Water Fluoridation as Mass Medication

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Article 5 – General rule

'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.' [1]

(Convention on Human Rights and Biomedicine)

Summary

Water fluoridation is the addition to public drinking water supplies of chemical substances containing fluorine that release ionic fluoride when dissolved in water. This intervention is generally carried out by a State with the aim of preventing or reducing the prevalence of dental decay, especially amongst children, and is effectively unavoidable. As a non-consensual invasive clinical intervention it is contrary to medical codes of practice and in violation of Article 8 of the European Convention on Human Rights. In virtually all cases, fluoridating States attempt to circumvent medical law by asserting that fluoridated water is not a medicinal product, and thereby attempt to falsely persuade the public that its use does not constitute mass medication.

In this brief review, this argument is examined with respect to internationally adopted definitions of what constitutes a medicinal product and of medication. It concludes that under internationally perceived definitions of what constitutes a medicinal product, the assertion by pubic authorities that fluoridated water has the therapeutic property of preventing tooth decay is sufficient to class it as a medicine, regardless of whether it has any such property or not.

The administration of fluoridated water with the intent to prevent disease, even amongst those who do not suffer from that disease, is a deliberate act of non-consensual mass medication, and as such is both unethical and in tension with medicinal law. The diversion of public funds to issue biased, unbalanced and misleading propaganda in order to increase public support for fluoridation is both undemocratic and contrary to international standards relating to the holding of public referenda.

Fluoridation and the violation of human rights

The most commonly used source material for fluoridating public drinking water supplies is low grade fluorosilicic acid, which originates as an extremely hazardous toxic waste product generated from the large-scale industrial processing of phosphate minerals to manufacture agricultural fertiliser In some countries, such as Australia, technical grade sodium fluoride is also used, mainly because it is more convenient for formulating the finished product in smaller water treatment works.

The practice is generally mandated by the State, and often imposed regardless of public opinion and consent. A recent court ruling in the UK[2] established that implementing health authorities are not required to desist if public opinion is against the practice, but only to take note of it - such lip-service to democracy renders any form of public referendum on proposals to fluoridate a public water supply entirely pointless.

There is considerable concern amongst members of the public that this form of public health intervention is oppressive and undemocratic. This is most commonly expressed as disquiet about unavoidable mass medication. This emotive term is used universally for any activity, generally derived from State-level political policy, that appears to over-ride the right of individuals to decide whether or not to allow themselves and, most especially, their children to be subject to medical treatment regardless of whether or not they consent.

The right to personal autonomy is clearly set out in many treaties, Conventions and laws protecting human rights. The relevant laws and agreements specifically prohibit the administration of any form of enforced or coerced medical treatment. The manifest violation of such a right by ordering the deliberate addition of a pharmacologically active substance to drinking water in a manner that is effectively unavoidable invariably causes feelings of alarm and resentment to many individuals in all communities that have become enrolled in this scientifically disreputable and discredited practice.

Concern over the human rights issue is entirely justified In the case of Jehl K Doberer v Switzerland [3], the European Commission on Human Rights (the Commission) ruled that water fluoridation violated the right to private and family life under Article 8 of the *European Convention on Human Rights*. At that time (1993) the Commission accepted the argument of the respondent, the Grand Council of Basel-Stadt, that the benefits of fluoridation outweighed any adverse effects, and that this violation was therefore permissible because it appeared to be proportionate.

But a decade later the respondent abolished fluoridation, despite the Commission's earlier ruling in its favour. The Grand Council had belatedly discovered that the presumed benefits were in fact illusory. Of even greater concern was the discovery that there had been an alarming increase in disfiguring dental fluorosis amongst adolescents in the city. Although no subsequent challenge to this decision has been placed before the European Court of Human Rights (ECHR, which replaced the Commission in 1998), it is questionable now that the Court would now reaffirm that the proportionality of the practice remains a reliable pretext for the continuation of fluoridation.

Moving the challenge from science across to law - why legal challenges to fluoridation are increasing.

