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# Weeping and wailing and gnashing of teeth: The legal fiction of water fluoridation

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**David Shaw**

University of Glasgow, UK

## Abstract

This paper provides an analysis of the jurisprudence and legislation concerning the fluoridation of water in the United Kingdom. Water fluoridation is currently permitted by the Water Act 2003, but this appears to contradict legislation and regulations governing food and healthcare in the UK and the EU. It is concluded that the status quo rests on the legal fiction that fluoridated water does not constitute a medication.

## Keywords

water fluoridation, public health, public health ethics, mass medication

## Introduction

While current UK legislation clearly permits water fluoridation, there is a degree of obfuscation concerning whether the practice amounts to medication. Were it to be acknowledged that fluoridated water constituted a medicine, the legality of the practice (as it currently occurs) might be put in serious doubt. This paper explores in detail the legal position of, and legal justifications for, water fluoridation in the UK. First, it examines the UK jurisprudence, which sets the stage for the subsequent legislative analysis. It then goes on to consider the wider European Union (EU) context and how that might (or should) impact on the UK's position. It concludes that an accurate and honest interpretation of the law would result in the conclusion that water fluoridation does indeed constitute medication, as it seeks to improve health by the addition of a chemical, with the result that the current manner of doing so is not compliant with the law.

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## Corresponding author:

David Shaw, School of Medicine, University of Glasgow, 378 Sauchiehall Street, Glasgow G2 3JZ, UK

Email: davidmartinshaw@gmail.com

## The UK jurisprudence

Before examining the current legislation regarding water fluoridation, it will be instructive to examine the most important jurisprudence.

### *The Strathclyde case*

A benchmark court case that predates more recent developments is *McColl v Strathclyde Regional Council*,<sup>1</sup> which involved an elderly lady from Glasgow defeating the plans of the local council to add fluoride to the public water supply. In addition to being notable for its length (143 days for hearing evidence alone<sup>2</sup>) and expense (the applicant, McColl, was receiving legal aid and both sides were funded by the taxpayer), this case was widely seen as striking a blow against water fluoridation. In a victory for personal liberty over the ‘nanny state’, McColl argued that water fluoridation was illegal for four different reasons:

1. it constituted a nuisance;
2. it would breach s. 8 of the *Water (Scotland) Act 1980*;
3. it would breach the *Medicines Act 1968*; and
4. it was *ultra vires*, or outwith the remit of the council.

Lord Jauncey’s 400-page judgment dealt mainly with the medical and scientific evidence for and against water fluoridation, with only a few dozen pages reserved for the legal issues. His summary of that medical and scientific evidence is as follows:<sup>3</sup>

1. Fluoride at a concentration of 1 ppm is not mutagenic.
2. No biochemical mechanism has been demonstrated whereby fluoride at a concentration of 1 ppm is likely to cause cancer or accelerate existing cancerous growth.
3. No association between fluoridation of water supplies and increased cancer death rates in the consumers has been demonstrated.
4. There is no reason to anticipate that fluoride at a concentration of 1 ppm is likely to have an adverse effect upon the migration of leucocytes in the consumer.
5. There is no reasonable likelihood that chronic renal failure patients drinking water fluoridated to 1 ppm will suffer harm.
6. Fluoridation of water supplies in Strathclyde would be likely to reduce considerably the incidence of caries.
7. Such fluoridation would be likely to produce a very small increase in the prevalence of dental mottling which would only be noticeable at very close quarters and would be very unlikely to create any aesthetic problems.
8. The present low levels of fluoride in the water supplies in Strathclyde do not cause caries.

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1. Lord Jauncey in causa *Mrs Catherine McColl (A.P.) against Strathclyde Regional Council*. Court of Session, Edinburgh (SLT, 1983).
  2. A. Johnstone, Battle stations for new fluoride war, *The Herald*, 19 August 1992, [www.heraldscotland.com/sport/spl/aberdeen/battle-stations-for-new-fluoride-war-1.797542](http://www.heraldscotland.com/sport/spl/aberdeen/battle-stations-for-new-fluoride-war-1.797542) (accessed 4 November 2010).
  3. *McColl v SRC*, at 619.

Lord Jauncey's eight statements represent his balanced view of the medical and scientific evidence presented to him by the expert witnesses of both parties. Somewhat remarkably, only one of them has since been disproved by science: it has since transpired that water fluoridation increases quite substantially the rates of both mild and serious fluorosis, the latter of which leads to unsightly mottling of the teeth.<sup>4</sup> In any event, given the evidence as accepted, it was a simple matter for Lord Jauncey to dismiss the plaintiff's claim that it constituted a nuisance:

Since I have reached the conclusion that there is no evidence to suggest that fluoride at the proposed concentration would have an adverse effect upon health it follows that the petitioner's case on nuisance as pleaded fails.<sup>5</sup>

Thus, the first of McColl's arguments failed.

