

A TOXIC MOUTHFUL: THE MISALIGNMENT OF DENTAL MERCURY REGULATIONS

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Abstract: Mercury amalgam dental fillings have been used for over one hundred and fifty years in hundreds of millions of patients around the world. In the past two decades, scientific evidence has shown that mercury fillings have harmful effects on human health. Still, the American Dental Association maintains the position that mercury fillings are safe and should continue to be used without warning requirements. Although the Occupational Safety and Health Administration promulgated regulations to protect dentists and other dental workers from mercury exposure, the Food and Drug Administration has yet to provide similar protections to dental patients. Additionally, because Medicaid does not cover alternative fillings, many low-income Americans are forced to choose between mercury fillings or no fillings at all. Although other countries have banned or severely restricted the use of mercury fillings, the United States has yet to enact federal legislation on the issue. This Note argues that Congress should ban mercury fillings or, at a minimum, implement uniform warning requirements and mandate insurance and Medicaid coverage for alternative fillings.

INTRODUCTION

Special Smiles LTD is a Medicaid-funded dental clinic in Northern Philadelphia that provides treatment to children with disabilities.¹ Several other clinics have been built on the Special Smiles model as part of Pennsylvania's effort to improve access to oral health services for low-

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¹ See ANDREW SNYDER, NAT'L ACAD. OF STATE HEALTH POLICY, INCREASING ACCESS TO DENTAL CARE IN MEDICAID: TARGETED PROGRAMS FOR FOUR POPULATIONS 4–5, 19–20 (Mar. 2009), *available at* http://nashp.org/sites/default/files/Dental_Reimbursements.pdf?q=files/Dental_Reimbursements.pdf; SPECIAL SMILES LTD, <http://www.specialsmiles.com> (last visited May 15, 2013). Special Smiles has a global budgeting arrangement where the Medicaid managed care organizations pay a fixed rate for the dentists to see one thousand patients per year. SNYDER, *supra*, at 19. Special Smiles uses a model “where the patient is first provided a screening/triage appointment, with a brief physical exam, confirmation of medical clearances and diagnostic lab tests that are provided by the patient’s physician, and obtaining consent from the caretaker,” and then returns to receive the necessary care under sedation. *See id.*

income, minority, and disabled populations.² In 2007, the city of Philadelphia passed a law requiring dentists to provide patients with a fact sheet detailing the health risks associated with amalgam, a type of dental filling material that contains elemental mercury.³ Before receiving a restoration with amalgam, patients or their legal guardians must sign off on the fact sheet.⁴

When the parents of Special Smiles's patients received the fact sheet and learned of the risks associated with mercury fillings, they were understandably alarmed.⁵ Elemental mercury is the purest form of mercury.⁶ It is liquid at room temperature, but evaporates into mercury vapor.⁷ Mercury vapor is toxic to humans when it is ingested or inhaled.⁸ Studies show that mercury vapor can damage the lungs, kidneys, and the nervous, digestive, respiratory, and immune systems.⁹ Mercury vapor has also been linked to tremors, impaired vision and hearing, paralysis, insomnia, emotional instability, and developmental deficits dur-

² See *Dental Information*, PA. DEPARTMENT PUB. WELFARE, <http://www.dpw.state.pa.us/communitypartners/informationforadvocatesandstakeholders/dentalinformation/index.htm> (last modified May 7, 2013) (explaining that as part of a joint effort between the Department of Public Welfare and Medicaid managed care organizations, clinics will be developed based on the Special Smiles model).

³ See PHILA., PA., CODE § 9-3100 (2008); Charles G. Brown, *Philadelphia Mandates Amalgam Fact Sheet*, INT'L ACAD. ORAL MED. & TOXICOLOGY (Dec. 14, 2007), <http://iaomt.org/philadelphia-mandates-amalgam-fact-sheet> (stating that the City of Philadelphia passed a law mandating that dentists give patients a fact sheet that "discloses that amalgam is mainly mercury and that mercury exposure poses health risks"). Mercury exists in three forms: elemental, organic, and inorganic. See Kimberly M. Baga, Note, *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, 172, 196 (2007). Mercury is toxic to living cells; it either kills the cells or reduces their function. See Sanford Pinna, *Dr. Mercola on Mercury Dental Fillings*, DR. PINNA (Sept. 6, 2011), <http://drpinna.com/dr-mercola-on-mercury-dental-fillings-23750>.

⁴ See *Information Sheet—Amalgam Dental Fillings Containing Mercury*, CAMPAIGN FOR MERCURY FREE DENTISTRY, <http://www.toxicteeth.org/Amalgambrochure-PDPL.aspx> (last visited May 15, 2013).

⁵ See Pinna, *supra* note 3.

⁶ See Baga, *supra* note 3, at 172, 196. Elemental mercury is also found in thermometers, fluorescent light bulbs, and batteries. See *id.* at 172 (citing HAL. A. HUGGINS & THOMAS E. LEVY, UNINFORMED CONSENT: THE HIDDEN DANGERS IN DENTAL CARE 171 (1999)).

⁷ See *id.*

⁸ See Pamela D. Harvey & C. Mark Smith, *The Mercury's Falling: The Massachusetts Approach to Reducing Mercury in the Environment*, 30 AM. J.L. & MED. 245, 252-53 (2004); Wendy Thomas, *Through the Looking Glass: A Reflection on Current Mercury Regulation*, 29 COLUM. J. ENVTL. L. 145, 148-49 (2004).

⁹ See Harvey & Smith, *supra* note 8, at 252-53; Thomas, *supra* note 8, at 148-49.

ing fetal development.¹⁰ These risks are particularly alarming for Special Smiles's patients, some of whom already have neurological disorders.¹¹

The parents of Special Smiles's patients refused to sign the fact sheet, requesting that alternative filling materials be placed in their children's mouths.¹² Special Smiles refused to provide treatment, including non-restorative treatments, such as basic cleanings, unless the parents would sign the fact sheet, thereby consenting to the use of mercury fillings.¹³ Because these parents could not afford to bring their children to other dentists, they were essentially forced to "take the crumbs their dentists offered: mercury fillings or no fillings."¹⁴

Both the Pennsylvania Dental Association (PDA) and the Philadelphia County Dental Association (PSDS) endorsed Special Smiles's ultimatum.¹⁵ The Clinical Director at Special Smiles acknowledged that it would be a challenge for these parents to find another dentist.¹⁶ Thus, the parents were left with the difficult choice between dental care and exposing their child to a potentially serious health risk.¹⁷

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¹⁰ See Harvey & Smith, *supra* note 8, at 252–53; Todd Miller, *Mercury Amalgam Fillings: Human and Environmental Issues Facing the Dental Profession*, 1 DEPAUL J. HEALTH CARE L. 355, 358–59 (1996); Thomas, *supra* note 8, at 148–49; Baga, *supra* note 3, at 180.

¹¹ See Harvey & Smith, *supra* note 8, at 252–53; Thomas, *supra* note 8, at 148–49; Charles G. Brown, *Pennsylvania Dental Association: Deny All Dental Treatment to Children with Disabilities Unless Parents Consent to Mercury Exposure*, CENT4DENT BLOG (Feb. 24, 2010), <http://blog.cent4dent.com/2010/02/pennsylvania-dental-association-deny-all-dental-treatment-to-children-with-disabilities-unless-parents-consent-to-mercury-exposure>; Dr. Mercola, *Never Do This with Your Teeth—No Matter How "Safe" They Say It Is*, MERCOLA.COM (Jan. 17, 2012), http://mercola.ebeaver.org/2012/01/17/never_do_this_with_your_teeth_-_no_matter_how_safe_they_say_it_is [hereinafter *Never Do This with Your Teeth*]; *Petition: The Philadelphia Board of Health Must Get Legal Advice from City Solicitor Smith Before Proceeding with Amalgam Information Sheet Revisions*, CONSUMERS FOR DENTAL CHOICE, http://www.phila.gov/health/pdfs/Attach%20B_CDC_Petition.pdf (last visited May 15, 2013) [hereinafter *Petition*].

¹² See *Petition*, *supra* note 11; *The "Silver Fillings" Deception*, CAMPAIGN FOR MERCURY FREE DENTISTRY, http://www.toxicteeth.org/pressRoom_recentNews/August-2011/The-silver-fillings-deception.aspx (last visited May 15, 2013) (noting that a fact sheet law makes parents aware of the dangers associated with mercury fillings, thus increasing the likelihood that parents will object to the use of mercury in their children's mouths).

¹³ See Brown, *supra* note 11.

¹⁴ Dr. Mercola, *Banned for Pets and Farm Animals, but Okay for You and Your Children?*, MERCOLA.COM (Sept. 5, 2011), <http://articles.mercola.com/sites/articles/archive/2011/09/05/silver-filling-deception.aspx> [hereinafter *Banned for Pets and Farm Animals*].

¹⁵ See *id.* The PDA and PCDS issued a statement on February 11, 2010, "giving their stamp of approval to dentists who deny all treatment to disabled children—no tooth cleanings, no preventative care, nothing—unless the parents 'consent' to exposing their children to mercury." See Brown, *supra* note 11; *Petition*, *supra* note 11.

¹⁶ See Brown, *supra* note 11; *Petition*, *supra* note 11.

¹⁷ See Brown, *supra* note 11; *The "Silver Fillings" Deception*, *supra* note 12.

Mercury amalgam fillings have been used for over one hundred and fifty years to repair cavities in countless patients.¹⁸ Mercury amalgam is formed when a soft powdered mixture of silver, tin, copper, and zinc binds with liquid mercury.¹⁹ The result is a putty-like material that hardens into a solid filling when it is placed in the tooth cavity.²⁰ The mercury component is what holds the putty together while the dentist fits it into the cavity and it is also what makes the hard filling strong and durable enough to withstand chewing.²¹

Although scientists once believed that mercury fillings did not release mercury vapor, it is now widely accepted that the fillings continuously leak mercury vapor into the oral cavity.²² The vapor is then absorbed through the lungs and intestinal tract and travels throughout

¹⁸ See *About Dental Amalgam Fillings*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm> (last updated Aug. 11, 2009). Mercury fillings have an extensive history. Wendy Fritz L. Lorscheider et al., *Mercury Exposure from "Silver" Tooth Fillings: Emerging Evidence Questions a Traditional Dental Paradigm*, 9 FASEB J. 504, 504 (1995); Thomas, *supra* note 8, at 145.

As early as the 7th century, the Chinese used a "silver paste" containing mercury (Hg) to fill decayed teeth. Throughout the Middle Ages, alchemists in China and Europe observed that this mysterious silvery liquid, extracted from cinnabar ore, was volatile and would quickly disappear as vapor when mildly heated. Alchemists were fascinated that at room temperature Hg appeared to 'dissolve powders of other metals such as silver, tin, and copper. By the early 1800s, the use of a Hg/silver paste as a tooth filling material was being popularized in England and France and it was eventually introduced into North American in the 1830s.

Thomas, *supra* note 8, at 171 (citing Lorscheider et al., *supra*, at 504).

¹⁹ See *About Dental Amalgam Fillings*, *supra* note 18. "Most amalgam used in the United States is made up of approximately 50% mercury, 35% silver, 13% tin, 2% copper, and trace amounts of zinc." Lorscheider et al., *supra* note 18, at 504.

²⁰ See Mary Ann Chirba-Martin & Carolyn M. Welshhans, *An Uncertain Risk and an Uncertain Future: Assessing the Legal Implications of Mercury Amalgam Fillings*, 14 HEALTH MATRIX 293, 295 (2004); *About Dental Amalgam Fillings*, *supra* note 18.

²¹ See *Dental Amalgam: A Health Risk?*, COLGATE ORAL & DENTAL HEALTH RESOURCE CENTER (Apr. 29, 2011), <http://www.colgate.com/app/CP/US/EN/OC/Information/Articles/Oral-and-Dental-Health-Basics/Checkups-and-Dental-Procedures/Fillings/article/Dental-Amalgam-A-Health-Risk.cvsp>.

²² See Miller, *supra* note 10, at 356; Thomas, *supra* note 8, at 169, 171–72 ("It was once thought that the mercury, once set in a filling, became stable and would not leak mercury vapor. However, after considerable research, it is now accepted that mercury escapes dental amalgams and enters the body in the form of elemental mercury vapor."). Although dentists were once taught that silver, tin, zinc, copper, and mercury produced an "inert, stable mass," new technology now demonstrates that this is false. See *Historic Resolution Adopted by Costa Mesa: Official Position Taken to Ban Dental Mercury Fillings*, PRWEB (Oct. 26, 2010), <http://www.prweb.com/releases/2010/10/prweb4334324.htm>.

the bloodstream.²³ Everyday activities such as brushing teeth, chewing, drinking hot beverages, and smoking cigarettes increase the amount of vapor that escapes from the fillings.²⁴ After brushing teeth, it takes almost ninety minutes for the rate of mercury vaporization to return to a normal level.²⁵

Despite its link to serious health problems, dentists remain divided over whether patients with intact mercury fillings should have them removed and replaced with alternative fillings.²⁶ Removal procedures are costly and difficult for dentists to perform.²⁷ Improper removal procedures are arguably more dangerous than the mercury fillings themselves as they can cause more mercury vapor to leak into the patient's mouth than intact mercury fillings.²⁸ In fact, studies estimate that patients may be exposed to one thousand times more mercury than the Environmental Protection Agency's (EPA) allowable limit during placement or extraction of amalgams fillings.²⁹ Nevertheless, removal has proven effective for some patients suffering from symptoms of mercury poisoning.³⁰

The EPA now recognizes that mercury fillings are the greatest source of inorganic mercury in the human body.³¹ Although people with more mercury fillings have higher rates of daily mercury exposure, one study suggests that as few as four fillings can generate enough exposure to cause health problems in an adult and just two fillings can put a

²³ See Baga, *supra* note 3, at 173 (citing HUGGINS & LEVY, *supra* note 6, at 171).

