccines, supra* note 5.

¹⁸² Donovan, *supra* note 83, at 229; Haertlein, *supra* note 3, at 219.

¹⁸³ *See Barraza et al., supra* note 3, at 318–19, 321–23 (noting the need for "effective public health education and advocacy" to combat the public's fear); Moreno, *supra* note 5, at 417 (noting that the inconsistent message about thimerosal's safety followed by its removal from the market caused a decrease in vaccination rates); Offit, *supra* note 11, at 1279 (noting the impact of mixed messages on professionals and the public).

¹⁸⁴ *See Holden, supra* note 9, at 131; Sinks et al., *supra* note 7, at 64.

¹⁸⁵ *See Holden, supra* note 9, at 127–28.

order to define the critical value for regulation or concretely prove ethylmercury's safety.¹⁸⁶

III. A COMPREHENSIVE PLAN TO SET A STANDARD FOR ETHYLMERCURY CAN RESOLVE THE PUBLIC'S VACCINE DISTRUST

Following such a controversial regulatory process, it may be an unreasonable risk to public health to ask the American people to trust a label describing ethylmercury as safe.¹⁸⁷ Any action taken to resolve the question of vaccine safety must be transparent, evidence-based, and thorough.¹⁸⁸ To meet this goal, the public health agencies must first structure the tasks to match the expertise of each agency.¹⁸⁹ Only then will they be prepared to take on the challenge of conducting the comprehensive research and public education program necessary.¹⁹⁰

A. Restructuring Responsibilities: Matching the Role to the Agency Expertise

The United States Department of Health and Human Services ("HHS") must first allocate responsibilities among the public health agencies (collectively the CDC, FDA and others, "Public Health Service," "the PHS agencies," or "the agencies") more appropriately.¹⁹¹ A complete reorganization of the federal administrative state is not required; rather, this public health crisis warrants a reassessment of each agency's use of its authority.¹⁹² HHS must utilize the core of each agency's expertise to ensure that the actions are properly executed and each agency is held accountable for its role.¹⁹³

The emergency situation presented by the now retracted study ("the study" or "the Wakefield study") linking the vaccine to Autism Spectrum Disorder (autism or "ASD") followed the standard risk assessment model, which hypothetically made sense but resulted in substantial practical problems.¹⁹⁴ The structure

¹⁸⁶ See *infra* notes 190–247 and accompanying text.

¹⁸⁷ See Barraza et al., *supra* note 3, at 325 ("The culture of denialism, if left unchecked, will increasingly risk harm to the public's health."); Haertlein, *supra* note 3, at 225–26 (citing Justice Stephen Breyer's assertion that the law must stay "within the boundaries of scientifically sound knowledge"); Moreno, *supra* note 5, at 417 (highlighting Justice Breyer's discussion of the intersection of law and science, "the law must seek decisions that fall within the boundaries of scientifically sound knowledge and approximately reflect the scientific state of the art"); Offit, *supra* note 11, at 1279 (describing the challenges to wide acceptance that thimerosal is safe after the ban).

¹⁸⁸ See *infra* notes 190–247 and accompanying text.

¹⁸⁹ See *infra* notes 190–230 and accompanying text.

¹⁹⁰ See *infra* notes 231–247 and accompanying text.

¹⁹¹ 42 U.S.C. § 300aa-27 (2012); see *Timeline: Thimerosal in Vaccines (1999–2010)*, *supra* note 15.

¹⁹² 42 U.S.C. §§ 300aa-2, 300aa-27.

¹⁹³ See *id.*; EPA MERCURY REPORT, *supra* note 4, at 3–12.

¹⁹⁴ See Fisher, *supra* note 33, at 129–30 (identifying the common problems that occur when agencies use the risk assessment model).

used to make the initial decision to ban thimerosal was a combination of all public health agencies, with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) attempting to address the issue, both individually and jointly.¹⁹⁵ This all-hands-on-deck approach resulted in a chaotic process, a flawed outcome, and a dearth of agency accountability.¹⁹⁶ To support an open and efficient sharing of resources and expertise between agencies, there must be one lead agency to consolidate all information, make the final decision, and be accountable to the public.¹⁹⁷

The CDC's de facto leadership initially made sense because the question—did thimerosal in vaccines create an epidemic of autism—was directly within the agency's expertise.¹⁹⁸ Under this construct, the CDC should utilize the resources of the other agencies, but rely on its own expertise as the final decision maker.¹⁹⁹ In hindsight, the question should have been whether thimerosal was safe at the level of exposure because, in reality, there was no epidemic caused by using thimerosal as a vaccine preservative.²⁰⁰ The recalibrated question shows that the FDA should have led the decision-making process.²⁰¹

