

Fluoridation: A Violation of Medical Ethics and Human Rights

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Silicofluorides, widely used in water fluoridation, are unlicensed medicinal substances, administered to large populations without informed consent or supervision by a qualified medical practitioner. Fluoridation fails the test of reliability and specificity, and, lacking toxicity testing of silicofluorides, constitutes unlawful medical research. It is banned in most of Europe; European Union human rights legislation makes it illegal. Silicofluorides have never been submitted to the U.S. FDA for approval as medicines. The ethical validity of fluoridation policy does not stand up to scrutiny relative to the Nuremberg Code and other codes of medical ethics, including the Council of Europe's Biomedical Convention of 1999. The police power of the State has been used in the United States to override health concerns, with the support of the courts, which have given deference to health authorities. *Key words:* fluoridation; fluoride; silicofluorides; medical ethics; human rights.

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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 dental caries. When the practice was initiated by the United States in 1944, it was based on questionable observations made by H. Trendley Dean, the first director of the National Institute of Dental Research, and others. Dean saw an inverse relationship in children in the southwest United States between the concentration of fluoride in the water supplies and tooth decay. This eventually gave rise to the idea that some water supplies had a "fluoride deficiency" that could be remedied by adding fluoride as a public health measure to reduce tooth decay.

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. The crude product, an approximately 25% solution of hydrofluosilicic acid, is a highly toxic hazardous waste, and its disposal would have been extremely costly to the industry. So the proposal that it could be used as a substitute for the origi-

nal chemical of choice, sodium fluoride, provided a novel solution that unfortunately opened the door to the practice of administering it to the general public in the water supply in the guise of a "medication."

While certain formulations of toothpaste containing fluoride are formally registered as ingestible drugs, neither sodium fluoride, nor the crude silicofluoride waste, nor its refined sodium derivative has been licensed as such in the United States. Sodium fluoride is licensed as a medicine for ingestion in the United Kingdom, but silicofluorides are not. All pharmaceutical products require formal licensing, quality control in manufacture, and safety testing, and their administration to patients is covered by medical Codes of Ethics that are extremely demanding in their objective to protect the patient. Yet governments, especially the U.S. government, permit these extremely toxic chemicals to be used as unlicensed medicines without any such safety testing, pharmaceutical-level quality control in manufacture, or patient specificity or medical monitoring in administration. Clearly, both ethical and legal issues are raised by this lack of protection of consumers.

BACKGROUND AND PURPOSE

The fluoridation controversy is now polarized into two opposing camps, split generally between the medical, dental, and government authorities and individual scientists and medical professionals and concerned citizens. The purpose of this paper is not to attempt to determine which, if either, is right, but to take an entirely distinct approach to the issues raised. We examine the ethical basis of compulsory fluoridation, and the consequent violation of the human rights of those forced to ingest fluoridated water. Current scientific and medical evidence exposes fluoridation to be so questionable and unreliable in its efficacy, and to have such potentially dangerous and as yet unquantified side effects, that it is improper to apply it as prophylactic treatment. Were it a registered medicinal treatment, then it would immediately be removed from use, in the same way that any other drug would be recalled under a similar onslaught of evidence for adverse effects.

Discussion. Since governments in the United States and United Kingdom are still determined to expand the exposure of large numbers of subjects, apparently hoping to gather yet more data on which to base justi-

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fication of the practice, fluoridation should in fact be reclassified as medical research, for which there are clear and extremely strict ethical procedures and sanctions aimed at protecting the public from improper medical activities. We return to a consideration of this thesis later in this paper, following an examination of the ethical basis of public-sector medical interventions.

MEDICATION AND HUMAN RIGHTS

The ethical issues raised by fluoridation are ultimately grounded in the Nuremberg Code. This code established the basis for all modern medical research and treatment involving human subjects. All subsequent codes of medical ethics have their origins in this document.¹ While the wording of various codes may differ, they all incorporate the fundamental basic requirement: research, or even routine medical procedures, must be done with the voluntary cooperation of the subjects, who must be fully informed of the risks and benefits of the medical procedures in which they are involved.