²⁴ Miller, *supra* note 10, at 357 (citing Murray J. Vimy & Fritz L. Lorscheider, *Intra-oral Air Mercury Released from Dental Amalgams*, 64 DENTAL RES. 1069, 1069–71 (1985)); Baga, *supra* note 3, at 173.

²⁵ See Miller, *supra* note 10, at 357.

²⁶ Compare Baga, *supra* note 3, at 186 (stating that most experts on both sides of the amalgam debate agree that there is no need to remove fillings that are still intact), with Bd. of Dental Exam'rs v. Hufford, 461 N.W.2d 194, 196 (Iowa 1990) (deciding whether a dentist's recommendation to remove mercury fillings to relieve symptoms of multiple sclerosis was unethical).

²⁷ See Baga, *supra* note 3, at 186–87 (explaining that removal is expensive and often done incorrectly).

²⁸ See *id.* at 186.

²⁹ See *id.*

³⁰ See Hufford, 461 N.W.2d at 1986 (noting that two of the dentist-defendant's other patients multiple sclerosis symptoms allegedly improved after their mercury fillings were removed).

³¹ See Chirba-Martin & Welshhans, *supra* note 20, at 297. According to a National Academy of Sciences report, mercury fillings "cause between 125 and 708 times more elemental Hg exposure in humans than . . . breathing air pollution." See Thomas, *supra* note 8, at 169.

child at risk.³² Mercury is even more hazardous to pregnant women and children.³³ As the Food and Drug Administration (FDA) admits, “[t]he developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects.”³⁴ The United States Department of Health and Human Services (HHS) also recognizes the “[a] correlation has been found between inorganic mercury in human breast milk and mercury-silver dental amalgams in the mother.”³⁵ Scientists warn that the risks are greater for patients with kidney disease because the mercury tends to accumulate in the kidneys.³⁶

Although there are several viable alternatives, mercury fillings are the least expensive, easiest to use, and most durable materials on the market.³⁷ In recent years, the use of mercury fillings has decreased with the decline in the amount of cavities in children and young adults and

³² See Miller, *supra* note 10, at 357 (“[A] greater number of fillings over a larger chewing surface area lead to even higher levels of mercury.”); Baga, *supra* note 3, at 179–80.

³³ See Thomas, *supra* note 8, at 148 (“Both adult and fetal brains are vulnerable to MeHg toxicity, but a preponderance of evidence points to the most severe damage occurring in the developing fetal brain.”); *Banned for Pets and Farm Animals*, *supra* note 14. “In studies where fillings were installed in the teeth of pregnant sheep, mercury amalgam was shown to cross the placenta and accumulate in the developing fetus within two days of the filling’s installation.” See Miller, *supra* note 10, at 358 (citing Murrar J. Vimy et al., *Maternal-Fetal Distribution of Mercury Released from Dental Amalgam Fillings*, 258 AM. J. PHYSIOL. R939, R939–45 (1990)). The highest levels of mercury were found in the fetal liver and the mother’s milk. See *id.*

³⁴ See *Appendix I: Summary of Changes to the Classification of Dental Amalgam and Mercury*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/dentalproducts/dentalamalgam/ucm171120.htm> (last modified Aug. 11, 2009) [hereinafter *Appendix I*].

³⁵ See Chirba-Martin & Welshhans, *supra* note 20, at 297 (quoting Jeri Weiss et al., *Mercury Exposure Risks: Human Exposure to Inorganic Mercury*, 114 PUB. HEALTH REP. 400, 400–01 (1999)).

³⁶ See Miller, *supra* note 10, at 358–59; Charles W. Moore, *Mercury Fillings: A Time Bomb in Your Head*, NAT. LIFE MAG., <http://www.naturallifemagazine.com/9702/mercury.htm> (last visited May 15, 2013) (noting that the German Health Ministry recommended to the German Dental Association that mercury fillings no longer be used in people with kidney disease). On experiments conducted on sheep and monkeys, the highest levels of mercury accumulated in the kidneys and liver. See Miller, *supra* note 10, at 358–59 (citing G. Danscher et al., *Traces of Mercury in Organs from Primates with Amalgam Fillings*, 52 EXPERIMENTAL & MOLECULAR PATHOLOGY 291, 291–99 (1990)).

³⁷ See *About Dental Amalgam Fillings*, *supra* note 18; Jane E. Allen, *FDA Panel Reviews Health Safety of Mercury Amalgam Fillings*, ABC NEWS (Dec. 15, 2010), <http://abcnews.go.com/Health/Dental/dental-fillings-mercury-risks-debated-food-drug-administration/story?id=12396643>; *Amalgam (Dental Filling Options)*, AM. DENTAL ASS’N, <http://www.ada.org/2524.aspx?currentTab=2> (last visited May 15, 2013). These alternatives include composite resin fillings, glass and plastic ionomer fillings, and gold foil fillings. See *Amalgam (Dental Filling Options)*, *supra*.

the increase in dentists opting to practice mercury-free.³⁸ Nevertheless, public and private dental insurance plans and Medicaid dental insurance plans still prefer to cover mercury fillings because they are less expensive and less likely to need replacements.³⁹ These preferences coincide with the economic realities for many families.⁴⁰ Dental care is extremely expensive and for some, a mercury filling “might be the only option to eliminate a severe toothache” and “the need to alleviate the immediate pain” prevents the patient from fully considering the possibility of future harm.⁴¹

Part I of this Note sets forth the controversy over mercury fillings, explains the American Dental Association’s view on mercury fillings, and traces the United States governments’ response through the competed and varied responses of its regulatory agencies. Part II explains why litigation is an insufficient solution to the problem. Part III then examines the steps taken by other countries. This Part also details states and cities attempts to ban or regulate the use of mercury fillings. Finally, Part IV argues that the United States should enact a complete ban on the use of mercury fillings or, at a minimum, implement uniform warning requirements and force insurance companies and Medicaid to pay for alternative fillings. Consequently the United States must act in order to properly protect low-income citizens from the harmful effects of mercury.

³⁸ See Baga, *supra* note 3, at 175–76; *Dental Amalgam*, VT. DEPARTMENT OF HEALTH, <http://healthvermont.gov/family/dental/amalgam.aspx> (last visited May 15, 2013); *Dental Amalgam Uses and Benefits*, HEALTH.GOV, <http://www.health.gov/environment/amalgam1/amalgamu.htm> (last visited May 15, 2013). “Dentists continue to use amalgam because it’s the most durable material for fillings, capable of withstanding the pressure of biting without shrinking or allowing bacteria [to] seep in and cause further decay, and because it’s relatively inexpensive when compared with alternatives.” Allen, *supra* note 37.

³⁹ See Baga, *supra* note 3, at 194–95 (explaining that low-income families on Medicaid must choose between mercury fillings or no fillings at all and moderate-income families are often forced to pay out-of-pocket for alternatives because they are not covered by most insurance plans); see also *Dental Amalgam Fillings to Be Further Reviewed for Safety*, 1 DENTAL.COM BLOG (Jan. 3, 2011), <http://www.1dental.com/blog/2011/01/03/dental-amalgam-fillings-reviewed> (noting that many support mercury fillings due to its affordability).

⁴⁰ Baga, *supra* note 3, at 194–95; *Dental Amalgam Fillings to Be Further Reviewed for Safety*, *supra* note 39.

⁴¹ See Baga, *supra* note 3, at 194–95; *Dental Amalgam Fillings to Be Further Reviewed for Safety*, *supra* note 39; see also MICHAEL D. FLEMING & JANINE E. JANOSKY, INT’L ACAD. OF ORAL MED. & TOXICOLOGY, THE ECONOMICS OF DENTAL AMALGAM REGULATION 7–8, available at <http://iaomt.guiadmin.com/wp-content/uploads/The-Economics-of-Dental-Amalgam-Regulation.pdf> (last visited May 15, 2013) (proposing a ban on amalgam fillings and discussing the potential increase in health care costs associated with such a ban). “The controversy over the use of mercury in the human body is not a controversy of science, it is one of money.” Pinna, *supra* note 3.

I. THE MERCURY FILLING CONTROVERSY

The controversy surrounding mercury fillings centers on the fact that little is known about the effects of mercury vapor on human health.⁴² Scientific evidence regarding how much vapor is released from the fillings and what level of exposure is sufficient to cause harm remains inconclusive because it is inherently difficult to study the long-term effects of mercury fillings.⁴³ Although some fear that a complete ban on mercury fillings would restrict access to dental care for disadvantaged populations, others believe that it is the only way to protect patient's rights and ensure better quality of care.⁴⁴ To date, there remains much disagreement among dentists, scientists, and the public over how the United States should regulate the continued use of mercury fillings.⁴⁵

A. *The American Dental Association's Response*

The American Dental Association (ADA) has taken a strong stance in favor of mercury fillings.⁴⁶ The ADA, as "the leading source of oral health related information for dentists and their patients," has signifi-

⁴² See Chirba-Martin & Welshhans, *supra* note 20, at 296.

⁴³ See *id.* at 298, 308–09; *Information Sheet—Amalgam Dental Fillings Containing Mercury*, *supra* note 4. "Studies conducted on sheep, monkeys and rats have demonstrated the correlation between mercury and adverse health effects such as immune suppression, neurotoxicity, renal impairments, and multiple sclerosis, as well as adverse health effects passed from mother to fetus, including brain damage, incoordination, blindness, and seizures." Chirba-Martin & Welshhans, *supra* note 20, at 308–09. Nevertheless, epidemiological studies conducted on human subjects are lacking. See *id.*

⁴⁴ See Chirba-Martin & Welshhans, *supra* note 20, at 319 (explaining how an informed consent statute would "vest[] any choice about safety in the individual patient where it properly belongs"); Pinna, *supra* note 3 ("People on . . . very limited dental insurance plans or on Medicaid often have no bargaining power with their dentists. . . . Some dentists treat their patients and those teeth like dollar signs."). The dangers of mercury fillings disproportionately impact working-class American families. See Pinna, *supra* note 3. When the state of Maine considered enacting a ban on mercury fillings, the American Dental Association threatened "[t]he result will be treatment delayed, treatment denied, and treatment never being sought." See *The "Silver Fillings" Deception*, *supra* note 12.

⁴⁵ See Chirba-Martin & Welshhans, *supra* note 20, at 319–20 (discussing the advantages and disadvantages of different methods of regulating mercury fillings); Baga, *supra* note 3, at 179 ("On one side of the debate are anti-amalgamists calling for the complete removal of mercury in dental fillings and in other areas of society. The other side supports the use of mercury amalgams, claiming that the 'benefits of restoring teeth with dental amalgam outweigh significantly the documented risks.'").

⁴⁶ See *Amalgam (Dental Filling Options)*, *supra* note 37; *Dental Amalgam*, AM. DENTAL ASS'N, <http://www.ada.org/2468.aspx> (last visited May 15, 2013).

cantly influenced the mercury filling controversy.⁴⁷ Because the ADA actively discourages dentists from advising their patients about the dangers of mercury fillings, it intensifies the need for government imposed warning requirements.⁴⁸

1. The American Dental Association's Position

Despite scientific evidence to the contrary, the ADA maintains the position that mercury fillings are safe and should continue to be used in patients without warnings.⁴⁹ When the ADA was founded in 1859, most dentists believed that mercury vapor could not escape from the fillings after they had hardened.⁵⁰ There was no identifiable reason to stop using them because the fillings were inexpensive, easy to place, long lasting, and supposedly safe.⁵¹ The scientific community now knows that the fillings constantly leak mercury vapor into the oral cavity.⁵² Although the ADA claims that mercury fillings emit only one to three micrograms of mercury per day, studies conducted by the World Health

⁴⁷ See Chirba-Martin & Welshhans, *supra* note 20, at 296; *About ADA*, AM. DENTAL ASS'N, <http://www.ada.org/aboutada.aspx> (last visited May 15, 2013). "The ADA . . . lends its dentists' seal of approval to a variety of amalgam products." Chirba-Martin & Welshhans, *supra* note 20, at 296. Furthermore, "the United States government . . . has largely deferred to the ADA's position that mercury amalgams are highly beneficial and pose only slight risks in rare cases." *Id.* at 298.

⁴⁸ PRINCIPLES OF ETHICS AND CODE OF PROF'L CONDUCT §§ 5.A, 5.B (Am. Dental Ass'n 2011), available at <http://www.ada.org/1383.aspx>; Chirba-Martin & Welshhans, *supra* note 20, at 323–24 ("Although a patient is legally entitled to information regarding the risks and benefits of proposed and alternative treatments, the ADA and state dental boards have vehemently resisted informing patients about the risks of mercury amalgams.").

⁴⁹ See Chirba-Martin & Welshhans, *supra* note 20, at 297–98; Baga, *supra* note 3, at 171–72; *Dental Amalgam*, *supra* note 46.

⁵⁰ See Chirba-Martin & Welshhans, *supra* note 20, at 294; Miller, *supra* note 10, at 356; Baga, *supra* note 3, at 171–72. "The public was receptive to the use of amalgam fillings because their only alternatives at the time were painful extractions without anesthesia or expensive hot gold fillings. The support from the ADA, coupled with the low cost of the mercury amalgam fillings, effectively overshadowed the warnings from mercury amalgam opponents." Baga, *supra* note 3, at 172.

⁵¹ See Miller, *supra* note 10, at 356 (explaining that the ADA's early position was based on the belief that mercury could not escape from dental fillings); Allen, *supra* note 37 (describing the advantages of mercury fillings). At the time when the ADA was founded, there was no instrumentation to measure the release of mercury from dental fillings. See Miller, *supra* note 10, at 356.

⁵² See Miller, *supra* note 10, at 356; Plaintiff's Brief in Support of Motion for Preliminary Injunction at 11, *Int'l Acad. of Oral Med. & Toxicology v. N.C. State Bd. of Dental Exam'rs*, 451 F. Supp. 2d 746 (E.D.N.C. 2006) (No. 5:05-CV-856-D2) [hereinafter Plaintiff's Brief] ("The collective results of numerous research investigations over the past decade clearly demonstrate that the continuous release of [mercury] from dental amalgam tooth fillings provides the major contribution to [mercury] body burden.")