The Food, Drug, and Cosmetic Act ("FDCA") directly authorizes the FDA to regulate "drugs," "devices," or "biological products."²⁰² If a substance fits within one of those categories, the agency must first determine if it is safe and then regulate the substance under the agencies' discretion.²⁰³ Vaccines, as a whole, are explicitly defined as a "biological product" under the FDCA and therefore the FDA possesses regulatory authority over vaccines.²⁰⁴ The FDA's authority to regulate thimerosal, though, does not directly fall within the FDA's authority because thimerosal itself is not a biological product, only a component of one.²⁰⁵ Similarly, it cannot be regulated as a "drug" because thimerosal is not intended to "cure . . . or prevent" disease, it does not directly "affect . . .

¹⁹⁵ See Vaccine Testimony, *supra* note 15; *Thimerosal in Vaccines*, *supra* note 5.

¹⁹⁶ See Vaccine Testimony, *supra* note 15 (describing the efforts as appropriate); *Thimerosal in Vaccines*, *supra* note 5 (describing the multi-agency actions leading to and following the ban).

¹⁹⁷ See Holden, *supra* note 9, at 104; Israel, *supra* note 57, at 516. When multiple agencies regulate a single area the need for agencies to compromise and consolidate efforts can create a tragedy of the commons problem. Holden, *supra* note 9, at 104.

¹⁹⁸ See *Thimerosal in Vaccines*, *supra* note 5.

¹⁹⁹ See *id.*

²⁰⁰ Hansen, *supra* note 89, 60–61 (concluding that the increased prevalence of ASD was the result of "the change in diagnostic criteria").

²⁰¹ See Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012) (creating the FDA and granting it authority over vaccine regulation); Vaccine Testimony, *supra* note 15 (defining the FDA's role in vaccine regulation as reviewing and approving safety of compounds used).

²⁰² 21 U.S.C. § 353(g); 42 U.S.C. § 262(i) (2012); see Vaccine Testimony, *supra* note 15.

²⁰³ 21 U.S.C. § 353(g); 42 U.S.C. § 262(i); see *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000).

²⁰⁴ 42 U.S.C. § 262(i)(1).

²⁰⁵ *Id.*

the body,” and does not act as a “component” in either of the preceding aims and, therefore, does not meet the statutory definition of a drug.²⁰⁶

The FDA nonetheless has authority to regulate thimerosal as a “device.”²⁰⁷ Thimerosal is a device under the authority of the FDA because it is part of a preventive vaccine but does not have a role in the vaccine’s disease prevention within the body.²⁰⁸ Historically, thimerosal was used to prevent contamination and vaccine injury in multi-dose vaccine vials.²⁰⁹ The primary purpose, then, is achieved within the vial rather than in or on the body and, as such, thimerosal falls squarely within the statutory definition of a device.²¹⁰ Although thimerosal meets the statutory definition of device because it is a means of preserving the vaccine but has no impact on the vaccine’s prevention of disease, its obsolescence in single use vials may limit this interpretation as its purpose is no longer essential.²¹¹

If the FDA does not have the statutory authority to regulate thimerosal as a device it may be able to do so within the scope of its own regulations, which require regulation of all “preservatives” in biological products.²¹² Agency regulations mandate that “[a]ny preservative used shall be *sufficiently nontoxic* so that the amount present in the recommended dose of the product will not be toxic to the recipient.”²¹³ Therefore, if the FDA allows even one vaccine to use thimerosal, it must prove that the substance is not toxic at the level used in vaccines.²¹⁴

Whether its authority to regulate thimerosal comes under the FDCA, the FDCA’s implementing regulations, or both, the FDA must determine whether ethylmercury is safe or at what level it becomes toxic.²¹⁵ The FDA, because of its expertise should be the lead regulatory agency and be held accountable to

²⁰⁶ 21 U.S.C. §§ 321(g)(1)(B)–321(g)(1)(D).

²⁰⁷ *Id.* §§ 321(h), 353.

²⁰⁸ 42 U.S.C. § 262(i).

²⁰⁹ Barraza et al., *supra* note 3, at 321.

²¹⁰ *Id.*

²¹¹ See *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1277 (D.C. Cir. 2012) (discussing the continued need for thimerosal in influenza vaccines); Barraza et al., *supra* note 3, at 321 (noting the removal of thimerosal from most childhood vaccines). *But see* Vaccine Testimony, *supra* note 15 (indicating the continued need for multi-dose influenza vaccine); Moreno, *supra* note 5, at 415–16 (identifying a potential international public health crisis if the pharmaceutical industry is unwilling to manufacture the thimerosal containing vaccines because multi-dose vials are still used in many countries outside of the United States).