Medical ethics unequivocally demands that the wishes of the individual must take precedence over actions imposed by the state, unless there is a valid and wider public health concern. A state's interest may legitimately override an individual's wishes if a person with a potentially life-threatening and contagious disease such as measles or Lassa fever refuses to accept treatment and/or quarantine. Obviously tooth decay does not qualify as such a disease, requiring the state to usurp individual rights. States continue, nonetheless, to insist on their "police power," having convinced the public through press releases that fluoridation is completely benign.

IS FLUORIDATION A MEDICINE?

At the heart of the medical ethics debate is the nature of the substances being administered. It would appear obvious that fluoridation chemicals are medicines, yet this is challenged by a number of states. The British Government's regulatory body, the Medicines Control Agency (MCA), claims that fluoridated water is not a medicine.² The U.S. tactic is not to deny that fluoride is a medicine, but to refuse to apply the laws governing medications to fluoridation.

Most states have some definition of what constitutes a medicinal substance. The definition of a medicinal substance has been established by the European Union since February 2002 by the Codified Pharmaceutical Directive 2001/83/EEC. Article 1 defines them as:

Any substance or combination of substances presented for treating or preventing disease in human beings or animals . . .

Any substance or combination of substances which may be administered to human beings or animals

with a view to making a diagnosis or to restoring, correcting or modifying physiological function in human beings or animals is likewise considered a medicinal product.

This is almost identical to the American Food and Drug Administration's definition,

Fluoride, 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.³

Thus fluoridated water in the United States and Europe should obviously be considered a medicine under their own rules, even without regard to the scientific and medical controversies that surround its safety and efficacy. But for fluoridation proponents in the United Kingdom and Ireland, the inclusion of the single word "presented" in the EU definition is crucial. If a product is represented to the public as if the substance might have a beneficial effect on some medical condition, then that substance is a medicine under the terms of this Directive, regardless of any scientific or medical controversy that may surround its efficacy.

TESTING MEDICINAL PRODUCTS FOR SAFETY

Medicinal substances must be tested for safety and must comply with the regulatory standards applied to the use of pharmaceutical products.⁴ The "Rules and Guidance" also includes the "Code of Practice for Qualified Persons," and guidance for "Responsible Persons." Strict professional guidelines and qualifications are stipulated for persons working in the industry, yet in many instances no such qualified persons exist on the staffs of manufacturers of fluoridation chemicals. As far as we are aware, the MCA has not dealt with any claims that these medicinal substances are defective, usually diverting the inquirer with claims that as fluoridated water is not a medicine, no such complaint would be accepted in any case. Similar rules for medicines apply in the United States.

In the United States, no safety tests have been carried out on silicofluorides. In a response to Congressman Calvert, House Committee on Science, concerning hydrofluosilicic acid and sodium fluorosilicate, the substances used in over 90% of U.S. fluoridation programs, the EPA states:

In collecting the data for the fact sheet, EPA was not able to identify chronic studies for these chemicals.⁵

The FDA has stated: "No New Drug Applications have been approved or rejected for fluoride drugs meant for ingestion."⁶

The National Sanitation Foundation, a private organization in the United States that certifies water-treatment chemicals, has stated in a letter to Congressman Calvert that no company had submitted to them any studies, confidential or not, on hydrofluosilicic acid or silicofluorides.⁷

However, silicofluorides have been tested in Europe, and have been almost universally rejected for failing the safety standards. Consequently, their use has been banned in most EU countries. Since they contain arsenic as a contaminant, it is impossible to use them without contaminating drinking water supplies with arsenic, a known human carcinogen.

Their manufacture and use as medicines is therefore unlawful throughout the European Union, in the United States, and probably in many other countries as well.

MEDICAL INTERVENTIONS BY THE STATE

Article 2 of the Council of Europe's Convention for the Protection of Human Rights and Dignity of Human Beings with Regard to the Application of Biology and Medicine, 1999 (referred to as the "Biomedical Convention" hereafter for convenience) affirms the primacy of the individual over the sole interest of science or society, establishing that the wishes of an individual in respect to his or her exposure to treatment for medical conditions takes precedence over state objectives. Those who elect not to have their dental caries treated (by any form of treatment) present no public health risk to the state, so the imposition of fluoridation is therefore covered by Article 2, and is subject to the consent of the individual.