The claim that water fluoridation would breach s. 8 of the *Water (Scotland) Act* hinged on the issue of 'wholesomeness', with Lord Jauncey stating that a breach of statute would occur only if the water supplied by the council in their mains and communication pipes were rendered unwholesome by the addition of fluoride. Given that the evidence showed that fluoridated water was not harmful, it followed that it therefore must not be unwholesome, so this argument failed for the same reason as the nuisance claim: a conclusion that fluorosis was not a significant issue. Jauncey's rejection of the plaintiff's claims on the grounds of nuisance and wholesomeness were based on his conclusion that fluorosis was not a significant issue. In 2012, the evidence shows that it is a problem, so McColl's arguments might carry more weight today. Some anti-fluoridation campaigners have also argued that new evidence shows that WF also causes cancer and kidney problems,<sup>6</sup> but all studies in this area provide only very weak exploratory evidence, and the consensus remains that fluorosis is the only negative medical consequence of WF.

Lord Jauncey's analysis of the argument concerning the *Medicines Act 1968* was rather more complicated. He made it clear that fluoride certainly falls within the definition of a medicinal product under the Act:

Section 130 defines 'medicinal product' and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within that definition.<sup>7</sup>

However, McColl's claim was that the council had no products licence under the terms of the Act, and thus that water fluoridation would be unlawful. Lord Jauncey stated that 'it is the supplier of a medicinal product and not the purchaser thereof who requires to be licensed'.<sup>8</sup> While McColl clearly regarded the council as the supplier, Lord Jauncey

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4. Medical Research Council, *Water Fluoridation and Health* (London, MRC, 2002).

5. *McColl v SRC*, at 624.

6. Fluoride and cancer. Fluoride Action Network. <http://www.fluoridealert.org/health/cancer/> (accessed 21 February 2012).

7. *McColl v SRC*, at 616.

8. *Op. cit.*, at 625.

argued that this would depend upon the council being responsible for the composition of the fluoride compound. McColl argued that the council met this criterion because it specified the composition of the fluoride, but Lord Jauncey held that specification of the particulars of the composition per se is not enough to render a person responsible for the composition of the product; the person must also have procured the manufacture thereof to his or her order. Because the council's supplier was not manufacturing the fluoride to order, but already had it in stock, the council was technically not specifying the concentration or the composition of the fluoride. As such, Lord Jauncey concluded:

The petitioner has failed to establish that any supply by the respondents of fluoride in the drinking water would be a supply to which s. 7(2)(a) [of the Act] applies. Any such supply without a products licence would not therefore be in breach of the Act.<sup>9</sup>

Lord Jauncey did not explore the possibility that fluoridated water itself was a medicinal product, as this was not what McColl had argued. He stated that he did not find it necessary to determine whether a supply of drinking water fluoridated to 1 part per million (ppm) would otherwise be a supply of a medicinal product, namely fluoride. Despite this clear statement, proponents of water fluoridation have misrepresented what Lord Jauncey said, with the British Fluoridation Society stating as follows:

Because fluoridation did not mean the supply of a medicinal product within the meaning of the *Medicines Act 1968* the judge ruled that there was no need for a products licence and hence the petitioner's plea that fluoridation constituted a breach of the Act was repelled.<sup>10</sup>

In fact, Lord Jauncey ruled only that the council, in adding fluoride to water, was not technically a supplier of the fluoride to the public. This leaves open the possibility that fluoridated water itself might constitute a medicinal product being supplied by the council. Indeed, if the relevant criterion for being a supplier is being responsible for the composition of the product, and the council ensures that the fluoridated water contains fluoride at precisely 1 ppm, then it could be argued that the council would be a supplier of a medicinal product under the Act, namely fluoridated water (as opposed to fluoride).

Lastly, McColl claimed that adding fluoride to the water supply was outwith the council's powers. Lord Jauncey explained that the council was also the water authority for the region, and he quoted from the *Water (Scotland) Act 1980* to establish that the law required the provision of 'wholesome water' by the council.<sup>11</sup> Beyond this requirement, 'there were no provisions in either Act which could reasonably be construed as relating to the advancement of the general health of consumers of water'.<sup>12</sup> Therefore, whether the council was acting beyond its powers depended on whether the addition of fluoride

9. Op. cit., at 626.

10. British Fluoridation Society. Comments on the case *Mrs Catherine McColl v Strathclyde Regional Council*, [www.bfsweb.org/documents/summary%20of%20jauncey.pdf](http://www.bfsweb.org/documents/summary%20of%20jauncey.pdf) (accessed 4 November 2010).

11. *McColl v SRC*, at 619.

12. Op. cit., at 619.

was required to make the water wholesome (as opposed to rendering it unwholesome, which was what McColl believed). The key question, as Lord Jauncey stated it, was:

Is wholesome in relation to health to be restricted to health consequent upon contamination of water, that is to say, is wholesome water no more than that which is neither contaminated nor in any other way dangerous to health nor obnoxious to sight or smell? Alternatively is wholesome to be construed as embracing also a positive benefit to health so that not only the health of the consumer consequent upon drinking the water in its natural state can be looked at but also any possible benefit to his general health? The petitioner contends for the former construction and the respondents for the latter.<sup>13</sup>

Lord Jauncey tended to agree with the petitioner on this issue. Although the council argued that it was rendering the water more wholesome by correcting a deficiency in fluoride which caused caries, Lord Jauncey decided in his analysis of the evidence that it was incorrect to say that low levels of fluoride in the water ‘caused’ caries.<sup>14</sup> While the addition of extra fluoride might indeed reduce caries rates, it was quite possible that people might obtain enough fluoride from other sources, and it would therefore be wrong to state that water fluoridation corrected a deficiency in the water.<sup>15</sup> Furthermore, unlike the other chemicals added to public water supplies to render them safe:

Fluoride is intended to produce a positive effect on the body of the consumer after ingestion. Thus the water instead of being the object of treatment becomes the means whereby fluoride is carried into the consumer’s body to effect a result which could also be achieved by the consumption of fluoride pills or of food and drink containing high levels of fluoride.<sup>16</sup>

Lord Jauncey also stated that it was unlikely that Parliament would have sought to give a water authority the power to improve the health of consumers generally, especially as water fluoridation would involve an ‘encroachment’ on individual rights. He then examines sources of authority on the subject of wholesome water. While space precludes a full analysis of this aspect of the case, the ultimate outcome was that Lord Jauncey could find no directly relevant precedent, which left him free to rule that ‘wholesome’ should be construed as was argued by McColl. Therefore, water fluoridation was indeed outwith the powers of the council.<sup>17</sup>

### *The Southampton case*

While the water fluoridation debate began in earnest in the UK with the *Strathclyde* case, the most recent legal developments have concerned Southampton. In early 2009, the South Central Strategic Health Authority announced that fluoride would be added to the public water supply of 200,000 people, despite the fact that 72% of the 10,000 people

13. *Op. cit.*, at 620.

14. So noted in point 8 of his summary of evidence.

15. *McColl v SRC*, at 621.

16. *Op. cit.*, at 621.

17. Note that, although this was a Scottish-based judgment, it applied to all of the UK.

who took part in the public consultation were opposed to the move. (Southampton Council supported water fluoridation, but Hampshire County Council opposed it.<sup>18</sup>) In response, Geraldine Milner, a local resident, sought judicial review of the decision, arguing that fluoridation should go ahead only if a majority of those consulted agreed.<sup>19</sup> In September 2009, her request was granted by Justice Milner of the High Court,<sup>20</sup> but the review did not take place until the beginning of 2011.<sup>21</sup> In February 2011, the review upheld the authority's decision to fluoridate the water supply, with Justice Holman stating:

[C]ontrary perhaps to the belief of Ms. Milner and others, it is not the law that fluoridation can only occur when a majority of the local population agree. . . . [T]he SHA have not acted unlawfully and no court can interfere with their decision.<sup>22</sup>

The draft regulations had stated that water fluoridation should take place only if a majority of the public approved, but, as noted by the reviewing court, this provision was removed from the final version approved by Parliament.<sup>23</sup> This brings us on to the legislation in question.

## The UK legislation

In England and Wales, water fluoridation is now governed by the *Water Act 2003*. This substantial piece of legislation entirely revamped and updated the law on many aspects of water provision, and fluoridation is not even mentioned in the introductory text.<sup>24</sup> Only s. 58 concerns water fluoridation, and this entire section is an amendment to s. 87 of the *Water Industry Act 1991*, which was entitled Fluoridation of Water Supplies at Request of Health Authorities.<sup>25</sup> The new s. 58 changes this to Fluoridation of Water

18. BBC News, NHS forces city to add fluoride, <http://news.bbc.co.uk/1/hi/england/hampshire/7911820.stm> (accessed 16 November 2010).
19. Dentistry.co.uk, Southampton fluoridation challenge launched, [www.dentistry.co.uk/news/2024-Southampton-fluoridation-challenge-launched](http://www.dentistry.co.uk/news/2024-Southampton-fluoridation-challenge-launched) (accessed 16 November 2010).
20. Dentistry.co.uk, Judge pours cold water on fluoridation plans. [www.dentistry.co.uk/news/news\\_detail.php?id=2219&e=Judge-pours-cold-water-on-fluoridation-plansinfo&newstype=patients](http://www.dentistry.co.uk/news/news_detail.php?id=2219&e=Judge-pours-cold-water-on-fluoridation-plansinfo&newstype=patients) (accessed 16 November 2010).
21. The Secret Truth, Southampton – Fluoride – Crucial High Court hearings are put back until January 2011, <http://thesecrettruth.co.uk/wordpress/?p=1400> (accessed 16 November 2010).
22. See *R (on the application of Milner) v Southampton Strategic Health Authority*, [2011] EWHC 218 (Admin), at para. 86. See also J. Reeve, High Court challenge to fluoridation plans for Southampton rejected. *The Daily Echo*, 11 February 2011, [www.dailyecho.co.uk/news/briefing/fluoride/8848663.Fluoride\\_challenge\\_rejected\\_in\\_the\\_High\\_Court/](http://www.dailyecho.co.uk/news/briefing/fluoride/8848663.Fluoride_challenge_rejected_in_the_High_Court/) (accessed 20 July 2011).
23. *Milner v Southampton*, n. 22, at para. 86.
24. See Introductory text, *Water Act 2003*, [www.legislation.gov.uk/ukpga/2003/37/introduction](http://www.legislation.gov.uk/ukpga/2003/37/introduction) (accessed 16 November 2010).
25. Op. cit., Part 3, s. 58, [www.legislation.gov.uk/ukpga/2003/37/section/58](http://www.legislation.gov.uk/ukpga/2003/37/section/58) (accessed 16 November 2010).