²¹² 21 C.F.R. §§ 310.545, 610.15(a) (2016); *Thimerosal in Vaccines*, *supra* note 5. For an overview of the historical need for vaccine preservative and the decision to mandate them in 1968 see *Thimerosal in Vaccines*, *supra* note 5.

²¹³ 21 C.F.R. § 610.15(a) (emphasis added).

²¹⁴ See *id.*

²¹⁵ See *Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst. (Benzene Case)*, 448 U.S. 607, 662 (1980); *Thimerosal in Vaccines*, *supra* note 5. Available studies indicate that ethylmercury may have a critical value. See *Thimerosal in Vaccines*, *supra* note 5.

the public for all decisions.²¹⁶ The Environmental Protection Agency (“EPA”), CDC, and the other public health agencies should work in consultation with the FDA to ensure a comprehensive source of knowledge.²¹⁷

A comprehensive ethylmercury study is not a novel concept and the National Toxicology Program (“NTP”) and Interagency Committee for Chemical Evaluation and Coordination (“ICCEC”) has recommended this type of project since the early 2000s.²¹⁸ Additionally, similar studies on mercurial substances, such as methylmercury have been undertaken by EPA for decades, providing timely research, explanations for updated exposure standards, and description of future plans for research and public communication.²¹⁹ Such reviews of toxic substances are generally brought on only when the substance is shown to cause health risks.²²⁰ With ethylmercury, the failure to provide clear, comprehensive information on the risks associated, not the substance itself, caused a health risk by decreasing vaccination rates.²²¹ Such a health risk, though non-traditional, warrants a more targeted and active research approach.²²²

A comprehensive ethylmercury study should follow the structure implemented by EPA in their study of methylmercury.²²³ The first step is to conduct a scientific literature review that looks at all available scientific data on ethylmercury and use this information to identify areas where further research is necessary.²²⁴ This review should look at negative effects on human health and the environment and include an up-to-date survey of all recorded claims against the substance from both the National Vaccine Injury Compensation Program (“NVICP”) and the Vaccine Adverse Event Reporting System (“VAERS”).²²⁵

²¹⁶ 21 C.F.R. § 610.15(a); see Israel, *supra* note 57, at 516.

²¹⁷ See EPA MERCURY REPORT, *supra* note 4, at 3–12; Bigham et al., *supra* note 1, at 30; Israel, *supra* note 57, at 479. EPA leads methylmercury regulation. Bigham et al., *supra* note 1, at 30.

²¹⁸ National Toxicology Program (NTP), 67 Fed. Reg. 40,329, 40,330 (June 12, 2002) (inviting public comment and requesting data from outside research on toxic substances and their impact on human health).

²¹⁹ EPA MERCURY REPORT *supra* note 4, at 3–12.

²²⁰ See Bigham et al., *supra* note 1, at 26–27, 30–31 (explaining the history of mercury regulation in the United States and highlighting the necessity of clear proof of harm before regulating).

²²¹ See Haertlein, *supra* note 3, at 230; Offit, *supra* note 11, at 1279.

²²² STATE OF THE WORLD'S VACCINES AND IMMUNIZATION, *supra* note 21, at 66 (discussing the impact of the Wakefield study on childhood vaccination rates); see Barraza et al., *supra* note 3, at 321–22, 325 (linking vaccine opt-outs due to fear and misunderstanding to increased risk of spread of disease); Haertlein, *supra* note 3, at 230 (discussing the impact of misinformation on public health); Offit, *supra* note 11, at 1279 (describing the public health risk of the vaccine controversy).

²²³ EPA MERCURY REPORT, *supra* note 4, at 3–12; see Israel, *supra* note 57, at 511–12.

²²⁴ EPA MERCURY REPORT, *supra* note 4, at 5; see Israel, *supra* note 57, at 511–15; see also Moreno, *supra* note 5, at 412–14 (highlighting the importance of a thorough understanding of the differences between methylmercury and ethylmercury).

²²⁵ See Haertlein, *supra* note 3, at 239 (noting the amount of data available during the OAP cases); Holland et al., *supra* note 148, at 482 (summarizing the results of a similar NVICP claims study).

