

# COMPULSORY WATER FLUORIDATION: JUSTIFIABLE PUBLIC HEALTH BENEFIT OR HUMAN EXPERIMENTAL RESEARCH WITHOUT INFORMED CONSENT?

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## INTRODUCTION

Most Americans are under the impression that compulsory water fluoridation is a safe and effective public health measure to fight tooth decay. Pro-fluoridation campaigns by the American Dental Association and the Department of Health and Human Services have ensured this perception, successfully obscuring the more disturbing reality that a significant number of leading scientists, medical and dental professionals, and educated members of the public continue to repudiate both the medical necessity and ethical legitimacy of compulsory water fluoridation.<sup>1</sup> In truth, scientific evidence is steadily mounting against water fluoridation, with emerging studies showing that not only is fluoridation not effective at achieving the stated public health goal of combating dental caries, but also that excess exposure to fluoride contributes to a host of far more serious health concerns, particularly in the very population the public health measure was originally alleged to benefit: children.<sup>2</sup> With growing evidence suggesting that systemic intake of excess fluoride is linked to dental and skeletal fluorosis, endocrine disruption, hypothyroidism, bone cancer, and lowered IQs in children, it is not surprising that hundreds of U.S. and Canadian cities and towns have now opted to either reject or cease fluoridating their water supplies, joining over 97% of Europe and most of the developed world in rejecting compulsory water fluoridation.<sup>3</sup>

In 2011, in light of new scientific evidence as well as a recommendation by the National Research Council (“NRC”), the Environmental

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<sup>1</sup> See discussion *infra* Part II.B.

<sup>2</sup> See discussion *infra* Part II.B. Dental caries is the scientific term for dental cavities.

<sup>3</sup> See discussion *infra* Part II.B. See also *Communities Which Have Rejected Fluoridation Since 1990*, FLUORIDE ACTION NETWORK, <http://fluoridealert.org/content/communities/> (last visited Nov. 13, 2014), archived at <http://perma.cc/L25D-ZWNH>.

Protection Agency (“EPA”) announced its intention to re-examine its currently allowed Maximum Contaminant Levels (“MCL”) of fluoride in drinking water.<sup>4</sup> EPA’s decision was based on a 2006 report by the NRC, which considered numerous studies linking a variety of serious health problems with excess exposure to fluoride, and concluded that EPA should lower its current maximum contaminant levels for fluoride, in order to minimize the risks of severe dental fluorosis, bone fractures, and possibly skeletal fluorosis.<sup>5</sup> The Department of Health and Human Services (“DHHS”) shortly thereafter recommended that community water districts lower their allowable fluoride levels to 0.7 parts per million (“ppm”), the lowest level in a range earlier recommended by DHHS.<sup>6</sup> This recommended change sprang from DHHS’s recognition that original “optimal” fluoride levels were set without considering human fluoride consumption from other products, including fluoridated toothpaste and food and beverages made with fluoridated water.<sup>7</sup>

As of the writing of this Article, EPA has not yet come out with any revised MCLs, and it is doubtful that a recommendation to entirely eliminate artificial fluoride in the public water supply will come easily from a federal agency long in support of the benefits of compulsory water fluoridation. Regardless of the outcome, federal agency reconsideration of the safe levels of fluoride in the drinking supply already raises significant questions about the continued public health justification of compulsory water fluoridation.

Over the last sixty years, courts have been highly deferential to state and local governments challenged on compulsory water fluoridation, generally applying the minimal scrutiny of the rational basis test to uphold the practice as a legitimate public health measure.<sup>8</sup> Yet even rational basis scrutiny requires that the public health measure be “reasonable and necessary to secure the . . . health . . . of the public.”<sup>9</sup> But what constitutes an unreasonable public health measure? Is there a scientific tipping point after which an entrenched public health measure is no longer justifiable? A number of public health law scholars have suggested that existing public

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<sup>4</sup> See MARY TIEMANN, CONG. RES. SERV., RL 33280, FLUORIDE IN DRINKING WATER: A REVIEW OF FLUORIDATION AND REGULATION ISSUES, 19 (2013) [hereinafter CRS REPORT].

<sup>5</sup> *Id.* at 19–20.

<sup>6</sup> *Id.* at 20.

<sup>7</sup> *Id.* at 19.

<sup>8</sup> See, e.g., Douglas A. Balog, *Fluoridation of Our Public Water Systems: Valid Exercise of State Police Powers or Constitutional Violation?*, 14 PACE ENVTL. L. REV. 645, 668 (1997).

<sup>9</sup> *Kraus v. City of Cleveland*, 121 N.E.2d 311, 315 (Ohio Ct. App. 1954).

health laws be continually reevaluated in light of current scientific knowledge and evolving public notions of personal liberty and bodily integrity.<sup>10</sup> Under one proffered system of evaluation, public health laws are only justified when public health authorities are able to demonstrate: (1) a significant risk to public health based on scientific evidence; (2) the intervention's effectiveness by showing a reasonable fit between means and ends; (3) that economic costs are reasonable; (4) that human rights burdens are reasonable; and (5) that benefits, costs, and burdens, are fairly distributed.<sup>11</sup> This Article argues that under this systematic approach, compulsory water fluoridation is no longer a justifiable public health measure and continued fluoridation schemes veer dangerously close to ongoing human research experiments without informed consent.

Part I of this Article explores the history of, stated public health justifications for, and primary legal challenges to compulsory water fluoridation. Part II then considers the most recent scientific evidence weighing against the practice. Part III discusses federal regulation of the public water supply and analyzes the potential significance of the EPA's current reexamination of allowable levels of artificial fluoride in the public water supplies in response to recommendations by the NRC. Part IV assesses whether compulsory water fluoridation can still be justified as a public health benefit, or whether significant gaps in fluoridation research indicate that compulsory water fluoridation is an ongoing research experiment on human subjects in violation of various ethical and legal informed consent protocols. The Conclusion states that under systematic scrutiny, compulsory water fluoridation is no longer a justifiable public health benefit.

## I. HISTORY OF AND LEGAL CHALLENGES TO COMPULSORY WATER FLUORIDATION

Water fluoridation is the “controversial practice of adding chemicals to drinking water to raise the naturally occurring level of the fluoride ion to about 1 mg/L in the belief that this can reduce the frequency of

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<sup>10</sup> See, e.g., Mark A. Rothstein, *Rethinking the Meaning of Public Health*, 30 J.L. MED. & ETHICS 144, 144 (2002); James G. Hodge et al., *Transforming Public Health Law: The Turning Point Model State Public Health Act*, 34 J.L. MED & ETHICS 77, 79 (2006) (“[S]tate public health laws often reflect outdated scientific understandings of disease, public health interventions, or legal norms for protection for individual rights.”).

<sup>11</sup> Lawrence O. Gostin, *Public Health Law in a New Century Part III: Public Health Regulation: A Systematic Evaluation*, 283 JAMA 3118, 3119–20 (2000) [hereinafter Gostin, *Part III*].

dental caries.”<sup>12</sup> Although trace amounts of natural fluoride (calcium fluoride) are found in virtually all foods and natural spring water, water fluoridation involves the purposeful adding of an artificial fluoride compound to the natural water supply, such as sodium fluoride, sodium fluorosilicate, or hexafluorosilicic acid.<sup>13</sup> The use of these fluoride compounds is generally not advertised to the public however, as sodium fluoride has been traditionally used as an insecticide and rodenticide, and hexafluorosilicic acid is captured industrial waste from the aluminum and phosphate fertilizer industries.<sup>14</sup>

Artificial water fluoridation began with pilot studies in the mid-1940s after researchers linked the mottled teeth caused by exposure to naturally occurring fluorides in certain water supplies to a decreased level of dental caries.<sup>15</sup> Although the original researchers were concerned about possible effects beyond the observed dental fluorosis and urged “further studies” before any widespread water fluoridation schemes were implemented, the U.S. Public Health Service supported the widespread introduction of compulsory water fluoridation in 1950, before the results of the pilot studies were even known.<sup>16</sup> Thereafter, proponents of water fluoridation used these early pilot studies to show a positive correlation between artificial fluoridation and a reduction in childhood tooth decay, despite severe criticism about both the methodological quality of the early studies and the skewed interpretation of the results.<sup>17</sup>

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<sup>12</sup> Douglas W. Cross & Robert J. Carton, *Fluoridation: A Violation of Medical Ethics and Human Rights*, 9 INT. J. OCCUP. ENVTL. HEALTH 24, 24 (2003) (1 mg/L is equivalent to 1 ppm).

<sup>13</sup> *Id.* at 24; Michael Czajka, *Systemic Effects of Fluoridation*, 27 J. ORTHOMOLECULAR MED. 123, 123 (2012); Stephen Peckham, *Slaying Sacred Cows: Is it Time to Pull the Plug on Water Fluoridation?*, 22 CRITICAL PUB. HEALTH 159, 160 (2012).

<sup>14</sup> Cross & Carton, *supra* note 12, at 24 (“Originally involving the use of sodium fluoride, fluoridation is now accomplished mainly by the use of silicofluorides obtained from the effluent scrubbers of the phosphate fertilizer industry.”); Czajka, *supra* note 13, at 123 (“Water fluoridation is usually carried out using hexafluorosilicic acid, which is a by-product of the aluminum and phosphate industries”); *see also* Balog, *supra* note 8, at 655 (“The government promoters seeking to add fluoride to the public water systems back in the 1950s held a conference and tried to diffuse this issue by instructing those in attendance not to use the word ‘artificial’ in conjunction with fluoridation and not to tell the public that sodium fluoride is being used because ‘that is rat poison’”).

<sup>15</sup> Peckham, *supra* note 13, at 160. Mottled teeth indicate a condition called “dental fluorosis,” or “enamel fluorosis,” a dark staining of the teeth and erosion of the enamel due to excessive exposure to fluoride.

<sup>16</sup> *Id.* *See also* L. Pierce Anthony, *The Effect of Fluorine on Dental Caries*, 31 JADA 1360, 1361 (1944).

<sup>17</sup> Peckham, *supra* note 13, at 164–65. *See also* John Remington Graham & Pierre-Jean Morin, *Highlights in North American Litigation During the Twentieth Century on Artificial*

A. *Compulsory Water Fluoridation as an Asserted Public Health Benefit*

Early proponents of compulsory water fluoridation were quick to tout the public health benefits of the practice. They claimed that water fluoridation would prevent tooth decay “mainly by providing teeth with frequent contact with low levels of fluoride throughout each day and throughout life.”<sup>18</sup> They further claimed that the practice was not only safe and effective, but that it was also the least expensive way to deliver the benefits of fluoride to “all residents of a community.”<sup>19</sup> Finally, proponents also claim that water fluoridation “benefits all people—regardless of age, income, education, or socioeconomic status,” despite evidence tending to show that the benefits of fluoride as a tooth decay preventative are only applicable during early years when permanent teeth are forming.<sup>20</sup>

Despite the alleged benefits, proponents had to acknowledge that exposure to excessive fluoride could potentially cause dental fluorosis, with effects ranging from small white specks on the teeth to darkly stained, pitted, and brittle teeth subject to fracture.<sup>21</sup> However, a theory was advanced that the “optimal” level of added artificial fluoride in the water supply—the dosage that would both prevent tooth decay and avoid dental fluorosis—was around 1 part of fluoride to one million parts of water, or 1 ppm.<sup>22</sup> Although this dosage was seized upon by public health officials, 1 ppm as an “optimal” dosage never received scientific consensus because

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*Fluoridation of Public Water Supplies*, 14 J. LAND USE & ENVTL. L. 195, 198–99 (1999); Gary Null, *Fluoridation: Medicating Our Water Part 2*, TOWNSEND LETTER, Dec. 2010, at 71, 77.

<sup>18</sup> See, e.g., *Community Water Fluoridation Basics*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/fluoridation/basics/index.htm> (last updated July 25, 2013), archived at <http://perma.cc/BHM8-A253> [hereinafter CDC, *Fluoridation*]. See also Bette Hileman, *Fluoridation of Water: Questions About Health Risks and Benefits Remain After More Than 40 Years*, CHEMICAL & ENGINEERING NEWS, Aug. 1, 1988, available at <http://www.slweb.org/hileman.html>, archived at <http://perma.cc/3UNF-LC2W> (noting that proponents, including most U.S. medical and dental associations, have insisted since the 1950s that “water fluoridated at levels of about 1ppm is a cheap, effective, and perfectly safe way to reduce cavities.”).

<sup>19</sup> CDC, *Fluoridation*, *supra* note 18 (noting that “a person’s income and ability to get routine dental care are not barriers since all residents of a community can enjoy fluoride’s protective benefits just by drinking tap water and consuming foods and beverages prepared with it.”).

<sup>20</sup> *Id.*; Balog, *supra* note 8, at 648–49 (noting that “the federal government has conceded that the purported benefit of fluoridation is limited, as it only applies to developing enamel in the teeth of children up to the age of nine” and that “even proponents of fluoridation admit that fluoride does not provide any health benefits when ingested by an adult.”).

<sup>21</sup> Hileman, *supra* note 18, at 14.