Supplies at Request of Relevant Authorities. In England, strategic health authorities (SHAs) continue to be the relevant authorities, but in Wales, the Welsh Assembly has assumed this role.<sup>26</sup> In any event, s. 87(1) of the *Water Industry Act* is amended such that it now states:

If requested in writing to do so by a relevant authority, a water undertaker shall enter into arrangements with the relevant authority to increase the fluoride content of the water supplied by that undertaker to premises within the area specified in the arrangements.<sup>27</sup>

This means that water companies must comply with a request from the Welsh Assembly or an SHA to increase the amount of fluoride in the water. However, before a health authority can make such a request, it must carry out a public consultation, as required by the revised s. 89(1), which states as follows:

Before taking any step mentioned in subsection (2) below, a relevant authority shall (a) consult and ascertain opinion in accordance with regulations made by the appropriate authority; and (b) comply with the requirements set out in regulations made by the appropriate authority.

There are another four subsections within s. 89, but none of them concerns consultation; they all relate to arrangements with the water supplier. A cynic might wonder why this section is named 'Consultation' when only a small part of it actually concerns that topic. In addition, authorities need only consult to the extent that their regulations require, so if they do not want a thorough consultation, they can simply change their own regulations. Note also that health authorities are required only to consult and to establish public opinion; they are not required to take any account of it, as Geraldine Milner found out when she took Southampton SHA to court. Just as s. 89 is entitled 'Consultation' but does not really concern itself with consultation, so the level of public consultation required before addition of fluoride to water supplies does not really involve true consultation in the sense of actually paying attention to what the public wants. Of course, even if the public were actually asked to vote on whether to proceed with water fluoridation, this might be ethically suspect, as it could lead to a majority decision coercing a minority into receiving medical treatment against the latter's wishes.

A few other provisions of the Act are relevant. The revised s. 87(A) concerns the target concentration of fluoride, which should be 'maintained at the general target concentration of one milligram per litre' (which is equivalent to one part per million).<sup>28</sup> Parenthetically, it was perhaps unwise for the legislation to specify a medically optimum amount when new research might indicate that more or less is desirable; it might have been more prudent to state that water fluoridation should be 'maintained at the concentration current science shows to be medically optimal'. In any event, the other s. 87(A) subsections are concerned with arrangements between the authority and the supplier, as is s. 87(B).

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26. Op. cit., s. 58(2) [87(3)].

27. Op. cit., s. 58(2) [87(1)].

28. Op. cit., s. 58(2) [87(A)].

The revised s. 87(C) specifies the authorised methods for adding fluoride to water supplies, stating as follows:

Where, pursuant to any such arrangements, the fluoride content of any water is increased, the increase may be effected only by the addition of one or more of the following compounds of fluorine: hexafluorosilicic acid ( $\text{H}_2\text{SiF}_6$ ) [or] disodium hexafluorosilicate ( $\text{Na}_2\text{SiF}_6$ ).<sup>29</sup>

We will return to these two chemicals later in this paper. In the meantime, s. 90 is worth mentioning, as it covers indemnity for any legal action that water suppliers might face as a consequence of water fluoridation:

The Secretary of State may, with the consent of the Treasury, agree to indemnify any water undertaker in respect of liabilities which it may incur in complying with arrangements entered into by it pursuant to section 87(1) above.<sup>30</sup>

Once again, a cynic might speculate as to why such a provision for indemnity is necessary if water fluoridation is perfectly safe, but it is understandable that the government would need to offer indemnity when the legislation forces water suppliers to comply with health authorities' requests. Section 90(A) requires any health authority that implements water fluoridation to monitor the effects of the arrangements on the health of persons living in the area specified in the arrangements, and to publish reports containing an analysis of those effects within four years of the commencement of water fluoridation, and every four years thereafter. While such reports might identify any increase in fluorosis, any more serious side-effects would be very difficult to detect because of all the potential confounders. And, once again, why are such precautionary measures necessary if water fluoridation is safe?

Finally, s. 91 covers fluoridation schemes that were in place prior to 1985, stating that relevant pre-1985 arrangements shall be treated for the purposes as if they were arrangements entered into by the water undertaker in question with the relevant authority under s. 87(1). This means that any historical water fluoridation schemes that were introduced without any public consultation can continue as if the public had been consulted.

In Scotland there is no recent legislation governing the addition of fluoride to public water supplies, although this is mitigated somewhat by the *Strathclyde* case. Fluoridation in Scotland is therefore still governed by the *Water (Fluoridation) Act 1985*. This legislation is very similar to that part of the *Water Act 2003*, although some of the wording is slightly different. The only substantial difference regards consultation, which is treated slightly more seriously than in the more recent Act. The former Act requires the health authority to publish details of the proposal in one or more newspapers circulating within the area affected by the proposal, and republish the same information within one week.<sup>31</sup> While the Act does not require that the health authority should abandon water fluoridation if the public is against the scheme, it does state that:

29. Op. cit., s. 58(2) [87(C)].

30. Op. cit., s. 58(2) [90].

31. *Water (Fluoridation) Act 1985*, s. 4(4).

Where a health authority have complied with this section in relation to the proposal they shall, in determining whether or not to proceed, have such regard as they consider appropriate to any representations which have been made to them with respect to it.<sup>32</sup>

Although this might seem more respectful of public opinion, the ‘such regard as they consider appropriate’ clause is very similar to the stipulation in the *Water Act 2003* that authorities need only consult as much as is required by their own regulations. In both cases, it is up to the authority to decide how much (if any) attention should be paid to what the public says.