Once the scientific literature review is completed, the agencies can begin the research phase of the project where agencies working together will maximize resources.²²⁶ A combination of the collective research by the public health agencies and EPA, as well as outside scholarship from universities and industries to ensure that the research is reliable, will be critical to the public's trust of the project's final standards.²²⁷ With the availability of accurate and easily accessible data, any controversy in the future can be resolved quickly and decisively based on scientific evidence rather than fear.²²⁸

Finally, and most critically, the regulatory process must be ongoing and responsive to future developments in order to be effective, preventive, and predictive of future controversies because, when new research like the Wakefield study appears, it can be scrutinized and considered against the body of evidence compiled.²²⁹ Based on scientific principles, the project would clearly identify the relevant factors to be used when the agencies decide between maintaining the current standard and making a quick change.²³⁰

B. Benefits of a Comprehensive Ethylmercury Review

Agencies must keep in mind is that the first impression is often all that matters.²³¹ As exemplified by the fish consumption recommendation, the first action taken by the agency must be thoughtful, balance caution and risk carefully, and make a timely recommendation.²³² When any of these elements is out of balance, the public loses trust in the final recommendation.²³³ Thus,

²²⁶ See Holden, *supra* note 9, at 107; Israel, *supra* note 57, at 511–15. Scholars note the benefits of joint agency action: “minimize inconsistency, maximize joint gains, plug gaps, and prevent systemic failures.” Holden, *supra* note 9, at 107.

²²⁷ See Israel, *supra* note 57, at 512, 516–19; Sinks et al., *supra* note 7, at 68.

²²⁸ See Israel, *supra* note 57, at 516 (recognizing that the risk assessment approach is appropriate in the face of public concern); Sinks et al., *supra* note 7, at 65 (identifying the risks of rapid policy decisions without a clear understanding of the scientific data underpinning the policy decisions).

²²⁹ See Offit, *supra* note 11, at 1279.

²³⁰ See *id.*

²³¹ See Barraza et al., *supra* note 3, at 319 (describing opinion polls that showed nearly 50% of people believed the Wakefield study and that less than half of respondents knew the study was retracted); Chirba-Martin & Welshhans, *supra* note 3, at 293–94 (providing data that the public awareness of the potential harm prevents acceptance of agency regulation); Haertlein, *supra* note 3, at 225 (comparing the impact of emotional evidence and dry scientific data on public perception); Holden, *supra* note 9, at 129–31 (discussing the additional administrative hardship created by the public's overprotective response to the agencies' initial fish consumption recommendation).

²³² Holden, *supra* note 9, at 129; Sinks et al., *supra* note 7, at 64. The FDA and EPA used a balancing test in drafting fish consumption guidelines. Holden, *supra* note 9, at 129.

²³³ See Barraza et al., *supra* note 3, at 317–18 (showing the limited public trust in vaccines even after the Wakefield study was retracted); Chirba-Martin & Welshhans, *supra* note 3, at 293–94 (noting the loss of public trust for mercury amalgam dental fillings despite government support); Holden, *supra* note 9, at 131 (demonstrating how contradiction between agencies leads to public confusion); Offit, *supra* note 11, at 1279 (describing the loss of public trust following the ban).

when the revised recommendation is made, it must be done with an abundance of support and transparency.²³⁴ By being able to point to a compilation of research data from a variety of sources in making a revised recommendation, the public will be more likely to trust the change.²³⁵

A thorough procedure for determining safety levels of ethylmercury offers benefits far beyond just the immediate concern of determining the safe levels for vaccinations.²³⁶ First, it will allow agencies to work together to create an efficient, cost-effective set of standards to apply in rapidly developing situations, similar to the ASD controversy, while spreading the burden between the public and private sectors.²³⁷ Most importantly, it will build consumer confidence in current and future regulation and recommendations made by the agencies, resulting in an increased likelihood of success for their regulatory goals.²³⁸

Although the process outlined may appear to be a mammoth project, the burden can be spread across the agencies in a way that will utilize each agency's expertise and industry specific knowledge.²³⁹ Through the review process, the agencies will become better educated on ethylmercury and the data supporting its safety, creating an efficient and robust source of knowledge for future decisions.²⁴⁰ Comprehensive ethylmercury data and standards will allow the agencies to make rapid determinations and streamline decision-making, particularly for the FDA, as its leadership will create efficiency.²⁴¹

More clearly defined safety standards will give the agencies a trustworthy and easily available resource when urgent questions arise.²⁴² The project would give agencies a clear understanding of both ethylmercury and methylmercury,

²³⁴ See Fisher, *supra* note 33, at 128.

²³⁵ See EPA MERCURY REPORT, *supra* note 4, at 3–12; STATE OF THE WORLD'S VACCINES, *supra* note 21, at 67; Barraza et al., *supra* note 3, at 319. WHO identifies public education as a key strategy for combatting decreasing immunization rates. STATE OF THE WORLD'S VACCINES, *supra* note 21, at 67.