<sup>22</sup> Peckham, *supra* note 13, at 160.

it failed to consider individual consumer variables such as age, weight, water consumption habits, or vulnerable population exposure risks.<sup>23</sup>

Almost immediately, water fluoridation schemes were endorsed by both the dental and medical lobbies, despite what should have been recognized as a considerable risk in advocating for a population-wide public health measure without first determining fluoride's potential effects on other organs of the body. The American Dental Association came out in support in 1950, and the American Medical Association endorsed it in 1957.<sup>24</sup> Water fluoridation schemes thereafter proliferated throughout the United States, and today, over 73% of the United States public water supplies are artificially fluoridated.<sup>25</sup>

Abroad, the alleged public health benefits of water fluoridation have not been readily embraced.<sup>26</sup> Although most of the English-speaking countries have joined with the United States in adopting various water fluoridation schemes, most other developed nations have declined to do so.<sup>27</sup> Countries rejecting fluoridation have objected not only on safety grounds, but also due to concerns about medicating their citizens without proper dosage control, continual medical monitoring, or informed consent.<sup>28</sup>

*B. Legal and Political Challenges to Compulsory Water Fluoridation Within the United States*

Although the United States Supreme Court to date has declined to consider the issue, compulsory water fluoridation schemes have been

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<sup>23</sup> *Id.* at 165.

<sup>24</sup> See, e.g., *Fluoride and Fluoridation*, AM. DENTAL ASS'N, <http://www.ada.org/en/home-ada/public-programs/advocating-for-the-public/fluoride-and-fluoridation> (last visited Nov. 13, 2014), archived at <http://perma.cc/G9U8-L6PF>; HEALTH RES. ADMIN., U.S. DEP'T OF HEALTH, EDUC., & WELFARE, FL-73, AMA RE-EMPHASIZES ENDORSEMENT OF FLUORIDATION (1975), available at <http://sfsbm.org/wiki2/images/Fl-73.pdf>.

<sup>25</sup> CDC, *Fluoridation*, *supra* note 18 (noting that as of 2012, 73.9% of the U.S. public water supply was artificially fluoridated).

<sup>26</sup> Dan Fagin, *Second Thoughts about Fluoride: New Research Indicates that a Cavity-Fighting Treatment Could Be Risky If Overused*, SCI. AM., Jan. 2008, at 74.

<sup>27</sup> See, e.g., Czajka, *supra* note 13, at 128 (less than 6% of the world's population drink fluoridated water and most fluoridated water is in the United States). Notably, in 2013, Israel became the most recent developed nation to reverse course on water fluoridation, with the Supreme Court of Israel ordering water providers to cease fluoridating their water supplies by summer 2014. See Justin Jalil, *Israel to Discontinue Fluoridation of Tap Water*, TIMES OF ISRAEL (Aug. 25, 2014), <http://www.timesofisrael.com/israel-to-discontinue-fluoridation-of-tap-water/>, archived at <http://perma.cc/AV8Y-9HKS>.

<sup>28</sup> See *Statements from European Health, Water, and Environment Authorities on Water Fluoridation*, FLUORIDE ACTION NETWORK (May 2007), <http://fluoridealert.org/content/europe-statements/>, archived at <http://perma.cc/M8BF-PAYC>.

legally and politically challenged for over sixty years.<sup>29</sup> Politically, where the public has been given any say in the matter, compulsory water fluoridation schemes have largely been defeated.<sup>30</sup> Legislatures and executive branches have maneuvered around this public resistance, often by mandating compulsory water fluoridation schemes by executive fiat or by enacting state-wide compulsory water fluoridation laws that remove any ability to put the issue to a local public vote.<sup>31</sup>

In the courts, compulsory water fluoridation schemes have been challenged on nearly every conceivable legal basis. There have been Constitutional challenges on First, Fourth, Fifth, Ninth, Tenth, and Fourteenth Amendment grounds, along with challenges based on violations of various state and federal laws.<sup>32</sup> Although some of these challenges

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<sup>29</sup> See, e.g., Balog, *supra* note 8, at 668; Graham & Morin, *supra* note 17, at 199; DENTAL DIDACTICS, LEGAL ISSUES ON FLUORIDATION (1999), available at <http://www.nofluoride.com/reports/Dental%20Diadactics%20Overview.pdf>. Legal and political challenges to fluoridation have been brought by individuals, public interest groups, local governing bodies, water providers, and cities or towns objecting to state fluoridation mandates. *Id.*

<sup>30</sup> See *Fluoridation vs. Democracy*, FLUORIDE ACTION NETWORK (Aug. 2012), <http://www.fluoridealert.org/content/fluoridation-vs-democracy/>, archived at <http://perma.cc/4P8R-NU2M>.

<sup>31</sup> *Id.* (“The big cities in the United States were mostly fluoridated by executive action in such a way as to avoid public referenda.”). See also e.g., *City of Port Angeles v. Our Water—Our Choice*, 239 P.3d 589 (Wash. 2010) (granting city council’s declaratory judgment against two anti-fluoridation initiatives that would have gone against city council’s support of fluoridation); *City of Canton v. Whitman*, 337 N.E.2d 766 (Ohio 1975) (finding that Ohio state law requiring fluoridation pre-empted city’s desire not to fluoridate); *City of Watsonville v. State Dep’t of Health Servs.*, 35 Cal. Rptr. 3d 216 (Cal. Ct. App. 2005) (California state law mandating fluoridation of public water systems with more than 10,000 hookups pre-empted city ordinance prohibiting fluoridation since fluoridation “was an issue of statewide concern.”); *New Haven Water Co. v. City of New Haven*, 210 A.2d 449 (Conn. 1965) (municipal ordinance requiring fluoridation superseded local ordinance enacted by city charter prohibiting it). See also *Minn. State Bd. of Health v. City of Brainerd*, 241 N.W.2d 624 (Minn. 1976) (upholding city statute requiring fluoridation despite special referendum vote of 1863 to 199 against fluoridation); *Citizens for Safe Drinking Water v. San Diego City Council*, 2002 WL 32353 (Cal. Ct. App. 2002) (allowing city to discard ordinance prohibiting fluoridation passed via ballot initiative because ordinance was now pre-empted by state law mandating fluoridation).

<sup>32</sup> See generally Balog, *supra* note 8; see also e.g., *Foli v. Metro. Water Dist.*, No. 11CV1765JLS (BLM), 2012 WL 1192763 (Apr. 10, 2012) (challenges based on constitutional grounds and violations of both Food, Drug and Cosmetic Act and California’s unfair business practices laws); *Coshov v. City of Escondido*, 34 Cal. Rptr. 3d 19 (Cal. Ct. App. 2005) (challenges based on substantive due process and bodily integrity violations); *Quiles v. City of Boynton Beach*, 802 So. 2d 397 (Fla. Dist. Ct. App. 2001) (challenges based on constitutional right to privacy/right to be free of forced medications); *Safe Water Ass’n. v. City of Fond du Lac*, 516 N.W. 2d 13 (Wisc. Ct. App. 1994) (challenges on due process grounds); *City of Watsonville v. State Dep’t of Health Servs.*, 35 Cal. Rptr. 3d 216

have prevailed at the trial court level, to date every court of last resort has upheld compulsory water fluoridation as a legitimate exercise of the state's police powers.<sup>33</sup> Many courts upholding compulsory fluoridation have done so by misplaced reliance on a 1905 case addressing compulsory vaccination for a contagious disease, *Jacobson v. Commonwealth of Massachusetts*.<sup>34</sup>

1. *Jacobson* and the "Pressure of Great Dangers" Test

In *Jacobson*, the defendant was fined for refusing to abide by a city of Cambridge board of health law that required all adults to submit to a smallpox vaccine or face a mandatory fine of five dollars.<sup>35</sup> The defendant argued that he had suffered greatly by an earlier vaccination scheme during his childhood, presented opinions from experts within the medical community who disagreed with the mainstream's consensus on the safety and efficacy of the smallpox vaccine, and argued that the coercive nature of the vaccination law was in derogation of the rights secured to him by the Constitution, particularly his rights under the 14th Amendment.<sup>36</sup>

The Court held that it was within the state's police power to enact "health laws of every description," which were constrained only by the condition that such laws not contravene the Constitution or infringe upon any right granted or secured by it.<sup>37</sup> In this case, although the Court generally recognized the right of an individual to care for his own body in a manner in which he saw fit, the Court nevertheless reasoned that the liberty secured by the Constitution "does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint."<sup>38</sup> Instead, there were "manifold restraints to which every person is necessarily subject for the common good."<sup>39</sup> Here, because of the recognizable dangers to the community of a smallpox epidemic, as well as the obvious problems that might arise if individuals were allowed to refuse the vaccine, the Court found no Constitutional violation in the coercive vaccination law.<sup>40</sup> "Under the pressure of great dangers," the Court reasoned, an

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(Cal. Ct. App. 2005) (challenges based on state preemption grounds); Ill. Pure Water Comm. v. Yoder, 286 N.E. 2d 155 (Ill. App. 1972) (challenges on First Amendment freedom of religion grounds).

<sup>33</sup> See Graham & Morin, *supra* note 17, at 228.

<sup>34</sup> 197 U.S. 11 (1905).

<sup>35</sup> *Id.* at 12.

<sup>36</sup> *Id.* at 13.

<sup>37</sup> *Id.* at 25.

<sup>38</sup> *Id.* at 26.

<sup>39</sup> *Id.*

<sup>40</sup> *Jacobson*, 197 U.S. at 27–28.



individual's liberty interests might properly be subjected to restraint "as the safety of the general public may demand."<sup>41</sup> Finally, while acknowledging that there existed conflicting medical opinions about the safety and effectiveness of the vaccine itself, the Court stated that it was not for a court to second guess public health officials' chosen public health measure, unless the measure had: (1) "no real or substantial relation" to the public health or safety objective sought, or (2) was "beyond all question, a plain or palpable invasion of rights secured by the Constitution."<sup>42</sup>

## 2. Extending *Jacobson* to Compulsory Water Fluoridation: The Rational Basis Test

Although limited in scope by its own "pressure of great dangers" language, *Jacobson's* rationale has been used to justify a wide range of public health measures that do not involve great dangers requiring individual sacrifices for the common good, including compulsory water fluoridation. For example, in the 1954 case of *Kraus v. City of Cleveland*, the court held that it was bound by the rationale of *Jacobson* in its review of a compulsory water fluoridation scheme challenged on Constitutional grounds.<sup>43</sup> In justifying its decision to uphold the challenged scheme, the *Kraus* court stated that under *Jacobson*, the court could only interfere with a legislative public health decision if the law either failed to bear a real or substantial relation to the state's asserted public health objectives, or if the law was *beyond all question* a plain and probable invasion of rights secured by fundamental law.<sup>44</sup> Interestingly, although the court emphasized *Jacobson's* interference with fundamental rights language, the *Kraus* court in fact only considered whether the fluoridation ordinances were rationally related to the state's stated objective of preventing dental caries in children.<sup>45</sup> It avoided entirely *Jacobson's* mandate to consider any fundamental rights that might have been invaded by the compulsory public health measure.

Several months after *Kraus*, the Supreme Court of Washington in *Kaul v. City of Chehalis* also considered *Jacobson's* relevance to compulsory water fluoridation laws.<sup>46</sup> In this case, the Court rejected any

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<sup>41</sup> *Id.* at 29.

<sup>42</sup> *Id.* at 30–31.

<sup>43</sup> 121 N.E. 2d 311, 315 (Ohio Ct. App. 1954).

<sup>44</sup> *Id.* at 314 (citing *Jacobson*, 197 U.S. 11, 31 (1905)).

<sup>45</sup> *Id.* at 315.

<sup>46</sup> 277 P.2d 352, 356–57 (Wash. 1954).

possibility that *Jacobson* might reasonably limit a state's ability to enact compulsory public health laws affecting an individual's bodily integrity in the absence of the pressure of great danger. Instead, noting that the relevant city statute did not restrict the city to preventing only the spread of "contagious" diseases, the *Kaul* court stated that it was also unwilling to place such a police power limitation upon the city.<sup>47</sup> The *Kaul* court then summarily rejected any fundamental rights argument by claiming that the plaintiff-appellant was not being compelled to do anything—he was not subject to a penalty, and presumably he was free to move away from the affected water district or purchase non-fluoridated water elsewhere.<sup>48</sup>

Three justices vigorously dissented in *Kaul*. In the first dissent, Justice Hill indicated that the majority failed to conduct the appropriate Constitutional analysis under *Jacobson*.<sup>49</sup> Under the *Jacobson* test, a public health law that invades an individual's bodily liberty must be either: (1) essential to the equal enjoyment of the same right by others, or (2) justified under the pressure of great dangers.<sup>50</sup> Justice Hill found that compulsory water fluoridation was not justified under either prong, and that extending compulsory public health laws affecting bodily liberty beyond contagious and infectious diseases would "open the door to compulsory mass medication or preventative treatment for any disease, solely on the ground that it is for the individual's own good, without regard to his inherent right to determine such matters for himself."<sup>51</sup> Justice Hill also found fault with the majority's assertion that public water fluoridation did not compel anyone to do anything. To Justice Hill, public water fluoridation was effectively compulsory to anyone who relied upon the public water supply, and the liberty right deprived by compulsory fluoridation was the right to decide of one's free will whether to medicate with fluoride or not.<sup>52</sup> Justice Hill concluded that, rather than being a settled issue, compulsory water fluoridation was a subject "on which there is marked and bitter divergence of opinion within the dental and medical professions."<sup>53</sup>

Both the *Kraus* and *Kaul* decisions have been followed by numerous courts upholding compulsory water fluoridation schemes using only rational basis scrutiny. Like these early decisions, each of these later

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<sup>47</sup> *Id.* at 356.

