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AN UNCERTAIN RISK AND AN UNCERTAIN FUTURE: ASSESSING THE LEGAL IMPLICATIONS OF MERCURY AMALGAM FILLINGS

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I. INTRODUCTION

Trying to buy a mercury thermometer at the local pharmacy these days will result in a deluge of information regarding the risks of mercury and the proper disposal protocol for mercury thermometers as hazardous waste. Yet, inquiring about the risks of placing mercury in one's mouth, in the form of a dental filling, is likely to meet with resounding assurances of safety from the dental profession. According to the American Dental Association, "[d]ental amalgam has been studied and reviewed extensively, and has established an extensively reviewed record of safety and effectiveness."¹ While such comforting disclaimers are meant to ease patient concerns, many continue to worry about the safety of dental mercury. Thus, "[t]here are a growing number of scientific studies that document pathophysiologic effects associated with amalgam mercury."² Today, according to a sur-

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¹ AM. DENTAL ASS'N, ADA STATEMENT ON DENTAL AMALGAM, at <http://www.ada.org/prof/resources/positions/statements/amalgam.asp> (last modified Jan. 8, 2002) [hereinafter ADA STATEMENT].

² DAMS Inc., Mercury Free and Healthy, at <http://www.amalgam.org> (January 2004).

vey of 1000 people, nearly 50% of Americans believe that mercury fillings cause health problems.³

Considering these widely disparate points of view and growing public concern, the delay in litigation involving mercury amalgam fillings may come as somewhat of a surprise. What is even more surprising is that the mercury amalgam debate began over 150 years ago. In the 1830s and '40s, the American Society of Dental Surgeons ("ASDS") caused an uproar when it demanded that its dentists sign a pledge *not* to use mercury fillings.⁴ By the 1850s, however, the ASDS's membership had declined to the point that it was forced to disband.⁵ In its place arose the American Dental Association ("ADA"), composed largely of mercury amalgam advocates.⁶

Despite this long and contentious history, there has been very little case law or clinical research dealing directly with mercury amalgams. As indicated by even those groups that support mercury fillings, it remains unclear exactly how much mercury enters the body from fillings, as well as at exactly what levels mercury becomes harmful to humans.⁷ While the debate over the scientific validity of mercury's perceived health risks continues, patient concerns about amalgams are quite genuine. And, because such patients view mercury risks as material to their decisions regarding treatment options, the doctrine of informed consent should apply. Nevertheless, the dental profession has basically ignored its duty to disclose material risks and has taken overt measures to ban its members from discussing potential risks with patients.

This article will begin by describing the many safety concerns that surround the use of dental amalgam. It will briefly overview how other nations and even the U.S. Food and Drug Administration ("FDA") have taken preliminary steps to safeguard patient safety. It will then examine the dental industry's use of professional discipline and malpractice litigation to prevent and even punish full disclosure of amalgam risks. This discussion will also examine how, given such bans on information, patients have sought recourse through litigation,

³ Laura Bradbard, *Dental Amalgam: Filling a Need or Foiling Health?*, FDA CONSUMER, Dec. 1993, at 22 (discussing consumer sentiment toward mercury amalgam fillings).

⁴ *Consumer Cause, Inc. v. Smilecare*, 110 Cal. Rptr. 2d 627, 630 (Cal. Ct. App. 2001).

⁵ *Id.*

⁶ *Id.*

⁷ See, e.g., Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy, 67 Fed. Reg. 7620, 7622 (proposed February 20, 2002) (codified at 21 C.F.R. pt. 872) [hereinafter "Dental Devices"].

but face numerous obstacles to recovery, including serious evidentiary hurdles regarding admissibility and causation.⁸ For these reasons, the article will conclude by showing how legislation at the state level appears to offer the best strategy for insuring that dental patients are adequately informed of the risks associated with mercury fillings. Nevertheless, it will explain why and how state laws must be carefully crafted in order to survive preemption by federal regulations. Sadly, patients who should be able to rely upon their dentists for complete and accurate information regarding the risks and benefits of amalgam, cannot expect such a disclosure.

Moreover, while 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. Only by disentangling conflicting concerns and competing strategies can a dental patient's right to informed and autonomous decision-making be effectuated. This article endeavors to begin that process.

II. DISCUSSION

A. Professional Regulation: ADA Hostility to the Anti-Amalgam Position

An amalgam is a mixture of metals, and dental mercury amalgams are comprised of approximately 50% mercury, 35% silver, 9% tin, 6% copper, and trace amounts of zinc.⁹ Although the mixture is soft at first, it eventually hardens and the mercury is bound within it.¹⁰ The Agency for Toxic Substances and Disease Registry, a branch of the Centers for Disease Control, admits that small amounts of mercury are released slowly from the filling into the body due to factors such as corrosion, chewing, and grinding of the teeth.¹¹ According to a study published by the American Academy of Pediatrics, "increased mer-

⁸ See, e.g., *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) (holding that in order for scientific evidence to be admitted at trial, the court must look at more than just "general acceptance" in the field).

⁹ AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, PUBLIC HEALTH STATEMENT FOR MERCURY (describing ways of being exposed to mercury and the possible consequences), available at <http://www.atsdr.cdc.gov/toxprofiles/phs46.html> (Mar. 1999).

¹⁰ *Id.*

¹¹ *Id.*

cury vapor concentrations can be measured in exhaled air from people with dental amalgams, but the biological significance is uncertain.”¹²

The ADA’s website is nevertheless replete with information extolling the safety and virtues of mercury amalgam.¹³ The ADA cites the World Health Organization, the FDA, and the United States Public Health Service, among others, as agencies that support mercury amalgam’s continuing safety.¹⁴ Among the purported advantages are mercury amalgam’s lower costs, easier use, and greater durability as compared to alternative materials.¹⁵ The ADA therefore lends its dentists’ seal of approval to a variety of amalgam products, an action that some challenge as a conflict of interest because the ADA allegedly is paid for such endorsements.¹⁶

The general controversy over the effects of mercury amalgam can be broken down into specific debates regarding: 1) what levels of mercury are released from fillings, 2) whether such exposure only affects those with a local mercury allergy, 3) how many people are susceptible to mercury allergies, and 4) what are the effects of mercury exposure to the overall population. To the extent that the ADA has acknowledged cases involving adverse reactions to mercury fillings, it has characterized them as “rare instances of local side effects of allergic reactions.”¹⁷ Local symptoms of a mercury allergy can resemble a typical skin rash. The ADA contends that “[o]ften patients who are truly allergic to amalgam have a medical or family history of allergies to metals,”¹⁸ and estimates that there have been less than 100 cases of allergic reactions to amalgam fillings.¹⁹ According to the Centers for Disease Control and Prevention, fifty cases of amalgam allergies have been reported in the scientific literature.²⁰ Yet, British authorities that, like the ADA, support amalgam use suggest that the

¹² Lynn R. Goldman et al., *Technical Report: Mercury in the Environment: Implications for Pediatricians*, 108 AM. ACAD. PEDIATRICS 197, 201 (2001) (reviewing current information on mercury treatment and prevention for pediatricians).

¹³ See ADA STATEMENT, *supra* note 1 (stating that there is a lack of research showing the adverse effects of amalgam).

¹⁴ *Id.*

¹⁵ See *id.* (stating the advantages of amalgam fillings, but not asserting that they are better than the alternatives).

¹⁶ Amy Pyle, *A Debate on Mercury in Fillings*, L.A. TIMES, Oct. 25, 1999, at 1A.

¹⁷ ADA STATEMENT, *supra* note 1.

¹⁸ ADA, ORAL HEALTH TOPICS A-Z: DENTAL FILLING OPTIONS – FREQUENTLY ASKED QUESTIONS, at <http://www.ada.org/public/topics/fillings-faq.asp> (last visited Jan. 28, 2004).

¹⁹ *Id.*

²⁰ Bradbard, *supra* note 3, at 24 (citing Stephen Corbin from the Centers for Disease Control and Prevention).

numbers of people prone to mercury allergies may be as high as three percent of the general population, or 1.75 million people in Great Britain alone.²¹

The amount of mercury vapor released by dental amalgams has garnered particular concern. According to the ADA, mercury fillings emit only one to three micrograms of mercury per day, as compared to five or six micrograms that most people ingest daily through food, water, and the air.²² The ADA reasons that at these low levels, it would take 500 fillings to do any damage to the human body.²³ In contrast, studies conducted by the World Health Organization posit that a single filling may release anywhere between three to seventeen micrograms of mercury per day.²⁴ That mercury amalgams pose a larger problem than the ADA is willing to admit is reinforced by a 1997 Environmental Protection Agency report indicating that "nothing deposits more inorganic mercury into the body than [mercury] fillings."²⁵ Plus, the United States Department of Health and Human Services states that "[a] correlation has been found between inorganic mercury in human breast milk and mercury-silver dental amalgams in the mother."²⁶

Such contrary viewpoints exist at the international level as well. For example, the British government agrees with the ADA that mercury fillings are safe and only cause health problems in those predisposed to mercury allergies. Nevertheless, it is more cautious than the ADA because it warns that "it may be prudent to avoid, where clinically reasonable, the placement or removal of amalgam fillings during pregnancy."²⁷ Moreover, unlike Britain's modest assessment of the risks of mercury amalgams, a growing number of countries view them as posing significant risks and, therefore, are becoming increasingly proactive in limiting their use. Accordingly, the Swedish government refuses to pay for amalgam fillings under the country's nationalized health plan.²⁸ Dentists in Denmark and Finland are ad-

²¹ Frances Ive, *Health: Are You Sick to the Back Teeth?*, MIRROR, Apr. 6, 2002, at 32 (discussing British dental concerns about mercury amalgams).