Organization (WHO) found that a single filling may release anywhere between three to twenty-seven micrograms of mercury per day.⁵³

Nevertheless, the ADA continues to assert that mercury fillings are safe, claiming the amount of vapor released from the fillings is inadequate to cause health problems.⁵⁴ In fact, the ADA's website states that mercury fillings boast a "strong record of safety" and are "the most thoroughly researched and tested restorative material" on the market.⁵⁵ In addition, the ADA notes that agencies such as the FDA remain satisfied that mercury fillings are "safe, reliable and effective."⁵⁶ The Dental Filling Options page reads like an advertisement for mercury fillings.⁵⁷ Prospective patients are assured that "the mercury in amalgam combines with other metals to render it safe and stable for use in filling teeth."⁵⁸ The ADA also uses its website to distribute press releases and other materials concerning the safety of mercury fillings.⁵⁹

Although there remains much disagreement over the accuracy of this assessment, the ADA's position on mercury fillings remains ex-

⁵³ See Chirba-Martin & Welshhans, *supra* note 20, at 297; Baga, *supra* note 3, at 179. Anti-amalgam advocacy groups speculate that the ADA works with amalgam manufacturers and is paid to endorse mercury fillings. See Chirba-Martin & Welshhans, *supra* note 20, at 296 (noting that some challenge the ADA lending its dentists' seal of approval to amalgam products as a conflict of interest because it is allegedly paid for these endorsements); Baga, *supra* note 3, at 181–82.

⁵⁴ See *Statement on Dental Amalgam*, AM. DENTAL ASS'N (Aug. 2009), <http://www.ada.org/1741.aspx>.

⁵⁵ See *Amalgam (Dental Filling Options)*, *supra* note 37; *Dental Amalgam*, *supra* note 46. This position has also affected the ADA's reputation. Chirba-Martin & Welshhans, *supra* note 20, at 324.

The health risks and legal issues surrounding mercury amalgams paint, at worst, a bullying image and, at best, a less than flattering portrayal of the ADA, an organization that is supposed to represent an entire profession, promote the safety of overall dental health, and protect—and respect—the patients it serves.

Id.

⁵⁶ See *Statement on Dental Amalgam*, *supra* note 54.

⁵⁷ See Chirba-Martin & Welshhans, *supra* note 20, at 296 (explaining that "[t]he ADA's website is . . . replete with information extolling the safety and virtues" of mercury fillings); *Amalgam (Dental Filling Options)*, *supra* note 37. On its website, the ADA emphasizes amalgam's advantages, stating that the fillings are particularly useful for restoring molars in the back of the mouth because they can "withstand very high chewing loads." *Amalgam (Dental Filling Options)*, *supra* note 37. The only purported disadvantages are that the "silver-colored filling is not as natural looking" and that the dentist may need to remove more tooth structure. See *id.*

⁵⁸ See *Amalgam (Dental Filling Options)*, *supra* note 37.

⁵⁹ See *Am. Dental Ass'n v. Khorrami*, No. CV 02–3853-RSWL (RZx), 2006 WL 5105271, at *1 (C.D. Cal. June 9, 2006).

tremely influential.⁶⁰ The ADA remains the dominant group among dentists and its “seal of approval” holds significant weight.⁶¹ Legislators and judges remain hesitant to condemn a dental device that is backed by the oldest and largest national dental association in the world.⁶² Dental patients are also inclined to consider the ADA’s views when deciding whether to get or remove mercury fillings.⁶³

2. Enforcement through the American Dental Association’s Code of Ethics

The ADA uses its Code of Ethics to ensure its members’ actions are consistent with its views on mercury fillings.⁶⁴ Dentists who violate the ADA’s Code of Ethics may be “sentenced, censured, suspended or expelled.”⁶⁵ The Code of Ethics enforces the ADA’s position by restricting removal procedures.⁶⁶ Rule 5.A states, “[d]entists shall not represent the care being rendered to their patients in a false or misleading manner.”⁶⁷ One advisory opinion on this rule deems it unethical for a dentist to remove mercury fillings to eliminate “toxic substances from the body.”⁶⁸ Rule 5.B is also used to discipline dentists for removing mercury fillings because under the Rule, removal is considered an “unnecessary” procedure, resulting in the misrepresentation of fees.⁶⁹ Addi-

⁶⁰ See Chirba-Martin & Welshhans, *supra* note 20, at 297–98.

⁶¹ See Chirba-Martin & Welshhans, *supra* note 20, at 296; Baga, *supra* note 3, at 182.

⁶² See Chirba-Martin & Welshhans, *supra* note 20, at 298, 319–20 (explaining that the ADA’s position has influenced the FDA and courts); *About ADA*, *supra* note 47. The ADA is responsible for the accreditation of U.S. dental schools and “plays a primary role in determining the standard of care for dentists.” Plaintiff’s Brief, *supra* note 52, at 17 n.38.

⁶³ See Memorandum in Support of Jurisdiction at *4, *Kerger v. Dentsply Int’l, Inc.*, 128 Ohio St. 3d 1557 (Ohio 2011) (No. 11–0514), 2011 WL 1391347 [hereinafter *Kerger* Memorandum]; *About ADA*, *supra* note 47 (stating that the ADA is the leading source of oral health related information for dental patients). For example, in *Kerger v. Dentsply International, Inc.*, a dental patient injured by mercury fillings claimed that she did not believe she had any reason to remove her mercury fillings because she relied on the ADA’s view that mercury fillings are safe. See *Kerger* Memorandum, at *4.

⁶⁴ PRINCIPLES OF ETHICS AND CODE OF PROF’L CONDUCT §§ 5.A, 5.B (Am. Dental Ass’n 2011), available at <http://www.ada.org/1383.aspx>; Chirba-Martin & Welshhans, *supra* note 20, at 323–24.

⁶⁵ PRINCIPLES OF ETHICS AND CODE OF PROF’L CONDUCT §§ 5.A, 5.B; Chirba-Martin & Welshhans, *supra* note 20, at 300.

⁶⁶ PRINCIPLES OF ETHICS AND CODE OF PROF’L CONDUCT §§ 5.A, 5.A.1, 5.B.

⁶⁷ See *id.* § 5.A.

⁶⁸ *Id.* § 5.A.1.

⁶⁹ See *id.* § 5.B; see also Bd. of Dental Exam’rs v. Hufford, 461 N.W.2d 194, 196 (Iowa 1990) (noting that the Iowa Board of Dental Examiners suspended a dentist’s license for five years after he advised a full-mouth extraction on a patient with mercury fillings suffering from multiple sclerosis). In 1990, in *Board of Dental Examiners v. Hufford*, the discipli-

tionally, the Code of Ethics enforces the ADA's position by preventing dentists from talking openly with their patients about the risks of mercury fillings.⁷⁰ Another advisory opinion to Rule 5.A states that a dentist who represents that a treatment "has the capacity to diagnose, cure or alleviate diseases, infections or other conditions, when such representations are not based upon accepted scientific knowledge or research, is acting unethically."⁷¹ Because the ADA does not consider information about toxicity of mercury fillings "accepted scientific knowledge," this provision functions as a "gag" rule, preventing dentists from advising their patients on the potential risks associated with mercury fillings.⁷² Attempts to challenge the ADA's use of its Code of Ethics to enforce its pro-amalgam position have been largely unsuccessful.⁷³

nary board and court adamantly refused to recognize reducing mercury exposure as a valid reason for extraction and reaffirmed the ADA's position that mercury fillings are completely safe. *See Hufford*, 461 N.W.2d at 196, 198; Chirba-Martin & Welshhans, *supra* note 20, at 300–01. It made no difference that the patient affirmatively sought out the dentist because of his anti-amalgam position and wanted the fillings removed. *See Hufford*, 461 N.W.2d at 198; Chirba-Martin & Welshhans, *supra* note 20, at 300. The following year, a dentist who removed his patient's mercury fillings and replaced them with alternative fillings was found to have practiced beyond the scope of dentistry. *Berger v. Bd. of Regents of the State of N.Y.*, 577 N.Y.S.2d 500, 503 (App. Div. 1991).

⁷⁰ *See* PRINCIPLES OF ETHICS AND CODE OF PROF'L CONDUCT §§ 5.A.1, 5.A.2; Chirba-Martin & Welshhans, *supra* note 20, at 323–24.

⁷¹ PRINCIPLES OF ETHICS AND CODE OF PROF'L CONDUCT § 5.A.2.

⁷² *See id.* § 5.A.1; Chirba-Martin & Welshhans, *supra* note 20, at 302–03. For example, in *Breiner v. State Dental Commission*, a dentist who believed "the removal of mercury amalgam fillings could alleviate symptoms of various medical conditions" was charged with incompetent or fraudulent conduct. *See Breiner v. State Dental Comm'n*, 750 A.2d 1111, 1114 (Conn. App. Ct. 2000). The disciplinary board attacked the dentist for his views and advice as opposed to a specific instance of treatment. *See id.*; Chirba-Martin & Welshhans, *supra* note 20, at 301. As a result, "*Breiner* evidences the willingness of the ADA and state boards to discipline dentists for their viewpoints, even when those beliefs may not translate into harmful dental procedures." Chirba-Martin & Welshhans, *supra* note 20, at 302.

⁷³ *See* Thomas, *supra* note 8, at 174–76. In addition, in 2001, an anti-amalgam advocacy group sued the ADA and the California Dental Association (CDA) asserting the organizations "misled the public . . . and that the professional rules of conduct for the ADA and CDA prevented dentists from discussing the dangers of mercury with patients." *See Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 467 (Ct. App. 2001); Thomas, *supra* note 8, at 174. The ADA fought back, claiming that mercury fillings are toxic before they are placed in the patient's mouth and when they are removed from the patient's mouth, but not while they are in the patient's mouth. *SmileCare*, 91 Cal. App. 4th at 467; Thomas, *supra* note 8, at 174. In a similar case, the CDA successfully used California's anti-SLAPP (strategic lawsuit against public participation) statute to claim that actions taken through its ethical rules to "prevent warnings and information from reaching patients" were constitutionally protected speech. *See Kids Against Pollution v. Cal. Dental Ass'n*, 108 Cal. App. 4th 1003, 1009, 1027 (2003), *vacated*, 143 P.3d 655 (Cal. 2006); Thomas, *supra* note 8, at 174.

B. *The United States' Response Through the Action and Inaction of Regulatory Agencies*

The United States government's response to the mercury filling controversy can be examined through the competing and varied responses of its regulatory agencies.⁷⁴ Congress creates regulatory agencies through enabling acts, which define the scope of their authority.⁷⁵ These agencies are then free to promulgate regulations that have the same force as statutory law.⁷⁶ In addition, they have the power to enforce these regulations and other laws through administrative decisions and rulings.⁷⁷ To date, three regulatory agencies have responded to the mercury amalgam controversy in vastly different ways.⁷⁸

1. The Food and Drug Administration's Response

Although the Food and Drug Administration (FDA) recently recognized that mercury fillings have potential health risks, the FDA still fails to provide any form of protection to the American public.⁷⁹ Historically, the FDA supported the ADA's position that mercury fillings are a safe and desirable option for dental patients.⁸⁰ The FDA's website states that mercury fillings are safe for adults and children over the age

⁷⁴ See CTRS. FOR MEDICARE & MEDICAID SERVS., GUIDE TO CHILDREN'S DENTAL CARE IN MEDICAID 3-6 (2004), available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/Child-Dental-Guide.pdf>; *Dental Care*, MEDICAID.GOV (Feb. 28, 2012), <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Dental-Care.html>; *Eligibility*, MEDICAID.GOV (Feb. 28, 2012), <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Eligibility/Eligibility.html>; *FDA Issues Final Regulation on Dental Amalgam*, U.S. FOOD & DRUG ADMIN. (July 28, 2009), <http://www.fda.gov/NewsEvents/Newsroom/Pressannouncements/ucm173992.htm>; *Occupational Safety and Health Guideline for Mercury Vapor*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <http://www.osha.gov/SLTC/healthguidelines/mercuryvapor/recognition.html> (last visited May 15, 2013); *infra* notes 79-112 and accompanying text.

⁷⁵ See CHARLES H. KOCH, JR., ADMINISTRATIVE LAW & PRACTICE, 1 ADMIN. L. & PRAC. § 2:30 (3d ed. 2013).

⁷⁶ See *id.* § 4.10.

⁷⁷ See *id.* § 5.1.

⁷⁸ See *Dental Care*, *supra* note 74; *FDA Issues Final Regulation on Dental Amalgam*, *supra* note 74; *Occupational Safety and Health Guideline for Mercury Vapor*, *supra* note 74; *infra* notes 79-112 and accompanying text.

⁷⁹ See U.S. Calls for "Phase Down" of Dental Mercury, PR NEWswire (Apr. 20, 2011), <http://www.prnewswire.com/news-releases/us-calls-for-phase-down-of-dental-mercury-120295539.html>. The FDA is responsible for protecting and promoting the public health by assuring the "safety, efficacy and security" of medical devices. See *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/default.htm> (last updated June 19, 2012).

⁸⁰ See Chirba-Martin & Welshhans, *supra* note 20, at 298 ("[T]he FDA, has largely deferred to the ADA's position that mercury amalgams are highly beneficial and pose only slight risks in rare cases. . . .").

of six because the levels of mercury emitted from the mercury fillings are too low to cause adverse health effects.⁸¹

The FDA classifies devices based on the level of control necessary to ensure safety and effectiveness.⁸² In 1987, the FDA provided separate classifications for the components of dental amalgam.⁸³ The mixture of silver, tin, copper, and zinc was labeled a Class II device, meaning that special controls will be used because general controls alone are insufficient to assure safety and effectiveness.⁸⁴ The liquid mercury was labeled as a Class I device, meaning that it “does not present a risk to humans and is subject only to the general FDA controls for goods manufacturing procedures.”⁸⁵ Nevertheless, the FDA neglected to provide a classification for the substance that forms when these components are combined.⁸⁶

In 2009, in response to a settlement, the FDA classified both dental amalgam and the liquid mercury component as Class II devices.⁸⁷ As a result, the FDA was able to place special controls on mercury fillings.⁸⁸ The FDA recommended that product labels include warnings about the use of dental amalgam in patients with mercury allergies and the need for dental professions to use adequate ventilation when handling mercury fillings.⁸⁹ In addition, the FDA recommended a statement ad-

⁸¹ See *About Dental Amalgam Fillings*, *supra* note 18.