## UK regulation

Given that water fluoridation aims to prevent dental disease by adding a supplement to the water supply, one might imagine that this constitutes medication, which would require regulation by some official (health-related) body. In fact, the Medicines and Healthcare Products Regulatory Agency (MHRA) has stated that water fluoridation is outwith its remit:

As drinking water is quite clearly a normal part of the diet the MHRA does not regard it to be a medicinal product.<sup>33</sup>

Although it is certainly true that water is a normal part of the diet, and is not itself a medicinal product, the MHRA seems to miss the point: if something is *added* to the water in order to achieve a medical aim, it could reasonably be argued that the water then *contains* a medicinal product – even if fluoride would have been present naturally in smaller amounts. The MHRA’s logic would seem to suggest that it would be outwith its remit to intervene if the government decided to add contraceptives to the water supply, as water would still be a normal part of the diet.

Furthermore, the MHRA’s stance is contradicted by the EU’s definition of a medicinal product as any substance or combination of substances ‘presented as having properties for treating or preventing disease in human beings’.<sup>34</sup> As stated above, fluoride is indeed presented as preventing oral disease; thus, water fluoridation adds a medicinal product to the water supply. In addition, we have seen that Lord Jauncey ruled that fluoride falls within the *Medicines Act 1968*.<sup>35</sup> The *Medicines Act 1968* states that:

Subject to the following provisions of this section, in this Act ‘medicinal product’ means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say – (a) use by being administered to one or more human beings or animals for a medicinal purpose; (b) use, in circumstances to which this paragraph

32. Op. cit., s. 4(5).

33. Personal communication, MHRA. Referenced in Nuffield Council on Bioethics Public Health: Ethical Issues. 2007, p.130, reference 59.

34. See *infra*, Article 1.2 of the EU Directive 2004/27/EC on Medicinal Products for Human Use.

35. *McCull v SRC*, at 616.

applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.<sup>36</sup>

While it might appear slightly circular to say that a medicinal product is something that is used for a medicinal purpose, that next section of the Act defines several different medicinal purposes, of which the first is ‘treating or preventing disease’ and the last is ‘otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way’.<sup>37</sup> The former of these purposes certainly appears to be true of adding fluoride to water, and the latter also seems to apply: fluoride aims to temporarily delay or permanently arrest the physiological process of decay development.

The only loophole that could allow proponents of water fluoridation to argue that it does not constitute a medicinal product would be to argue that only s. 1(b) applies to water fluoridation inasmuch as fluoride is not being directly administered as required by s. 1(a). If we accept this logic, then s. 3 comes into play; it states that s. 1(b) refers only to ‘use in a pharmacy or in a hospital; use by a practitioner; [or] use in the course of a business which consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies’.<sup>38</sup> This would obviously exclude the addition of fluoride to water by water companies. However, this strategy is somewhat suspect; water fluoridation is a method of administering fluoride to people, so s. 1(a) does seem to apply.

The MHRA’s website has a section entitled ‘Borderline products’, which sets out the organisation’s criteria for medicinal products in more detail. This explains that foods, beverages and dietary supplements such as vitamins and minerals are subject to food regulation rather than medicine regulation. This would tend to support the MHRA’s line that fluoridated water is a foodstuff rather than a medicine. But there are exceptions to this rule:

However, should any of the above contain a pharmacologically active substance or make medicinal claims (claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicinal) [sic]. For example, a toothpaste would generally be considered as a cosmetic, but if it is marketed with claims to treat or prevent ‘sensitive’ teeth or it contains an active ingredient known to have such an effect then it would fall within the definition of a medicinal product and be subject to medicines control.<sup>39</sup>

Once again, medicinal claims are certainly made on behalf of water fluoridation. Furthermore, it is ironic that the MHRA should use toothpaste as an example of a product that could be classed as medicinal if certain claims are made about it. Fluoride toothpaste

36. *Medicines Act 1968*, s. 1.

37. *Op. cit.*, s. 2.

38. *Op. cit.*, s. 3.

39. Medicine and Healthcare Regulatory Agency (MHRA). Borderline products, [www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Borderlineproducts/index.htm](http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Borderlineproducts/index.htm) (accessed 26 July 2011).

is frequently claimed to protect teeth from decay, so under the MHRA's definition, it is subject to medicinal control. Indeed, in a marketing authorisation for a Colgate tooth-paste, the MHRA states:

Sodium fluoride applied topically after tooth eruption reduces caries by inhibiting demineralisation and promoting remineralisation of the tooth surface and by inhibiting the cariogenic microbial process.<sup>40</sup>

Is the same not true of fluoridated water simply because it is a normal part of our diet? The MHRA's stance on water fluoridation is muddled because it seems to have forgotten its own rules on borderline products. Its own rules state that it is not enough to simply state that something is a foodstuff; as stated above, if medical claims are made on behalf of that foodstuff, it is a medicine.