²² David Wahlberg, *Health Living: Fill It Up But With What?*, ATLANTA J. & CONST., April 9, 2002, at 1F.

²³ ADA, DENTAL AMALGAM: MYTHS VS. FACTS, at http://www.ada.org/public/media/releases/0207_release01.asp (July 2002).

²⁴ Ive, *supra* note 21.

²⁵ Pyle, *supra* note 16.

²⁶ Jeri Weiss et al., *Mercury Exposure Risks: Human Exposure to Inorganic Mercury*, 114 PUB. HEALTH REP. 400, 400-01 (1999) (illustrating the various sources of inorganic mercury exposure).

²⁷ Ive, *supra* note 21.

²⁸ *Id.*

vised to use alternative materials in dental restorations.²⁹ The Australian, Austrian, Canadian, German, and Norwegian governments recommend that mercury amalgams not be used in pregnant women, children, and people with kidney diseases.³⁰ The ADA and the anti-amalgam organizations hotly contest the position of the international community with regard to the risks of mercury amalgam.³¹ The existence of this debate shows that the amalgam issue is far from settled. What is clear, however, is that these countries, like the United States, will continue to grapple with how to weigh the benefits of mercury amalgam against its uncertain, but potentially serious, risks.

To date, the United States government, acting primarily through the FDA, has largely deferred to the ADA's position that mercury amalgams are highly beneficial and pose only slight risks in rare cases. Nevertheless, the FDA does acknowledge that it lacks the information necessary to state with certainty that mercury amalgam is entirely safe.³² In response to growing pressures from consumer safety advocates, the FDA decided in 2002 to reclassify dental amalgam from a Class I to a Class II device.³³ This change requires dental amalgam manufacturers to list all ingredients on the product's label³⁴ and encourages dentists and patients to report side effects as "adverse events."³⁵ Such a move "will provide consistent regulation of dental mercury and dental amalgam products," and it is accompanied by a consideration of even more stringent labeling and warning requirements for dental amalgam.³⁶ Nevertheless, the FDA continues to share the ADA's position on mercury amalgam safety, justifying the

²⁹ Wahlberg, *supra* note 22.

³⁰ Ive, *supra* note 21; Pyle, *supra* note 16.

³¹ See, e.g., Mercury in Dental Fillings Disclosure and Prohibition Act, H.R. 4163, 107th Cong. (2002) (citing Health Canada as recognizing that children and pregnant women are at risk from mercury amalgam); CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMIN., CONSUMER UPDATE: DENTAL AMALGAMS (citing Health Canada as an example of disagreement between the U.S. and Canada on whether to limit the use of dental amalgams in certain members of the population), at <http://www.fda.gov/cdrh/consumer/amalgams/html> (last modified Dec. 31, 2002).

³² See Dental Devices, *supra* note 7, at 7627.

³³ *Id.* at 7620.

³⁴ *Id.* at 7627.

³⁵ See U.S. FOOD AND DRUG ADMIN., STATEMENT BY DAVID W. FEIGAL, M.D., M.P.H., DIR., CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, BEFORE THE COMM. ON GOV'T REFORM, U.S. HOUSE OF REPS., NOV. 14, 2002 ("Class II devices . . . are subject to 'special controls.' These range from post-market surveillance studies to conformance with mandatory performance standards."), at <http://www.fda.gov/ola/2002/dental1114.html> (last visited Apr. 21, 2004).

³⁶ See Dental Devices, *supra* note 7, at 7620.

new classification as protecting those few individuals who may be allergic to mercury.³⁷

Despite the assurances of the FDA and ADA, many continue to question the safety of mercury amalgam and the wisdom behind placing mercury in one's mouth. The growing concern about long-term exposure to even small amounts of mercury is demonstrated by changing practice patterns in the dental profession. In 2001, 24% of dentists used no mercury fillings at all.³⁸ This figure represented an increase of almost 15% in just four years of dentists who refused to use mercury amalgams.³⁹ The Director of the ADA Health Foundation's Paffenbarger Research Center attributes the decline in amalgam use to aesthetics, patient preferences, and scientific advances, rather than to safety concerns, stating, "there is no indication that these general trends are related to so-called 'toxicity.'"⁴⁰ Yet, according to a survey by Dental Products Report, 80% of dentists say they have received patient requests to remove mercury amalgam fillings for non-aesthetic reasons.⁴¹

The ADA's ethical rules, which typically are adopted in similar form by state dental boards, reflect the ADA's suspicions about dentists who advocate mercury removal. Rule 5.A states that "[d]entists shall not represent the care being rendered to their patients in a false or misleading manner."⁴² An advisory opinion on this rule explains that:

Based on current scientific data, the ADA has determined that the removal of amalgam restorations from the non-allergic patient for the alleged purpose of removing toxic substances from the body, when such treatment is performed solely at the recommendation or suggestion of the dentist, is improper and unethical. The same principle of veracity applies to the dentist's recommendation concerning the removal of any dental restorative material.⁴³

³⁷ *Id.* at 7627.

³⁸ Carol M. Ostron, *Fillings Made With Mercury Have Supporters, Detractors Among Experts*, SEATTLE TIMES, June 8, 2002, Domestic News Section.

³⁹ *Id.*

⁴⁰ Mark Berthold, *Restoratives: Trend Data Show Shift in Use of Materials*, June 4, 2002, at <http://www.ada.org/prof/pubs/daily/0206/0604res.html>.

⁴¹ Ostron, *supra* note 38.

⁴² PRINCIPLES OF ETHICS AND CODE OF PROF'L CONDUCT § 5.A. (Am. Dental Ass'n 2003), available at <http://www.ada.org/prof/prac/law/code/index.asp> (last visited Feb. 13, 2004).

⁴³ *Id.* at § 5.A.1.

A dentist who is found guilty of violating the ADA Code of Ethics may be sentenced, censured, suspended, or expelled from the ADA.⁴⁴

Other ADA rules also have implications for potential disciplinary proceedings over mercury amalgams. Advisory Opinion 5.A.2 provides that a dentist who represents that a dental treatment or technique "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."⁴⁵ Further, since the ADA views amalgam removal as unnecessary, recommending removal can run afoul of Rule 5.B, which makes it unethical for a dentist to represent fees in a "false or misleading manner."⁴⁶ As a result, "[a] dentist who recommends and performs unnecessary dental services or procedures is engaged in unethical conduct."⁴⁷

One early example of professional discipline in this context is the 1990 case of *Board of Dental Examiners v. Hufford*, which involved a dentist who advised a full mouth extraction of his patient's mercury-filled teeth in order to arrest the progression of her multiple sclerosis.⁴⁸ Iowa's state dental board suspended Dr. Hufford's license for five years on the grounds that extracting all of his patient's teeth was fraudulent and violated numerous statutes and professional rules pertaining to the practice of dentistry.⁴⁹ Dr. Hufford appealed the board's ruling, emphasizing that the patient affirmatively sought him out specifically because of his anti-amalgam position.⁵⁰ Although the court acknowledged this fact, it focused on Dr. Hufford's failure to explicitly discuss the majority position on mercury amalgam safety.⁵¹ Of even greater concern to the court, however, were the prohibitive costs of alternative treatments, which led the patient to choose the less expensive, but riskier, full mouth extraction.⁵² In the court's view, these price figures indicated that Dr. Hufford did not believe his amalgam position, but rather was interested in the personal profit he could obtain from the removal procedure.⁵³ In this regard, the court referred to

⁴⁴ *Id.* at ch. IV.

⁴⁵ *Id.* at § 5.A.2.

⁴⁶ *Id.* at § 5.B.

⁴⁷ *Id.* at § 5.B.6.

⁴⁸ *Bd. of Dental Exam'rs v. Hufford*, 461 N.W.2d 194 (Iowa 1990) (holding that dentist's treatment of multiple sclerosis by full mouth extraction of patient's teeth fell far below the standard of care).

⁴⁹ *Id.* at 196.

⁵⁰ *Id.*

⁵¹ *Id.* at 198.

⁵² *Id.* at 197.

⁵³ *See id.* at 197-98.

the dentistry board's findings that Dr. Hufford did not extract the teeth for dental reasons—but, again, that board was not about to recognize reducing mercury exposure as a valid reason for treatment.⁵⁴

While the *Hufford* facts raise issues of informed consent and duty of care, the disciplinary board and court minimized the significance of the patient's wishes. Instead, both the state dental board and the affirming court unequivocally embraced the ADA's position on mercury amalgam's unconditional safety. What is even more troubling, however, was their endorsement of the ADA's view that critics of its viewpoint must be motivated by more sinister concerns than patient health and respect for patient autonomy.⁵⁵

As the 1990s continued, dentists who advocated against mercury amalgams were subjected to further state dental association disciplinary proceedings. Although brought before state commissions, these actions and their later court appeals continued to involve the ADA and its position on several levels. State dental associations and disciplinary boards not only adopted the ADA's position as a matter of routine, but the board members themselves often belonged to the ADA as well.⁵⁶ This deeply entrenched reluctance to countenance open discourse on the risks of mercury amalgam was further stoked by the courts, which were bound to employ deferential standards of appellate review on such matters.⁵⁷

Breiner v. State Dental Commission illustrates the strong ties between the ADA and state dental commissions. It therefore demonstrates the obstacles facing anti-amalgam dentists, which have led some to charge the ADA with engaging in a "witch-hunt" of anti-amalgam dentists.⁵⁸ In *Breiner*, a dentist was brought before the state dental commission for "incompetent or fraudulent conduct by claiming that the removal of mercury amalgam fillings could alleviate

⁵⁴ *Id.* at 198. The court supported the board's finding that Dr. Hufford "unnecessarily extract[ed] all of the patient's remaining teeth *with no scientific basis* for the treatment." *Id.* (emphasis added).