⁸² See 21 C.F.R. § 860.3(c) (2001) (outlining medical device classification procedures); *Device Classification*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last updated Dec. 3, 2012) (explaining the difference between Class I and Class II classifications).

⁸³ See Baga, *supra* note 3, at 177–78.

⁸⁴ See 21 C.F.R. § 860.3(c) (2) (defining Class II devices); Baga, *supra* note 3, at 177.

⁸⁵ See 21 C.F.R. § 860.3(c) (1) (defining Class I devices); Baga, *supra* note 3, at 177.

⁸⁶ See *Appendix I*, *supra* note 34.

⁸⁷ See *id.* The FDA acted in accordance with the terms of a settlement reached on a lawsuit filed by the anti-amalgam advocacy group, Consumers for Dental Choice. Kathy Kincade, *FDA Revises Its Position on Dental Amalgams*, DR. BICUSPID.COM (June 5, 2008), <http://www.drbcuspids.com/index.aspx?sec=nws&sub=rad&pag=dis&ItemId=300646> (explaining that the FDA agreed to add warnings regarding the use of amalgams in some patient groups and complete a review that could lead to more stringent regulation as part of a settlement). The ADA urged the FDA to avoid “draconian regulatory action” in reclassifying mercury fillings, claiming that current scientific evidence did not support the use of special controls such as warnings or limitations. See Craig Palmer, *ADA Urges Caution in Shaping New Amalgam Regulation*, AM. DENTAL ASS’N (July 28, 2008), <http://www.ada.org/news/1931.aspx>.

⁸⁸ See 21 C.F.R. § 860.3(c) (stating that Class II devices are subject to special controls); *Device Classification*, *supra* note 82.

⁸⁹ See *Class II Special Controls Guidance Document: Dental Amalgam, Mercury and Amalgam Alloy: Guidance for Industry and FDA Staff*, U.S. FOOD & DRUG ADMIN. (July 28, 2009), <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073311.htm> [hereinafter *Class II Special Controls*]; *FDA Issues Final Regulation on Dental Amalgam*, *supra* note 74.

addressing the benefits and risks associated with mercury fillings to assist dentists and patients in making informed decisions about whether to use mercury fillings.⁹⁰

Less than one year later, the FDA announced plans to reexamine the safety of dental amalgam because of concerns about the adequacy of the risk assessment method and clinical studies used in labeling it as a Class II device.⁹¹ The FDA publically agreed to reopen its investigation into the “potential long term health risks” associated with mercury fillings.⁹² Nevertheless, the FDA has yet to make an announcement on a new amalgam policy.⁹³

Coincidentally, in 2011, the World Health Organization (WHO) released a report on the “Future Use of Materials for Dental Restorations,” recommending a global “phase down” of dental amalgam.⁹⁴ The report stated that “[d]ental amalgam is a significant source of [mercury] exposure” and “[n]ational, regional and global actions, both immediate and long term, are needed to reduce or eliminate releases of mercury and its compounds to the environment.”⁹⁵

Despite these warnings, the FDA continues to allow mercury fillings to be used in all patients, even pregnant women and children, and “aids and abets the ‘silver fillings’ deception” by failing to educate the public about the mercury component.⁹⁶ These practices are inconsistent with the recommendations of the FDA’s advisory panel and the

⁹⁰ See *Class II Special Controls*, *supra* note 89; *FDA Issues Final Regulation on Dental Amalgam*, *supra* note 74.

⁹¹ See *FDA Note to Correspondents*, U.S. FOOD & DRUG ADMIN. (June 10, 2010), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm215061.htm> (announcing plans to revisit the safety of dental amalgams).

⁹² See Edward Group, *FDA Announces They Will Consider Ban on Mercury Amalgam Fillings*, GLOBAL HEALING CENTER (July 7, 2011), <http://www.globalhealingcenter.com/natural-health/mercury-amalgam-fillings/>.

⁹³ Dr. Mercola, *Dental Patients Beware: FDA Lets Dental Mercury Amalgam Action Deadline Pass Unmet*, ORGANIC CONSUMERS ASS’N (Jan. 17, 2012), http://www.organicconsumers.org/articles/article_24694.cfm. On December 30, 2011, the “FDA conceded that no announcement was forthcoming—not in 2011, and maybe not at all.” *Id.*

⁹⁴ WHO Report Suggests “Phase Down” of Dental Amalgam Globally; Breakthrough Will Lead to Phase Out of Dental Mercury, Say NGOs, PR NEWswire (Oct. 11, 2011), <http://www.prnewswire.com/news-releases/who-report-suggests-phase-down-of-dental-amalgam-globally-break-through-will-lead-to-phase-out-of-dental-mercury-say-ngos-131548538.html> [hereinafter *WHO Report Suggests “Phase Down”*]. Dental amalgam releases a significant amount of mercury into the environment, including the atmosphere, surface water, groundwater, and soil. See *id.*

⁹⁵ POUL ERIK PETERSEN ET AL., WORLD HEALTH ORG. FUTURE USE OF MATERIALS FOR DENTAL RESTORATION 26 (2010), available at http://mercurypolicy.org/wp-content/uploads/2010/12/who_mtg_report_nov_20102.pdf.

⁹⁶ See *U.S. Calls for “Phase Down” of Dental Mercury*, *supra* note 79.

regulations promulgated by the Occupational Safety and Health Administration (OSHA).⁹⁷

2. Centers for Medicare and Medicaid Services' Response

Centers for Medicare and Medicaid Services (CMS) has responded as though mercury fillings pose no health risk to low-income Americans by failing to mandate coverage for alternative fillings.⁹⁸ CMS is the branch of HHS that works with state governments to administer Medicaid and Child's Health Insurance Program (CHIP).⁹⁹ Combined, these programs provide health care to "almost one in every three Americans."¹⁰⁰ Although the programs vary across states, CMS guidelines set the minimum requirements for all programs.¹⁰¹

CMS guidelines require states to provide dental services to children, but the states are not obligated to offer dental services to adults.¹⁰² Medicaid's website explains that at a minimum, children's dental services must include "relief of pain and infections, restoration of teeth and maintenance of dental health" and services must be provided at intervals that meet reasonable standards of dental practice after consultation with recognized dental organizations involved in child health care.¹⁰³

Medicaid considers mercury fillings appropriate for both primary and permanent teeth, noting that the only disadvantage to mercury

⁹⁷ See *id.*; *infra* notes 107–112 and accompanying text.

⁹⁸ See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 74, at 3–6. States can decide whether to opt into the programs. Letter from Cindy Mann, Dir., Center for Medicaid, CHIP and Survey & Certification & Melanie Bella, Dir., Medicare-Medicaid Coordination Office, to State Medicaid Director (July 8, 2011), *available at* https://www.cms.gov/smdl/downloads/Financial_Models_Supporting_Integrated_Care_SMDL.pdf.

⁹⁹ See *What We Do*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://www.hhs.gov/about/whatwedo.html> (last visited Mar. 16, 2013).

¹⁰⁰ *Id.* Medicaid and CHIP provide health insurance coverage to individuals who meet certain financial criteria or are part of a categorical group. *Id.* Categorical groups include pregnant women and people with disabilities. *Id.* Medicaid provides health coverage for an estimated fifty million low-income individuals and twenty-four million children. *Id.*

¹⁰¹ *Id.* Participating states must follow CMS guidelines, but can also expand upon them to extend eligibility and provide more comprehensive coverage. *Id.*

¹⁰² See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 74, at 6; Arianna Tunsky-Brashich, *The Medical Legal Partnership for Children: Policy Strategies for Expanding a Gateway Program*, 28 B.C. THIRD WORLD L.J. 558, 571 (2008). Children are defined as individuals under the age of twenty-one years old. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 74, at 6. CMS estimates that majority of states offer emergency dental services for adults, but less than half of states provide comprehensive dental care. See *id.*; *Medicaid/CHIP Oral Health Services Fact Sheet*, Centers for Medicare & Medicaid Services (Oct. 2010), <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/2010-Dental-Fact-sheet.pdf>.

¹⁰³ See *Dental Care*, *supra* note 74.

fillings is that they are “not considered to be esthetic.”¹⁰⁴ As a result, states can decide whether to provide coverage for alternative fillings.¹⁰⁵ Many states provide only limited coverage for alternative fillings, so low-income Americans are forced to decide between getting a mercury filling or no filling at all.¹⁰⁶

3. The Occupational Safety and Health Administration’s Response

OSHA is a branch of the Department of Labor that is responsible for creating a safe and healthy work environment for all Americans.¹⁰⁷ Recognizing that mercury fillings pose more than a hypothetical health risk, OSHA promulgated regulations to protect dentists and dental workers from exposure to mercury vapor during the placement and removal of mercury fillings.¹⁰⁸ OSHA established Guidelines for Mercury Exposure, including a permissible exposure limit, thereby declaring that mercury fillings pose a serious health risk.¹⁰⁹ OSHA recognizes

¹⁰⁴ See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 74, at app. A, 4.

¹⁰⁵ See *id.*

¹⁰⁶ See STATE OF IOWA DEPT. OF HUMAN SERVS., Medicaid Provider Manual: Dental Services 30 (2011), available at http://www.dhs.iowa.gov/policyanalysis/PolicyManualPages/Manual_Documents/Provman/dental.pdf; Baga, *supra* note 3, at 194–95; *Dental Benefits: Medicaid, CHIP, PCN*, UTAH DEPARTMENT OF HEALTH (Feb. 2011), <http://health.utah.gov/umb/forms/pdf/dental.pdf>. For example, Utah only offers coverage for alternative fillings on front teeth and “some limited small fillings on back teeth.” See *Dental Benefits: Medicaid, CHIP, PCN, supra*. All other fillings on back teeth must be mercury fillings or they will not be covered. See *id.* In addition, Iowa covers mercury fillings and alternative fillings, but the alternative fillings are considered “payable benefits” and are reimbursable only once in a two year period. See STATE OF IOWA DEPT. OF HUMAN SERVS., *supra*.

¹⁰⁷ About OSHA, U.S. DEPARTMENT OF LABOR: OCCUPATIONAL SAFETY & HEALTH ADMIN., <http://www.osha.gov/about.html> (last visited May 15, 2013).

¹⁰⁸ See Thomas, *supra* note 8, at 170 (“[T]hose working in the dental profession show significant occupational exposure to mercury vapor from amalgam.”); *Mercury*, U.S. DEPARTMENT OF LABOR: OCCUPATIONAL SAFETY & HEALTH ADMIN., <http://www.osha.gov/SLTC/mercury/index.html> (last visited May 15, 2013). According to an OSHA investigation, in about ten percent of dental offices in the United States the mercury vapor concentration is double the threshold limit. See Miller, *supra* note 10, at 361–62. Some research indicates “that the high suicide rate among dentists may be related to the bioaccumulation of mercury in the brain of exposed dental professionals.” See Thomas, *supra* note 8, at 170.

¹⁰⁹ *Occupational Safety and Health Guideline for Mercury Vapor, supra* note 74. OSHA’s permissible exposure limit is 0.1 milligram per cubic meter of air. See *id.* On its website, OSHA notes that the National Institute for Occupational Safety and Health recommends a limit of 0.05 milligrams per cubic meter of air for a ten hour workday and a forty hour workweek and the American Conference of Governmental Industrial Hygienists assigns a threshold limit of 0.025 milligrams per cubic meter of air for an eight hour workday and a forty hour workweek. *Id.* Interestingly, an individual with mercury fillings can be exposed to higher levels of mercury vapor than OSHA allows just by brushing his teeth. See Curt Eastin, *Is Your Dentist Mercury Free? Find a Mercury Free Dentist Now*, EASTIN CENTER FOR MODERN DENTISTRY (Aug.

that mercury vapor can cause damage to the central and peripheral nervous systems, lungs, kidneys, skin, and eyes.¹¹⁰

Although OSHA's response indicates that the U.S. government takes the exposure of mercury to dentists very seriously, it has done nothing to protect those who have to carry that mercury in their mouth.¹¹¹ The FDA and CMS should likewise recognize the serious risks associated with mercury fillings and provide similar protections to dental patients.¹¹²

II. CHALLENGES OF MERCURY FILLING LITIGATION

Although some individuals who have suffered harm from mercury fillings have sought relief in court, tort litigation has proven to be ineffective.¹¹³ In order to succeed on a tort claim, the plaintiff must rely on scientific evidence to prove that mercury fillings generally cause adverse health effects and specifically caused their injuries.¹¹⁴ In 1993, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court set forth the standard for the admission of scientific evidence.¹¹⁵ The Court explained that the trial court judge has an explicit gatekeeper role and must apply a flexible test of non-exclusive factors to determine whether scientific evidence should be admitted.¹¹⁶

Although the *Daubert* test makes it difficult for all product safety and medical malpractice plaintiffs to prove their case, it makes it nearly impossible for mercury filling plaintiffs.¹¹⁷ First, mercury filling plain-

15, 2011), <http://idahonaturaldentist.com/is-your-dentist-mercury-free-mercury-free-dentist-mercury-safe-dentistry>.

¹¹⁰ *Occupational Safety and Health Guideline for Mercury Vapor*, *supra* note 74.

¹¹¹ See Eastin, *supra* note 109; *Dental Care*, *supra* note 74; *FDA Issues Final Regulation on Dental Amalgam*, *supra* note 74; *Occupational Safety and Health Guideline for Mercury Vapor*, *supra* note 74.