The term "intervention" covers all medical acts, including any action performed for the purpose of preventive care. All interventions must be carried out in accordance with the law in general, as supplemented and developed by professional rules of conduct.

Article 3 aims to ensure equitable access to health care in accordance with the person's medical needs. "Health care" includes preventive interventions, designed to maintain or improve a person's state of health or alleviate a person's suffering. This care must be of a fitting standard in the light of scientific progress, and be subject to continuous quality assessment.

In the case of fluoridation, the intervention is imposed upon the whole population, regardless of the medical condition of the individuals—consider, for example, the quite common example of those members of the population, particularly the elderly, who are toothless. Nor does it take into account any additional sources of fluoride that may be derived from other sources, such as highly fluoridated dentifrices or processed foods prepared with fluoridated water.

And crucially, it does not permit those members of the population that are more susceptible to fluoride intoxication to regulate their intake by avoiding this

component of their overall exposure. The U.S. EPA notes that subsets of the population listed as sensitive include: elderly, 52,000,000; cardiovascular disease, 22,000,000; renal disorders, 2,000,000; vitamin C deficiency, 27%; magnesium deficiency, 37%; calcium deficiency, 44%.⁸

Nor does it allow their medical advisers to monitor their reactions to the unregulated dosages of these medicinal substances. Fluoridation is therefore the indiscriminate medication of patients without any of the fundamental precautions and protections that medical ethics demands from qualified medical practitioners working under specified codes of medical practice. So persuasive are the provisions of the Biomedicine Convention that Patricia McKenna, an Irish Member of the European Parliament, recently demanded that the Irish Government ratify the Convention, specifically citing Article 5, so that its provisions can be used to force the state to abandon its unethical policy of fluoridation.⁹

But the violation of medical ethics does not end here. Anyone involved in the administration of fluoridation to the public is a "health care professional" under the definitions of the Convention. Article 4 applies to doctors and health care professionals generally. It states,

Doctors and, in general, all professionals who participate in a medical act are subject to legal and ethical imperatives. They must act with care and competence, and pay careful attention to the needs of each patient.

Competence must be determined primarily in relation to the scientific knowledge and clinical experience appropriate to a profession or speciality at a given time. It is accepted that professional standards do not necessarily prescribe one line of action as being the only one possible: recognised medical practice may, indeed, allow several possible forms of intervention, thus leaving some freedom of choice as to methods or techniques.

Further, a particular course of action must be judged in the light of the specific health problem raised by a given patient. In particular, an intervention must meet criteria of relevance and proportionality between the aim pursued and the means employed.

In both the private and the public sectors that are variously responsible for delivering fluoridated water supplies to the public, the treatment is applied by engineers and other corporate workers with no medical qualifications or clinical experience. They have no access, nor right of access under the law, to the medical records of each consumer (or as they should be classed, each patient) and no mandate to provide medication to the public, other than the permission of the state itself.

Nor are they qualified to determine whether an alternative treatment would be appropriate for any

member of the public. Since the right to medical treatment includes the right to refuse medical treatment unless there is an overriding public health interest, this is a gross violation of the rights of the individual to proper medical treatment, even if the individual consented to it.

So under the terms of the Biomedicine Convention, fluoridation as a practice is clearly unethical. It employs unlicensed substances for which there is no specific clinical need by the population at large, let alone by identified individual patients. The medication itself is administered by persons without medical qualification, following no professional code of medical ethics or practice. The substances administered are produced under conditions that fail to meet the GMP standards universally demanded for pharmaceutical products, and no clinical safety trials have been completed on the complex chemicals now widely used.

THE ISSUE OF INFORMED CONSENT TO MEDICATION

The issue of consent is central to the ethical argument against fluoridation of the public water supplies. Article 5 states that the Convention:

... affirms at the international level an already well-established rule, i.e. that no one may in principle be forced to undergo an intervention without his or her consent. Human beings must therefore be able freely to give or refuse their consent to any intervention involving their person.

In Article 5, the word "intervention" is understood in its widest sense, and covers all medical acts, including any action performed for the purpose of preventive care. All interventions must be carried out in accordance with the law in general, as supplemented and developed by professional rules of conduct. Adding fluoride to the public water supply cannot be regarded as an optional intervention—anyone, and particularly the disabled, who wishes to opt out would be at a serious disadvantage to the rest of the population. The ethical imperative in such cases is that people must be required to actively opt into, and not out of, medical interventions.