⁵⁵ *See id.* at 197 (concluding that "there is no justification for the removal of serviceable amalgams" before favorably citing to the ADA position prohibiting dentists from advocating for mercury amalgam removal).

⁵⁶ *E.g.*, *Breiner v. State Dental Comm'n*, 750 A.2d 1111, 1115 (Conn. App. 2000) (involving a disciplinary board's review where the board consisted of two ADA dentists and one public member).

⁵⁷ *See id.* (denying injunctive relief until after all administrative proceedings are exhausted).

⁵⁸ *See* Maura Lerner & Karen Youso, *Health Claims in Dispute Over Replacing Fillings*, STAR TRIBUNE (Minneapolis), Oct. 8, 1995, at 1A (describing the allegations that a Minnesota dentist committed fraud by removing mercury fillings in his patients); Pyle, *supra* note 16 (noting several cases where dentists have been sectioned for distributing information about the dangers of amalgam fillings).

symptoms of various medical conditions.”⁵⁹ These charges, which attacked the dentist’s views and advice rather than a concrete episode of actual treatment, were brought not by his patients, but by other dentists.⁶⁰ Thus, *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.⁶¹

In *Breiner*, the ADA’s role in determining the proper scope and content of the practice of dentistry was exhibited in other ways, too. The defendant argued that two members of the commission were biased by their view that the commission should be bound by the ADA’s guidelines and their own support of the ADA’s specific position on mercury amalgam.⁶² The court found that the personal opinions of these two members did not constitute bias, reasoning that “whether removing mercury fillings because of toxicity is appropriate are not adjudicative facts in this matter.”⁶³ In fact, while the ADA forbids its dentists from suggesting mercury removal under threat of license suspension, it does not officially prohibit mercury amalgam removal if the patient initiates such a request.⁶⁴ Additionally, insofar as the state board’s position on mercury amalgam took the form of a general standard of practice that was aimed at the entire profession, it did not constitute bias since it had not been developed against that individual dentist.⁶⁵ The dentist further argued that the commission’s adoption of the ADA guidelines on mercury amalgam were binding, making his administrative hearing before the commission futile.⁶⁶ The court dismissed this argument, contending that the commission had adopted a “mere guideline” and “not a statute or regulation requiring compliance.”⁶⁷

As indicated by its current guidelines, the ADA continues to endorse the safety of mercury amalgam and seems to have grown even more aggressive in insisting that practicing dentists conform to this view. For example, in 2002, the *Atlanta Journal and Constitution* reported allegations that the ADA had imposed *de facto* “gag rules” in

⁵⁹ *Breiner*, 750 A.2d at 1114. These “various medical conditions” included amyotrophic lateral sclerosis, anemia, and Hodgkin’s disease. *Id.* at 1114.

⁶⁰ *Id.*

⁶¹ See *id.* (acknowledging that the allegations rested on claims made by the dentist-defendant as to the health benefits of mercury amalgam removal).

⁶² *Id.* at 1116.

⁶³ *Id.*

⁶⁴ PRINCIPLES OF ETHICS AND CODE OF PROF’L CONDUCT, *supra* note 42 (inferring permission of mercury amalgam from the absence of a provision in the code of professional conduct prohibiting removal).

⁶⁵ *Breiner*, 750 A.2d at 1117.

⁶⁶ *Id.*

⁶⁷ *Id.* at 1118.

California and Maryland by forbidding anti-amalgamists from discussing their position with patients.⁶⁸ A cursory review of recent publications indicates that dentists in Arizona, California, Colorado, Maryland, and Minnesota have faced disciplinary actions for their mercury amalgam viewpoints over the past few years.⁶⁹ If anything, these examples are likely to under-represent the true number of actions that have been brought because of anti-amalgam viewpoints. Additionally, unlike *Breiner*, many actions are not appealed to the courts; a large percentage may settle or result in board-issued sanctions that may include confidentiality agreements.

In addition, the ADA no longer relies solely on its influence over professional discipline to effectuate its views on mercury amalgam. The ADA has recently entered into a new type of discipline: litigation aimed at defending its reputation and discouraging further lawsuits by patient-plaintiffs against mercury amalgam.⁷⁰ For example, after a Los Angeles attorney sued the ADA on behalf of patient-plaintiffs claiming that mercury amalgam caused autism in children, the Association counter-sued the attorney on the grounds of defamation.⁷¹ The ADA alleges that the lawyer falsely accused it “of defrauding and endangering the lives of the American public by promoting allegedly unsafe dental practices—specifically the use of dental amalgam fillings—and of exerting ‘undue and unfair pressure’ on dentists as a result of a purported ‘vested economic interest’ of the ADA in amalgam.”⁷² The ADA has requested a jury trial and is seeking unspecified compensatory and punitive damages.⁷³ The ADA has also intervened in mercury amalgam suits brought by patient-plaintiffs in which the ADA argues in favor of mercury amalgam’s safety.⁷⁴

⁶⁸ Wahlberg, *supra* note 22.

⁶⁹ See Pyle, *supra* note 16 (reporting that an Arizona dentist is facing sanctions for advocating alternative materials; a California dentist lost his license for running an advertisement entitled: “Mercury Emission from Silver Fillings Unsafe by Government Standards;” and a Maryland dentist was sanctioned for writing an article on mercury amalgam removal); Lerner & Youso, *supra* note 58 (discussing sanctions by state dental boards against dentists in Colorado and Minnesota for advocating against mercury amalgam).

⁷⁰ See, e.g., Pyle, *supra* note 16 (describing ADA action against dentists who encourage the negative image of mercury amalgams).

⁷¹ Petitioner’s Complaint, Am. Dental Ass’n v. Khorrami, No. 02-3852, (C.D. Cal. filed May 14, 2002), available at http://www.ada.org/prof/advocacy/legal/leg_020514_khorrami.pdf.

⁷² *Id.* at 2.

⁷³ James Berry, A “Campaign of Lies”: ADA Sues “Self-Promoting” L.A. Lawyer for Defamation, at <http://www.testfoundation.org/hglawsuits.htm>.

⁷⁴ See, e.g., Pyle, *supra* note 16.

While undoubtedly designed to quash the debate over amalgam safety, the ADA's litigation strategy seems to have achieved the very opposite result. It has angered some dentists, generated bad press for the ADA, and exacerbated the already deep divide between pro- and anti-amalgamists. It has also placed those dentists who would fall into the "middle" in an increasingly difficult "Catch 22." On the one hand, they may hold a legitimate fear of advocating against, or even discussing, mercury amalgam risks because of potential ADA sanctions. On the other, they may experience significant discomfort with suggesting the use or the removal of mercury fillings to their patients because of the potential health risks, financial cost, and dearth of solid information regarding safe removal practices.⁷⁵

B. Informed Consent: Litigation Alone Cannot Protect Patient Safety or Autonomy

Despite—or perhaps because of—the ADA's efforts to extinguish the amalgam controversy, the anti-amalgam movement continues to grow, with patient-plaintiffs taking the lead in a new wave of personal injury litigation. These cases do not involve actions for negligent mercury amalgam removal but, rather, allege negligent non-removal of mercury fillings and/or lack of informed consent involving their original insertion. Like most claims of professional negligence and/or product liability, plaintiffs need to rely upon expert testimony to prove that mercury amalgam generally causes adverse health effects and specifically caused the health problems in the individual plaintiff's case. While such litigation in the amalgam context is embryonic at best, lessons gleaned from these cases to date as well as from other product liability cases predict that any barriers erected by the ADA are likely to pale in comparison with the difficulties in overcoming *Daubert* requirements for evidentiary admissibility.

As they do in all forms of product safety and medical malpractice litigation, the *Daubert* standards are likely to vex the mercury amalgam issue and generate pages of conflicting judicial opinions about the viability of such claims. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the United States Supreme Court enunciated a standard by which the judge is required to have a gate-keeping role, in which "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."⁷⁶ While *Daubert*

⁷⁵ See, e.g., *id.* (observing that Dr. Robert Hepps stopped using mercury amalgam after the ADA intervened in a negligence lawsuit to disclaim its own liability, and that he does not express his opinions to his patients out of fear of reprisals by the ADA).

⁷⁶ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993).

seemed to suggest that expert testimony that had the potential for "misleading the jury" could be addressed through Federal Rule of Evidence 403,⁷⁷ later courts have concluded that the purpose behind *Daubert's* gate-keeping function is to preserve the integrity and efficacy of a trial's fact-finding function by keeping "unreliable and irrelevant information" from the jury.⁷⁸ Under Federal Rule of Evidence 702, scientific expert testimony is admissible:

[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.⁷⁹

In addition to the factors listed in Rule 702, to determine the proffered testimony's reliability, the court should look at (1) whether the theory or technique can be tested; (2) whether it has been subjected to peer review; (3) whether the technique has a high known or potential rate of error; and (4) whether the theory has attained general acceptance within the scientific community.⁸⁰

Although the *Daubert* factors were intended to function as a non-exclusive set of guidelines rather than a closed set of inflexible requirements, their application in practice has served to preclude much expert testimony, particularly in the absence of supporting epidemiology.⁸¹ In the context of dental mercury, the ADA's and amalgam manufacturers' investment in the status quo provides no incentive to conduct epidemiological studies. Even under optimal circumstances, conclusive epidemiological results would be difficult to obtain given

⁷⁷ *Id.* at 595.