<sup>48</sup> *Id.* at 355.

<sup>49</sup> *Id.* at 359.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 360.

<sup>52</sup> 277 P.2d at 361.

<sup>53</sup> *Id.* at 358.

courts has ignored *Jacobson's* clear distinction between measures that are justified under the pressure of great danger, and those that are not. They have also rejected any meaningful fundamental rights analysis, often by adopting *Kaul's* fiction that individuals in fluoridated water districts are not being compelled to do anything, because compulsory fluoride stops at the tap.<sup>54</sup>

### 3. Brainerd's Balancing Test

The *Kraus* and *Kaul* decisions paved the way for numerous courts to avoid any meaningful scrutiny of compulsory fluoridation laws by applying the rational basis test.<sup>55</sup> However, in 1976, the Minnesota Supreme Court in *Minnesota State Bd. of Health vs. City of Brainerd* properly recognized that compulsory water fluoridation did invade a fundamental right—the right to determine what one will or will not ingest into one's body.<sup>56</sup> In *Brainerd*, the court had to determine whether the city of Brainerd could refuse the State Board of Health's directive to begin fluoridating the city's waters in light of a special referendum, which resulted in a public vote of 1863 to 199 against fluoridation.<sup>57</sup> After first determining that the city had standing to object to the fluoridation directive, the Court held that the city was not entitled to refuse to comply with it. However, rather than applying the rational basis test, the court acknowledged that a fundamental right was indeed involved: the right of personal privacy, which the

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<sup>54</sup> See, e.g., *Rogowski v. City of Detroit*, 132 N.W.2d 16, 24 (Mich. 1965) (“it is true the smallpox disease involved in that case is infectious or contagious while dental caries is not. Plaintiffs cite no cases to the effect that element is essential to the power of the State to protect or improve public health”); *Coshow v. City of Escondido*, 34 Cal. Rptr. 3d 19, 31 (Cal. Ct. App. 2005) (“City’s use of [hydrofluorosilicic acid] to fluoridate its drinking water does not force Coshow to do anything. Fluoridation occurs before it enters each household and stops with the water faucet”); *Quiles v. City of Boynton Beach*, 802 So.2d 397, 399 (Fla. Dist. Ct. App. 2001) (“The city proposes to fluoridate the water before it enters each household in the city; it is not seeking to introduce the mineral directly into Quiles bloodstream . . . His freedom to choose remains intact”); *Espronceda v. City of San Antonio*, No. 04-02-00561-CV, 2003 WL 21203878 at \*4 (Tex. App. May 22, 2003) (relying upon *Quiles*); *Pure Water Comm. of W. Md., Inc. v. Mayor & City Council*, No. Civ. JFM-01-2611, 2003 WL 22095654, at \*3 (D. Md. Sept. 4, 2003) (“Plaintiffs still have the choice to avoid drinking the fluoridated water . . . accordingly, plaintiffs have failed to show that they will suffer an invasion of a legally protected interest that impacts specifically upon them in a concrete manner”). Recent courts have also suggested that there is no fundamental right involved because individuals do not have a “fundamental” right to clean air or water. See, e.g., *Coshow*, 34 Cal. Rptr. 3d. at 31.

<sup>55</sup> See generally Balog, *supra* note 8.

<sup>56</sup> *Minn. State Bd. of Health v. City of Brainerd*, 241 N.W.2d 624, 631 (Minn. 1976).

<sup>57</sup> *Id.* at 626.

court agreed could also extend to protect an individual's bodily integrity.<sup>58</sup> The Court reasoned, however, that this right to bodily integrity was not "absolute," and needed to be balanced against: (1) the importance of the state's purpose for requiring fluoridation, (2) the nature and magnitude of the effect of forced fluoridation on the individual, (3) whether the state's purpose justified the intrusion of forced fluoridation, and (4) whether the means adopted by the state were proper and reasonable.<sup>59</sup>

Applying these factors to the fluoridation directive, the Court found that the state's interest in protecting against childhood tooth decay outweighed the individual's right to bodily integrity. Importantly, in reaching its decision, the court assumed that the clear weight of scientific authority suggested that fluoridation was safe and effective in preventing tooth decay in children, and that any harms caused by fluoride consumption were "negligible."<sup>60</sup> Under these assumptions, the Court found that compulsory water fluoridation was a justifiable intrusion into an individual's bodily integrity.<sup>61</sup> "While forced fluoridation does, to a limited extent, infringe on an individual's freedom to decide whether he will or will not ingest fluoride, such an infringement, *absent any significant adverse consequences to the individual*, cannot be accorded substantial weight."<sup>62</sup>

Justice Yetka dissented, stating that the majority had failed to conduct the final part of the heightened scrutiny balancing test: ensuring that the state's intrusion was reasonable and least intrusive in light of the alternative means available.<sup>63</sup> In this case, because an overwhelming majority of voting citizens had voted against compulsory water fluoridation, Justice Yetka believed that the state's intrusion was neither reasonable nor the least intrusive method to provide the alleged public health benefit. Other methods, such as providing fluorine tablets or dental application of fluoride to those who wanted it, were far less intrusive than the means chosen, particularly where some evidence suggested that fluoride was a carcinogen. "There must be a point where state action must yield to the asserted rights of the individual," Justice Yetka concluded, "I believe that this point has clearly been reached in this case."<sup>64</sup>

The *Brainerd* case is significant in that it is one of the few water fluoridation cases recognizing that fundamental rights are involved when

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<sup>58</sup> *Id.* at 631.

<sup>59</sup> *Id.* at 632–33.

<sup>60</sup> *Id.* at 632.

<sup>61</sup> *Id.* at 633.

<sup>62</sup> *City of Brainerd*, 241 N.W.2d at 632 (emphasis added).

<sup>63</sup> *Id.* at 634 (Yetka, J. dissenting).

<sup>64</sup> *Id.* at 635 (Yetka, J. dissenting).

compulsory fluoridation schemes are imposed upon citizens, and in applying the appropriate level of judicial scrutiny to determine whether these rights are outweighed by the state's interest in preventing tooth decay. Although the *Brainerd* court in 1976 concluded that compulsory water fluoridation was justified as a public health measure, it did so largely based on assuming that the science supported fluoride's benefits and risks. In light of scientific evidence amassed forty years later, it is likely that any court applying *Brainerd* today would find that individual fundamental rights significantly outweigh any police power interest in treating or preventing tooth decay.

## II. SCIENTIFIC EVIDENCE AGAINST COMPULSORY WATER FLUORIDATION

Fluoridation proponents have historically characterized those opposing or questioning fluoridation as "irrational, fanatical, unscientific and fraudulent," regardless of the legitimate scientific credentials of those opposing fluoridation.<sup>65</sup> However, mounting scientific evidence against fluoridation has begun to persuade an increasing number of scientific researchers and dental and medical professionals, and even some formerly avid fluoride proponents.<sup>66</sup>

While a comprehensive review of all existing and emerging toxicological, clinical and epidemiological studies weighing against fluoridation or urging further research is beyond the purview of this Article, a brief discussion of some current areas of concern follows.

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<sup>65</sup> Hileman, *supra* note 18, at 4. See Graham & Morin, *supra* note 17, at 195 (noting a pro-fluoridation report characterizing fluoride opponents as follows: "The opposition stems from several sources, chiefly food faddists, cultists, chiropractors, misguided and misinformed persons who are ignorant of the scientific facts on the ingestion of water fluorides, and, strange as it may seem, even among a few uninformed physicians and dentists"); see also Leila Barraza et al., *Denialism and Its Adverse Effect on Public Health*, 53 JURIMETRICS J. 307, 307 (calling those who oppose fluoridation "denialists" who "misuse science to advocate positions that contradict the overwhelming weight of existing evidence.").

<sup>66</sup> See, e.g., John Colquhoun, *Why I Changed My Mind About Water Fluoridation*, 41 PERSP. BIOLOGY & MED. 1 (1997); Dr. Hardy Limeback, *Why I Am Now Officially Opposed to Adding Fluoride to Drinking Water*, FLUORIDE ACTION NETWORK (Apr. 2000), <http://fluoridealert.org/articles/limeback/>, archived at <http://perma.cc/HV95-WD5A>; J. William Hirzy, *Dr. William Hirzy, Former Head of EPA's Headquarters Union Recommends Portland Flush Fluoridation Proposal* (Mar. 2013), FLUORIDE ACTION NETWORK, [http://fluoridealert.org/content/hirzy\\_portland/](http://fluoridealert.org/content/hirzy_portland/), archived at <http://perma.cc/C539-EWGH>.

A. *Dental Fluorosis*

Dental fluorosis occurs when children absorb too much fluoride. This excess fluoride causes the biochemical signal to go awry, “thereby creating gaps in the crystalline enamel structure.”<sup>67</sup> When the tooth finally erupts, it is unevenly colored, and may even be pitted and brown.<sup>68</sup>

Although early fluoride proponents claimed that mild dental fluorosis was the only potential, and relatively rare, negative side effect to systemic fluoride exposure, today about 30–40% of American teenagers show visible signs of dental fluorosis, with the rate as high as 70–80% in some fluoridated areas.<sup>69</sup>

Exposure to multiple sources of fluoride beyond fluoridated water supplies may partly explain higher than expected rates of dental fluorosis, the first sign of fluoride toxicity. Indeed, it is nearly impossible today to avoid consuming fluoride even in non-fluoridated areas, since fluoride is now found in fluoridated toothpaste, the pesticide residue on fresh produce, processed food and beverages made with fluoridated water, and many pharmaceuticals.<sup>70</sup> Yet research from the Iowa Fluoride Study, the largest long-running investigation on the effects of fluoride, has indicated that the most important risk factor for dental fluorosis is exposure to fluoridated water.<sup>71</sup> Perhaps for this reason, the American Dental Association now recommends that parents use non-fluoridated water for infant baby formula, while the Institute of Medicine recommends that babies only consume a minuscule 10 micrograms of fluoride daily, a near-impossible feat when babies are fed infant formula reconstituted with fluoridated water—even where levels are within the “optimal” range of 0.7–1 ppm.<sup>72</sup>

Despite the fact that dental fluorosis not only produces unattractive teeth but may also increase the risk of tooth loss, the EPA and other U.S. public health officials downgraded even moderate to severe dental fluorosis from an adverse health effect to a purely cosmetic one.<sup>73</sup> This downgrade

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<sup>67</sup> Fagin, *supra* note 26, at 78.

<sup>68</sup> *Id.*; Hileman, *supra* note 18, at 9.

<sup>69</sup> See EUGENIO D. BELTRAN-AGUILAR ET AL., U.S. DEPT OF HEALTH & HUMAN SERVS., NCHS DATA BRIEF NO. 53, PREVALENCE AND SEVERITY OF DENTAL FLUOROSIS IN THE UNITED STATES, 1999–2004 (2010), *available at* <http://www.cdc.gov/nchs/data/databriefs/db53.pdf>; *see also* Czajka, *supra* note 13, at 125.

<sup>70</sup> BELTRAN-AGUILAR ET AL., *supra* note 69; Peckham, *supra* note 13, at 165.

<sup>71</sup> Fagin, *supra* note 26, at 79 (children exposed to fluoridated water were 50% more likely to have dental fluorosis than children living in non-fluoridated areas).

<sup>72</sup> Peckham, *supra* note 13, at 165–66.

<sup>73</sup> *See* Hileman, *supra* note 18, at 10.

has been largely perceived as a bow to political pressure rather than a legitimate health risk assessment.<sup>74</sup> In any event, “it is widely accepted that dental fluorosis is a manifestation of systemic toxicity,” leading to far more serious health risks than unattractive teeth alone.<sup>75</sup>

*B. Skeletal Fluorosis and Bone Fractures*

Fluoride, of course, is not equipped with a smart GPS, able to provide benefits to teeth while bypassing bone and other organs of the human body.<sup>76</sup> Instead, approximately 93% of ingested fluoride is absorbed into the bloodstream, and while some of it is excreted, roughly 50% is deposited into bone, potentially leading to skeletal fluorosis.<sup>77</sup> Skeletal fluorosis is characterized by painful and limited joint movement, spinal deformities, muscle wasting, and calcification of the ligaments.<sup>78</sup> Numerous studies have already linked skeletal fluorosis to excess fluoride intake, and although health officials had formerly insisted that skeletal fluorosis would not develop unless a person ingested 20 milligrams of fluoride per day for over 10 years, current research now suggests that doses as low as 6 mg/day can cause early stages of the disease, and that skeletal fluorosis can develop even with fluoride levels as low as 0.7 to 1.5 ppm, the range used in many fluoridation schemes throughout the United States.<sup>79</sup> Unfortunately, skeletal fluorosis may go undetected or misdiagnosed because some of the symptoms mimic symptoms of arthritis or other bone diseases, and because many doctors do not know how to diagnose it.<sup>80</sup>

In addition to skeletal fluorosis, epidemiological studies have now also linked high fluoride exposure to an increase in bone fractures, especially in vulnerable populations such as the elderly and diabetics.<sup>81</sup> Related studies have shown that people once given fluoride to “cure” osteoporosis wound up having increased fracture rates.<sup>82</sup>

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<sup>74</sup> *Id.*

<sup>75</sup> Peckham, *supra* note 13, at 166.