The Convention's definition of consent corresponds closely to the previously quoted AMA definition of consent:

The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause.

Consent must be based on an understanding by the subject of the nature and the potential consequences of

fluoridation and its alternatives. The subject must have been informed by health care professionals about all relevant facts, including the risks, which must include a full assessment of the risks related to the individual characteristics of each patient, such as age or the existence of other disease. Clearly, in the case of the fluoridation of the public water supply no such actions have been taken or are planned, so no informed consent is possible. Nor has the state the power to take upon itself the right to make such a decision on behalf of the individual.

MEDICAL MALPRACTICE—INTERVENTION WITHOUT CONSENT

In the case of any state medical intervention, each person exposed is regarded as a patient, and must be accorded his or her full rights as such. Failure to do so constitutes medical malpractice. Yet there has been no example of fluoridation of the public water supply in which every member of the public living in, or visiting, a target area has been informed, directly and individually, by the state or by its medical agents at any level, of the risks they may personally face from any of the known adverse effects of water fluoridation.

The need for full disclosure poses some extremely difficult problems for advocates of fluoridation. It would require health authority representatives to explain the risk to all people in a target area. Freedom to consent to an intervention also demands that such consent may be withdrawn at any time. But in the case of fluoridation, once exposed the subjects cannot effectively opt out. Around half of the fluoride contained in drinking water is absorbed and permanently stored in the body, especially in bone tissue.

There is no currently accepted technique that will remove this substance from the body once it has been absorbed and incorporated into tissue. It is therefore not possible for an objector to withdraw consent effectively and fully—once exposed he or she will continue to bear the residual burden of the consequences of their period of exposure, with no possible prospect of the alleviation of the residual cumulative effects of such exposure.

Article 6 deals with the special cases of individuals who may not be able to give full and valid consent to an intervention, particularly children and those with mental incapacity. This section states that

when a minor or an adult is not capable of consenting to an intervention, the intervention may be carried out only with the consent of parents who have custody of the minor, his or her legal representative, or any person or body provided for by law.

Anyone who has a duty of care towards people within this category—in practice a large proportion of the populace, since it includes children—has the legal right to refuse exposure to the intervention. This right

is also guaranteed under Article 12 of the United Nations Convention on the Rights of the Child.

The protection of the rights of those unable to provide lawfully valid consent to exposure to medical interventions by the state are supported elsewhere under existing international conventions. The UN Convention on the Rights of the Child specifically states that

States Parties (*to the Convention*) shall take all appropriate . . . measures to protect the child from all forms of . . . negligent treatment, [*or*] maltreatment [Article 19] . . . [*and*] shall take appropriate measures to combat disease and malnutrition including . . . the provision of . . . clean drinking water [Article 24]

Clearly, the deliberate contamination of public drinking water supplies with a cumulative toxin that may damage the future life of the child is totally incompatible with this fundamental right of young people. Nor is there any escape clause available that a state might attempt to invoke on the grounds of public health—the provision is absolute and inflexible.

Thus, the issue of consent is a major obstruction to state policies of fluoridation, since it is not possible to secure legal consent (in the full medical definition) from whole populations, and there will always be large numbers of people within any population who are in any case incapable of providing consent except through their legal guardians.

FLUORIDATION AND THE ETHICS OF MEDICAL RESEARCH

Clearly, the investigation of the effects of silicofluorides on large populations must be regarded as medical research, since their full health implications are unclear even as their efficacy in terms of their primary objective is coming under increasing challenge.

This raises the whole issue of the management of medical research, and how the public should be protected against inadequate or dangerous medical experimentation. All medical research on human subjects is controlled by extremely strict ethical codes of practice, under the supervision and scrutiny of medical ethics committees. Article 15 of the Biomedical Convention requires independent examination of the scientific merit of all research, and of the legal and social ethics of the research project, carried out by independent multidisciplinary ethics committees. Detailed specifications regarding the purpose, the method, and statistical analysis of the results of the study must be provided in advance for scrutiny, and these must include ethical justification for the objectives and method of the study.