⁷⁸ *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1311-12 (11th Cir. 1999) (applying the *Daubert* standard for the admissibility of epidemiological studies in silicone breast implant litigation).

⁷⁹ FED. R. EVID. 702.

⁸⁰ *Daubert*, 509 U.S. at 593-94.

⁸¹ *See Allison*, 184 F.3d at 1313-15; *Grant v. Bristol-Meyers Squibb*, 97 F. Supp. 2d 986, 991-92 (D. Ariz. 2000) (stating that because the experts' inability to specify the criteria that caused systemic disease from breast implants was "incapable of epidemiological testing," it was insufficiently reliable); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1227 (D. Colo. 1998) (rejecting expert testimony because the studies did not demonstrate a relative risk factor greater than two from silicone breast implants).

the diverse nature, potentially low prevalence, and under-reporting of adverse health effects.

The experiences of other medical product liability cases are instructive in assessing how *Daubert* is likely to hamper amalgam litigation. For example, in silicone breast implant litigation, plaintiffs' experts frequently were prohibited from testifying about general causation (i.e., that the product is capable of causing the alleged harm in general) and specific causation (i.e., that the product caused the harm alleged in this specific case). Reasons for excluding such testimony included that the methodology and conclusions were not subjected to peer review, not accepted by the general scientific community, or otherwise insufficient when compared to epidemiological studies conducted by defendants' experts.⁸² The court in *In re Breast Implant Litigation* was particularly disturbed that the plaintiff lacked any epidemiological studies to support a showing of general causation despite the plaintiff's proffer of other types of scientific support.⁸³ Furthermore, the court rejected the temporal relationship between the plaintiff's breast implants and health problems because, at most, it only constituted evidence of general and not specific causation.⁸⁴ Thus, the plaintiff first had to prove the general causal link between implants and health problems before she could show that silicone breast implants had caused her specific ailments.⁸⁵ With the plaintiff's proffered evidence excluded, there was no evidence of either type of causation, and the defendant therefore was awarded summary judgment.⁸⁶

Similarly, in *Grant v. Bristol-Myers Squibb*, the court criticized the patient's failure to produce epidemiological studies to demonstrate causation of harm by breast implants.⁸⁷ Although the patient wished to point to differential diagnosis and clinical studies, the court held that such evidence did not meet *Daubert* standards for reliability and relevance, especially in light of the defendant's proffer of numerous epidemiological studies showing no association between the product and harm.⁸⁸ Again, the inadmissibility of the plaintiff's evidence meant a failure to prove causation and resulted in summary judgment

⁸² See *Allison*, 184 F.3d at 1313, 1316; *Grant*, 97 F. Supp. 2d at 992; *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1217.

⁸³ *In re Breast Implant Litig.*, 11 F. Supp.2d at 1228 (stating that "[e]xperts fail to present a single peer-reviewed, controlled epidemiological study that support[s] their causation theories.").

⁸⁴ *Id.* at 1232. The court, however, was clear that specific causation would not withstand *Daubert* either.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Grant*, 97 F. Supp. 2d at 992.

⁸⁸ *Id.*

for defendant.⁸⁹ Since an appellate court must defer to a trial court's *Daubert* rulings, the plaintiff's case is usually over at this stage.

Many courts in silicone breast implant litigation also refused to admit scientific studies conducted on animals, which did indicate a causal link between the implants and various illnesses, because they too could not hold their own against the defense's epidemiological studies.⁹⁰ For example, in *Allison v. McGhan Medical Corp.*, the plaintiff experienced numerous health problems, including diabetes, fatigue, and nerve pain following silicone breast implantation.⁹¹ These symptoms steadily improved after the patient had her implants removed.⁹² She then sued the implant manufacturers, but could not advance to trial because, following a *Daubert* hearing, the court refused to admit her evidence of causation.⁹³ The plaintiff's expert planned to discuss studies conducted on rats and to explain the link between those studies and the health problems suffered by the plaintiff.⁹⁴ The court rejected such testimony because the plaintiff did "not explain why the results of these animal studies should trump more than twenty controlled epidemiological studies of breast implants in humans which have found no valid increased risk of autoimmune disease."⁹⁵

Even when plaintiffs do rely upon epidemiology, this proof is still 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. Thus, what is even more troubling about *Allison* is that plaintiff did manage to accumulate several epidemiological studies, but the court still excluded them because they directly contradicted the defendant's twenty studies.⁹⁶ The court in *Allison* denied that it was looking at conclusions rather than the methodology of the plaintiff's studies, but stated that nevertheless, the courts were not precluded from doing so in the *Daubert* hearing.⁹⁷

A minority of courts dealing with silicone breast implants and other medical product liability cases have allowed such litigation to proceed to trial in the absence of epidemiological studies. For example, in *Jennings v. Baxter Healthcare Corp.*, the plaintiff sued her silicone breast implant manufacturer, claiming that the implants rup-

⁸⁹ *Id.*

⁹⁰ *E.g., Allison*, 184 F.3d at 1313-14.

⁹¹ *Id.* at 1304-05.

⁹² *Id.* at 1305.

⁹³ *Id.* at 1322.

⁹⁴ *Id.* at 1313.

⁹⁵ *Id.* at 1314.

⁹⁶ *Id.* at 1314, 1315.

⁹⁷ *Id.* at 1315.

tured and caused her personal injuries.⁹⁸ The Supreme Court of Oregon allowed the plaintiff's expert to testify on the basis of differential diagnosis and case reports based on clinical observations.⁹⁹ The court observed that while epidemiology is "at the top" of the evidentiary hierarchy, other forms of evidence "may have some utility in attempting to ascertain whether a causal connection exists."¹⁰⁰ The court therefore admitted the expert's testimony, rejecting the belief that "an expert opinion on causation based on anything other than statistically significant, peer-reviewed, published epidemiological studies is inadmissible."¹⁰¹

Similarly, in *Kuhn v. Sandoz Pharm. Corp.*, the Kansas Supreme Court ruled in a products liability case that differential diagnosis evidence was admissible.¹⁰² The court determined that the established evidentiary admissibility tests did not apply when an expert "reach[ed] a conclusion by deduction from applying a new or novel scientific principal [sic], formula, or procedure developed by others."¹⁰³ In the absence of large epidemiological records, the plaintiff's alternative evidence was sufficient to survive the defendant's summary judgment motion.¹⁰⁴ These courts reason that as long as the particular methodology employed (e.g., animal studies) is valid, the inferences to be drawn from it concerning general or specific causation are properly tested through cross-examination, impeachment, and other methods of consideration at trial.¹⁰⁵ While the minority approach correctly understands and applies the *Daubert* holding, it is still just that—a minority.

For these reasons, mercury amalgam plaintiffs are likely to encounter formidable barriers to reaching the merits of their claims due to a lack of admissible scientific evidence of causation, particularly in the form of epidemiological studies conducted on human subjects. 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

⁹⁸ *Jennings v. Baxter Healthcare Corp.*, 14 P.3d 596, 597 (Or. 2000).

⁹⁹ *Id.* at 608-09.

¹⁰⁰ *Id.* at 607 (quoting Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 658 (1992)).

¹⁰¹ *Id.* at 609.

¹⁰² *Kuhn v. Sandoz Pharm. Corp.*, 14 P.3d 1170, 1177, 1185 (Kan. 2000) (admitting the evidence of differential diagnosis under the *Frye* test).

¹⁰³ *Id.* at 1179.

¹⁰⁴ *See id.* at 1184-85.

¹⁰⁵ *Id.* at 1184-85. *See also Jennings*, 14 P.3d at 609 (allowing court reconsideration of previously inadmissible evidence due to the changing nature of science and research).

sclerosis, as well as adverse health effects passed from mother to fetus, including brain damage, incoordination, blindness, and seizures.¹⁰⁶ They also indicate that mercury can be transmitted across the placenta and through breast-feeding, a link further acknowledged by the United States Department of Health and Human Services.¹⁰⁷ While they are only animal studies, they still cast doubt on the ADA's findings of no statistically significant effects in humans.

As discussed above, further controversy exists regarding how much mercury is released by fillings as well as the exposure level at which mercury becomes harmful to humans.¹⁰⁸ Rather than arguing the credibility of their anti-amalgam claims before a jury, however, patient-plaintiffs are finding that they cannot survive pre-trial *Daubert* challenges. Nevertheless, some studies regarding mercury emissions and their effects have received recognition from the courts.¹⁰⁹ This recognition, however, has come in the form of dicta in statutory warning violation suits and therefore does not constitute the definitive ruling that anti-amalgamists desire on the evidence's admissibility for negligent causation purposes.¹¹⁰ Still, when coupled with the numerous conflicts regarding how *Daubert* should be interpreted and applied, it offers some hope that a patient's anti-amalgam case may one day reach a trial on the merits.