<sup>76</sup> Limeback, *supra* note 66 (“[I]t is illogical to assume that tooth enamel is the only tissue affected by low daily doses of fluoride ingestion”); Colquhoun, *supra* note 66 (“Common sense should tell us that if a poison circulating in a child’s body can damage the tooth-forming cells, then other harm also is likely”).

<sup>77</sup> Czajka, *supra* note 13, at 125.

<sup>78</sup> Null, *supra* note 17, at 74.

<sup>79</sup> Czajka, *supra* note 13, at 125.

<sup>80</sup> Null, *supra* note 17, at 74; Hileman, *supra* note 18, at 13.

<sup>81</sup> Fagin, *supra* note 26, at 79.

<sup>82</sup> See Null, *supra* note 17, at 74–75.

C. *Pineal Gland and Endocrine Disruption Studies*

Researchers have now discovered that an even greater amount of fluoride accumulates in the pineal gland than in teeth and bone.<sup>83</sup> The pineal gland is responsible for the synthesis and secretion of the hormone melatonin, which regulates the body's circadian rhythm cycle and puberty in females, and helps to protect the body from cell damage from free radicals.<sup>84</sup> While it is not yet known if fluoride accumulation affects pineal gland function in humans, experiments have already found that fluoride reduced melatonin levels, interfered with sleep-wake cycles, and shortened the time to puberty in animals.<sup>85</sup>

In addition, studies have now shown that fluoride can contribute to hypothyroidism (an underactive thyroid), which is unsurprising since fluoride was once used as a prescription drug to reduce thyroid gland function in patients with hyperthyroidism (an overactive thyroid).<sup>86</sup> The fluoride dose capable of reducing thyroid function is low—just 2 to 5 mg per day over several months. This is well within the range of what individuals living in fluoridated communities are receiving on a regular basis.<sup>87</sup>

D. *Cancer Studies*

Numerous studies have now suggested a link between cancer and fluoride.<sup>88</sup> However, perhaps even more disturbing than evidence

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<sup>83</sup> Jennifer Luke, *Fluoride Deposition in the Aged Human Pineal Gland*, 35 *CARIES RES.* 125–128 (2001); see also Czajka, *supra* note 13, at 126.

<sup>84</sup> Jennifer Luke, *The Effect of Fluoride on the Physiology of the Pineal Gland* (1997) (Ph.D. Thesis, University of Surrey, Guildford), available at <http://epubs.surrey.ac.uk/895/1/fulltext.pdf>.

<sup>85</sup> *Id.* See also *Pineal Gland*, FLUORIDE ACTION NETWORK, <http://www.fluoridealert.org/issues/health/pineal-gland/> (last visited Nov. 13, 2014), archived at <http://perma.cc/93-93CV>.

<sup>86</sup> *Thyroid*, FLUORIDE ACTION NETWORK, <http://www.fluoridealert.org/issues/health/thyroid/> (last visited Nov. 13, 2014), archived at <http://perma.cc/EP78-GF9E> (discussing numerous thyroid studies).

<sup>87</sup> Null, *supra* note 17, at 71; see also Pierre M. Galletti & Gustave Joyet, *Effect of Fluorine on Thyroidal Iodine Metabolism in Hyperthyroidism*, 18 *J. CLINICAL ENDOCRINOLOGY* 1102–10 (1958); *Endocrine*, FLUORIDE ACTION NETWORK, <http://www.fluoridealert.org/issues/health/endocrine/> (last visited Nov. 13, 2014), archived at <http://perma.cc/L664-U753> (listing numerous endocrine system studies).

<sup>88</sup> See Kathleen M. Thiessen, Comments on the Fluoridation of Drinking Water for Prevention of Dental Caries 8-9 (Sept. 10, 2013) (on file with author) (listing numerous carcinogenicity studies); *Cancer*, FLUORIDE ACTION NETWORK, <http://fluoridealert.org/issues/health/cancer/> (last visited Nov. 13, 2014), archived at <http://perma.cc/ED8Z-7BDV> (listing numerous cancer studies).



supporting the fluoride-cancer link is evidence suggesting that political and other agendas have played a large part in the outright suppression of this evidence.<sup>89</sup>

First, in the early 1950s Dr. Alfred Taylor, a biochemist at the University of Texas, conducted a series of experiments in which cancer-prone mice consuming water treated with sodium fluoride were found to have shorter lifespans than cancer-prone mice drinking non-fluoridated water.<sup>90</sup> After discovering that his first round of tests had been contaminated because both groups of mice had eaten food containing fluoride, Dr. Taylor repeated the experiment and found the same results—a shorter life span for the mice drinking the fluoridated water. However, because these damaging results appeared around the launch time of the early fluoridation schemes and because public health officials had already come out in staunch support of fluoridation, Dr. Taylor’s work was misrepresented. Specifically, fluoridation proponents falsely claimed that Dr. Taylor had never conducted the second study revealing that the fluoride-cancer link was still present when the necessary controls were put in place.<sup>91</sup>

Then, in 1990, a study conducted by the U.S. government’s National Toxicology Program (“NTP”) found a positive relation for osteosarcoma (bone cancer) in male rats exposed to different amounts of fluoride in drinking water.<sup>92</sup> When NTP downplayed the results in order to avoid a public outcry over compulsory fluoridation, a storm of controversy erupted, with a number of scientists outraged at the failure to report the cancer-linked results accurately.<sup>93</sup>

Finally, in 2006, Elise Bassin and her colleagues at the Harvard School of Dental Medicine published a study in the peer-reviewed journal *Cancer Causes and Control*, which also showed a link between fluoridation and osteosarcoma in young men.<sup>94</sup> Incredibly, Bassin’s own dissertation

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<sup>89</sup> See Null, *supra* note 17, at 77; Graham & Morin, *supra* note 17, at 229–40.

<sup>90</sup> Null, *supra* note 17, at 77.

<sup>91</sup> *Id.*

<sup>92</sup> *NTP Toxicology and Carcinogenesis Studies of Sodium Fluoride in F344/N Rats and B6C3F1 Mice (Drinking Water Studies)*, 393 NATL. TOXICOL. PROGRAM TECH REP SERV. 1, 42-5, 71-3 (1990).

<sup>93</sup> Null, *supra* note 17, at 78–79.

<sup>94</sup> E. B. Bassin et al., *Age Specific Fluoride Exposure in Drinking Water and Osteosarcoma*, 17 *CANCER CAUSES & CONTROL* 421–28 (2006) (finding an association between fluoride exposure in drinking water during childhood and the incidence of osteosarcoma among males but not consistently among females); see also S Kharb et al., *Fluoride Levels and Osteosarcoma*, 1 *S. ASIAN J. CANCER* 76–77 (2012) (finding positive correlation between fluoride and osteosarcoma).

advisor at Harvard, Chester Douglass, wrote a commentary in the same journal warning readers to be “especially cautious” about Bassin’s results. This led to yet another controversy, with Bassin’s defenders calling for an ethical investigation of Douglass, since, as it turned out, Douglass had some conflicts of interest and was the editor in chief of a newsletter for dentists funded by Colgate.<sup>95</sup>

*E. Lower IQs in Children*

Researchers have also begun to focus on the damaging effects fluorides appear to have on the human brain. In the 1990s, researcher Phyllis Mullenix studied the brain and behavioral effects of sodium fluoride on rats.<sup>96</sup> Her study revealed that pre-natal exposure to fluoride correlated with hyperactivity in young rats, while post-natal exposures often had the opposite, “couch potato” effect.<sup>97</sup> Although Mullenix’s research was published in a well-respected peer reviewed journal, fluoride proponents attacked her methodology and declared her results flawed.<sup>98</sup> Since then, however, forty-six other studies have emerged showing a connection between excess exposure to fluoride and lowered IQs in children, with thirty-nine of the forty-six finding that elevated fluoride exposure is associated with decreased IQ, and twenty-nine of thirty-one animal studies showing that fluoride exposure impairs the learning and/or memory capacity of animals.<sup>99</sup>

In March of 2012, after conducting a meta-analysis of twenty-seven fluoride-human IQ studies conducted mostly in China, a team of scientists at Harvard concluded that these studies suggest an average IQ decrease of about seven points in children exposed to raised fluoride concentrations.<sup>100</sup> In 2014, one of the chief authors of the initial 2012 meta-analysis, Harvard

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<sup>95</sup> Fagin, *supra* note 26, at 80.

<sup>96</sup> Phyllis J. Mullenix, *Neurotoxicity of Sodium Fluoride in Rats*, 17 NEUROTOXICOLOGY & TERATOLOGY 169, 169–77 (1995).

<sup>97</sup> Fagin, *supra* note 26, at 80; *see also* Null, *supra* note 17, at 74 (describing an ad campaign promoting a fluoridated spring water “for kids who can’t sit still”).

<sup>98</sup> Fagin, *supra* note 26, at 80.

<sup>99</sup> Thiessen, *supra* note 88, at 11 (listing neurotoxicity studies); *Brain*, FLUORIDE ACTION NETWORK, <http://fluoridealert.org/issues/health/brain/> (last visited Nov. 13, 2014), *archived at* <http://perma.cc/98X7-KMPA> (listing neurological studies).

<sup>100</sup> *See* Anna L. Choi et al., *Developmental Fluoride Neurotoxicity: A Systematic Review and Meta-Analysis*, 120 ENVTL. HEALTH PERSP. 1362-68 (2012); *see also* Anna L. Choi, Correspondence, *Developmental Fluoride Neurotoxicity: Choi et al. Respond*, 121 ENVTL. HEALTH PERSP. A70 (2013) (noting that “[a] shift to the left of IQ distributions in a population will have substantial impacts, especially among those in the high and low ranges of the IQ distribution.”).

professor Philippe Grandjean, concluded in a follow-up article that “our very great concern is that children worldwide are being exposed to unrecognized toxic chemicals that are silently eroding intelligence,” and that fluoride’s effect on the young brain should now be a “high research priority.”<sup>101</sup> Notably, a majority of the twenty-seven studies analyzed were of water fluoride levels of less than 4 mg/L, which falls under the allowable concentrations of fluoride under current EPA regulations.<sup>102</sup>

*F. Benefits from Systemic Fluoride Intake?*

With so many current studies linking fluoride to serious health risks beyond dental fluorosis, the question remains whether fluoride’s public health benefits outweigh any and all of these risks. The Centers for Disease Control has deemed water fluoridation one of the “ten great public health achievements in the 20th Century.”<sup>103</sup> Proponents therefore insist that even if there are a number of recognized risks of fluoridation, there has been enough evidence to show that these risks are remote and are far outweighed by the benefits.<sup>104</sup> Yet much of the available scientific data today suggests that any benefit from fluoride in terms of preventing tooth decay derives from topical application, rather than systemic ingestion.<sup>105</sup> Moreover, even the benefits of topical fluoride treatments have been recently questioned, since most dental caries today are in the “pits and fissures” of the molars rather than on the flat surface of teeth, and various studies have now indicated that fluoride has no impact on pits and fissures.<sup>106</sup>

Research conducted over the last twenty years has also shown that the estimated reduction in tooth decay due to compulsory water fluoridation has been grossly exaggerated. While at one time proponents boasted

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<sup>101</sup> Philippe Grandjean & Philip Landrigan, *Neurobehavioural Effects of Developmental Toxicity*, 13 LANCET NEUROLOGY 330–38 (2014) (“[U]ntested chemicals should not be presumed to be safe to brain development, and chemicals in existing use and all new chemicals must therefore be tested for developmental neurotoxicity”); see Diana Rocha-Amador et al., *Disminución de la inteligencia en niños y exposición al flúor y arsénico en el agua potable [Decreased Intelligence in Children and Exposure to Fluoride and Arsenic in Drinking Water]*, 23 CADERNOS DE SAUDE PUBLICA S579, S579-87 (2007) (Braz.), available at <http://www.scielo.br/pdf/csp/v23s4/10.pdf>.

<sup>102</sup> See discussion *infra* Part III.

<sup>103</sup> CDC, *Fluoridation*, *supra* note 18.

<sup>104</sup> Hileman, *supra* note 18, at 2.

<sup>105</sup> See Czajka, *supra* note 13, at 127; Thiessen, *supra* note 88, at 2.