¹¹² See Eastin, *supra* note 109; *Dental Care*, *supra* note 74; *FDA Issues Final Regulation on Dental Amalgam*, *supra* note 74; *Occupational Safety and Health Guideline for Mercury Vapor*, *supra* note 74.

¹¹³ See Chirba-Martin & Welshhans, *supra* note 20, at 304; Baga, *supra* note 3, at 183–84.

¹¹⁴ See Chirba-Martin & Welshhans, *supra* note 20, at 304.

¹¹⁵ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589–90 (1993).

¹¹⁶ See *id.* at 595. The holding of *Daubert v. Merrell Dow Pharmaceutical, Inc.* is encapsulated in Federal Rule of Evidence 702, which states that a witness qualified as an expert may testify in the form of an opinion if the opinion is based on sufficient facts or data that are the product of reliable principles and methods and these principles and methods were applied reliably to the case. FED. R. EVID. 702.

¹¹⁷ See *Daubert*, 509 U.S. at 595; Chirba-Martin & Welshhans, *supra* note 20, at 304–05; Baga, *supra* note 3, at 183–85. Some of the factors a court could consider are whether the evidence has been peer reviewed or published, whether there is a known error rate,

tiffs are “likely to encounter formidable barriers” proving general causation because of the lack of admissible scientific evidence “particularly in the form of epidemiological studies conducted on human subjects.”¹¹⁸ Although studies conducted on sheep, monkeys, and rats have linked mercury exposure to adverse health effects, it is impossible for scientists to conduct similar studies on humans and courts are hesitant to admit animal studies.¹¹⁹ In addition, the evidence is “subject to challenge over its design, conduct and results due to the many judgment calls made in the course of conducting the study and analyzing the data.”¹²⁰

Second, due to the nature of mercury filling plaintiffs’ injuries, it is particularly difficult to establish specific causation.¹²¹ For example, in order to prove nerve injury from toxic substance exposure, a plaintiff must demonstrate that his symptoms are of the type caused by the substance and that his level of exposure was “potentially high enough” to cause the injury.¹²² Although blood or urine tests can be used to determine an individual’s level of exposure, it is unlikely that either test would be particularly useful in the litigation context.¹²³ This is in part due to the fact that blood tests are not accurate unless they are conducted within a few days of exposure and do not distinguish between the three types of mercury, and urine tests do not detect organic mercury.¹²⁴ In addition, mercury vaccine litigation demonstrates that it will be difficult for mercury filling plaintiff’s to prove the source of their mercury exposure as there are other points of exposure such as diet, vaccines, and medical procedures.¹²⁵

Mercury filling litigation does not provide adequate protections for low-income Americans.¹²⁶ Many patients get mercury fillings because they cannot afford alternatives and therefore, it is unlikely that

whether the evidence complies with industry standards, and whether the evidence has been generally accepted. *Daubert*, 509 U.S. at 595.

¹¹⁸ Chirba-Martin & Welshhans, *supra* note 20, at 308.

¹¹⁹ *See id.* at 308–09.

¹²⁰ *See id.* at 307.

¹²¹ *See Baga, supra* note 3, at 184. For example, in *Barnes v. Kerr Corp.*, these evidentiary hurdles prevented a dentist from succeeding on a claim against an amalgam provider. *See Barnes v. Kerr Corp.*, 418 F.3d 583, 589–90 (6th Cir. 2005). The dentist could not prove what percentage of his mercury exposure came from the mercury fillings made by the defendant. *See id.*

¹²² *See Baga, supra* note 3, at 184.

¹²³ *See id.*

¹²⁴ *See id.*

¹²⁵ *See Dwyer ex. rel. Dwyer v. Sec’y of Health and Human Servs.*, No. 03–1202V, 2010 WL 892250, at *77–81 (Fed. Cl. Mar. 12, 2010).

¹²⁶ *See Baga, supra* note 3, at 183–85, 194–95; *The “Silver Fillings” Deception, supra* note 12.

they could finance expensive litigation.¹²⁷ Because mercury filling controversy is a broad public issue, episodic private litigation is an insufficient solution.¹²⁸

III. LEGISLATIVE RESPONSES IN THE UNITED STATES AND ABROAD

Although the United States has yet to enact legislation that would regulate mercury fillings, several other countries have taken action.¹²⁹ Countries such as Sweden, Austria, Denmark, Norway, and Finland have completely banned mercury fillings, whereas Canada, Germany, and Japan have restricted their use.¹³⁰ These dramatic measures reveal the seriousness of the problem and the danger of the United States' inaction.¹³¹

A. *International Response to Mercury Fillings*

Sweden was the first country to enact a complete ban on mercury fillings.¹³² The Swedish health department announced the ban after concluding that mercury fillings are "unsuitable from a toxicological point of view."¹³³ The Swedish dental association also publically admitted that mercury fillings are unsafe.¹³⁴ Austria, Denmark, Finland, and

¹²⁷ See Baga, *supra* note 3, at 194–95; *The "Silver Fillings" Deception*, *supra* note 12.

¹²⁸ See Chirba-Martin & Welshhans, *supra* note 20, at 304–12; Baga, *supra* note 3, at 183–85; *The "Silver Fillings" Deception*, *supra* note 12.

¹²⁹ See Baga, *supra* note 3, at 191–92; Sam Greenhill, *Mercury Fillings ARE Dangerous Say Regulators—but British Health Bosses Still Refuse to Take Action*, MAILONLINE.COM (June 30, 2008, 8:43 AM), <http://www.dailymail.co.uk/health/article-1030417/Mercury-fillings-ARE-dangerous-say-regulators—British-health-bosses-refuse-action.html>; *Is an Amalgam Filling Safe?*, ASK DR. SUN (Mar. 14, 2009), <http://sundds.wordpress.com/2009/03/14/is-an-amalgam-filling-safe/>.

¹³⁰ See Baga, *supra* note 3, at 191–92 (explaining that Sweden, Austria, Denmark, and Norway have banned mercury fillings and Canada and Germany have restrictions); Greenhill, *supra* note 129 (stating that Norway and Denmark banned mercury fillings earlier in 2008 and Finland and Japan have severe restrictions); *Is an Amalgam Filling Safe?*, *supra* note 129 (noting that Sweden, Norway, and Finland have outlawed mercury fillings). In Japan, dental schools no longer teach the placement techniques for mercury fillings. *The Environmental Effects of Amalgam Fillings Affect Everyone*, FLA. LEAGUE OF CONSERVATION VOTERS EDUC. FUND, <http://www.flcv.com/damspr2.html> (last visited May 15, 2013).

¹³¹ See Baga, *supra* note 3, at 191.

¹³² See *id.*

¹³³ See Miller, *supra* note 10, at 360. The ban came in response to a report commissioned by the Swedish government. See *id.* In 1995, Sweden banned the use of mercury fillings on children and adolescents and two years later, the ban was extended to adults. See *id.*

¹³⁴ See *id.* The ADA released a statement explaining that Sweden's ban was for "environmental reasons" and that a similar ban would not be necessary in the United States because "dentists already capture nearly 80 percent of waste amalgam with standard equipment in

Norway followed shortly thereafter.¹³⁵ When Norway announced plans for a ban, the Minister of Environment and Development stated that mercury is “among the most dangerous environmental toxins” and recognized that “satisfactory alternatives” are available.¹³⁶

Other countries focus on protecting vulnerable populations.¹³⁷ Canada recommends that mercury fillings not be given to pregnant women, children, and people with kidney problems, braces, or mercury hypersensitivity.¹³⁸ Germany partially bans mercury fillings by prohibiting their use on people with kidney problems and strongly advising against their use in pregnant women and children.¹³⁹ More European countries may take action to regulate mercury fillings in the near future.¹⁴⁰ In the spring of 2011, the Parliamentary Assembly of the Council of Europe passed a resolution calling for an end to the use of amalgam.¹⁴¹ As more countries begin to express willingness to ban or limit

their practices.” *Sweden to Ban All Mercury for Environmental Reasons*, AM. DENTAL ASS’N (Jan. 20, 2009), <http://www.ada.org/news/1204.aspx>.

¹³⁵ See Baga, *supra* note 3, at 191; Greenhill, *supra* note 129; *Is an Amalgam Filling Safe?*, *supra* note 129.

¹³⁶ See Arvind Shenoy, *Is It the End of the Road for Dental Amalgam? A Critical Review*, 11 J. CONSERVATIVE DENTISTRY 99, 99–107 (2008), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2813106>; *Amalgam Ban Causes Stir*, DENTISTRY (Feb. 14, 2008), <http://www.dentistry.co.uk/news/amalgam-ban-causes-stir>. Nevertheless, the ADA claimed that Norway’s ban was also for environmental reasons. Craig Palmer, *Norway Announces Mercury Ban*, AM. DENTAL ASS’N (Jan. 21, 2008), <http://www.ada.org/news/2422.aspx>.

¹³⁷ See Baga, *supra* note 3, at 191; Greenhill, *supra* note 129.

¹³⁸ See *The Safety of Dental Amalgam*, HEALTH CAN., http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pubs/dent_amalgam-eng.php (last modified Nov. 17, 2006). In addition, dentists should “provide their patients with sufficient information to make an informed choice regarding the material used to fill their teeth, including information on the risks and benefits of the material and suitable alternatives.” *Id.* These recommendations came in response to a 1995 health report stating that mercury fillings “contribute[] detectable amounts of mercury to the human body and [are] the largest source of mercury exposure for average Canadians.” See Baga, *supra* note 3, 191.

¹³⁹ See Baga, *supra* note 3, 191. In fact, the world’s leading amalgam manufacturer was based in Germany and has “ceased manufacturing mercury amalgams entirely and has switched all of its production to alternative filling materials.” *Id.*

¹⁴⁰ See *Council of Europe Calls for End of Amalgam*, INT’L ACAD. ORAL MEDICINE & TOXICOLOGY (July 7, 2011), <http://www.iaomt.org/news/index.asp?intReleaseID=373&month=7&year=2011>.

¹⁴¹ See *id.*; Dr. Mercola, *How the FDA Covered Up the Mercury Dental Amalgam Issue*, HEALTH IMPACT NEWS DAILY, <http://healthimpactnews.com/2011/how-the-fda-covered-up-the-mercury-dental-amalgam-issue> (last visited May 15, 2013). “With this resolution, the Council of Europe joins the growing international call for the amalgam phase-out.” *Council of Europe Calls for End of Amalgam*, *supra* note 140.

the use of mercury fillings, the United States will fall further behind the rest of the world on this critical health issue.¹⁴²

B. *Legislative Response in the United States*

In the United States, mercury filling legislation has emerged at the state and local level.¹⁴³ These laws provide incomplete, but informative models for national-level legislation.¹⁴⁴

1. State Statutes and Local Laws

One such response, California's Proposition 65, has proven successful.¹⁴⁵ Enacted in 1986, California's Proposition 65 was the first state statute to mandate informed consent for mercury fillings.¹⁴⁶ Proposition 65 requires businesses using certain reproductive toxins, including mercury, to warn patients and employees about the dangers of these toxins.¹⁴⁷ Proposition 65 is not specific to the context of mercury fillings, but it has been effective in compelling dentists to warn their patients about the dangers associated with them.¹⁴⁸ For example, in 1996, in *Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, the U.S. Court of Appeals for the Ninth Circuit upheld the application of Proposition 65's warning requirements to the mercury in mercury fillings finding that "as a matter of logic. . . any regulation of dental mercury will, ipso facto, regulate any product containing dental mercury, including dental amalgam."¹⁴⁹

¹⁴² See Baga, *supra* note 3, at 191; Dr. Mercola, *Don't Let Dentists Badger You with This Outdated Practice*, MERCOLA.COM (Sept. 6, 2011), <http://articles.mercola.com/sites/articles/archive/2011/09/06/take-action-day.aspx>.

¹⁴³ See CAL. HEALTH & SAFETY CODE §§ 25249.5–.13 (West 2006); CONN. GEN. STAT. § 22a-616 (2006); ME. REV. STAT. tit. 32, § 1094-C (West Supp. 2012); N.H. REV. STAT. ANN. § 317-A:38 (West 2005); PHILADELPHIA, PA., CODE § 9–3100 (2008).

¹⁴⁴ See CAL. HEALTH & SAFETY CODE §§ 25249.5–.13; CONN. GEN. STAT. § 22a-616; ME. REV. STAT. tit. 32, § 1094-C; N.H. REV. STAT. ANN. § 317-A:38; Baga, *supra* note 3, at 193 (explaining that there are two problems with amalgam-specific state-level legislation that federal legislation could address and correct).

¹⁴⁵ See CAL. HEALTH & SAFETY CODE §§ 25249.5–.13; Chirba-Martin & Welshhans, *supra* note 20, at 313.

¹⁴⁶ See CAL. HEALTH & SAFETY CODE §§ 25249.5–.13; Chirba-Martin & Welshhans, *supra* note 20, at 318; Baga, *supra* note 3, at 192.

¹⁴⁷ See CAL. HEALTH & SAFETY CODE §§ 25249.5–.13; Chirba-Martin & Welshhans, *supra* note 20, at 313; Baga, *supra* note 3, at 192.

¹⁴⁸ See Chirba-Martin & Welshhans, *supra* note 20, at 313.

¹⁴⁹ See *Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton*, 92 F.3d 807, 810, 813 (9th Cir. 1996); Chirba-Martin & Welshhans, *supra* note 20, at 320.