In the meantime, dentists who advocate against mercury amalgam have found their diagnostic testing methods severely questioned in terms reminiscent of those found in silicone breast implant litigation. In *Hufford*, the dentist used a volt meter to test the mercury levels found in the patient's mouth and applied kinesiology to determine that the patient was allergic to certain types of restorative materials.¹¹¹ Expert witnesses for the state dental board testified that such methods have no scientific basis and that, according to the ADA, suspected mercury allergies should be determined by blood tests administered by qualified medical personnel.¹¹² Similarly, in *Berger v. Board of Regents*, the state's expert witness testified that the dentist's mercury

¹⁰⁶ See, e.g., *Consumer Cause, Inc. v. Smilecare*, 110 Cal. Rptr. 2d 637, 641 (citing Miller, *Mercury Amalgam Fillings: Human and Environmental Issues Facing the Dental Profession*, 1 DEPAUL J. HEALTH CARE L. 355, 355-59 (1996) and Agency for Toxic Substances and Disease Registry, Chemical Abstracts Service No. 7439-97-6 (Apr. 1999), at <http://www.atsdr.cdc.gov/tfacts46.html> (last visited Aug. 8, 2001)).

¹⁰⁷ *Smilecare*, 110 Cal. Rptr. 2d at 631; DAMS, *supra* note 2; Weiss, *supra* note 26.

¹⁰⁸ See Ive, *supra* note 21.

¹⁰⁹ See *Smilecare*, 110 Cal. Rptr. 2d at 631.

¹¹⁰ See *id.*

¹¹¹ Bd. of Dental Exam'rs v. Hufford, 461 N.W.2d 194, 196-97 (Iowa 1990).

¹¹² *Id.* at 197-98.

tests were unreliable and that medical approval was required for the mercury amalgam removal procedure.¹¹³ Since these were disciplinary actions rather than personal injury claims, they did not turn on the kinds of causation of harm issues that form the core of cases brought by patients. Nevertheless, they do foreshadow the bases for challenging the methodology of anti-amalgamists in future negligence cases.

To date, there has been only one reported case dealing directly with mercury amalgam, negligence, and evidentiary admissibility. In *McReynolds v. Mindrup* ("McReynolds I"), the plaintiff sued her dentist for malpractice, assault, battery, loss of consortium, and punitive damages after he replaced her old filling with one containing mercury against her express wishes.¹¹⁴ The trial court excluded the patient's expert witnesses, including the patient's treating physician, a specialist in risk assessment, an immunologist, and a dentist prepared to testify that the minority position on mercury amalgam was correct and that the ADA was wrong.¹¹⁵ Unfortunately, the brief trial opinion does not articulate the court's specific reasoning for excluding this testimony other than to say that evidentiary standards under *Frye*¹¹⁶ were not met.¹¹⁷ Nevertheless, *McReynolds I* indicates that mercury amalgam litigation will face the same obstacles posed by *Daubert*'s evidentiary standards that have plagued other forms of medical product personal injury litigation.

Ultimately, *McReynolds* was appealed, remanded, re-tried and appealed for a second time.¹¹⁸ At the case's second trip to the appellate level ("McReynolds II"), the Missouri Court of Appeals found that the trial court had exceeded its discretion with its "wholesale exclusion" of any testimony from the plaintiff's witnesses.¹¹⁹ Thus, any testimony from the plaintiff's treating physician regarding the *facts* of her

¹¹³ *Berger v. Bd. of Regents*, 577 N.Y.S.2d 500, 503 (N.Y. App. Div. 1991).

¹¹⁴ *McReynolds v. Mindrup*, 32 S.W.3d 163, 165 (Mo. Ct. App. 2000) [hereinafter *McReynolds I*], *appeal after remand*, *McReynolds v. Mindrup*, 108 S.W.3d 662 (Mo. Ct. App. 2002) [hereinafter *McReynolds II*].

¹¹⁵ *McReynolds I*, 32 S.W.3d at 165.

¹¹⁶ *Frye v. U.S.*, 293 F. 1013, 1014 (1923) (holding that the scientific principles from which the testimony is derived "must be sufficiently established to have gained general acceptance in the particular field in which it belongs."). While *Frye* was superseded by the Federal Rules of Evidence (*see Daubert*, 509 U.S. 587), it is still the prevailing standard in some states' rules of evidence, including Missouri, (*see McReynolds I*, 32 S.W.3d at 165).

¹¹⁷ *McReynolds I*, 32 S.W.3d at 165.

¹¹⁸ *McReynolds v. Mindrup*, 108 S.W.3d 662 (Mo.App. 2002) (hereinafter *McReynolds II*).

¹¹⁹ *Id.* at 666-67.

condition should have been admitted.¹²⁰ The appeals court noted, however, that the trial court correctly excluded testimony “from treating medical professionals that related to scientific studies, methodologies, principles, tests, and technology that are not generally accepted in the relevant field and any medical opinions, diagnosis, [sic] or conclusions drawn by those individuals.”¹²¹ The court of appeals further stated that testimony about the invalidity of the ADA’s position on mercury amalgam safety was correctly excluded as “irrelevant.”¹²² Considering the widespread adoption of the ADA’s position by the scientific community, the government, and the dental profession, the *McReynolds II* approach would effectively shut down any means for challenging the safety of amalgams in a *Frye* jurisdiction.

That *Daubert* will be just as daunting for amalgam plaintiffs as it has been for patients alleging harm from countless medical products is clear from the few cases that have been initiated so far. Lawsuits were recently filed in Georgia and California on behalf of autistic children, claiming that their mothers’ mercury fillings caused the disease.¹²³ The ADA’s counsel responded by stating, “we are not aware of any reputable science that suggests that there is any harm caused by dental amalgams.”¹²⁴ Similarly, in its defamation suit against the lawyer in the California case, the ADA asserted that the attorney was well aware of the scientific evidence demonstrating the absolute safety of mercury amalgam.¹²⁵ As indicated by the ADA’s statements, the ADA likely will pit the studies conducted by the FDA, World Health Organization and others against the animal studies that support the plaintiffs’ contentions.¹²⁶ Obviously, therefore, the ADA will challenge causation vigorously, and will surely invoke *Daubert* to challenge the reliability of a patient’s expert testimony.

In addition, a class action was recently filed in Maryland, contending that the ADA engaged in fraud by not telling consumers that amalgam fillings contained mercury.¹²⁷ The plaintiffs have requested reimbursement for the removal of their mercury amalgam fillings.¹²⁸

¹²⁰ See *id.* at 667.

¹²¹ *Id.*

¹²² *Id.* at 668.

¹²³ Erin McClam, *Suit to Blame Dental Groups, Companies for Children’s Autism*, CHATTANOOGA TIMES, April 3, 2002, at NG3; Belfast News Letter, *Autistic Boy’s Parents Sue Over “Toxic” Dental Fillings*, March 22, 2002, at 13.

¹²⁴ McClam, *supra* note 123.

¹²⁵ Petitioner’s Complaint at 9, *Am. Dental Ass’n v. Khorrami*, No. 02-3852, (C.D. Cal. filed May 14, 2002), available at http://www.ada.org/prof/advocacy/legal/leg_020514_khorrami.pdf.

¹²⁶ *Id.* at 4-6.

¹²⁷ Jennifer Huget, *Filling in for Mercury*, WASH. POST, Mar. 26, 2002, at F1.

¹²⁸ Allison Klein, *Dental Groups Sued Over Use of Amalgam Fillings*,

The class representative claimed that she suffered from numbness, metallic taste, depression, and hormone imbalance because of her fillings and further alleged that these symptoms declined after her fillings were removed.¹²⁹ As with *In re Breast Implant Litigation*, however, the temporal relationship between the product's removal and symptom alleviation was not deemed by the court to be sufficiently reliable under *Daubert* to be admitted as evidence of general causation, especially when unaccompanied by supporting epidemiological studies.¹³⁰

Since patient personal injury litigation is likely to be so hindered by *Daubert* problems, the ADA's confidence in its pro-amalgam position will surely endure. Perhaps, however, such litigation may finally force the ADA to substantiate its own claims of amalgam safety instead of relying so heavily on such tactics as challenging the gaps in plaintiffs' evidence or gagging candid discourse among its own members. Dental professionals allegedly have hesitated to fund and participate in in-depth studies of the effects of mercury amalgam.¹³¹ The ADA itself cannot point to any large scale epidemiological studies to substantiate its conclusion that amalgam fillings pose no greater health risks than non-metallic composites.¹³² Unlike the defendants in silicone breast implant litigation, which did have epidemiological studies to rebut claims of causation, the ADA may be less successful in excluding the animal and case studies that plaintiffs may offer.¹³³ Thus, while *Daubert* is likely to obfuscate patient-plaintiffs in mercury amalgam suits, some room may exist for admitting animal studies and differential diagnosis that support the anti-amalgam viewpoint.

BALTIMORE SUN, Feb. 22, 2002, at B3.

¹²⁹ *Id.*

¹³⁰ *McReynolds I*, 32 S.W.3d at 165; *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1232.

¹³¹ *The Mercury in Your Mouth*, CONSUMER REP., May 1991, at 316 [hereinafter CONSUMER REPORTS] (discussing the controversy surrounding the use of dental mercury amalgam fillings).

¹³² Neither the FDA or the World Health Organization studies used by the ADA were large scale or epidemiological. See *supra* text accompanying note 125.

¹³³ Compare *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1314 (11th Cir. 1999) (dismissing the plaintiff's animal studies because they stood in direct contrast with the defendant's twenty epidemiological studies) with *Consumer Cause, Inc. v. Smilecare*, 110 Cal. Rptr. 2d 627, 632 (Cal. Ct. App. 2001) (discussing the various animal studies on both sides of the mercury amalgam debate, none of which constitute the sort of controlled epidemiological studies championed in silicone breast implant litigation).