²³⁶ See EPA MERCURY REPORT, *supra* note 4, at 3–12 (analogous EPA methylmercury report).

²³⁷ See Vaccine Testimony, *supra* note 15 (describing the inefficient process used to research the safety of thimerosal after the precautionary ban because the agencies lacked a trusted and comprehensive review of thimerosal); Sinks et al., *supra* note 7, at 65 (describing the need for clear understanding of the science by policy makers for quick decision-making).

²³⁸ See Barraza et al., *supra* note 3, at 323; Offit, *supra* note 11, at 1279.

²³⁹ See Holden, *supra* note 9, at 137–40 (explaining how joint action may lead to “improved decisionmaking” as well as decrease the financial burden).

²⁴⁰ See EPA MERCURY REPORT, *supra* note 4, at 3–12 (compiling all available research and identifying areas that need additional study); Sinks et al., *supra* note 7, at 65 (discussing the challenges faced by legislators asked to regulate without sufficient scientific data); *Thimerosal in Vaccines*, *supra* note 5 (exemplifying the benefit of conducting a thorough review of the data under non-urgent circumstances in defining the risks and knowledge gaps).

²⁴¹ See Vaccine Testimony, *supra* note 15 (exemplifying the need for data to improve the constant approval process, particularly with respect to the influenza vaccine).

²⁴² See Sinks et al., *supra* note 7, at 65 (attributing a lack of scientific knowledge as a risk for rapid policy decision making).

their differences, and which, if any, standards are comparable and interchangeable.²⁴³ Under this scheme, if the Wakefield study were released today, it could be quickly compared to the breadth of recently verified data on ethylmercury and its acceptable standards.²⁴⁴ There would be, therefore, no question to the public health agencies in a Wakefield-like scenario that the methylmercury standards were not analogous to ethylmercury standards.²⁴⁵

What the vaccine controversy underlines most is that although government agencies may be comfortable with classifying a substance as safe without comprehensive study, the American public is not.²⁴⁶ Lack of public trust can rapidly derail the goals of regulation, just as the ASD controversy undermined the broad public health aims of herd immunity.²⁴⁷

CONCLUSION

When viewed within the scheme of the United States' regulatory history with mercurial substances, the vaccine controversy was neither unpredictable nor out of the ordinary. It was, however, preventable. Thus, the agencies must view the event as a cautionary tale and, while healing the wounds it caused, work to prevent them from repeating in the future.

The agencies' decision to trust a single study and borrow EPA's methylmercury standards in banning thimerosal from vaccines was dangerous and went against both scientific methodology and legal causation requirements. Their later reversal was similarly shortsighted and risky in the face of the growing public health threat of noncompliance with vaccinations. Thus, the government must first resolve the controversy by definitively proving the safety of ethylmercury.

The FDA must take the lead, in coordination with the other public health agencies and EPA, to create a comprehensive body of research sufficient to determine what level of exposure to ethylmercury is safe. The agencies must

²⁴³ See Israel, *supra* note 57, at 484–85; Sinks et al., *supra* note 7, at 65. For a discussion of the importance of dose/response in risk analysis, see Israel, *supra* note 57, at 484–85.

²⁴⁴ See Israel, *supra* note 57, at 478 (arguing that the proper analysis of risk allows agencies more flexibility although the use of generalized data provides for rapid decision making); *Thimerosal in Vaccines*, *supra* note 5 (demonstrating that the most significant data available during the decision-making was several decades old and not directly relevant, creating a challenge for determining its relevance to the question at hand).

²⁴⁵ See *WHO Thimerosal Statement*, *supra* note 14; Offit, *supra* note 11, at 1278.

²⁴⁶ See Barraza et al., *supra* note 3, at 317–19; Moreno, *supra* note 5, at 414–15; Offit, *supra* note 11, at 1279.

²⁴⁷ See Barraza et al., *supra* note 3, at 319, 321–22; Haertlein, *supra* note 3, at 225–26; Moreno, *supra* note 187, at 415–16; Offit, *supra* note 11, at 1279. The public's awareness of the Wakefield study far outweighed the awareness of its retraction. Barraza et al., *supra* note 3, at 319, 321–22; see Wakefield et al., *supra* note 12, at 641. In the long term, this could pose significant negative long-term consequences on herd immunity. Barraza et al., *supra* note 3, at 319, 321–22; see Wakefield et al., *supra* note 12, at 641.

also work with the private sector to continue scientific scholarship on ethylmercury to increase public trust of the results. The unique history of mercury regulation requires a heavier burden, but the effort will reap benefits for future public health events.