Even if we grant that the MHRA is correct in arguing that water fluoridation is out-with its remit, we might still think that adding fluoride to an essential component of everyone's diet would require some kind of regulation. Thus, we turn to the Food Standards Agency (FSA), where more suspect logic is to be found. The FSA's Expert Group on Vitamins and Minerals has stated the following:

Two of the major sources of [fluoride] exposure (drinking water and dental products, the latter being considered either licensed medicines or cosmetics) are neither foods nor food supplements.<sup>41</sup>

To the layperson, it might come as something of a surprise to learn that drinking water is not a foodstuff, given that it is the most important foodstuff of all. In fact, the FSA's stance is slightly misrepresented by this statement. Drinking water is indeed regarded as a foodstuff, but only once it emerges from the tap; this means that the addition of fluoride to water is outwith the remit of the FSA, as water fluoridation takes place before the water becomes a foodstuff, which it must be before the FSA has any power to monitor any supplementation.<sup>42</sup> Thus, we have a situation where the MHRA says that water fluoridation is not its concern because water is obviously part of the normal diet, and the FSA says that water fluoridation is not its concern because water is only part of the normal diet once it comes out of our taps.

With both the MHRA and the FSA denying responsibility for overseeing water fluoridation, the only regulators left are the Drinking Water Quality Regulator for Scotland (where there is no fluoridation) and the Drinking Water Inspectorate in England and Wales. This latter organisation aims to provide independent reassurance that water

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40. MHRA. Public Assessment Report: Colgate Sensitive Toothpaste, [www.mhra.gov.uk/home/groups/l-unit1/documents/websitesresources/con2023699.pdf](http://www.mhra.gov.uk/home/groups/l-unit1/documents/websitesresources/con2023699.pdf) (accessed 26 July 2011).

41. Expert Group on Vitamins and Minerals. Safe Upper Levels for Vitamins and Minerals (London, Food Standards Agency, 2003). Available at: [www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf](http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf) (accessed 21 October 2010).

42. Personal communication, Food Standards Agency. Referenced in Nuffield Council Report on Public Health Ethics, op. cit., p. 130, footnote 60.

supplies in England and Wales are safe and drinking water quality is acceptable to consumers.<sup>43</sup> Part of its role is therefore to make sure that fluoride is not present at too high a level, as dictated by the *Water Act 2003*. Perhaps unsurprisingly, fluoride and fluoridation are not mentioned anywhere on the Inspectorate's website.<sup>44</sup>

Before moving on to European legislation, one other aspect of UK law is worth mentioning. Douglas Cross, an anti-fluoridation campaigner, has suggested that fluoride is a poison and that adding it to water might be akin to assault:

In fact, the Offences Against the Person Act 1861 prohibits the administration of any 'noxious or poisonous' substance, including any material containing such substances, to any person. Sodium fluorosilicate is specifically listed as a poison in Part II of the UK Poisons List Order 1982. Fluorosilicic acid, the fluoridation substance of choice and somewhat more toxic than the sodium salt, contains another Part II listed poison, hydrogen fluoride. Adding either to the public drinking water supply could be interpreted as a violation of the 1861 Act.<sup>45</sup>

This somewhat extreme claim has not been subjected to peer review. The relevant sections of the Act concern maliciously administering poison, etc. so as to endanger life or inflict grievous bodily harm, or with intent to injure, aggrieve or annoy any other person.<sup>46</sup> Cross's claim would seem to fail on the basis of intent, as water fluoridation is certainly not intended to harm maliciously. Only if a case could be made that the near-certainty of causing fluorosis in some persons constituted intent to injure, aggrieve or annoy could such a case be made, and even then any such harm would seem to be more foreseen than intended.

## European legislation

All the UK legislation concerning the supply of water to the public must be compliant with the EU's Water Directive, which states that the maximum permissible concentration of fluoride in drinking water is 1.5 ppm, but says nothing specific about water fluoridation.<sup>47</sup> The FSA's stance on water fluoridation appears to be in contradiction to the EU Water Directive, Article 2 of which states:

'Water intended for human consumption' shall mean: '... all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers'.<sup>48</sup>

43. See Drinking Water Inspectorate, at [www.dwi.gov.uk/](http://www.dwi.gov.uk/) (accessed 1 November 2010).

44. Op. cit.

45. D. Cross, 'Response: the "Alice in Wonderland" world of the ethics of water fluoridation', *British Medical Journal* 355 (2007), p. 699, [www.bmj.com/content/335/7622/699/reply](http://www.bmj.com/content/335/7622/699/reply) (accessed 1 November 2010).

46. *Offences Against the Person Act 1861*, ss. 23 and 24.

47. EU Directive 98/83/EC Relating to the Quality of Water Intended for Human Consumption, at p. 14, <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1998/L/01998L0083-20031120-en.pdf> (accessed 21 February 2012).

48. Op. cit., Article 2.

This would certainly seem to imply that water could be regarded as a foodstuff even before fluoride is added. However, things are rather more complicated than that. Could proponents of water fluoridation argue that the Water Directive does not apply in the case of water fluoridation? Article 3(a) exempts water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the consumers concerned. This cannot be true of fluoridated water, as it can both improve oral health through a protective effect and harm it via fluorosis. Article 3(b) states that waters intended for medicinal products are exempt from the provisions of the Water Directive, but if the FSA conceded that fluoridated water is medicinal, then the MHRA would have to change its stance.