C. State Statutes: The Best Protection for Patients

While the ADA has succeeded in maintaining the dominance of its position on amalgams through its use of professional discipline and the successful defense against personal injury and consumer protection litigation, anti-amalgam advocates have made significant inroads at the state legislative level. Today, a growing number of state legislatures are at least considering the imposition of a duty upon dentists to discuss the risks of mercury amalgam with their patients. These statutes should directly affect both the practice of dentistry and the discipline of that profession. It may also have the indirect but no less dramatic impact of opening an alternative route of litigation for patients and consumer safety advocates under a theory of statutory violation.

The earliest statute to address mercury amalgam risks appeared in California. Popularly known as Proposition 65, the statute was enacted by statewide initiative in 1986.¹³⁴ Proposition 65 is not specific to dental amalgams; rather, it requires users of identified reproductive toxins, including mercury and mercury amalgams, to warn employees and patients of the risks of exposure to these products.¹³⁵ To date, Proposition 65 has been used successfully to compel dentists to warn their patients of mercury's potential toxicity.¹³⁶

Maine recently enacted an even more specific statute that requires any dentist who uses mercury amalgam in any dental procedure to display a poster in the waiting area and provide each patient with a brochure about mercury amalgam.¹³⁷ The poster and brochure were developed by the Maine Bureau of Health and discuss "the potential advantages and disadvantages to oral health, overall human health and the environment of using mercury or mercury amalgam in dental procedures."¹³⁸ The brochure must also explain "what alternatives are available" and what their risks and benefits are.¹³⁹ The legislation, however, leaves ample room for professional disagreement and discretion, adding that the brochure may include "other information that contributes to a patient's ability to make an informed decision choos-

¹³⁴ Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (West 1999). See *Smilecare*, 110 Cal. Rptr. 2d at 633.

¹³⁵ See *id.* § 25249.6 (stating that no one during the course of business shall expose individuals to cancer causing chemicals "without first giving clear and reasonable warning.").

¹³⁶ See *Smilecare*, 110 Cal. Rptr. 2d 627, discussed in greater detail *infra* at n. 171 and accompanying text.

¹³⁷ ME. REV. STAT. ANN. 32 §1094-C(1) (Supp. 2002).

¹³⁸ *Id.* § 1094-C(2).

¹³⁹ *Id.*

ing between the use of mercury amalgam or an alternative material in a dental procedure.”¹⁴⁰ Since its initial enactment, the Maine legislature has amended the statute to strengthen the poster’s language.¹⁴¹ Specifically, the poster must include the words “Your dentist is required to give you a copy of this brochure in accordance with state law” and not the words “Ask for a copy of this brochure.”¹⁴² In addition, the brochure now must state “to be careful, Canada and several countries in Europe recommend limits on the use of mercury amalgam. They advise that pregnant women should not have amalgam fillings placed or removed from their teeth.”¹⁴³

In May 2002, New Hampshire adopted a similar measure, which requires the state’s Department of Health and Human Services to develop a pamphlet discussing the risks and benefits of mercury amalgam, as well as alternative materials.¹⁴⁴ In turn, dentists are required to give this pamphlet to patients and to discuss it with them.¹⁴⁵ In addition, the health department will inform New Hampshire residents about the risks and benefits of dental restorative materials, including the use of mercury amalgam in children under the age of six.¹⁴⁶ While the bill was under consideration by the New Hampshire legislature, the ADA stated that it was “working closely with the New Hampshire Dental Society to improve the onerous aspects of this legislation or request the governor to veto it.”¹⁴⁷ Despite the ADA’s efforts to derail the law, it took effect on January 1, 2003.¹⁴⁸

Other states are considering bills that would greatly restrict or ban mercury amalgam use. In Washington, pending legislation focuses on a patient’s informed consent.¹⁴⁹ The bill sets forth a detailed informed consent form, including statements such as “[e]xposure to mercury can permanently damage the brain, kidneys, and developing fetus,” “[t]he harmful effects of mercury that may be passed from the mother to the developing fetus include brain damage, mental retardation, incoordination, blindness, seizures, and an inability to speak,” and “[m]ercury vapor is released from dental materials containing mer-

¹⁴⁰ *Id.*

¹⁴¹ See H.B. 1637, 120th Leg., 2d Reg. Sess. (Me. 2001).

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ H.B. 1251, 157th Gen. Ct., 2d. Reg. Sess. (N.H. 2002).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ Mark Berthold, *California Defeats Amalgam Bill*, ADA NEWS, May 6, 2002, at 12 (illustrating the ongoing battle against anti-amalgam legislation).

¹⁴⁸ N.H. H.B. 1251.

¹⁴⁹ S.B. 5066, 58th Leg., Reg. Sess. (Wa. 2003) (amending Ch. 18.32 RCW by creating additional sections).

cury, which is the number one source of mercury in the human body.”¹⁵⁰ Importantly, the bill also prohibits disciplinary action against a dentist for providing a patient with information about the risks or benefits of a dental restorative material “as long as there is a peer-reviewed scientific publication and one other dentist to support the information” that was communicated.¹⁵¹ The bill also would protect dentists who failed “to conform to policies or codes of private organizations that are inconsistent with state law.”¹⁵² Under Alabama’s “Mercury in Dental Filling Disclosure and Prohibition Act,” dental amalgam must bear a label, stating, “[d]ental amalgam contains approximately fifty percent mercury, an acute neurotoxin.”¹⁵³ It prohibits dentists from placing mercury amalgam in children under the age of eighteen, and all pregnant or lactating women.¹⁵⁴ All other patients must first receive a warning that mercury causes health risks before the dentist could proceed.¹⁵⁵

As the number of states ready to legislate in this area grows, so too does the extent to which they are willing to act. In 2002, California considered a bill that would have completely prohibited dentists from providing mercury fillings to any patient after July 1, 2007.¹⁵⁶ Before that date, a dentist would have been required to provide each patient with a written disclosure stating: “[t]his dental amalgam contains approximately 50 percent mercury, a highly toxic element, and therefore poses health risks. This product should not be administered to children less than 18 years of age, pregnant women, or lactating women.”¹⁵⁷ The bill failed to proceed beyond the legislature’s Health Committee, but one of the bill’s sponsors has introduced a very similar bill at the federal level.¹⁵⁸ Similarly, Arizona, Georgia, and Ohio all are considering proposals that would forbid mercury amalgam in children under eighteen, women under forty-six, and pregnant women of any age.¹⁵⁹ For other patients, a dentist would be required to discuss the advantages and disadvantages of amalgam and alternative

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ H.B. 378, 2002 Leg., Reg. Sess. (Ala. 2002).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ Assem. B. 2270, 2001-02 Legis., Reg. Sess. (Cal. 2002).

¹⁵⁷ *Id.*

¹⁵⁸ See Mercury in Dental Filling Disclosure and Prohibition Act, H.R. 4163, 107th Cong. (2002), discussed *infra* at note 182 (proposing a ban on mercury fillings).

¹⁵⁹ H.B. 2536, 45th Leg., 2d Reg. Sess. (Ariz. 2002); H.B. 1715, 146th Gen. Assemb., Reg. Sess. (Ga. 2002); H.B. 598, 124th Gen. Assemb., Reg. Sess. (Ohio 2002).

materials, and display in a public area a warning about the dangers of mercury amalgam fillings.¹⁶⁰

The state of Washington is considering a slightly different approach to the amalgam problem by seeking to resolve some of the uncertainties regarding amalgam risks and also trying to increase patient access to mercury alternatives. House Bill 2786 would create a task force to study mercury amalgam fillings and the scientific research on its adverse health effects.¹⁶¹ The task force would include two “mercury-free” dentists and would be required to report to the legislature.¹⁶² This report would include a statement on the FDA’s approval process, a summary of the evidence supporting the conclusion that mercury amalgam is safe, the task force’s conclusions regarding the safety of mercury amalgam, and an estimate of the beneficial and adverse economic effects of a state-wide ban on mercury amalgam.¹⁶³ The task force would also propose legislation that would articulate a dentist’s disclosure obligations.

Recognizing that cost, and not just a lack of information, is another significant barrier to opting for amalgam alternatives, the Washington measure would also require dental insurance coverage to include mercury amalgam alternatives.¹⁶⁴ In this regard, Rhode Island recently enacted legislation requiring, as of January 1, 2003, state dental insurance contracts to provide coverage for non-mercury fillings at no additional expense for Rhode Island’s state employees.¹⁶⁵ Illinois is also considering extending insurance coverage for non-mercury fillings.¹⁶⁶ A bill before the Illinois state legislature would require the state to “enact laws to provide choices to all consumers, so that Medicaid families and moderate-income consumers on insurance plans will be able to choose alternatives to mercury amalgam.”¹⁶⁷

Although such measures would make it financially more palatable to choose non-mercury fillings, they do not necessarily extend coverage to removal of amalgams already in place. A 1997 Maine case held that Blue Cross was not required to cover the costs of mercury amalgam removal.¹⁶⁸ The Supreme Judicial Court of Maine noted that

¹⁶⁰ H.B. 2536, 45th Leg., 2d Reg. Sess. (Ariz. 2002); H.B. 1715, 146th Gen. Assemb., Reg. Sess. (Ga. 2002); H.B. 598, 124th Gen. Assemb., Reg. Sess. (Ohio 2002).