<sup>106</sup> See, e.g., Dinah H. Kitchens, *The Economics of Pit and Fissure Sealants in Preventative Dentistry: A Review*, 6 J. CONTEMP. DENTAL PRAC. 1, 3 (2005).

a 50–65% reduction in tooth decay, a great deal of current evidence suggests the real percentage is significantly lower, with some studies showing no measurable reduction at all.<sup>107</sup> Confounding claims of benefit even further, numerous studies have shown a substantially similar decline in the dental caries rate in countries that do not fluoridate, and in areas within the United States that remain unfluoridated.<sup>108</sup>

Nor have the asserted economic benefits of compulsory water fluoridation come to fruition. In fact, a number of economic evaluation studies have indicated that the costs of dental care may actually be higher in fluoridated communities than in non-fluoridated communities.<sup>109</sup>

Unfortunately, rather than considering new data objectively, public health officials and dental lobbies spearheading fluoridation schemes often ignore, reject, or suppress the evidence that does not toe the pro-fluoride party line.<sup>110</sup> Nevertheless, as evidence against fluoride ingestion continues to accumulate in a variety of health risk areas, two conclusions seem readily apparent. First, there remain significant unanswered questions about the risks and benefits of systemic fluoride, and further research before imposing or continuing fluoridation schemes seems not only scientifically prudent, but ethically necessary. Second, it is no longer acceptable for public health officials to simply dismiss the accruing negative data and to continue to insist that the levels of fluoride children and adults are receiving on a daily basis are without any serious health consequences. Fortunately, tentative moves by the EPA and other federal agencies suggest that at least some public health authorities are inching towards similar conclusions.

### III. EPA'S REGULATION OF FLUORIDE IN PUBLIC WATER SUPPLIES

The states and local governments alone have the power to mandate public water fluoridation.<sup>111</sup> Nevertheless, the federal Safe Drinking

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<sup>107</sup> Hileman, *supra* note 18, at 7.

<sup>108</sup> Hileman, *supra* note 18, at 6–7; *see also* K.K. Cheng et al., *Adding Fluoride to Water Supplies*, 335 BRIT. MED. J. 699, 700 (2007); C. Neurath, *Tooth Decay Trends for 12 Year Olds in Nonfluoridated and Fluoridated Countries*, 38 FLUORIDE 324-35 (2005); John A. Yiamouyiannis, *Water Fluoridation and Tooth Decay: Results from the 1986–1987 National Survey of U.S. Schoolchildren*, 23 FLUORIDE 55–56 (1990).

<sup>109</sup> Hileman, *supra* note 18, at 11.

<sup>110</sup> *See, e.g., Voices of Opposition Have Been Suppressed Since Early Days of Fluoridation*, CHEMICAL & ENGINEERING NEWS, Aug. 1, 1988, available at [http://www.nofluoride.com/CEN\\_Voices\\_of\\_opposition.cfm](http://www.nofluoride.com/CEN_Voices_of_opposition.cfm), archived at <http://perma.cc/6T59-AA9T>.

<sup>111</sup> CRS REPORT, *supra* note 4, at 1.

Water Act (“SDWA”) requires EPA to promulgate national primary drinking water regulations for contaminants that may pose health risks and that are likely to be present in public water supplies.<sup>112</sup> Fluoride is among the contaminants to be regulated.<sup>113</sup>

For each contaminant that EPA regulates, EPA sets a non-enforceable maximum contaminant level goal (“MCLG”) at a level at which no known or anticipated adverse health effects occur and that allows for an adequate margin of safety.<sup>114</sup> Using the MCLG as a starting point, EPA then sets an enforceable standard, the maximum contaminant level (“MCL”). The MCL must be set as close to the MCLG as feasible, taking costs into consideration.<sup>115</sup> EPA also may issue secondary MCLs (“SMCLs”) that establish non-mandatory water quality standards for substances. These SMCLs presumably serve as “guidelines” to help public water systems manage drinking water for aesthetic, cosmetic, and technical effects.<sup>116</sup> Thus, although EPA is not responsible for water fluoridation, by allowing fluoride into the public water supply as a regulated contaminant, EPA dictates the maximum amounts of fluoride a water provider can have in the water supply before it can be held liable for public harms. The SDWA requires the EPA to “review and revise, as appropriate, each drinking water regulation at least every six years.”<sup>117</sup> Any revision promulgated “must maintain or provide for greater protection of human health.”<sup>118</sup>

A. *EPA’s Controversial Current Maximum Contaminant Levels of Fluoride*

In 1986, EPA issued the current national primary drinking water regulation for fluoride.<sup>119</sup> This regulation included an MCLG and an MCL for fluoride of 4 mg/L, which was intended to protect against fluoride’s effects on bones.<sup>120</sup> This new 4 mg/L standard was highly controversial however, as it replaced a stricter interim standard of 1.4 to 2.4 mg/L established in 1975 to protect against moderate dental fluorosis, which

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<sup>112</sup> 42 U.S.C. §§ 300f–j-26 (1996).

<sup>113</sup> CRS REPORT, *supra* note 4, at 11.

<sup>114</sup> *Id.* at 11–12.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 13.

<sup>118</sup> *Id.*

<sup>119</sup> CRS REPORT, *supra* note 4, at 12.

<sup>120</sup> *Id.*

EPA had previously considered an adverse health effect.<sup>121</sup> The EPA then issued a non-binding SMCL of 2 mg/L, in acknowledgement that 4 mg/L would likely cause dental fluorosis in many children, and further required public water systems exceeding this amount to notify customers that alternative sources of water should be used for infants and children.<sup>122</sup> However, the effectiveness of this notification system was severely undermined because the regulations allow providers twelve months to notify customers when this SMCL is exceeded.<sup>123</sup>

Not surprisingly, many fluoride opponents saw the EPA's decision to increase the allowable MCL of fluoride to 4 mg/L in 1986 as a political decision not in the best interests of public health.<sup>124</sup> Perhaps what was more surprising was that inside the agency itself, many EPA scientists agreed. In a document entitled *Why EPA Headquarters Union of Scientists Opposes Fluoridation*, prepared by Dr. William Hirzy, Senior Vice President of Chapter 280 of the National Treasury Employees Union ("NTEU Union"), a union representing the over 1,500 scientists employed at EPA Headquarters in Washington D.C., Dr. Hirzy explained why the NTEU Union was coming out publicly against water fluoridation.<sup>125</sup> Dr. Hirzy revealed that the NTEU Union had become aware that the EPA was under some political pressure to raise the fluoride contaminant levels to 4 mg/L, despite the fact that the EPA knew that a significant number of children would develop moderate to severe dental fluorosis at that level.<sup>126</sup> To get around this potentially damaging public relations issue, the EPA had pressured some of its scientists to re-characterize dental fluorosis as a 'cosmetic' rather than an 'adverse health' effect.<sup>127</sup> The NTEU Union protested internally, but after realizing that the EPA was either "unable or unwilling to resist external political pressure," the NTEU Union went

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<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> See OFFICE OF WATER, U.S. ENVTL. PROT. AGENCY, EPA 815-F-11-001, QUESTIONS AND ANSWERS ON FLUORIDE 3 (2011), available at [http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/sixyearreview/upload/2011\\_Fluoride\\_QuestionsAnswers.pdf](http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/sixyearreview/upload/2011_Fluoride_QuestionsAnswers.pdf).

<sup>124</sup> See *Fluoride, Politics, and the EPA* (WCAV-TV Channel 7 television broadcast 1986), available at <http://fluoridealert.org/fan-tv/epa-politics/>, archived at <http://perma.cc/3LAD-M3ED>.

<sup>125</sup> See J. William Hirzy, *Why EPA Headquarters Union of Scientists Opposes Fluoridation*, NAT'L TREASURY EMPLOYEES UNION CHAPTER 280, <http://www.nteu280.org/Issues/Fluoride/NTEU280-Fluoride.htm> (last visited Nov. 13, 2014), archived at <http://perm.cc/VD6U-WBHS>.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

public with its opposition to fluoridation.<sup>128</sup> Citing the preponderance of scientific literature documenting increasing over-exposure to fluoride, the lack of benefit to dental health, and the hazards to human health from fluoride ingestion, the NTEU Union concluded that it was “irresponsible at best” to continue fluoridation in light of the evidence.<sup>129</sup> NTEU Union then called for “an immediate halt to the use of the nation’s drinking water reservoirs as disposal sites for the toxic waste of the phosphate fertilizer industry.”<sup>130</sup>

The EPA, along with the American Dental Association, tried to minimize the NTEU Union’s defection from official policy by suggesting that the NTEU Union did not represent the scientists involved in fluoride risk assessment and that attendance at the NTEU Union’s unanimous vote against fluoridation was minimal. The NTEU Union promptly filed a grievance demanding that the EPA correct these misstatements.<sup>131</sup>

Although the EPA managed to keep the general public from fully comprehending the significance of its internal fluoride battle, in 2002, the EPA could no longer ignore the data weighing against its own MCLs and SMCLs for fluoride, and it enlisted the help of the NRC.<sup>132</sup>

### B. *The NRC Report*

In 2002, in response to additional scientific, clinical, and epidemiological data suggesting fluoride’s damaging effects on the skeletal system, the EPA asked the NRC to conduct a review of fluoride data.<sup>133</sup> Although it was not specifically charged with considering the risks and benefits of water fluoridation itself, the NRC was asked to review toxicological, epidemiological, and clinical data on fluoride, as well as exposure data on ingested fluoride, and to advise the EPA on the adequacy of its MCLG to protect children and others from adverse effects.<sup>134</sup> The NRC took the next four years to do so, focusing on data that had become available since its last 1993 report.<sup>135</sup>

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<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> See Memorandum from J. William Hirzy, Senior Vice President, Nat’l Treasury Emp. Union Chapter 280, to Cynthia C. Dougherty, Dir., Office of Ground Water & Drinking Water (Aug. 7, 1998), available at <http://fluoridation.com/epa.htm>, archived at <http://perma.cc/VAB9-JNZA>.

<sup>132</sup> CRS REPORT, *supra* note 4, at 13–14.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 14.

<sup>135</sup> *Id.*

In March of 2006, the NRC issued its final report, entitled: *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* ("NRC Report").<sup>136</sup> The NRC Report considered voluminous data assessing fluoride's effects on dental fluorosis, skeletal fluorosis, bone fractures, carcinogenicity, endocrine effects, gastrointestinal effects, and effects on the liver, kidney, and immune system.<sup>137</sup> Significantly, in a number of these areas, the NRC Report concluded that a fluoride level of 4 mg/L (EPA's current MCL) or even 2 mg/L (EPA's current SMCL) showed increased risks of bodily harm, while in other health impact areas it determined that more research was needed to make a definitive assessment.<sup>138</sup> Ultimately, the NRC Report advised the EPA that its MCLG of 4 mg/L should be lowered, and that significant gaps in research prevented the NRC committee from making some judgments about the safety or the risks of fluoride at concentrations of 2 to 4 mg/L.<sup>139</sup>

Despite the NRC's recommendation to lower MCL and SMCL levels, it took the EPA four more years to take any discernable action. In December of 2010, the EPA announced that it intended to review all new fluoride risk assessments and relative source assessment documents to determine whether the revisions to the MCLG, the MCL, or the SMCL would be appropriate.<sup>140</sup> The EPA indicated that it could take several years to complete its final assessment.

As of the date of this Article, the EPA has issued no further announcements about its intention to revise the MCL or SMCL for fluoride in the public drinking supply. Nevertheless, following the EPA's announcement that it would reassess fluoride levels in the public water supply, the DHHS issued a recommendation that water districts should consider lowering their allowable fluoride levels to 0.7 ppm, the lowest level in the range originally recommended by DHHS.<sup>141</sup> DHHS's recommendation sprung from belated acknowledgement that the public was now exposed to numerous sources of fluoride beyond the public water

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<sup>136</sup> COMM. ON FLUORIDE IN DRINKING WATER, NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., *FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA'S STANDARDS* (Nat'l Acad. Press 2006).

<sup>137</sup> CRS REPORT, *supra* note 4, at 14.

<sup>138</sup> *Id.* at 14–16.

<sup>139</sup> *Id.* at 14.

<sup>140</sup> *Id.* at 17.

<sup>141</sup> See Sandra Young, *Government Recommends Lowering Fluoride Levels in U.S. Drinking Water*, CNN HEALTH (Jan. 7, 2011), <http://www.cnn.com/2011/HEALTH/01/07/fluoride.recommendations/index.html>, archived at <http://perma.cc/8AEY-PM7U>.



supply, making the potential for overexposure, particularly in fluoridated areas, more likely.<sup>142</sup>

Federal agency willingness to reassess appropriate levels of fluoride in the nation's drinking water suggests at least some recognition that the current levels are not protective of human health. Yet an immediate halt to compulsory water fluoridation seems unlikely. As one EPA scientist surmised, the EPA and other public health agencies long in support of water fluoridation are "riding a tiger that they can't get off."<sup>143</sup>

Still, the NRC Report's major findings and federal agency response to its findings suggest, at minimum, public health recognition that further study is necessary. As Dr. John Doull, professor emeritus of pharmacology and toxicology at the University of Kansas Medical Center and chair of the NRC Committee concluded:

What the committee found is that we've gone with the status quo regarding fluoride for many years—for too long, really—and now we need to take a fresh look. In the scientific community, people tend to think it is settled. I mean, when the U.S. surgeon general comes out and says this is one of the 10 greatest achievements of the 20th century, that's a hard hurdle to get over. But when we looked at the studies that have been done, we find that many of these questions are unsettled and we have much less information than we should, considering how long [fluoridation] has been going on. I think that's why fluoridation is still being challenged so many years after it began. In the face of ignorance, controversy is rampant.<sup>144</sup>

Merely acknowledging the need for further study is unlikely to satisfy long-time fluoridation opponents, however. Instead, they might reasonably argue that the gap in knowledge about fluoridation's safety and benefits suggests that a full reassessment of the sixty-year-old practice of compulsory water fluoridation as a justifiable public health benefit is long overdue.