Proposition 65, however, has one potential loophole: Dentists do not have to provide a warning if they can demonstrate that “exposure at 1,000 times the amount in question would not cause any observable reproductive harm.”¹⁵⁰ Nevertheless, when a dentist tried to assert this defense in *Consumers Cause, Inc. v. SmileCare*, the California Appellate Court held that the dentist bears the burden of proving that the risk was too low to necessitate a warning.¹⁵¹ As a result, a patient’s inability to establish a specific level of exposure will not automatically excuse the dentist from Proposition 65’s warning requirement.¹⁵² When a warning is required, it must be “reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure.”¹⁵³ Nonetheless, in *Environmental Law Foundation v. Wykle Research*, the court found that even though a warning was “small, ‘combined with information required by the [ADA] and did not refer specifically to mercury,’” it was sufficient to satisfy this requirement.¹⁵⁴

Other states have enacted more specific statutes to provide patients with the opportunity to make an informed decision about whether to receive a mercury filling.¹⁵⁵ Maine requires dentists to display posters in their waiting rooms and provide patients with a brochure prepared by

¹⁵⁰ See CAL. HEALTH & SAFETY CODE § 25249.10(c); Chirba-Martin & Welshhans, *supra* note 20, at 318.

¹⁵¹ See *Consumer Cause, Inc. v. SmileCare*, 110 Cal. Rptr. 2d 627, 641 (Ct. App. 2001). The Dental Board of California now provides an additional level of protection, mandating dentists to distribute a fact sheet detailing the dangers of mercury fillings. See THE DENTAL BOARD OF CALIFORNIA, THE FACTS ABOUT FILLINGS 2 (2004), available at http://www.dbc.ca.gov/formspubs/pub_dmfs_english_webview.pdf.

¹⁵² See *SmileCare*, 110 Cal. Rptr. 2d at 641. “[T]he dentist could not base his claim for an exemption on the plaintiff’s lack of evidence to disprove the defense nor on the plaintiff’s failure to fund scientific studies or collect data to establish the actual exposure language or the exemption exposure level.” Chirba-Martin & Welshhans, *supra* note 20, at 318.

¹⁵³ See CAL. HEALTH & SAFETY CODE § 12601(a) (West 2006).

¹⁵⁴ See *Env’tl. Law Found. v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 71 (Ct. App. 2005); Baga, *supra* note 3, at 185. The court explained that the warnings would only be read by the dentists and dental workers responsible for the care of the patient and proper use of the material and that “given [their] professional obligations,” they would be able to understand it. *Env’tl. Law Found.*, 134 Cal. App. 4th at 71; Baga, *supra* note 3, at 185.

¹⁵⁵ See CONN. GEN. STAT. § 22a-616 (2006); ME. REV. STAT. tit. 32, § 1094-C (West Supp. 2012); N.H. REV. STAT. ANN. § 317-A:38 (West 2005); Baga, *supra* note 3, at 193. “[S]tatutorily requiring disclosure of amalgam ‘risks,’ however remote or uncertain they may be, is likely to fuel the public’s perception that mercury amalgam is a dangerous toxin and thus, accelerate the trend away from its use. It is therefore not surprising that the ADA opposes such informed consent laws.” Chirba-Martin & Welshhans, *supra* note 20, at 317.

the Bureau of Health discussing the dangers of mercury fillings.¹⁵⁶ Specifically, the brochure must warn patients “[t]o be careful, Canada and several other countries in Europe recommend limits on the use of mercury amalgam.”¹⁵⁷ Connecticut requires dentists to distribute similar brochures.¹⁵⁸ Connecticut’s statute calls for the development of “Best Management Practices” for mercury fillings and states that where appropriate, amalgam substitutes should be used.¹⁵⁹ The Connecticut law is part of the Mercury Reduction and Education Act of 2002, which “bans or phases out mercury-containing products.”¹⁶⁰ Although the Commissioner of the State Department of Environmental Protection stated that the Act did not intend to ban mercury-containing dental fillings, it did result in the development of the “Best Management Practices for Mercury Amalgam.”¹⁶¹ As part of these practices, dental offices must make information about dangers of mercury fillings and the availability of alternative materials available to patients.¹⁶² New Hampshire also has a similar statute that requires the Department of Health and Human Services to inform residents about the risks and benefits of mercury fillings.¹⁶³ The ADA tried unsuccessfully to “derail” the New Hampshire law before it took effect in 2003.¹⁶⁴

Nevertheless, these statutes provide insufficient protection to disadvantaged populations because insurance companies and Medicaid

¹⁵⁶ See ME. REV. STAT. tit. 32, § 1094-C; Chirba-Martin & Welshhans, *supra* note 20, at 313–14. To ensure that all patients were receiving the brochure, the Maine legislature amended the statute to require that the poster contain the words “Your dentist is required to give you a copy of this brochure in accordance with state law.” See Chirba-Martin & Welshhans, *supra* note 20, at 314.

¹⁵⁷ See ME. REV. STAT. tit. 32, § 1094-C; Chirba-Martin & Welshhans, *supra* note 20, at 313 (quoting H.B. 1637, 120th Leg., 2d Reg. Sess. (Me. 2001)). In addition, the brochure must state, “[t]hey advise that pregnant women should not have amalgam fillings placed or removed from their teeth.” Chirba-Martin & Welshhans, *supra* note 20, at 313 (quoting H.B. 1637, 120th Leg., 2d Reg. Sess. (Me. 2001)). Nevertheless, the Maine statute leaves room for “professional disagreement and discretion,” specifying that the brochure may include other information that would help patients to make informed decisions when choosing between mercury amalgam and alternative materials. See ME. REV. STAT. tit. 32, § 1094-C; Chirba-Martin & Welshhans, *supra* note 20, at 313.

¹⁵⁸ See CONN. GEN. STAT. §§ 22a-616, 22a-622; Baga, *supra* note 3, at 192.

¹⁵⁹ See *Best Management Practices for Mercury Amalgam*, DEPARTMENT ENERGY & ENVTL. PROTECTION, <http://www.ct.gov/dep/cwp/view.asp?A=2708&Q=323996> (last updated Dec. 15, 2006).

¹⁶⁰ Baga, *supra* note 3, at 192.

¹⁶¹ See *Best Management Practices for Mercury Amalgam*, *supra* note 159.

¹⁶² See *id.*

¹⁶³ See N.H. REV. STAT. ANN. § 317-A:38 (West 2005); Chirba-Martin & Welshhans, *supra* note 20, at 314.

¹⁶⁴ See Chirba-Martin & Welshhans, *supra* note 20, at 314.

are not forced to pay for alternative filling materials.¹⁶⁵ Because cost—and not just a lack of information—is a significant barrier to opting for amalgam alternatives, some states are attempting to mandate equal coverage for alternative fillings.¹⁶⁶ Rhode Island and Louisiana require state dental insurance contracts to provide coverage for non-mercury fillings at no additional cost to state employees.¹⁶⁷ New York's Mercury Free Water Resources and Mercury Reduction Strategy Act bans health insurance discrimination relating to the dental use of mercury.¹⁶⁸

Additionally, some local laws provide protection to dental patients.¹⁶⁹ Philadelphia mandates that patients sign off on a fact sheet advising them that mercury fillings have neurological risks and that other filling materials are available.¹⁷⁰ In addition, the city of Costa Mesa, California, passed a resolution to ban mercury fillings in 2010.¹⁷¹ The resolution was initiated by anti-amalgam activists who teamed up with health professionals and green businesses to organize a petition and collect signatures.¹⁷² In 2011, Santa Ana, California, issued a proclamation in support of mercury-free dentistry and called dentists to

¹⁶⁵ Baga, *supra* note 3, at 193–95 (explaining that state informed consent statutes do not go far enough because they do not require insurance companies or Medicaid to pay for alternative fillings).

¹⁶⁶ LA. REV. STAT. ANN. § 30:2586 (2006); N.Y. ENVTL. CONSERV. LAW § 27–0926 (McKinney Supp. 2013); R.I. GEN. LAWS § 23–24.9–15(c) (West 2005).

¹⁶⁷ LA. REV. STAT. ANN. § 30:2586; R.I. GEN. LAWS § 23–24.9–15(c) (providing coverage for non-mercury fillings to state employees).

¹⁶⁸ See N.Y. ENVTL. CONSERV. LAW § 27–0926.

¹⁶⁹ See PHILADELPHIA, PA., CODE § 9–3100 (2008); *Another Calif. Town Considers Banning Dental Amalgam*, DR. BICUSPID'S COMMUNITY RESTORATIVES (Aug. 11, 2011), <http://www.drbcuspids.com/index.aspx?sec=sup&sub=rst&pag=dis&ItemID=308356>; *Historic Resolution Adopted by Costa Mesa: Official Position Taken to Ban Dental Mercury Fillings*, *supra* note 22.

¹⁷⁰ See PHILADELPHIA, PA., CODE § 9–3100; Brown, *supra* note 3; *Philadelphia Ordinance Requires Information Sheet on Restorative Option*, PA. DENTAL ASS'N, <http://www.padental.org/AM/Template.cfm?Section=Search&CONTENTID=24308&TEMPLATE=/CM/HTMLDisplay.cfm> (last visited May 15, 2013).

¹⁷¹ *Historic Resolution Adopted by Costa Mesa: Official Position Taken to Ban Dental Mercury Fillings*, *supra* note 22. The ADA and the California Dental Association (CDA) strongly opposed the ban. See *California City Seeks Amalgam Ban*, AM. DENTAL ASS'N (Nov. 5, 2010), <http://www.ada.org/news/5032.aspx>. In an article posted on the ADA's website, the president of the CDA called the resolution “unfortunate” and “extremely troubling.” See *id.* He also went on to state that Costa Mesa's ban “serves as a reminder to us that we need to be vigilant in monitoring all branches of government to make sure policymakers receive accurate information.” *Id.*

¹⁷² Dr. Mercola, *The Hazardous Gas in Your Mouth: Is This the First Crack in the ADA's Corrupt Cover-Up?*, MERCOLA.COM (Nov. 10, 2010), <http://articles.mercola.com/sites/articles/archive/2010/11/10/first-legal-victory-to-ban-mercury-from-amalgams-in-the-us.aspx>.

“voluntarily cease the use of dental amalgam and switch to interchangeable, modern alternatives.”¹⁷³

2. Obstacles to State-Level Legislation

Although some states have considered enacting more progressive laws to regulate mercury fillings, they have faced strong opposition from the ADA and the possibility of federal preemption.¹⁷⁴ California considered enacting a statewide ban on mercury fillings that would prohibit dentists from providing mercury fillings to any patient after 2007.¹⁷⁵ Washington also considered a bill that would prohibit mercury fillings from being placed in children and pregnant women after 2010 and any person in the state of Washington after 2012.¹⁷⁶ Under Washington’s proposed bill all government and private sector dental insurance plans, including Medicaid, would be required to provide coverage for alternative fillings.¹⁷⁷ In addition, Georgia and Ohio both considered partial bans on mercury fillings, limiting use on children under eighteen, women under forty-six, and pregnant woman.¹⁷⁸

The ADA’s firm opposition to these bills may have ultimately contributed to their demise.¹⁷⁹ The ADA uses its website to publicize its views on state-level mercury filling legislation.¹⁸⁰ In addition, the ADA writes letters to representatives, discouraging them from supporting mercury filling legislation, and pointing out the economic disadvantages of banning or regulating mercury fillings.¹⁸¹ For example, the executive director of the ADA wrote a letter to the co-chairman of the

¹⁷³ See *Another Calif. Town Considers Banning Dental Amalgam*, *supra* note 169.

¹⁷⁴ See *Am. Dental Ass’n v. Khorrami*, No. CV 02–3853-RSWL (RZx), 2006 WL 5105271, at *1 (C.D. Cal. June 9, 2006) (stating that the ADA uses its website to “disseminate press releases and position statements regarding the safety of dental amalgam” and writes letters to Congress opposing mercury filling legislation); Chirba-Martin & Welshhans, *supra* note 20, at 321–22 (“[I]t is not certain that mercury amalgam warning statutes will always survive preemption.”); Baga, *supra* note 3, at 193 (noting that federal preemption is one of the problems with state-level amalgam legislation).

¹⁷⁵ See Assemb. B. 2270, 2001–02 Leg., Reg. Sess. (Cal. 2002).

¹⁷⁶ See S.B. 5066, 58th Leg., Reg. Sess. (Wa. 2003).

¹⁷⁷ See *id.*; 2009 House Bill 1860: *Regarding the Use of Mercury in Dentistry*, <http://www.washingtonvotes.org/2009-HB-1860> (last visited May 15, 2013). In addition, institutes that offer training in dentistry would be required to “teach the risks of exposure to mercury in dental offices . . . and safe techniques for protection of workers and patients.” 2009 House Bill 1860: *Regarding the Use of Mercury in Dentistry*, *supra*.

¹⁷⁸ See H.B. 1715, 146th Gen. Assemb., Reg. Sess. (Ga. 2002); H.B. 598, 124th Gen. Assemb., Reg. Sess. (Ohio 2002).

¹⁷⁹ See *Khorrami*, 2006 WL 5105271, at *1; *The “Silver Fillings” Deception*, *supra* note 12.

¹⁸⁰ See *Khorrami*, 2006 WL 5105271, at *1.

¹⁸¹ See *The “Silver Fillings” Deception*, *supra* note 12.

Joint Standing Committee on Natural Resources, stating that if Maine bans mercury fillings, “[t]he result will be treatment delayed, treatment denied, and treatment never being sought.”¹⁸² The ADA also claims that these laws are “directly at odds and incompatible with the federal requirements set forth by the FDA.”¹⁸³

Additionally, state and local laws that regulate mercury fillings may be preempted.¹⁸⁴ For example, in *Stratton*, California’s Proposition 65 narrowly escaped preemption.¹⁸⁵ There the Ninth Circuit held that Proposition 65 is not preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) or the FDA’s decision not to impose warning requirements on mercury fillings.¹⁸⁶ The court was concerned that if inaction by the FDA was enough to trigger preemption, manufacturers would not be required to follow state consumer laws while the FDA is in the process of deciding whether to regulate or has decided “through inaction” not to issue a regulation on a particular device.¹⁸⁷ Nevertheless, the court made clear that if the state statute or federal regulations concerned a particular medical device, it would find preemption.¹⁸⁸ Therefore, it is unclear whether state statutes with more specific language than Proposition 65 would survive federal preemption.¹⁸⁹

3. Proposed Federal Legislation

Although the federal government has yet to enact legislation that would regulate mercury fillings, California Representative Diane Wat-

¹⁸² See *id.*

¹⁸³ Chirba-Martin & Welshhans, *supra* note 20, at 323. The ADA explains that “it is ‘not in the public interest to have competing state requirements that conflict with special controls proposed by the [FDA].’” See *id.*

¹⁸⁴ See Chirba-Martin & Welshhans, *supra* note 20, at 321–22; Baga, *supra* note 3, at 193 (noting that federal preemption is one of the problems with state-level amalgam legislation).