¹⁶¹ H.B. 2786, 57th Leg., Reg. Sess. (Wash. 2002).

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ R.I. GEN. LAWS § 23-24.9-15(c) (2001).

¹⁶⁶ H.R. 0689, 92d Gen. Assemb., Reg. Sess. (Ill. 2002).

¹⁶⁷ *Id.*

¹⁶⁸ *Fecteau v. State Employee Health Comm’n*, 690 A.2d 500, 502 (Me.

“[n]o scientific basis has been established to confirm that removal of amalgam fillings is essential to [the] health of [the] patient” in question.¹⁶⁹ The court observed that the medical evidence regarding the necessity of mercury amalgam removal was conflicting in general, but only specifically cited the ADA position that mercury amalgam was safe.¹⁷⁰ Still, while the Rhode Island statute and the Illinois bill would not require coverage for mercury amalgam removal, they arguably move in that direction by contemplating coverage for the more expensive alternative materials, at least for some segments of the population, doing so due to safety concerns.¹⁷¹

While enacting a full or partial ban on amalgams may be too radical at this time, these statutes and bills demonstrate the growing public concern about the potential risks of mercury even if its adverse health effects are not yet well understood. As exemplified by the Maine statute, the debate at the statehouse level is, for the most part, being framed as a matter of a patient's right to make an informed choice between mercury or an alternative material.¹⁷² Such legislative efforts achieve what common law tort actions, particularly those rooted in the doctrine of informed consent, should do but are unlikely to accomplish: respect a patient's right to receive material information in order to make informed, autonomous decisions. An informed decision need not be popular, reflective of the majority view, aligned with the weight of medical authority, or even rational. It must, however, be the patient's own, not the dentist's or the ADA's. Granted, statutorily 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 precisely because they are predicated on the concept that dental amalgams pose health risks.¹⁷³

Since these statutes are new, there is very little case law addressing statutory violations. Some litigation has emerged in California,

1997) (holding that despite the recommendation of a physician, the insurer is not required to remove amalgam fillings since it was not a covered service under its contract provisions).

¹⁶⁹ *Id.* at 501 (quoting the review of the insurer's denial of coverage by the State Employee Health Commission appeals panel, which affirmed the denial).

¹⁷⁰ *Id.* at 502 n.1.

¹⁷¹ R.I. GEN. LAWS § 23-24.9-15(c) (2001) (providing coverage for non-mercury fillings to state employees only); ILL. H.R. 689 (concluding that laws should be enacted to provide alternatives to mercury amalgam to Medicaid and moderate-income consumers).

¹⁷² See ME. REV. STAT. ANN. 32 § 1094-C(2) (Supp. 2002).

¹⁷³ CONSUMER REPORTS, *supra* note 131, at 318.

the first state to enact a mandatory disclosure law for certain toxins, including mercury amalgam. Plaintiffs successfully alleged violations of the Safe Drinking Water and Toxic Enforcement Act in a case where dentists did not follow Proposition 65's provisions for warning patients that their fillings contained mercury.¹⁷⁴ Under Proposition 65, dentists cannot expose patients to mercury without a warning.¹⁷⁵ An affirmative defense does exist: if the dentist can demonstrate that an exposure at 1,000 times the amount in question would not cause any observable reproductive harm, the warning is unnecessary.¹⁷⁶ If the dentist is not exempt on those grounds, the warning must be "reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure."¹⁷⁷ Failure to provide this warning can result in a civil penalty of up to \$2,500 per day for each violation in addition to any other penalty established by law.¹⁷⁸

Arguably, a Proposition 65 claim involves the kind of evidentiary hurdles that exist with regard to *Daubert* in the tort context. However, while a dentist charged with violating Proposition 65 will argue that the amalgam risk was so *de minimis* that no affirmative duty to warn attached, the burden of proving the extent of the risk rests on the defendant, not the plaintiff as it does in a product liability case. Thus, in *Consumer Cause, Inc. v. Smilecare*, the 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.¹⁷⁹ Rather, under the California law, the dentists had the burden to prove that the amalgam risk was too low to require a warning to be given to the patient.¹⁸⁰

Smilecare signals a critical shift in thinking about the mercury amalgam debate. Although the court acknowledged the pro-amalgam positions of the ADA and other health agencies and organizations, it did not accept the ADA's position *per se*.¹⁸¹ Furthermore, the existence of a statute, enacted by the citizens of California, gave sufficient

¹⁷⁴ *Consumer Cause, Inc. v. Smilecare*, 110 Cal Rptr. 2d 627, 641 (Cal. Ct. App. 2001).

¹⁷⁵ See Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), CAL. HEALTH & SAFETY CODE § 25249.6 (West 1999).

¹⁷⁶ *Id.* § 25249.10(c).

¹⁷⁷ *Id.* §§ 25249.6, 25249.11 (requiring a clear and reasonable warning and defining warning.).

¹⁷⁸ *Id.* § 25249.7(b)(1) (Supp. 2004).

¹⁷⁹ *Smilecare*, 110 Cal. Rptr. 2d at 642.

¹⁸⁰ *Id.*

¹⁸¹ See *id.* at 631-33.

credence to the anti-amalgam position, and allowed the court to avoid deciding which position was correct.¹⁸² Consequently, the statute merely ensures disclosure of information and vests any choice about safety in the individual patient where it properly belongs. As a result, the case devolved to the simple but fundamental question of whether a statutorily required warning was issued and, if not, whether an exemption applied.¹⁸³ Because such a theory of statutory violation may provide fewer evidentiary obstacles than the *Daubert* dilemmas of tort claims, this form of litigation may ultimately provide the most successful strategy for patient-plaintiffs. It should be noted, however, that the ADA has opposed the California statute vehemently and, to date at least, the law's enforcement seems dependent upon consumer watchdog organizations rather than the state.¹⁸⁴

As the statutory movement continues to expand at the state level, the United States government is considering a national proposal to eventually ban mercury amalgam fillings.¹⁸⁵ House Resolution 4163 closely mirrors the bill considered by the California state legislature last year.¹⁸⁶ Indeed, one of the congressional bill's co-sponsors, Representative Diane Watson, is from California and helped lead the anti-amalgam statutory movement in that state.¹⁸⁷ Although Rep. Watson's bill has yet to move beyond the committee stage, it has already unleashed a flurry of statements in opposition from the ADA.¹⁸⁸ Like its California counterpart, Watson's bill would eventually ban mercury amalgam and, in the interim, would require strict labeling, disclosure, and use restrictions.¹⁸⁹

Despite the early promise of the state statutory movement in fostering consumer choice while side-stepping *Daubert*'s hurdles, it is not without problems. In addition to the countless difficulties in getting a law passed and enforced, the ADA and amalgam producers will

¹⁸² See *id.* at 633.

¹⁸³ See *id.* at 636-37.

¹⁸⁴ See Pyle, *supra* note 16.

¹⁸⁵ Mercury in Dental Filling Disclosure and Prohibition Act, H.R. 4163, 107th Cong. (2002) (proposing a ban on mercury dental fillings).

¹⁸⁶ See Assem. B. 2270, 2001-2001 Legis. Reg. Sess. (Cal. 2002).

¹⁸⁷ See *id.* See also Stephen Barrett, U.S. Rep. Diane Watson Introduces Anti-Amalgam Bill, at <http://www.quackwatch.org/11Ind/Watson/watson.html> (last modified May 12, 2002).

¹⁸⁸ See, e.g., *American Dental Association Statement on H.R. 4163, the Mercury Fillings Disclosure and Prohibition Act*, U.S. NEWSWIRE, Apr. 12, 2002 (quoting ADA Executive Director that House Resolution 4163 will increase costs and deprive patients of a material that is "scientifically substantiated to be safe and effective"), available at <http://releases.usnewswire.com/printing.asp?id=130-04122002>.

¹⁸⁹ H.R. 4163 § 3.

argue that such statutes are preempted by federal law.¹⁹⁰ While they have yet to succeed on this point, current Supreme Court opinions create enough loopholes and ambiguities to ensure that vulnerability to preemption is a serious concern.

In *Committee of Dental Amalgam Manufacturers and Distributors v. Stratton*,¹⁹¹ for example, amalgam manufacturers sought a declaratory judgment that California's Proposition 65 was preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA").¹⁹² Both the district and appellate courts found that dental amalgam did constitute a medical device, thereby bringing it within the purviews of the MDA.¹⁹³ The issue thus became whether Proposition 65's warning requirements were preempted by the MDA.¹⁹⁴ Section 360(k) of the MDA provides:

[N]o state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement: "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."¹⁹⁵

The district court held that the FDA affirmatively chose not to impose any reproductive toxicity warning requirements on dental amalgam.¹⁹⁶ Accordingly, Proposition 65 was different from, and in addition to, the FDA's requirements and therefore was preempted.¹⁹⁷ The Court of Appeals for the Ninth Circuit reversed, relying heavily upon the Supreme Court's holding in *Medtronic, Inc. v. Lohr*,¹⁹⁸ which dealt with the same MDA preemption provision as in *Stratton*.¹⁹⁹ In *Medtronic*, the Court held that the MDA did not preempt

¹⁹⁰ See, e.g., *Comm. of Dental Mfrs. v. Henry*, 871 F. Supp. 1278 (S.D. Cal. 1994), *rev'd sub nom.*, *Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton*, 92 F.3d 807 (9th Cir. 1996).

¹⁹¹ 92 F.3d 807.

¹⁹² Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360(c)-(k).