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<sup>142</sup> *Id.*

<sup>143</sup> See Dr. William Hirzy & EPA Union on Fluoridation, FLUORIDE ACTION NETWORK, <http://fluoridealert.org/fan-tv/hirzy/> (last visited Nov. 13, 2014), archived at <http://perma.cc/JL7V-PDE4>.

<sup>144</sup> See Fagin, *supra* note 26, at 81.

IV. IS COMPULSORY WATER FLUORIDATION A JUSTIFIABLE PUBLIC HEALTH MEASURE OR RESEARCH ON HUMAN SUBJECTS?

Although various definitions of what “public health” is or should be have been proposed, one of the most commonly accepted definitions comes from the Institute of Medicine: “[p]ublic health is what we, as a society, do collectively to assure the conditions for people to be healthy.”<sup>145</sup> Public health measures accomplished by regulation assume that individuals acting alone cannot ensure the health of society, and therefore that some measure of governmental intervention is required to assure the cooperation of the population to address an identified health risk.<sup>146</sup>

Undoubtedly, certain public health measures have been instrumental in helping to create conditions for people to live healthier lives.<sup>147</sup> They have, for example, helped to stem mass outbreaks of contagious disease, improved general sanitation, and provided consumers with more informed food choices through mandatory labeling laws.<sup>148</sup> At the same time, public health measures are sometimes only accomplished through coercive and even unpopular regulations that infringe on fundamental individual privacy and liberty interests.<sup>149</sup> This in turn requires a balancing of public and individual interests.<sup>150</sup> Not surprisingly, the proper level of governmental intervention to achieve any asserted public health benefit has been the subject of much debate.<sup>151</sup> Some public health scholars and practitioners advocate for broad coercive governmental actions to address a wide swath of societal issues potentially affecting population health.<sup>152</sup> Others favor a much more limited definition of public health, arguing that coercive governmental intervention is only justified where there is a genuine threat to the public at large, and where the government is best positioned to respond to that particular threat.<sup>153</sup>

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<sup>145</sup> See Rothstein, *supra* note 10, at 145.

<sup>146</sup> *Id.*

<sup>147</sup> See Lawrence O. Gostin, *Public Health Law in a New Century Part I: Law as a Tool to Advance the Community's Health*, 283 JAMA 2837, 2838 (2000) [hereinafter Gostin, *Part I*].

<sup>148</sup> *Id.*

<sup>149</sup> *Id.* at 2837, 2840–41.

<sup>150</sup> *Id.* at 2839–40.

<sup>151</sup> See Rothstein, *supra* note 10, at 144; see also Marcel Verweij & Angus Dawson, *The Meaning of 'Public' in Public Health*, in ETHICS, PREVENTION & PUBLIC HEALTH 13–29 (Clarendon Press 2007) (providing background information for the various ways public health is defined).

<sup>152</sup> Rothstein, *supra* note 10, at 144.

<sup>153</sup> *Id.* at 146 (“Without a threat to the public, it is much more difficult to make a case for

The appropriateness of some existing public health measures is also subject to debate. Measures that were once enacted to address a perceived public health threat may now “reflect outdated scientific understandings of disease, public health interventions, or legal norms for protection of individual rights.”<sup>154</sup> Certainly there is a continuing need to reassess and justify existing public health measures to determine their current legal, ethical, and scientific legitimacy.<sup>155</sup> Otherwise, outdated measures that intrude on individual liberty and persist despite scientific advances undermining the measure’s legitimacy would veer dangerously close to experimentation on human subjects.

A. *Compulsory Water Fluoridation as Justifiable Public Health Benefit*

In his three-part article, *Public Health Law in a New Century*, Lawrence Gostin posits that there are three types of justifications for coercive public health laws: (1) laws that are justified on the basis of preventing an individual from harming others (such as quarantine or vaccines addressing contagious diseases), (2) laws that are justified on the basis of protecting incompetent persons (such as mental health institutionalization), and (3) laws justified on the basis of protecting the individual against himself (such as mandatory motorcycle helmet laws, gambling prohibitions, and compulsory water fluoridation).<sup>156</sup> Gostin acknowledges that laws justified on the basis of protecting the individual against himself are the most controversial because such laws seek to affect an individual whose actions are not affecting or diminishing the health or well-being of others.<sup>157</sup> While such laws are often upheld by the courts and justified on the basis of presumed aggregated societal health or economic consequences, in truth such laws are paternalistic and should instead be evaluated on the basis of whether the paternalism is justified.<sup>158</sup> To justify paternalistic public health measures, Gostin suggests that public health officials should be able to demonstrate: (1) a significant risk to public health based on objective scientific methods; (2) the intervention’s effectiveness by showing a reasonable fit between means and ends;

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the use of coercive powers; in the absence of such legal authority, the participation of individuals in health-enhancing activities ordinarily must be voluntary.”).

<sup>154</sup> See Hodge et al., *supra* note 10, at 79.

<sup>155</sup> See Rothstein, *supra* note 10, at 144; see also Hodge et al., *supra* note 10, at 79.

<sup>156</sup> See Gostin, *Part III*, *supra* note 11, at 3118.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* at 3119–20.

(3) that the economic costs of the public health measure are reasonable when compared to the probable benefits; (4) that human rights burdens are reasonable when compared with the probable benefits; and (5) that benefits, costs, and burdens are fairly distributed so that services are provided only where needed and regulatory burdens are imposed only where a risk to community health exists.<sup>159</sup> This Article suggests that under this approach, compulsory water fluoridation is an outdated measure no longer justifiable as a public health benefit.

1. Significant Risks to Public Health Based on Objective Scientific Methods?

The first factor in Gostin's evaluation system suggests that public health officials demonstrate a significant risk to public health that would necessitate coercive governmental intervention, based on scientific methods. "Science-based risk assessments provide a more secure ground for decision making and avoid reflexive actions based on irrational fears, speculation, stereotypes, or pernicious mythologies."<sup>160</sup> The risk should be shown to be significant rather than speculative or remote, and thus requires an analysis of: (1) the nature of the risk, (2) the duration of the risk, (3) the probability of the harm, and (4) the severity of the harm as part of its overall risk assessment.<sup>161</sup> Any identified risks should then be measured against the proposed measure's human burden and economic costs, as well as against any risks involved in choosing the public health measure itself.<sup>162</sup>

Public health officials have long justified water fluoridation by pointing to the risk of childhood tooth decay.<sup>163</sup> Admittedly, at the time of the initial fluoridation schemes in the 1940s, the rate of tooth decay in the United States was significant.<sup>164</sup>

However, tooth decay rates have dropped dramatically in all Western nations over the last sixty years, including non-fluoridated nations and in non-fluoridated parts of the United States.<sup>165</sup> Public

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<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 3120.

<sup>161</sup> *Id.*

<sup>162</sup> See Gostin, *Part III*, *supra* note 11, at 3120.

<sup>163</sup> See discussion *supra* Part I.A.

<sup>164</sup> See Fagin, *supra* note 26, at 76.

<sup>165</sup> See Hileman, *supra* note 18, at 6-7; K.K. Cheng et al., *supra* note 108, 165; C. Neurath, *supra* note 108, 165; John A. Yiamouyiannis, *supra* note 108, 165; see also discussion *supra* Part II.F.

health officials supporting fluoridation have suggested that the tooth decay decline in all Western nations and non-fluoridated areas simply reflects the fact that most people now have access to fluoridated products through fluoridated toothpaste and foods or beverages made with fluoridated water. However, many other researchers have concluded that improvements in nutrition, oral hygiene, and possibly the immune status of the population itself are the more likely contributors to tooth decay decline.<sup>166</sup> Thus, in reassessing compulsory water fluoridation today, public health officials should be required to show that tooth decay is still a population wide health risk justifying widespread compulsory fluoridation schemes.

Assuming a significant public health risk could be established, officials would then need to weigh the risk of childhood tooth decay against: (1) the potential human and economic burdens involved in choosing fluoridation as the public health measure, and (2) other health risks that might arise through the choice of fluoridation over other potential interventions.<sup>167</sup> In making this assessment for water fluoridation, officials would have to carefully consider the data highlighted in the NRC Report as well as the numerous other studies suggesting various adverse health effects from excess fluoride exposure, including increased risks for moderate to severe dental fluorosis, skeletal fluorosis, osteosarcoma, pineal gland and endocrine system disruption, and damage to brain function and children's IQ.<sup>168</sup>

## 2. Intervention's Effectiveness and Reasonable Means-End Fit?

After establishing the existence of a serious public health threat, public health officials would next need to demonstrate a reasonable means-end fit between the chosen intervention and the public health objective sought.<sup>169</sup> Authorities should be sure to consider whether reliable data exist to demonstrate the effectiveness of the chosen intervention.<sup>170</sup> In addition, unless the intervention is the only way to deliver the public health

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<sup>166</sup> Hileman, *supra* note 18, at 6 (noting that most people whose diets include little sugar and few processed foods have very low rates of tooth decay).

<sup>167</sup> See Gostin, *Part III, supra* note 11, at 3121.

<sup>168</sup> See discussion *supra* Parts II.A–E.

<sup>169</sup> See Gostin, *Part III, supra* note 11, at 3121 (“In fact, since the proposed regulation entails personal burdens and economic costs, government should affirmatively demonstrate, through scientific data, that the methods adopted are reasonably likely to achieve the public health objective.”).

<sup>170</sup> *Id.*

benefit to the intended beneficiaries, public health officials should strive for interventions that are well-targeted and not overbroad.<sup>171</sup>

Here, a number of problems arise in trying to justify the means-end fit of compulsory water fluoridation to prevent childhood tooth decay. First, compulsory water fluoridation inarguably affects a majority of individuals who do not benefit from, and may actually be harmed by, the intervention.<sup>172</sup> Thus, by definition, the intervention is overbroad. Although fluoride proponents have often suggested that compulsory water fluoridation is necessary in order to reach those in the population with little access to regular dental health care, public health officials should reexamine whether this rationale justifies imposing an intervention meant for a targeted minority on an entire public water community, particularly in light of evidence establishing that many vulnerable members of that affected population, including infants and the elderly, are harmed by their exposure to fluoride in the 0.7-1 ppm range allowed in the water supplies today.<sup>173</sup>

In addition, public health officials must also consider whether the weight of the current scientific evidence supports systemic fluoride as an effective tooth decay preventative. Because numerous studies have already suggested that the benefits of fluoride in preventing tooth decay are derived through topical means only, public health officials would likely face a significant hurdle in establishing this means-end factor.<sup>174</sup>

### 3. Reasonable Economic Costs?

Third, because society has finite and relatively scarce public resources available for public health interventions, officials should then be able to show that the economic costs of fluoridation are reasonable when compared to the benefits. This would also require an analysis of whether the chosen intervention is more economical than other potential interventions.<sup>175</sup>

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<sup>171</sup> See Hodge et al., *supra* note 10, at 81 (“An agency should avoid using compulsory powers in a manner that is overbroad (applying to more individuals than is necessary for the public’s health).”).

<sup>172</sup> See discussion *supra* Parts II.A–E.

<sup>173</sup> See discussion *supra* Parts II.A–E; see also *Minn. State Bd. of Health v. City of Brainerd*, 241 N.W.2d 624, 634 (Minn. 1976) (J. Yetka, dissenting) (noting that the court could have “achieved the same purpose by compelling the city to furnish fluorine tablets or dental application to those who wished it, without infringing on the rights of the majority”).

<sup>174</sup> See discussion *supra* Part II.F.

<sup>175</sup> Gostin, *Part III*, *supra* note 11, at 3121.