For many years the primary arena in which public resistance to fluoridation has been fought is that of medical and dental science. But whilst scientists acknowledge that all research entails some degree of uncertainty, proponents of fluoridation invariably adopt a rigid position of absolute certainty that the practice is completely safe and effective.

It is relevant to note that few of these proponents have any post-graduate training or expertise in scientific disciplines. They habitually rely for support for their claims on on the apparent correlation between dental decay in children and the presence or absence of fluoride in drinking water, failing to recognise that correlation does not constitute proof of causation.

Most of the data on which the pro-fluoridation lobby rely are derived from epidemiological and ecological studies that generate information that is invariably of uncertain quality. The information is subject to very large errors and confounding factors, and may even have been generated by using deliberately improper methodology. For example the unbiased collection of dental disease statistics in the UK is subverted by instructing enumerators to regard even moderately or severely fluorosed teeth as 'sound'. In fact there are no official data on the prevalence of dental fluorosis amongst children in the UK, and its existence is subject to a deliberate and robust policy of concealment and denial by health authorities.

Where reliable scientific evidence discloses valid cause for concern over the alleged safety and efficacy of fluoridation, advocates frequently resort to misquoting such inconvenient source materials, alleging that the research supports their claims when it actually refutes them [4]. On occasions they even engage in the blatant misreporting of data, as for example in an apparently reputable (and now widely cited) Press Release on the prevalence of fluorosis in the United States[5]. These fraudulent tactics have resulted in the rejection of all and any evidence against the practice by many governments and State authorities, no matter how reliable and damning evidence against this public health intervention may be.

Such disreputable practice, reinforced by well-funded political lobbying, has diverted debate away from the robust arguments against the practice that emerge from analysis of the application of food and medicinal law to water fluoridation. In relatively recent times the argument over the acceptability - and even the permissibility - of water fluoridation have now begun to take centre stage in the world-wide controversy over this practice.

The regulation of fluoridated water occupies the shifting and uncertain ground between food and medicinal law, and its persistence in the face of mounting adverse scientific evidence against it is increasingly coming to rely on the absurd claim that the product is not a medicine. Instead proponents - and this also includes regulators - assert that the product is drinking water that has been fortified with the mineral fluoride in order to restore a supposed deficiency in most natural water sources. There is no legal justification for this extraordinary evasion.

In this review I examines decisions of Courts in both the European Union and in Australia that are relevant to this confrontation. It concludes that however the argument is formulated, fluoridated water is indeed a medicine or therapeutic good, and that its delivery through public water supply distribution networks (known as reticulation systems in Australia) is indeed a prohibited and unethical form of mass medication.

Medicines and drugs

Perhaps surprisingly, there appears to be no formal definition of 'mass medication'. Medication can refer to either a product - a medicine - or to the practice of administering or supplying a medicine. However, if the product is not classed as a medicine then one may question whether or not its administration to the public is indeed 'mass medication'.

The terms medicine and drug are often used interchangeably, but this is unjustified in its social context - 'drug' has the connotation of a substance that may be prohibited or harmful - but many medicines are themselves undoubtedly also harmful if not used according to prescription The common public perception of medication is that it means the use of a product that has specifically beneficial uses, and is not mainly recreational or used with some form of aggressive intent, so I will use the ordinary layman's understanding of 'medicine' in this review.

Therapeutic products

Under Australian law, medicines are therapeutic goods. The Therapeutic Goods Act 1989 recognised both conventional (allopathic) medicines and homeopathic remedies as such, and requires both kinds to be registered and regulated under the Act. The European legislation has virtually the same provisions.

This implies that the dilution of a substance or preparation derived from a mother substance or source material is irrelevant in deciding if a preparation or good is a medicinal product or good. The commonly issued claim that fluoridated drinking water is not a medicine because it is only water that has been 'fortified to achieve the optimum concentration' is both foolish and diversionary - all medicines are formulated with this intent.

The two arms of the definition of a medicine - function and presentation

A therapeutic medicinal product is one that is used to diagnose, prevent of cure a human disease. There are other 'therapeutic goods' that are classed as, for example, devices - these are not medicines, and are dealt with differently to medicinal substances.