¹⁸⁵ See Chirba-Martin & Welshhans, *supra* note 20, at 321 (explaining that Proposition 65 escaped preemption because the Medical Device Amendments to the Food, Drug, and Cosmetic Act dealt with regulation generally and not with specific devices); Baga, *supra* note 3, at 192–93.

¹⁸⁶ See *Stratton*, 92 F.3d at 813; Chirba-Martin & Welshhans, *supra* note 20, at 321; Baga, *supra* note 3, at 193.

¹⁸⁷ See *Stratton*, 92 F.3d at 813; Chirba-Martin & Welshhans, *supra* note 20, at 320. The court relied on *Medtronic, Inc. v. Lohr*, where the Supreme Court held that a Florida law regulating pacemakers escaped preemption by the Medical Device Amendments because the language was not specific to the device. See 518 U.S. 470, 500, 502 (1996); *Stratton*, 92 F.3d at 813.

¹⁸⁸ See *Medtronic*, 518 U.S. at 500, 502.

¹⁸⁹ See *id.* at 500, 502; Chirba-Martin & Welshhans, *supra* note 20, at 320.

son has introduced a few bills that would address the dangers of mercury fillings.¹⁹⁰ One of the bills would implement uniform warning requirements and slowly phase out mercury fillings.¹⁹¹ Another bill would require dentists to provide patients with a fact sheet before performing any restorative work.¹⁹² The ADA strongly opposed both, claiming that scientific evidence demonstrates mercury fillings are safe.¹⁹³

In 2002, Representative Watson introduced the Mercury in Dental Filling Disclosure and Prohibition Act, which would amend the FDCA to prohibit any “mercury intended for use in a dental filling” to be used in interstate commerce.¹⁹⁴ Nevertheless, the bill “fails to require insurance companies or Medicaid to pay for alternative filling materials and does not provide sanctioning for dentists who violate the statute.”¹⁹⁵ Thus, even if warned of the health risks associated with amalgam fillings, many low-income families would not be able to choose an alternative filling due to financial constraints.¹⁹⁶ The ADA vehemently opposed the bill, providing “written statements to the House of Representatives in 2002 and 2003 discouraging . . . action that would limit or prevent the use of dental amalgam fillings” and using its website to publicize its views about the bill.¹⁹⁷ Unfortunately, the bill did not pass and was referred to the House Subcommittee on Health where it eventually ex-

¹⁹⁰ See Consumers Have Options for Molar Protection (CHOMP) Act of 2009, H.R. 4615, 111th Cong. (2010); Mercury in Dental Filling Disclosure and Prohibition Act, H.R. 1680, 108th Cong. (2003).

¹⁹¹ See H.R. 4615.

¹⁹² See H.R. 1680. A third bill would amend the Social Security Act to ensure that the amount of cost-sharing charged for alternative fillings does not exceed the amount charged for mercury fillings. See Medicaid Options for Dental Fillings Act, H.R. 4731, 111th Cong. (2010). The bill was ultimately referred to the Committee on Energy and Commerce. *Id.*

¹⁹³ See *Khorrami*, 2006 WL 5105271, at *1; *The “Silver Fillings” Deception*, *supra* note 12. The ADA continues to assert that there is not enough evidence to cease the use of mercury fillings. SANDRA N. DUFFY, U.S. FOOD & DRUG ADMIN., CRITIQUE OF THE CHILDREN’S AMALGAM STUDY CONSENT FORMS 2 (2004), available at <http://www.fda.gov/ohrms/dockets/dockets/06n0352/06n-0352-emc0108-23-duffy.pdf>.

Despite a large body of scientific studies showing mercury to be a neurotoxin, a nephrotoxin, a cytotoxin and to adversely affect the human body, the ADA, and federal agencies staffed with ADA dentists, have insisted that there is not enough evidence linking amalgams to a specific disease to reconsider the use of amalgam as a dental filling material.

Id.

¹⁹⁴ See H.R. 1680; Baga, *supra* note 3, at 194.

¹⁹⁵ See Baga, *supra* note 3, at 194.

¹⁹⁶ See *id.*

¹⁹⁷ See *Khorrami*, 2006 WL 5105271, at *1.

pired.¹⁹⁸ Representative Watson reintroduced the bill in 2005 and it was again referred to the House Subcommittee on Health.¹⁹⁹

In 2009, Representative Watson again attempted to combat the use of mercury fillings, this time by sponsoring the Consumers Have Options for Moral Protection Act (CHOMP).²⁰⁰ CHOMP would amend the FDCA to require dentists to provide patients with a fact sheet and “obtain the patients signature acknowledging receipt of that sheet” before performing any restorative work.²⁰¹ The ADA once again fought back, claiming that the bill would raise “an unfounded fear in patients that may prevent them from seeking needed and necessary care.”²⁰² The ADA wrote letters to members of Congress urging them not to support the bill, explaining that the FDA’s final ruling “confirms the broadly accepted position that dental amalgam is safe and has not caused harm to patients.”²⁰³ The ADA went on to state that mercury fillings are “often . . . the best treatment option available to a dentist for restorative work” and offer “a number of benefits that other restorative materials do not.”²⁰⁴

¹⁹⁸ See H.R. 1680; Baga, *supra* note 3, at 194.

¹⁹⁹ See H.R. 1680; Baga, *supra* note 3, at 194.

²⁰⁰ Consumers Have Options for Molar Protection (CHOMP) Act of 2009, H.R. 4615, 111th Cong. (2010).

²⁰¹ H.R. 4615. The fact sheet would be developed by the Secretary of Health and Human Services and would be periodically reviewed and updated. See *id.* Dentists who failed to provide the fact sheet to their patients would be fined five thousand dollars for each restoration performed without consent. See *id.* In addition, the FDA would be required to develop warning labels for dental restorative materials. See *id.*

²⁰² See Letter from Ronald L. Tankersley, President, Am. Dental Ass’n, & Kathleen T. O’Loughlin, Exec. Dir., Am. Dental Ass’n, to Representative (Feb. 24, 2010), *available at* http://www.ada.org/sections/advocacy/pdfs/ltr_100224_hr4615_amalgam.pdf. Similarly, the ADA opposed a resolution introduced by Representative Watson in 2009 that would encourage the “dissemination of information regarding mercury, its uses, and its effects to allow consumers to make informed decisions.” See Expressing the Need for Enhanced Public Awareness of Potential Health Effects Posed by Mercury, H.R. Res. 648, 111th Cong. (2009); Palmer, *supra* note 87. The ADA claimed that the resolution would advance the “misconception that because dental amalgam contains mercury, it is toxic.” See Palmer, *supra* note 87. In addition, the ADA stated that the contention that mercury fillings are harmful is based on “junk science.” See *id.*

²⁰³ Letter from Ronald L. Tankersley & Kathleen T. O’Loughlin to Representative, *supra* note 202, at 1.

²⁰⁴ See *id.*

IV. LOOKING TO THE FUTURE: A PROPOSED SOLUTION TO THE MERCURY FILLING CONTROVERSY

Given the potential risks associated with mercury fillings and the availability of viable alternatives, the United States should ban mercury fillings.²⁰⁵ OSHA promulgated regulations to protect dentists and dental workers from mercury exposure, but the FDA fails to provide similar protections to dental patients and CMS fails to mandate Medicaid coverage for alternatives.²⁰⁶ Furthermore, the FDA is unresponsive to the recommendations of its own advisory panel.²⁰⁷ Therefore, the FDA and CMS must step-up to the plate or Congress should step in and enact legislation to correct this misalignment of regulations.²⁰⁸

A. Legislation Banning Mercury Fillings

Although an immediate ban on all mercury fillings would provide enhanced protection for patients, a “phase out” is more realistic.²⁰⁹ A “phase out” could start by restricting the use of mercury fillings on high-risk populations, such as pregnant women and children, then, over time, institute a complete ban on mercury fillings.²¹⁰ A “phase

²⁰⁵ See Baga, *supra* note 3, at 196 (“Congress must pass comprehensive national legislation to completely ban the use of mercury amalgam dental fillings in the United States.”); *About Dental Amalgam Fillings*, *supra* note 18 (describing the viable alternatives to mercury fillings).

²⁰⁶ See *Dental Care*, *supra* note 74; *FDA Issues Final Regulation on Dental Amalgam*, *supra* note 74; *Occupational Safety and Health Guideline for Mercury Vapor*, *supra* note 74; *supra* notes 79–112 and accompanying text.

²⁰⁷ See U.S. Calls for “Phase Down” of Dental Mercury, *supra* note 79.

²⁰⁸ See Baga, *supra* note 3, at 194–96; *Never Do This with Your Teeth*, *supra* note 11.

²⁰⁹ See FLEMING & JANOSKY, *supra* note 41, at 7; PETERSEN ET AL., *supra* note 95, at 18–19; Baga, *supra* note 3, at 196 (“As each session of Congress closes without the passage of the Mercury in Dental Filling Disclosure and Prohibition Act, the longer dentists are able to place a toxic substance into their unsuspecting patients’ mouths.”).

²¹⁰ See Thomas, *supra* note 8, at 148; Dr. Mercola, *Just 1 Single Drop of This Would Poison a Lake Enough to Ban Fishing on It . . .*, MERCOLA.COM (Oct. 18, 2011), <http://articles.mercola.com/sites/articles/archive/2011/10/18/charlie-brown-on-movement-to-end-mercury-in-dentistry.aspx> (stating that the State Department has called for a “phase down” followed by an “eventual” phase out); *The Safety of Dental Amalgam*, *supra* note 138 (explaining that Canada advises against the use of mercury fillings in high risk populations); *WHO Report Suggests “Phase Down”*, *supra* note 94 (urging nations to phase out the use of mercury fillings). The harmful effects of mercury fillings on pregnant women and children are particularly alarming. See Plaintiff’s Brief, *supra* note 52, at 13 (citing Drasch et al., *Mercury Burden of Human Fetal and Infant Tissues*, EUR. J. PEDIATRICS (Aug. 1994)).

The National Academy of Sciences estimates that 60,000 newborns a year could be at risk of learning disabilities because of mercury their mothers absorbed during pregnancy. Significantly, mercury in the tissues of fetuses and

out” should focus on pregnant women and children because these groups are “disproportionately affected” by mercury exposure; it is therefore imperative that dentists stop placing mercury fillings in their mouths as soon as possible.²¹¹

It is in the best interest of the American public to completely ban mercury fillings because the risks are not limited to vulnerable populations.²¹² Mercury is toxic to all humans and can cause damage to the lungs, kidneys, and the nervous, digestive, respiratory, and immune systems.²¹³ In the interim period, it is necessary to implement warning requirements and mandate insurance coverage for alternative fillings.²¹⁴ Only then will patients be able to make informed and autonomous decisions about whether to get mercury fillings.²¹⁵

Although enacting a ban on mercury fillings will provide the American public with the highest level of protection, even a “phase out” may be too radical at this time.²¹⁶ Given that the ADA aggressively opposes mercury filling legislation and the Mercury Filling Disclosure and Prohibition Act never got past the House Subcommittee on Health, it is uncertain whether even a “phase out” would garner enough Congress-

infants (11–50 weeks of life) correlates significantly with the number of dental amalgam fillings of the mother.

Id.

²¹¹ See Plaintiff’s Brief, *supra* note 52, at 13 (stating that efforts should be made to reduce exposure to pregnant women and children); Baga, *supra* note 3, at 196; Dr. Mercola, *The Smoking Time Bomb Sitting Next to Your Brain—Has Its Moment Finally Arrived?*, MERCOLA.COM (Jan. 28, 2011), <http://articles.mercola.com/sites/articles/archive/2011/01/28/scientists-urge-fda-to-stop-amalgam-use-in-children-pregnant-women-and-hypersensitive.aspx> (stating that the FDA’s scientific panel “told the agency to stop amalgam use in children, pregnant women, and hypersensitive populations”).

²¹² See Plaintiff’s Brief, *supra* note 52, at 11 (“The collective results of numerous research investigations over the past decade clearly demonstrate that the continuous release of [mercury] from dental amalgam tooth fillings provides the major contribution to [mercury] body burden.”); Mercola, *supra* note 211 (stating that “anyone can be impacted” by the harmful effects of mercury fillings).

²¹³ See Harvey & Smith, *supra* note 8, at 252; Thomas, *supra* note 8, at 148–49.

²¹⁴ See Chirba-Martin & Welshhans, *supra* note 20, at 323 (stating that patients are legally entitled to receive information regarding the risks and benefits of proposed and alternative treatments); Baga, *supra* note 3, at 194 (“Requiring insurance companies that provide dental benefits to cover non-mercury fillings to at least the same extent they cover mercury fillings would be beneficial.”).

²¹⁵ See Chirba-Martin & Welshhans, *supra* note 20, at 323; Baga, *supra* note 3, at 194 (“Patients must not be induced into receiving mercury amalgams because they cannot pay for alternative filling materials; patients must be given a choice.”).