Fluoridation proponents have often argued that there are no real economic costs to fluoridation, and that fluoridated populations actually save money in the long run.<sup>176</sup> Indeed, in an often-cited 2001 economic evaluation study, CDC researchers estimated that the annual per person cost *savings* resulting from fluoridation ranged from \$15.95 in very small communities to \$18.62 in large communities.<sup>177</sup> The study purportedly took into consideration the estimated costs of installing and maintaining the necessary fluoridation equipment, the cost of the fluoride itself, and the costs of operating the water plants, and subtracted these direct costs from the estimated savings achieved due to “averted disease.”<sup>178</sup> Averted disease was determined by making a number of assumptions: an assumed effectiveness rate of fluoridation, estimates of expected cavities in non-fluoridated communities, estimates of dental costs of cavity treatment, and estimates of time lost visiting dentists for treatment.<sup>179</sup>

In arriving at its “net benefits” conclusion, however, the 2001 CDC study made several assumptions that have now been shown to be false. First, the study simply assumed that fluoride benefited almost all members of an affected population, including all adults and children between the ages of 6 and 65 years of age.<sup>180</sup> Yet most fluoride proponents concede that fluoridation only benefits young children during their teeth formation years.<sup>181</sup> In addition, the study simply assumed that dental care costs would be reduced in fluoridated communities as opposed to un-fluoridated communities, where in fact the opposite has been shown to be true.<sup>182</sup> Moreover, the study considered only the benefits of fluoridation in terms of averted tooth decay disease.<sup>183</sup> It neglected to consider any negative health care costs that might be incurred by individuals ingesting fluoride at all, such as costs to treat dental fluorosis, skeletal fluorosis, bone

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<sup>176</sup> See, e.g., S. O. Griffin et al., *An Economic Evaluation of Community Water Fluoridation*, 61 J. PUBLIC HEALTH DENT. 78–86 (2001); Joan M. O’Connell et al., *Costs and Savings Associated with Community Water Fluoridation Programs in Colorado*, 2 PREVENTING CHRONIC DISEASE 1 (2005), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459459/pdf/PCD2SIA06.pdf>.

<sup>177</sup> Griffin et al., *supra* note 176, at 78.

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> See Balog, *supra* note 8, at 648–49.

<sup>182</sup> See, e.g., Hileman, *supra* note 18, at 7 (discussing a study showing that although dentists’ fees and the nature of treatment in the two groups of cities did not differ significantly, the cost per patient and average number of visits to the dentist per year were greater in fluoridated communities).

<sup>183</sup> Griffin et al., *supra* note 176, at 78.

fractures, hypothyroidism, or any other diseases linked to excess exposure to fluoride.<sup>184</sup>

With respect to the study's assumed costs themselves, allocating one-time only direct costs for the necessary fluoridation equipment failed to consider that fluorosilicates are extremely corrosive, and may significantly shorten the lifespan of water distribution equipment and facilities.<sup>185</sup> Nor did the study consider any out-of-pocket costs borne by individuals choosing to avoid fluoridated water, or any environmental costs of fluoride exposure.<sup>186</sup> Moreover, it is also worth noting that the relatively low cost of the fluoride itself is likely due to its status as a hazardous waste product from the phosphate fertilizer industry—a hazardous waste the fertilizer industry would have otherwise had to dispose of itself.<sup>187</sup>

Thus, existing economic evaluations of fluoridation schemes appear to have both greatly exaggerated the economic benefits and greatly underestimated the economic costs. Interestingly, a number of cities within the United States have recently ceased or have determined to cease fluoridation schemes, citing significant anticipated savings in doing so.<sup>188</sup> Public health officials reassessing compulsory water fluoridation schemes should look to these cities' cost-benefit analyses when considering whether the economic costs of fluoridation are reasonable.

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<sup>184</sup> See discussion *supra* Parts II.A–E.

<sup>185</sup> See, e.g., NATICK FLUORIDATION STUDY COMM., SHOULD NATICK FLUORIDATE: A REPORT TO THE TOWN AND BOARD OF SELECTMEN 1, 47 (1997) (study advising against fluoridation) [hereinafter NATICK REPORT]; see also *Minn. State Bd. of Health v. City of Brainerd*, 241 N.W.2d 624, 634 (Minn. 1976) (J. Yetka, dissenting) (noting affidavit suggesting strong likelihood that adding fluoride to the water filtration system might destroy delicate chemical balance in the system).

<sup>186</sup> NATICK REPORT, *supra* note 185, at 42; see also Antonia Giedwoyn, *Martin Turns 50: Fluoridation Litigation, Then and Now*, 65 OR. ST. B. BULL. 27 (Aug./Sept. 2005) (discussing devastating environmental impact of fluoride exposure on livestock).

<sup>187</sup> DENTAL DIDACTICS, *supra* note 29, at 7 (noting that with the advent of public fluoridation, chemical industries were presented with a profitable means of divesting themselves of an industrial poison: selling it to water districts as a beneficial additive).

<sup>188</sup> See, e.g., Richard Kerns, *Keyser May Eliminate Fluoride in Water to Save Money*, MINERAL DAILY NEWS-TRIBUNE (Jan. 15, 2014), <http://www.newstribune.info/article/20140115/NEWS/140119925>, archived at <http://perma.cc/7F88-T5QQ>; *Dallas City Council Moves to Stop Forced Water Fluoridation*, HEALTH IMPACT NEWS (Apr. 29, 2014), <http://healthimpactnews.com/2014/dallas-city-council-moves-to-stop-water-fluoridation/>, archived at <http://perma.cc/5APT-9SWD>; Michael D. Bates, *Hernando Commissioners Say No to Fluoridation*, HERNANDO TODAY (Feb. 25, 2014), <http://hernandotoday.com/he/list/news/hernando-commissioners-say-no-to-fluoridation-20140225/>, archived at <http://perma.cc/VL8Z-F5H6>; Emily Wood, *Fluoride Will No Longer Be Added to Bolivar Water*, KY3 NEWS (Feb. 8, 2012), [http://articles.ky3.com/2012-02-08/fluoride\\_31039995](http://articles.ky3.com/2012-02-08/fluoride_31039995), archived at <http://perma.cc/FE9E-JZE5>.



#### 4. Reasonable Human Rights Burdens?

Assuming public health officials could justify the economic costs, officials would then need to determine whether the human rights burden of the public health measure is justifiable. In making this determination, officials should consider the intervention's: (1) level of invasiveness (to what degree does the proposed measure intrude on an identified right); (2) frequency and scope (does it apply to one person, a group, or an entire population); and (3) duration (how long of a period is a person/group subject to the infringement).<sup>189</sup> In addition, because fundamental human rights are often involved in coercive public health interventions, officials should aim for the "least restrictive alternative"—i.e., those interventions that might achieve the public health goal as well as—or better than—the more restrictive intervention.<sup>190</sup>

Public health officials assessing compulsory water fluoridation schemes must first acknowledge that fluoridation is an attempt to medicate the population in order to prevent the disease of tooth decay.<sup>191</sup> As compulsory medication given without the legal and ethical protections of medical informed consent, the invasiveness is significant. There are also no opt-out choices once compulsory water fluoridation is imposed upon any particular public water community, and affected consumers cannot easily avoid it simply through the purchase of bottled water or costly filtration systems.<sup>192</sup> With respect to the frequency and duration of the intervention, many consumers in fluoridated districts will consume artificial fluoride daily for possibly their entire lives, long after the alleged tooth decay preventative benefits have ceased. Additionally, as numerous studies have already shown, long-time exposure to fluoride may place a particularly heavy burden on certain vulnerable human populations, such as persons with kidney disease or the very young or very old.<sup>193</sup>

Considering the heavy human rights burden of forced medication, public health officials must question whether compulsory water

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<sup>189</sup> See Gostin, *Part III, supra* note 11, at 3121.

<sup>190</sup> *Id.*

<sup>191</sup> See DENTAL DIDACTICS, *supra* note 29, at 1 ("The fact that fluoridation is usually proposed and advocated by dental and medical professionals, and numerous fluoride supplements are available only by prescription, lends credence to this argument classifying fluoride supplements as mass 'medication'").

<sup>192</sup> For example, even if a consumer purchases bottled water for drinking purposes, she is still likely to ingest fluoridated water through bathing, cooking, and oral health hygiene, as well as through foods and beverages made with fluoridated water.

<sup>193</sup> Hileman, *supra* note 18, at 14–15.

fluoridation is the least restrictive intervention to achieve their stated public health goal. While the public health objective of preventing childhood tooth decay is laudable, the means to achieve it has caused considerable acrimony between opposing viewpoints, with little room for consensus or conciliation due to the all-or-nothing nature of the coercive measure. Public health officials should therefore consider whether there is a less intrusive intervention that would achieve the public health goal without invading the bodily integrity rights of the many who find the measure objectionable on health, ethical, and/or legal grounds.

##### 5. Benefits, Costs, and Burdens so that Services Are Only Provided Where Needed

Finally, officials should assess whether the selected public health intervention is fair. Fairness requires that public health interventions are provided only to those who need them.<sup>194</sup> This is because coercive measures aimed at persons who don't need them, particularly where there is no actual danger to the public health at large, "impose costs and burdens without a corresponding public benefit."<sup>195</sup>

Part of the initial justification for compulsory water fluoridation was to provide dental health services to those who may not have had regular access to dental care.<sup>196</sup> Today, however, compulsory water fluoridation schemes affect roughly 73% of the U.S. population using public water supplies, regardless of any lack of access to regular dental health care or socioeconomic need.<sup>197</sup> Many affluent communities are fluoridated despite no lack of access to regular dental health care.<sup>198</sup> Nor has fluoridation helped to remediate tooth decay rates or improve the lack of access to dental care in urban low-income populations. In fact, studies have shown that many urban low-income areas in the United States still have high rates of tooth decay, despite years of fluoridated water supplies.<sup>199</sup> The

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<sup>194</sup> Gostin, *Part III, supra* note 11, at 3122.

<sup>195</sup> *Id.*

<sup>196</sup> *See generally* CDC, *Fluoridation, supra* note 18.

<sup>197</sup> *Id.*

<sup>198</sup> *See Community Water Fluoridation*, MASSACHUSETTS OFF. OF ORAL HEALTH, <http://www.mass.gov/eohhs/docs/dph/com-health/oral-fluoride-community-water-factsheet.pdf> (last visited Nov. 13, 2014).

<sup>199</sup> *See Ten Facts About Fluoride, Fact #10*, FLUORIDE ACTION NETWORK (Apr. 8, 2013), <http://www.fluoridealert.org/articles/fluoride-facts/>, archived at <http://perma.cc/YP2B-F4FQ> ("Despite claims that fluoridation can prevent the high rates of tooth decay seen in poor

problem, it appears, is not lack of access to fluoridation, but continued lack of access to real dental health care.<sup>200</sup> Moreover, now that emerging science is suggesting that excess exposure to fluoride may do far more harm than good, those who are most in danger of overexposure to fluoride—and thus at risk for a whole host of adverse health effects—are those who can least afford to avoid it.<sup>201</sup> Thus, compulsory water fluoridation imposes numerous costs and burdens without a corresponding public health benefit for many.

A complete reassessment of compulsory water fluoridation utilizing the above factors would reveal that it is no longer justifiable as a public health benefit. Taking politics and long-entrenched agendas out of the mix, the risks of tooth decay, while perhaps still significant for a minority of individuals, are significantly outweighed by the human rights burdens, economic costs, and risks of other bodily harm for the majority of those affected. Unfortunately, despite federal agency movement to reconsider the allowable levels of fluoride in drinking water, continued public objection, and scientific evidence trending against water fluoridation, many public health officials and dental professionals continue to advocate its spread. Stephen Peckham at the London School of Hygiene and Tropical Medicine suggests that the refusal to reexamine the sacred cow of water fluoridation may be due to what is known as the “Gold Effect,” a process by which an idea comes to be held as a generally accepted truth, even in the face of substantial conflicting evidence.<sup>202</sup> Once the idea has reached a level of general consensus, it becomes “something akin to a religion with a following of devout believers,” making it extremely difficult for those with opposing views or contradictory evidence to be heard.<sup>203</sup> Because there is already a strong “fluoride is good” discourse as conveyed by the food and chemical industries and reinforced by the mainstream dental and medical establishments, the contrary evidence regarding fluoride’s high-risk and questionable benefit is often dismissed or regarded as “misguided or just plain wrong.”<sup>204</sup> Nonetheless, it cannot be said that

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areas, the vast majority of poor urban communities have been fluoridated for over 30 years, and yet are still suffering from a severe oral health crisis.”)

<sup>200</sup> *Id.*

<sup>201</sup> See, e.g., *Statements from Black/Hispanic Leaders*, FLUORIDE ACTION NETWORK, <http://www.fluoridealert.org/issues/ej/statements/> (last visited Nov. 13, 2014), *archived at* <http://perma.cc/BS3L-PJ83> (statements from various leaders opposing water fluoridation as studies have shown disproportionately negative effects on minorities).

<sup>202</sup> Peckham, *supra* note 13, at 163–64.

<sup>203</sup> *Id.* at 164 (quoting Raymond A. Lyttleton, *The Gold Effect*, in LYING TRUTHS: A CRITICAL SCRUTINY OF CURRENT BELIEFS AND CONVENTIONS 181, 189 (1990)).

<sup>204</sup> *Id.*

public health officials or the mainstream medical and dental establishments have been without error as to the touted health benefits of various medications or health practices. Indeed, history is replete with examples of health practices or medications once endorsed by health officials that are now widely recognized as detrimental to public health.<sup>205</sup> Public health officials thus have an ethical as well as legal obligation to reexamine public health measures in the face of credible contrary evidence, particularly when such public health measures are paternalistic. Failure to undertake an honest, systematic inquiry into a public health measure's continued legitimacy renders a once justifiable public health measure an illegitimate human research experiment.