¹⁹³ *Henry*, 871 F. Supp. at 1281; *Stratton*, 92 F.3d at 810-11.

¹⁹⁴ *Stratton*, 92 F.3d at 812-14 (rejecting district court's holding that Proposition 65 is preempted).

¹⁹⁵ 21 U.S.C. § 360k(a).

¹⁹⁶ *Henry*, 871 F. Supp. at 1284.

¹⁹⁷ *Id.*

¹⁹⁸ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502 (1996) (plurality opinion) (holding that § 360(k) did not preempt all potential state common law causes of action, particularly where the common law rule was general rather than pertaining to specific devices).

¹⁹⁹ See *Stratton*, 92 F.3d at 811-13.

Lohr's common law claims against a defective pacemaker.²⁰⁰ Preemption would conceivably occur where the statute was specific as to a particular device, but because the MDA requirements, however, dealt with regulation generally and not with specific devices, they were "not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements."²⁰¹ Moreover, the Florida common law requirements at issue were general and not developed "with respect to [a] medical device[]." ²⁰² Such non-specificity allowed the state law to evade federal preemption.

If, on the other hand, the state statute and/or federal regulation specifically concerned a particular medical device, the plurality in *Medtronic* would seemingly find preemption.²⁰³ Justice Breyer was more explicit in stating that state common law claims could sometimes be preempted by the MDA when its application created a "requirement...which [is] different from, or in addition to, any [federal] requirement."²⁰⁴ Justice Breyer also suggested that preemption could be extended to the corresponding standards of care for common law claims.²⁰⁵ The dissent would go even further, reasoning that state common law claims were in fact "requirements" under the MDA and, therefore, preempted when they impose something different from the FDCA's requirements.²⁰⁶ Justice O'Connor contended that some of the common law claims dealt with the labeling and warning of Medtronic's pacemaker device, compelling requirements different from those imposed under the FDCA and resulting in preemption under the extensive labeling requirements already imposed by federal law.²⁰⁷

In applying these principles of *Medtronic*, the Ninth Circuit in *Stratton* interpreted the MDA's provisions to mean that preemption occurs only if a specific requirement or regulation exists in reference to a particular device.²⁰⁸ It found no such preemption of Proposition 65 since it was a general state law that was not enacted with respect to medical devices specifically. Rather, Proposition 65 applies to all products and services that meet the definition of a reproductive

²⁰⁰ *Medtronic*, 518 U.S. at 502.

²⁰¹ *Id.* at 501 (distinguishing the facts in *Medtronic* from a hypothetical case in which Congress regulated a specific device or field of devices in the face of "potentially contradictory state requirements").

²⁰² *Id.*

²⁰³ *See id.*

²⁰⁴ *Id.* at 503 (Breyer, J., concurring) (quoting § 360(k)(a) of the MDA).

²⁰⁵ *Id.* at 504-05 (Breyer, J., concurring).

²⁰⁶ *Id.* at 509 (O'Connor, J., concurring and dissenting).

²⁰⁷ *Id.* at 513-14 (O'Connor, J., concurring and dissenting).

²⁰⁸ *Stratton*, 92 F.3d at 812 (relying on FDA regulation 808.1(d)).

toxin.²⁰⁹ Mercury is listed as one of many reproductive toxins, and thereby requires certain warnings, but no specific regulation or requirement is aimed solely at mercury or mercury amalgam.²¹⁰

Based on *Stratton* and *Medtronic*, it is not certain that mercury amalgam warning statutes will always survive preemption. The dissenting opinion in *Medtronic* certainly envisions that state common law warning requirements are different from and in addition to the FDCA provisions, and can trigger preemption.²¹¹ It is likely that these Justices would therefore find explicit product-specific labeling or warning requirements even more obviously deserving of preemption. The plurality opinion, moreover, suggests that in certain circumstances, a state statute could be preempted.²¹² This uncertainty should worry anti-amalgamists, especially when considering such statutes as those in Maine and New Hampshire and the partial bans proposed in Alabama, Arizona, and Georgia, among others.²¹³ Unlike California's product-neutral Proposition 65, these bills specifically deal with warning requirements for the particular device of mercury amalgam.²¹⁴ As such, they may contain the specificity and particularity necessary for MDA preemption.

It is therefore essential that states contemplating legislation as a way to address concerns about mercury's safety should consider *Medtronics'* implications for the actual focus and content of such a measure. Additionally, legislators must recognize that, should Congress amend the FDCA or pass other legislation regulating mercury amalgam specifically, preemption may occur. The FDA currently is considering suggestions for more stringent labeling requirements for mercury amalgam, which would go above and beyond those already in place for all Class II devices.²¹⁵ If these requirements are adopted, an even stronger case for preemption would occur, particularly where the state statute involved specifically targets mercury amalgams.

²⁰⁹ *Id.* at 813.

²¹⁰ *See id.* at 810.

²¹¹ *Medtronic, Inc.*, 518 U.S. at 509 (O'Connor, J., concurring and dissenting).

²¹² *Id.* at 500-02.

²¹³ ME. REV. STAT. ANN. 32 § 1094-C (Supp. 2002); H.B. 378, 2002 Leg., Reg. Sess. (Ala. 2002); H.B. 2536, 45th Leg., 2d Reg. Sess. (Ariz. 2002); H.B. 1715, 146th Gen. Assemb., 2d Reg. Sess. (2002 Ga.); H.B. 1251, 157th Gen. Ct., 2d. Reg. Sess. (N.H. 2002).

²¹⁴ ME. REV. STAT. ANN. 32 § 1094-C (Supp. 2002); H.B. 378, 2002 Leg., Reg. Sess. (Ala. 2002); H.B. 2536, 45th Leg., 2d Reg. Sess. (Ariz. 2002); H.B. 1715, 146th Gen. Assemb., 2d Reg. Sess. (2002 Ga.); H.B. 1251, 157th Gen. Ct., 2d. Reg. Sess. (N.H. 2002).

²¹⁵ *See Dental Devices*, *supra* note 7.

The ADA clearly recognizes the continuing potential of the preemption argument. In its comments on the FDA's new guidelines for reclassifying mercury amalgam as a Class II device, the ADA argues that this very reclassification "should operate to preempt state laws that conflict with the requirements encompassed by the proposed rule."²¹⁶ The ADA claims that state laws requiring disclosure of risks to patients or abolishing dental amalgam are "directly at odds and incompatible with the federal requirements set forth by the FDA."²¹⁷ Additionally, the Association contends that it is "not in the public interest to have competing state requirements that conflict with special controls proposed by the [FDA], nor is it appropriate under the [FDCA] to permit states to ban the sale of dental amalgam products, which are cleared to market by [the] FDA."²¹⁸ The ADA argues that under *Medtronic*, state legislation conflicted with the FDCA, adding, "Congress expressly provided for federal preemption of state laws regarding medical devices . . . and [the] ADA strongly believes that the proposed rule should be construed as preempting all state regulations regarding dental amalgam products which are in significant contravention of the FDA imposed federal requirements."²¹⁹ However, should Rep. Watson ever succeed in her efforts to have Congress ban mercury amalgams, the state statutory movement and its potential preemption would become moot in the face of a federal prohibition on mercury amalgam.²²⁰

III. CONCLUSION

The mercury amalgam debate allows for a fascinating examination of the intersection of law and science and the allocation of decision-making authority in matters of risk and uncertainty. Despite the ADA's enduring endorsement of mercury amalgams, science has yet to: (1) state with certainty that mercury amalgam is safe, (2) identify at what levels it becomes harmful to humans, or (3) ascertain how much mercury is released into the body from mercury fillings. Although a patient is legally entitled to information regarding the risks and benefits of proposed and alternative treatments, the ADA and

²¹⁶ AM. DENTAL ASS'N, AMERICAN DENTAL ASSOCIATION'S COMMENTS ON FDA'S PROPOSED RULE & SPECIAL CONTROL GUIDANCE ON DENTAL AMALGAM PRODUCTS 38, *available at* www.ada.org/prof/resources/positions/statements/amalgam3.asp.

²¹⁷ *Id.* at 38-39.

²¹⁸ *Id.* at 39.

²¹⁹ *Id.* at 43.

²²⁰ Mercury in Dental Filling Disclosure and Prohibition Act, H.R. 4163, 107th Cong. (2002).

state dental boards have vehemently resisted informing patients about the risks of mercury amalgams. Instead, professional regulation has been aimed at disciplining dentists who advocate against mercury amalgams or simply want to inform the patient about both sides of the controversy.

An increase in litigation by patients against dentists and the ADA for failure to warn or for non-removal of mercury amalgams may inspire additional scientific research. However, in the short-term, *Daubert* issues portend limited successes for these patient-plaintiffs. For this reason, state statutes offer the best method of protecting patients and effectuating their autonomy. Statutory violation suits largely avoid the obstacles posed by *Daubert*, while protecting the patient's right to be informed about mercury's potential risks. Additionally, enacting and enforcing such statutes will raise public awareness about the risks of mercury amalgam and the need for further study. These laws, however, must be drafted with care in order to avoid federal preemption.

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. Instead of troubling the ADA, the scientific uncertainty regarding amalgams poses real obstacles for patient-plaintiffs in both the health and legal contexts. Hopefully, both litigation and legislation will serve as an incentive for further in-depth study of mercury amalgam and its effects, and begin to answer the many questions about this material's risks.

In the meantime, legislators, 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. And the law is quite certain that, at a minimum, the patient has a right to be informed of those risks.