²¹⁶ See Chirba-Martin & Welshhans, *supra* note 20, at 317 (stating that a full or partial ban on mercury fillings may be too radical).

sional support.²¹⁷ Many fear that a ban on mercury fillings would have severe economic ramifications and ultimately restrict access to dental care.²¹⁸

B. Uniform Warning Requirements

If enacting a full or partial ban on mercury fillings is too radical, then at a minimum, Congress must implement uniform warning requirements and mandate insurance and Medicaid coverage for alternative fillings.²¹⁹ At this time, state-level informed consent legislation is insufficient to protect patients' rights as only a handful of states have enacted warning requirements, leaving millions of Americans uninformed about the dangers of mercury fillings.²²⁰ From a legal and moral standpoint, patients must be able to decide whether to get a mercury filling "after full disclosure of the risks and benefits of each available treatment."²²¹ In most states patients are not fully aware of the risks associated with mercury fillings.²²² Consequently, many patients will get mercury fillings, particularly in back molars, to avoid paying out-of-pocket for alternatives because they believe that the only difference between mercury fillings and alternatives is aesthetics.²²³ Nevertheless, if

²¹⁷ See *Am. Dental Ass'n v. Khorrami*, No. CV 02-3853-RSWL (RZx), 2006 WL 5105271, at *1 (C.D. Cal. June 9, 2006); *Mercury in Dental Filling Disclosure and Prohibition Act*, H.R. 1680, 108th Cong. (2003); Baga, *supra* note 3, at 194-95; *The "Silver Fillings" Deception*, *supra* note 12.

²¹⁸ See FLEMING & JANOSKY, *supra* note 41, at 7; PETERSEN ET AL., *supra* note 95, at 18-19; *The "Silver Fillings" Deception*, *supra* note 12.

²¹⁹ See Chirba-Martin & Welshhans, *supra* note 20, at 317; Baga, *supra* note 3, at 194 (arguing that national-level informed consent legislation should require insurance companies and Medicaid to pay for alternative fillings).

²²⁰ CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (West 2006); CONN. GEN. STAT. § 22a-616 (2006); ME. REV. STAT. tit. 32, § 1094-C (West Supp. 2012); N.H. REV. STAT. ANN. § 317-A:38 (West 2005); see Baga, *supra* note 3, at 193-94 (explaining that state-level mercury filling legislation is flawed because it does not require insurance companies or Medicaid to pay for alternative fillings and it does not offer any sanctions for dentists who violate the statute).

²²¹ See Plaintiff's Brief, *supra* note 52, at 29 (stating that treatment for a particular patient is an issue that should be decided by the patient). "[W]hile a patient's legal right to information concerning the risks and benefits of amalgams should be straightforward, the interplay of professional regulation with state statutory and tort law, FDA regulations, and the shadow of federal preemption add to the uncertainties and worries of dental patients." Chirba-Martin & Welshhans, *supra* note 20, at 295.

²²² See Baga, *supra* note 3, at 192-93.

²²³ See Chirba-Martin & Welshhans, *supra* note 20, at 324 ("[L]egislators, litigants and (most especially) dental professionals must realize that, uncertain or not, the risks of mercury amalgams ultimately must be weighed by the person who will bear them: the individual patient."); Baga, *supra* note 3, at 194-95 (explaining that low-income families on Medicaid must

patients were aware that mercury fillings constantly leak mercury vapor and have been linked to serious health problems, they might decide differently.²²⁴ Therefore, Congress must implement warning requirements to ensure that all Americans have the opportunity to make an informed and autonomous choice about whether to get a mercury filling.²²⁵

In order to accomplish the ultimate goal of informing all Americans about the dangers of mercury fillings, the warning requirements must be uniform.²²⁶ When states employ different warning requirements, it is uncertain whether all patients will receive the necessary information.²²⁷ The federal government is best equipped to ensure the warnings are clear and accurate, and the federal government can more readily update the warnings when new information becomes available.²²⁸

The CHOMP Act provides an ideal model for national-level warning requirements.²²⁹ The CHOMP Act would require dentists to provide their patients with a fact sheet detailing the risks associated with different restorative materials and patients would need to sign off on the sheet before they received any restorative work.²³⁰ Requiring patients to sign off on the fact sheet adds an additional level of protection because it provides a means of verifying that dentists are complying

choose between mercury fillings or no fillings at all and moderate income families are often forced to pay out-of-pocket for alternatives because they are not covered by most insurance plans); *The "Silver Fillings" Deception*, *supra* note 12 (explaining that consumers are deceived by the fact that mercury fillings are also called silver fillings).

²²⁴ See *Costa Mesa Bans Dental Amalgam*, DR. NEAL GRABER (Nov. 5, 2010), <http://www.drnealgraber.com/dental-detective/costa-mesa-bans-dental-amal.html> (noting that in a 2006 poll, over eighty percent of California residents stated that they would pay more money to get non-mercury filling, but only forty percent knew that mercury fillings contain mercury); *The "Silver Fillings" Deception*, *supra* note 12 (stating that parents insisted on mercury-free dentistry once they became aware of "amalgam's horrid health risks").

²²⁵ See Chirba-Martin & Welshhans, *supra* note 20, at 317 (stating that patients are legally entitled to receive information regarding the risks and benefits of proposed and alternative treatments); *Never Do This with Your Teeth*, *supra* note 11 (noting that an FDA panel recommended that consumers be made aware that amalgam fillings are mainly mercury).

²²⁶ See *Env'tl. Law Found. v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 71 (2005); Baga, *supra* note 3, at 195 ("A benefit of federal legislation, as opposed to state-level legislation, is uniformity.").

²²⁷ See *Env'tl. Law Found.*, 134 Cal. App. 4th at 71; Baga, *supra* note 3, at 195.

²²⁸ See *Env'tl. Law Found.*, 134 Cal. App. 4th at 71; Baga, *supra* note 3, at 195.

²²⁹ See *Consumers Have Options for Molar Protection (CHOMP) Act of 2009*, H.R. 4615, 111th Cong. (2010).

²³⁰ See *id.*

with the law.²³¹ The CHOMP Act would also impose a fine of five thousand dollars for each restoration a dentist performed without providing the fact sheet and obtaining the patient's signature.²³² Thus, dentists would likely be deterred from breaking the law and performing restorations without the patient's express consent.²³³ National-level warning requirements, however, must be accompanied by an insurance and Medicaid mandate for the effectiveness to be fully realized.²³⁴

C. Insurance and Medicaid Mandate

In addition to warning requirements, an insurance and Medicaid mandate are necessary to sufficiently protect patients' rights and eradicate the social injustice of mercury fillings.²³⁵ Most states with warning requirements do not mandate insurance and Medicaid coverage for alternative fillings; conversely, some states that have taken steps toward equal coverage do not require warnings.²³⁶ When low-income Americans are informed of the risks associated with mercury fillings, but unable to afford the alternatives, they cannot make an autonomous decision.²³⁷ Instead of choosing between all of the available treatment options, they must choose between one potentially harmful treatment option and no treatment at all.²³⁸

²³¹ See *id.*; Baga, *supra* note 3, at 194–95 (stating that one of the problems with state-level amalgam statutes is that they do not provide sanctioning for dentists who violate the statute).

²³² H.R. 4615.

²³³ See Baga, *supra* note 3, at 195 (arguing that an effective mercury filling statute must include a harsh penalty structure for dentists who violate the statute).

²³⁴ See Chirba-Martin & Welshhans, *supra* note 20, at 316 (stating that an insurance or Medicaid mandate would make it “financially more palatable to choose non-mercury fillings”); Baga, *supra* note 3, at 194–95; Pinna, *supra* note 3.

²³⁵ See Chirba-Martin & Welshhans, *supra* note 20, at 316; Baga, *supra* note 3, at 194–95; Pinna, *supra* note 3.

²³⁶ See LA. REV. STAT. ANN. § 30:2586 (2006) (“State dental insurance contracts negotiated after the effective date of this Act shall provide equal coverage for non-mercury fillings and dental amalgam fillings at no additional expense to the state employee.”); ME. REV. STAT. tit. 32, § 1094-C (West Supp. 2012) (providing warning requirements for mercury fillings, but no insurance or Medicaid mandate); N.H. REV. STAT. ANN. § 317-A:38 (providing warning requirements for mercury fillings, but no insurance or Medicaid mandate); R.I. GEN. LAWS § 23–24.9–15(c) (West 2005) (providing coverage for non-mercury fillings to state employees); Baga, *supra* note 3, at 194–95 (stating that one of the problems with state-level warning statutes is that they do not force insurance companies or Medicaid to pay for alternative fillings).

²³⁷ See Baga, *supra* note 3, at 194.

²³⁸ See *id.* at 194–95.

Although insurance companies and Medicaid resist providing coverage for alternative fillings because of cost considerations, alternatives have come a long way in recent years and are arguably as durable and long-lasting as mercury fillings.²³⁹ It is no longer true that mercury fillings are significantly less likely to need replacement.²⁴⁰ In addition, the difference in cost between mercury fillings and alternatives pales in comparison to the money that insurance companies and Medicaid would spend when the years of mercury exposure causes severe health problems.²⁴¹ For example, the European Environmental Bureau estimates that after factoring in the cost on the environment and human health, composite fillings are more cost-effective than mercury fillings.²⁴²

The Medicaid Options for Dental Fillings Act provides a useful model for a Medicaid mandate.²⁴³ The Act would amend the Social Security Act to ensure that the amount of cost-sharing charged for alternative fillings does not exceed the amount charged for mercury fillings.²⁴⁴ Some fear that a Medicaid mandate would restrict access to dental care because alternatives are more difficult and time-consuming for dentists to place; however, this fails to account for the fact that more dentists would be willing to accept Medicaid patients if alternatives

²³⁹ See *Environmental Groups Highlight Financial Benefits of Phasing Out Dental Mercury*, INT'L ACAD. ORAL MED. & TOXICOLOGY (Mar. 30, 2012), <http://iaomt.org/environmental-groups-highlight-financial-benefits-phasing-dental-mercury/> (estimating that the cost of a mercury filling is \$144 and the cost of a composite filling is \$185); Dr. Mercola, *Toxic Enough to Require Haz-Mat Transport . . . Yet Safe for You and Your Children*, MERCOLA.COM (Jan. 08, 2012), <http://articles.mercola.com/sites/articles/archive/2012/01/08/major-progress-in-eliminating-mercury-in-dentistry.aspx>.

²⁴⁰ See Dr. Mercola, *Negative Impacts of Dental Mercury Surpass Those of Alternatives*, MERCOLA.COM (July 3, 2012), <http://articles.mercola.com/sites/articles/archive/2012/07/03/dental-mercury-fillings-negative-impacts.aspx>. Recent research from the World Health Organization indicates that resin-based fillings "perform equally well" as amalgam and comonomers have a higher survival rate. See *id.* In fact, "adhesive resin materials allow for less tooth destruction and, as a result, a longer survival of the tooth itself." See *Never Do This with Your Teeth*, *supra* note 11.

²⁴¹ See Thomas, *supra* note 8, at 148–49 (detailing the negative health effects of mercury fillings); *Environmental Groups Highlight Financial Benefits of Phasing Out Dental Mercury*, *supra* note 239 (finding alternative fillings less expensive given the costs associated with the negative health effects of mercury vapor); *Never Do This with Your Teeth*, *supra* note 11 (stating that there are viable and cost-effective alternatives to mercury fillings).

²⁴² *Environmental Groups Highlight Financial Benefits of Phasing Out Dental Mercury*, *supra* note 239. By including these considerations in the financial cost estimate, the report concludes that the use of composite fillings could be up to eighty-seven dollars cheaper than the equivalent amalgam item. *Id.*

²⁴³ See Medicaid Options for Dental Fillings Act, H.R. 4731, 111th Cong. (2010).

²⁴⁴ *Id.*

were covered.²⁴⁵ For example, in Kansas dentists are hesitant to accept Medicaid patients because the agreement only pays for mercury fillings in rear teeth despite evidence that most dentists only use composite fillings.²⁴⁶ As a result, the dentists would be forced to treat Medicaid patients differently from the rest of their patients.²⁴⁷ Therefore, mandating Medicaid coverage for alternatives is essential to protect patients' rights and increase low-income access to dental care.²⁴⁸

CONCLUSION

Mercury amalgam dental fillings pose a serious health risk to the American public. Despite the ADA's assurances that mercury fillings are safe, scientific evidence reveals that the mercury vapor released from the fillings can cause damage to the lungs, kidneys, and the nervous, digestive, respiratory, and immune systems. Although the use of mercury fillings has declined in recent years with the increase in dentists opting to practice mercury-free, low-income children are still routinely forced to get mercury fillings because Medicaid does not cover alternatives. For these children, a mercury filling is the only way to alleviate a severe toothache and prevent an imminent infection.

Other countries are banning or restricting the use of mercury fillings, revealing the seriousness of the problem and the danger of the United States's inaction. Furthermore, OSHA has promulgated regulations to protect dentists and dental workers from mercury exposure, thereby declaring that mercury fillings pose a real health risk.

Nevertheless, the FDA and CMS have failed to provide similar protections to dental patients. Despite promises to reconsider, the FDA continues to allow mercury fillings to be placed in even the most vulnerable populations and CMS does not require state Medicaid programs to cover alternative fillings. Episodic private litigation and state and local laws do not extend far enough to remedy this broad public issue. Thus, Congress should enact a complete ban on the use of mer-

²⁴⁵ See Dave Ranney, *Only One in Four Kansas Dentists Accept Medicaid Patients*, TOPEKA INDEP. LIVING RESOURCE CENTER (Nov. 15, 2010), <http://www.tilrc.org/assests/news/1110news/1110state15.html>; *The "Silver Fillings" Deception*, *supra* note 12.

²⁴⁶ See Ranney, *supra* note 245.

²⁴⁷ See *id.*

²⁴⁸ See Chirba-Martin & Welshhans, *supra* note 20, at 323–24 (“Although a patient is legally entitled to information regarding the risks and benefits of proposed and alternative treatments, the ADA and state dental boards vehemently resisted informing patients about the risks of mercury amalgams.”); Baga, *supra* note 3, at 195; Ranney, *supra* note 245 (explaining that the reason many dentists in Kansas do not accept Medicaid patients is because the Medicaid agreement does not cover alternative fillings).

cury fillings or at a minimum implement uniform warning requirements and mandate both insurance and Medicaid coverage for alternative fillings.