*B. Human Subjects Research Experimentation*

Human subjects research is generally defined as “a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalized knowledge that involves living human subjects.”<sup>206</sup> While public health practices are supposed to involve “application of proven methods” to implement preventative control measures, research involves testing new, unproven treatments or strategies that are not known to be efficacious.<sup>207</sup> Of course, the legal and ethical line between a legitimate public health measure and unproven human subjects research is not always clear.<sup>208</sup> This distinction is vitally important, however, because each is governed by a different set of legal and ethical principles. While public health practices are authorized by constitutional, statutory, and regulatory provisions, human subjects research is subject to various ethical principles or legal requirements set out in the federal Common Rule, various state laws governing human subjects research, bioethics advisory committees, and international treaties or

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<sup>205</sup> Recall, for example, that the American Medical Association was a long-time supporter of the health benefits of tobacco. See *American Medical Association Promoted Tobacco*, TOBACCO CAMPAIGN (July 25, 2009), <http://www.tobaccocampaign.com/american-medical-association-promoted-tobacco>, archived at <http://perma.cc/FTW2-FV3G> (“The Journal of the American Medical Association (JAMA) published its first cigarette advertisement in 1933, stating that it had done so only ‘after careful consideration of the extent to which cigarettes were used by physicians in practice.’”).

<sup>206</sup> 32 C.F.R. § 219.102(d) (2013).

<sup>207</sup> James G. Hodge, *An Enhanced Approach to Distinguishing Public Health Practice and Human Subjects Research*, 33 J. L. MED. & ETHICS 125, 127 (2005).

<sup>208</sup> *Id.* at 125 (“[L]ost in an ethical gray zone are a host of public health activities that are not neatly characterized as either practice or research”).

codes of medical and scientific ethics, such as the Nuremberg Code.<sup>209</sup> Knowing which code of ethics applies is critical because when characterized and acknowledged as “research,” the experimental practice must only be conducted with the voluntary cooperation of the human subjects, who must be fully informed of the risks and benefits of the experimental measure.<sup>210</sup> The research must also be subject to rigorous monitoring of potential adverse effects and identified vulnerable populations should be carefully excluded from participation.<sup>211</sup>

As acknowledged by the NRC Report and advanced by numerous scientists and medical and dental professionals over the last sixty years, it is clear that not enough is known about either the risks or the benefits of fluoride ingestion to unequivocally support its practice.<sup>212</sup> Yet public health officials and fluoride proponents seem determined to expand the practice of compulsory water fluoridation, even in the wake of uncertainty.<sup>213</sup> Expansion will subject even more human subjects to “unproven . . . strategies that are not known to be efficacious.”<sup>214</sup> Consequently, compulsory water fluoridation should be properly considered human subjects research, subject to the following legal and ethical parameters.

#### 1. Informed Consent

From the Tuskegee syphilis experiment to MK-Ultra to various eugenics schemes, the United States’s medical and public health professionals have a sordid history when it comes to illegal and unauthorized

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<sup>209</sup> *Id.* at 130 (discussing Common Rule, a series of federal regulations governing human subjects research conducted by or receiving funds from federal agencies); see also Scott Burris et al., *The Role of State Law in Protecting Human Subjects of Public Health Research and Practice*, 31 J.L. MED. & ETHICS 654, 654 (2003); Mark Lundgren & Daniel Smith, *The Ethical and Scientific Case Against Public Water Fluoridation*, DAILY PAUL (Nov. 15, 2011), <http://www.dailypaul.com/187406/dental-students-against-public-water-fluoridation>, archived at <http://perma.cc/73DK-P45U> (discussing the Nuremberg Code).

<sup>210</sup> See *WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects*, WORLD MEDICAL ASS’N, <http://www.wma.net/en/30publications/10policies/b3/> (last visited Nov. 13, 2014), archived at <http://perma.cc/UKN7-D5Z2>.

<sup>211</sup> Hodge, *supra* note 207, at 127.

<sup>212</sup> See *supra* note 66; see also Lundgren & Smith, *supra* note 209.

<sup>213</sup> See *ADA Fluoridation Policy and Statements*, AM. DENTAL ASS’N, <http://www.ada.org/en/public-programs/advocating-for-the-public/fluoride-and-fluoridation/ada-fluoridation-policy-and-statements> (last visited Nov. 13, 2014), archived at <http://perma.cc/LAN7-VPDE> [hereinafter ADA, *Fluoridation Policy*].

<sup>214</sup> Hodge, *supra* note 207, at 127.

human subject experimentation.<sup>215</sup> Attempts to curb such abuses have resulted in various human subjects research laws and ethical guidelines, all of which mandate the informed consent of the human subjects.<sup>216</sup> The Nuremberg Code, for example, provides that:

The voluntary consent of the human subject is absolutely essential. This means the person involved should have legal capacity to consent; should be so situated as to be able to exercise free power of choice, without the intervention of any power of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and involved as to enable him to make an understanding of enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.<sup>217</sup>

Through compulsory water fluoridation schemes, public health officials have been experimenting on communities for nearly sixty years without disclosing the risks, benefits, and alternative treatment options to fluoridation. Claims that fluoridation is not mass medication are unconvincing.<sup>218</sup> Adding a drug to the water supply to treat or prevent the disease

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<sup>215</sup> See, e.g., Mike Stobbe, *Ugly Past of U.S. Human Experiments Uncovered*, NBC NEWS (Feb. 27, 2011), [http://www.nbcnews.com/id/41811750/ns/health-health\\_care/#.U8QzsBzn85s](http://www.nbcnews.com/id/41811750/ns/health-health_care/#.U8QzsBzn85s), archived at <http://perma.cc/3CVN-UD3F>; David Gorski, *Ethics in Human Experimentation in Science-Based Medicine*, SCI-BASED MED. (Mar. 7, 2011), <http://www.sciencebasedmedicine.org/ethics-in-human-experimentation-in-science-based-medicine/>, archived at <http://perma.cc/N8A7-MX98>. MK-Ultra was an experimental psychological warfare program run by CIA-affiliated medical professionals in the 1950s–1970s, whereby human subjects were given various substances including LSD without their knowledge or consent. See COLIN A. ROSS, *THE CIA DOCTORS: HUMAN RIGHTS VIOLATIONS BY AMERICAN PSYCHIATRISTS* (2011).

<sup>216</sup> See Cross & Carton, *supra* note 12, at 29 (“All ethical codes for the protection of individuals who are subject to medical procedures, whether research or routine medical treatment, endorse the basic requirement of voluntary informed consent.”).

<sup>217</sup> *The Nuremberg Code*, 313 BRIT. MED. J. NO. 7070 1448, 1448–49 (1996), available at <http://www.cirp.org/library/ethics/nuremberg/>, archived at <http://perma.cc/RG9Q-9A7K>.

<sup>218</sup> See Mark Diesendorf, *How Science Can Illuminate Ethical Debates: A Case Study on Water Fluoridation*, 28 FLUORIDE 2 (1995) (“Some leading proponents of fluoridation

of tooth decay is unquestionably a medical intervention, and the fact that the risks of this drug are still being determined by public agencies supports an argument that water fluoridation is an ongoing human medical experiment. As such, this experiment should be subject to informed consent for each human subject affected.

Unfortunately, public health officials currently provide very little disclosure when it comes to compulsory water fluoridation. Fluoride's alleged benefits are emphasized, even exaggerated, while its risks go unmentioned or significantly downplayed. Without adequate disclosure about the risks, benefits, and alternatives to fluoridation, individuals in fluoridated communities can hardly be said to have given informed consent to the unproven experiment. Nor can informed consent be given where individual subjects cannot opt out of the experiment.<sup>219</sup>

## 2. Rigorous Monitoring of Results and Vulnerable Population Protection

Rules and ethical guidelines governing human subjects research also generally require that researchers monitor their human subject experiments for adverse effects, and ensure that identified vulnerable populations are protected or excluded from participation.<sup>220</sup>

Here, while the actual levels of fluoride in the water supplies are monitored to ensure compliance with the EPA's MCL of 4 ppm and compliance with any state or local drinking water fluoride levels set, no widespread monitoring of the adverse health effects fluorides are having on individuals within fluoridated areas is being conducted.<sup>221</sup> Nor are there

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attempt to evade such ethical issues by quasi-scientific argument. For instance, they claim that fluoridation is not medication, but merely an 'adjustment' of the natural fluoride concentrations in drinking water to the 'optimal' level for reducing tooth decay. Or they allege that fluoride is an essential nutrient, rather than a medication."); *see also* Letter from Melinda K. Plaisier, Assoc. Comm'r for Legislation, Dep't of Health & Human Servs., to the Honorable Ken Calvert, Chairman, Subcomm. on Energy & Environment, House of Representatives (Dec. 21, 2000), *available at* <http://www.fluoridealert.org/wp-content/uploads/fda-2000a.pdf> (indicating that "[f]luoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal, is a drug that is subject to Food and Drug Administration (FDA) regulation").

<sup>219</sup> Cross & Carton, *supra* note 12, at 27.

<sup>220</sup> Hodge, *supra* note 207, at 130.

<sup>221</sup> Cross & Carton, *supra* note 12, at 25–26 (EPA's Safe Drinking Water Information System ("SDWIS") only tracks fluoride concentrations in water systems with naturally occurring fluoride levels above the established regulatory maximum of 4ppm. The Department of Public Health and the CDC also engage in various tracking programs,

any mechanisms in place to ensure protection for or exclusion from the mass experiment of vulnerable populations such as infants, the elderly, or those with certain identified health problems shown to be particularly sensitive to fluoride consumption.<sup>222</sup>

Despite lack of widespread risk and safety monitoring and vulnerable population protection controls, public health officials and fluoride proponents appear intent on expanding compulsory water fluoridation schemes throughout the United States.<sup>223</sup> As several researchers have already noted, it is highly improper to actually expand the number of subjects exposed where a human subjects experiment is challenged with reliable data revealing contrary results to those anticipated or claimed.<sup>224</sup> Public health officials engaged in this ongoing human research experiment should instead either “concede that their hypothesis is defective, and that further action would be both redundant and unethical,” or “accept that the whole adventure needs to be reformulated.”<sup>225</sup>

## CONCLUSION

The evidence continues to suggest that compulsory water fluoridation is no longer justifiable as a public health benefit. Using a systematic approach, public health officials willing to revisit fluoridation would likely find that the risk of fluoridating significantly outweighs the risk of not fluoridating, that the means chosen are not a good fit to the ends, and that the human rights burden and economic costs are not reasonable or justifiable. In addition, in light of NRC and EPA acknowledgement of

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mainly to keep track of which communities are fluoridated. Various state agencies may also track fluoride levels in the water supplies to ensure compliance with EPA MCLs and state or local water fluoridation level requirements.)

<sup>222</sup> This would include adults or children with diabetes or kidney disease. *See Kidney*, FLUORIDE ACTION NETWORK, <http://fluoridealert.org/issues/health/kidney/> (last visited Nov. 13, 2014), *archived at* <http://perma.cc/YL5D-2TD3> (“Individuals with advanced kidney disease are known to have a very high susceptibility to fluoride toxicity since their bones and other tissues accumulate fluoride at levels far higher than healthy individuals”); *Diabetes*, FLUORIDE ACTION NETWORK, <http://fluoridealert.org/issues/health/diabetes/> (last visited Nov. 13, 2014), *archived at* <http://perma.cc/FLE-9EKS> (quoting the NRC Report, which stated that “[t]he conclusion from the available studies is that sufficient fluoride exposure appears to bring about increases in blood glucose or impaired glucose tolerance in some individuals and to increase the severity of some types of diabetes”).

<sup>223</sup> *See, e.g.*, CDC, *Fluoridation*, *supra* note 18; ADA, *Fluoridation Policy*, *supra* note 213.

<sup>224</sup> Cross & Carton, *supra* note 12, at 28.

<sup>225</sup> DOUG CROSS, FLUORIDATION AND HUMAN RIGHTS 8–14 (2000), *available at* <http://www.nofluoride.com/reports/Fluoridation%20and%20Human%20Rights.pdf>.



the significant gaps in research on the safety of ingested fluoride, water fluoridation is in effect an unproven human subjects research experiment and continued imposition of compulsory water fluoridation schemes violates numerous legal and ethical human subjects research protocols. Public health authorities still hoping to determine the population-wide need for water fluoridation should do so only in compliance with these research protocols and provide for informed consent and voluntary participation of all human subjects. In addition, courts reviewing existing compulsory water fluoridation laws should no longer deny the fundamental rights implicated by compulsory water fluoridation schemes, and should instead conduct the proper heightened scrutiny review under *Brainerd*, utilizing all scientific evidence available today.

It remains to be seen whether the EPA will in fact lower the maximum contaminant levels of fluoride in public water supplies, although a refusal to do so despite the NRC's recommendation might reflect an unfortunate political rather than scientific assessment. Although lowering the MCL and SMCL for fluoride would belatedly recognize the excess amount of fluoride most children and adults are exposed to today, the cessation of all compulsory water fluoridation schemes should be the goal of all public health agencies, ethical lawmakers, and informed citizens.