The FSA's claim that water is only a food once it emerges from taps stems from the parameters stated in Article 6(1)(a) of the Water Directive, which states that the quality standards laid down in Article 5 apply, in the case of water supplied from a distribution network, 'at the point, within premises or an establishment, at which it emerges from the taps that are normally used for human consumption'. In addition, European Parliamentary Regulations on food stipulate as follows:

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.<sup>49</sup>

Thus, the FSA's stance does appear to be correct. However, the EU instruments are in a state of tension with one another. Article 2 of the Water Directive makes it clear that water is regarded as 'intended for human consumption' in its original state or after treatment, which implies that it is a foodstuff even before it enters the distribution network; yet Article 2 of the Food Regulations states that water is regarded as food only once it exits the taps. This leads to the curious situation where the water is intended for human consumption, but is not a foodstuff, from the reservoir all the way through treatment and to the pipes in our houses, yet it becomes a foodstuff once we pour it. This disparity could be due to the fact that Article 6 of the Water Directive lays down criteria for when quality measures should be imposed on water, whereas the Food Regulation treats this compliance point as being definitive of the status, rather than of the quality of the water. Furthermore, Article 1 of the Water Directive states that waters are medicinal products within the meaning of Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.<sup>50</sup> This suggests that both the MHRA and the FSA are wrong about the foodstuff status of fluoridated water: legally speaking, it is not a

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49. Article 2, European Union Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

50. EU Directive, 'Quality of water', Article 3.1(b).

foodstuff at all, but a medication. This in turn means that the Water Directive is not the relevant authority.<sup>51</sup>

This leads us to the Medicinal Products Directive, which defines a ‘medicinal product’ as:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.<sup>52</sup>

The European Court of Justice has ruled that meeting (a) or (b) is sufficient for a product to be regarded as medicinal.<sup>53</sup> As we have seen, the proponents of water fluoridation certainly present the addition of fluoride to water supplies as being preventative of oral disease via the action of fluoride on the teeth. Given this definition, it is difficult to see how they (or the MHRA) could deny that fluoridated water is indeed a medicinal product. Article 2(1) states that ‘This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process’. The addition of fluoride to water and production of fluoridated water would also appear to fulfil these criteria. Cross has suggested that water fluoridation in Britain breaches further Articles of this Directive:

Article 6 prohibits placing any medicinal product on the market without a marketing authorization. Article 87 of 2001/83/EC is retained unchanged in 2004/27/EC; it is illegal to advertise or otherwise promote any unlicensed medicinal product. Persons, organizations, and even State administrations promoting medicinal claims for it, are in breach of the legislation. In the UK, advertising unlicensed medicines can carry a sentence of up to 2 years in prison.<sup>54</sup>

Marketing authorisation in the UK would be obtained from the MHRA, which denies that fluoridated water is a medicinal product. Cross also argues that once fluoride – in any form whatsoever – is added to water with the intent to medicate, it ceases to be a

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51. It is also worth noting that the Preamble to the Water Directive states that it applies where (1) the parametric values are based on the scientific knowledge available and (2) the precautionary principle has been taken into account. A case could also be made that the precautionary principle would rule out the use of substances such as fluoride, which may pose a small risk of long-term adverse effects as well as fluorosis. For more on the precautionary principle, see UNESCO, The precautionary principle, [unesdoc.unesco.org/images/0013/001395/139578e.pdf](http://unesdoc.unesco.org/images/0013/001395/139578e.pdf) (accessed 25 July 2011).
52. EU Directive 2004/27/EC on medicinal products for human use, Article 1.2.
53. *Upjohn* 1989 C-112/89; referenced in MHRA, What is a medicinal product?, [www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007544.pdf](http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007544.pdf) (accessed 1 November 2010).
54. D. Cross, The status of fluoridated water in European Community legislation, *Fluoride* 38 (2005), pp. 335–336, [www.fluorideresearch.org/384/files/384335-336.pdf](http://www.fluorideresearch.org/384/files/384335-336.pdf) (accessed 1 November 2010).

food, and becomes a medicinal product, subject to the Medicinal Products Directive. This line of argument would obviate the FSA's stance that fluoridated water is not a food, and put the onus firmly back on the MHRA. Despite the protestations of the latter, and the controversial nature of Cross's claims, it appears to be true that fluoridated water is a medicinal product under EU law. The simple fact that everyone needs to drink water does not change this, despite the curious arguments of the MHRA.

Other European activity is worthy of consideration. Article 5 of the Council of Europe's Convention on Human Rights and Biomedicine (Biomedicine Convention) states that:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.<sup>55</sup>

This is a typical statement regarding the importance of obtaining informed consent before carrying out any medical intervention. If water fluoridation does indeed constitute such an intervention, and we make the reasonable assumption that not everyone in a given area would consent to water fluoridation, then it would appear to be in breach of the Biomedicine Convention. Of course, the UK is not a signatory to the Biomedicine Convention, which in any case does not have the full force of law. Even if the UK were obliged to adhere to it, Article 26 states that no restrictions shall be placed on the exercise of the rights and protective provisions contained in the Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.<sup>56</sup> Once again, proponents of water fluoridation could argue that the protection given to public health by water fluoridation provides exemption from the consent rule. While water fluoridation certainly protects some people's health, it also harms others by causing fluorosis, so it is not obvious that fluoridation meets this criterion. Indeed, given the importance placed on the rights and freedoms of others by this Article, it might be somewhat disingenuous for supporters of water fluoridation to take this line. Furthermore, as the All-Party Parliamentary Group Against Fluoridation has pointed out, fluoridation is a different type of public health measure from (for example) vaccination; in the case of the latter, the vaccinated person poses less of a risk to others because he cannot infect them; in the case of water fluoridation, there is not the same public health benefit between persons.<sup>57</sup> In addition, vaccination is the only effective method if we wish to prevent certain infections; there are many other ways of reducing caries.