Ethical validation of a research program is not the sole prerogative of the holders of a specific view regarding the subject. Authorization for the research must take into account any contrary evidence against the hypotheses postulated by the group and an assessment

of the balance of potential benefit and potential harm that the work may present to those subject to it. Where a medical procedure may be challenged with reliable data revealing results contrary to those claimed, and especially where these contraindications are of such a severe nature that they present a significant threat to the well-being of the subjects, extending the research beyond the specifications of the original proposal would be a serious breach of medical ethics.

THE USE OF STATE POLICE POWERS IN THE UNITED STATES

Legal challenges to fluoridation in the United States have tended to take an approach different from those currently developing in Europe. Recent comprehensive reports by Balog¹⁰ and Graham and Morin¹¹ provide detailed analyses of the different forms of challenge that have been attempted in the United States, and the reader is referred to them for full details. Balog's conclusions are that the application of police powers to enforce fluoridation has been widely challenged, but these challenges to fluoridation legislation have failed because they have been judged on the "rational basis" of judicial review. In this there is a presumption that all legislation is constitutional, and that fluoridation meets the requirement to have a reasonable purpose.

However, the "rational basis" does not apply if a statute interferes with a citizen's right to the exercise of a personal right or liberty. Because tooth decay is not a life-threatening and contagious disease, the exercise of police powers is inappropriate, and a higher standard of judicial review, called "strict scrutiny," should be applied.

Forcible medical treatment has been held by the Supreme Court to constitute a violation of a citizen's liberty, in which case a judicial review must apply the much more stringent test of strict scrutiny. If courts were to apply this criterion, then U.S. fluoridation laws would be shown to be unconstitutional because they fail to recognize the constitutionally protected liberty interest to be free from unwanted medical treatment.

Graham and Morin review three important American court decisions that found that either fluoridation was either harmful or its efficacy was not supported by the evidence. The third case was particularly damning. The court:

. . . entered comprehensive findings **based on a preponderance of the evidence**, expressly sustained on appeal, condemning fluoridation as posing a tangible danger of cancer and a good many other human diseases, while expressing doubt even of its capacity to reduce tooth decay. [emphasis added]

Carton and Hirzy, on behalf of the union representing the professionals within the headquarters of the

U.S. Environmental Protection Agency in Washington, DC, have raised the issue of scientific fraud on the part of the government in the fluoride-in-drinking water regulation of 1985.¹² Graham and Morin also identify cases of lying by the government with respect to the cancer-causing potential of fluoridation. If an independent investigation with the appropriate backing of Congress confirms these allegations, then the courts may be more amenable to re-examining this governmental policy.

CONCLUSIONS

We suggest that the fundamental human rights for protection of the individual from medical interventions without consent have not changed in substance since the Nuremburg Code. All ethical codes for the protection of individuals who are subject to medical procedures, whether research or routine medical treatment, endorse the basic requirement for voluntary informed consent.

In those states where fluoridation is practiced, public authorities have failed to submit silicofluorides for assessment for safety in use, or to license them as medicinal substances or drugs, and to ensure that their manufacture complies with the strict quality control regulations under which pharmaceutical chemicals are produced, distributed, and administered. This constitutes a gross breach of national legislation and a violation of the medical ethics to which all medical interventions are required to conform.

The use of fluoridation as a prophylactic medical intervention without the fully informed consent of the public violates numerous articles of international conventions aimed at the protection of human rights with respect to State-sponsored medical interventions and health care, and undoubtedly constitutes medical malpractice.

Recent EU-wide human rights legislation clearly outlaws the practice of fluoridation, and it is only a matter of time before states such as the United Kingdom and Ireland will be forced to comply, since those subject to it may now seek remediation through the European Court.

In the United States, the adoption of the standard of "strict scrutiny" in reviewing the complaints of citizens objecting to the use of state police powers to justify fluoridation should be tested in court, eliminating the anomaly of the use of the lesser standard of "rational basis" that assumes that all legislation is, by definition, constitutional. An independent evaluation of allegations that government policy has been supported by deliberate bias and fraud should be investigated, and should assist greatly in challenging fluoridation in court if these allegations are upheld.

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