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55. Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Article 2.

56. *Op. cit.*, Article 26(1).

57. All-Party Parliamentary Group Against Fluoridation. Response to Nuffield Council Report. 3. 13, [http://www.appgaf.org.uk/reports/reports\\_nuffield\\_apr08/](http://www.appgaf.org.uk/reports/reports_nuffield_apr08/) (accessed 1 November 2010).

The European Convention on Human Rights (ECHR) itself has also been used to argue against fluoridation. In the case of *Jehl K Doberer v Switzerland*, it was argued that water fluoridation violated the right to private and family life under Article 8 of the ECHR.<sup>58</sup> However, the European Commission on Human Rights (predecessor of the European Court of Human Rights) ruled that this right is conditional and can be outweighed by other considerations. In this case, as the weight of evidence submitted by the state convinced the Commission that fluoridation does confer such benefits, the argument for the presumed medical advantage to the general public took precedent over the claimed violation of the petitioner's right to privacy.<sup>59</sup> Given the legislation, this decision was legally correct, but perhaps ethically questionable.<sup>60</sup>

The only case where a court has ruled that water fluoridation was in violation of Article 8 of the ECHR was in the Netherlands. In 1973 a group of plaintiffs sought an injunction to stop the city of Amsterdam from adding fluoride to the water supply. They argued that interference with the right to privacy by the state is justified only in accordance with the law. The Dutch Supreme Court ruled that this phrase meant 'permissible under an Act of Parliament'. This in turn meant that water fluoridation was indeed illegal, as the Water Supply Act prescribed the supply of good drinking water, and adding fluoride to drinking water goes beyond this legal purpose.<sup>61</sup> This judgment, which is very similar to Lord Jauncey's ruling in the Strathclyde case put an end to all water fluoridation in the Netherlands, and it is somewhat surprising that more reference is not made to it by opponents of water fluoridation. If it were successfully argued in the UK that water fluoridation constitutes medication, then a case could perhaps be made that this too goes beyond the powers conferred by law.

It has also been suggested (somewhat tenuously) that water fluoridation could constitute a violation of Article 3 of the ECHR, which states that no one shall be subjected to torture or to inhuman or degrading treatment or punishment. Cross argues that the court in *Doberer v Switzerland* should have used Article 3 rather than Article 8 because this right cannot be abrogated.<sup>62</sup> However, Cross concedes that the threshold for such treatment is quite high, and it is unlikely that an individual challenge under Article 3 would succeed. Cross goes on to make the unusual move of suggesting that a community's rights are violated by water fluoridation. He argues that, while it is impossible to know in advance exactly who will be affected adversely by water fluoridation, it is a statistical

58. Application No. 17667/91, 1993, European Commission of Human Rights (First Chamber).

59. As noted by D. Cross, A conflict of interests: Human rights, civil liberties and water fluoridation, [www.xproexperts.co.uk/newsletters/mar11/fluoridation%20article.pdf](http://www.xproexperts.co.uk/newsletters/mar11/fluoridation%20article.pdf) (accessed ).

60. Switzerland stopped all water fluoridation in favour of salt fluoridation in 2003: see J. Meyer and P. Wiehl, *Schweiz Monatsschr, Zahnmed* 113 (2003), pp. 702 (in French) and 728–729 (in German).

61. H. Van Schooten, 'Law as fact, law as fiction: a tripartite model of legal communication', in A Wagner, W Werner and D Cao eds, *Interpretation, Law and the Construction of Meaning* (Germany, Springer, 2007). Available at: [www.springerlink.com/content/j669t714u3t63782/fulltext.pdf](http://www.springerlink.com/content/j669t714u3t63782/fulltext.pdf) (accessed 21 February 2012).

62. D. Cross, 'Status of fluoridated water'.

certainly that some will develop fluorosis (this is one disadvantage of giving a generally beneficial drug to everyone).<sup>63</sup>

Although this argument is unlikely to succeed in court, it does highlight the interesting point that we cannot know in advance who will benefit and who will be harmed by water fluoridation, although we can assume that those who are already receiving sufficient fluoride are both less likely to benefit and more likely to be harmed.

## **Conclusion**

UK legislation currently permits water fluoridation, but we have also seen that the FSA's and MHRA's views on the regulation of fluoride do not bear up to scrutiny, and it seems likely that FW does meet the UK and EU definitions of a medicinal product. If this is the case, then UK legislation currently permits the addition of a medicine to public water supplies, which in effect makes the water itself a medicine. It is unsurprising that government agencies would prefer to deny that this is the case through the use of a legal fiction, but it is not obviously unethical to provide a medication to the public in this way (although Lord Jauncey clearly thought it was outwith a council's remit to do so). Whether it is ethical to provide fluoride to the public in this way is another question, but if the arguments in this paper are correct, there are major implications for the continuation of water fluoridation in the UK.

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63. Op. cit.