Medicinal products (medicines) may be medicinal by function or by presentation In almost all codes of medicinal law, there are two quite distinct ways in which a product may be classed as a medicine. They may be medicinal because they are formulated to exert a specified pharmacological effect on the recipient. Or they may be presented - that is, claimed, promoted or advertised - as having such an effect. Article 1 of the EU's *Medicines for Human Use Directive* 2004/27/EC 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.'*

The Australian Therapeutic Goods Act 1989 rather more tersely defines medicines as being

> *therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human*

In this Australian definition, the term 'representation' is equivalent to 'presentation' in the European law; American and Canadian legislation also takes approximately the same approach in defining medicines or, as they prefer, 'drugs'.

Many, if not all, recognised medicines are medicinal both by presentation and by function, but a medicinal product or therapeutic good may also be medicinal by presentation alone. If it is claimed to have, or promoted as having, the capacity to prevent or cure a disease, then its actual pharmacological properties (or, indeed, its lack of them) are entirely irrelevant. This provides a legal hook on which regulators can hang a prosecution for attempting to supply a fake medicine! But the assertion by State dental public health sectors that fluoridation is completely 'safe and effective' is the principal prop on which the entire fluoridation House of Cards depends.

So under both European and Australian medicinal codes, a therapeutic good is a medicine if it is formulated with the intent to exert an established pharmacological action on the body of the recipient. But equally, it is still a medicine if it is administered with the intent to persuade the public that it has such a property, even if it does not actually work! This even applies if the consumer product to which the fluoride is added is normally regarded - like drinking water - as a food, and the final concentration is not greater than that which is permitted to occur naturally in that product. As several European Court of Justice rulings have emphasised this point. In the ter Voort decision the ECJ stated ‘

> *A product which is recommended or described as having preventive or curative properties is a medicinal product . . . even if it is generally considered as a foodstuff and even if it has no known therapeutic effect in the present state of scientific knowledge’.* [6]

Can a person be medicated if they do not have a disease to be cured?

Proponents may argue that medication cannot be said to occur if those to whom a product is administered do not actually have a disease - that medication can only exist in the presence of a disease. Such nonsense simply does not wash with the Courts. ‘Medication' is not dependent on the subject having an existing disease, but refers to the act of administering the product or substance to an individual with the intent to prevent or cure a disease.

This spurious argument was roundly dismissed by the ECJ when it ruled that

> *a product which is not "for treating or preventing disease in human beings or animals" is a medicinal product if it may be administered "with a view to ... restoring, correcting or modifying physiological functions" [. . .] products which alter physiological functions in the absence of disease, such as contraceptive substances, also fall within the scope of that definition.* [7]

Both the European commission and some State regulators of medicines have on occasions fallen back on the circular argument that a product (such as fluoridated water) that has not been registered as a medicine, cannot therefore be a medicine. This perversely ignores the acknowledged existence of a very large number of unlicensed medicines and drugs - ‘specials’ - that are in wide use in medicine.

But if a preparation - whether licensed or not - is given 'with a view to modifying physiological function' - as for example, by administering fluoride to an entire community in the hope of preventing dental disease in some (usually ‘deprived’ group) of individuals - then it is a medicine in law. Giving any product to people who do not have any medical need for it remains ‘medication’, regardless of whether or not the product is appropriately licensed.

Note that this implies that medication occurs when a preparation is given to a third party - it is an action solely on the part of the person administrating the substance, and does not imply any active - or even conscious or consenting participation of the recipient. (Self-medication is clearly an entirely separate action, clearly entailing personal consent, although not necessarily adequate understanding!)

Protection of the public against unregistered or fake medicines

European law is designed to prevent the administration of unregistered, ineffective or fake medicinal products to the public. In 1986 the Court held that

> *the "presentation" criterion used in the first subparagraph of Article 1(2) [of 65/65/EEC - now replaced by 2004/27/EC] is designed to catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which their presentation might lead to expect, in order to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. The concept of the "presentation" of a product must therefore be broadly construed* [8]

The relevance of this to the alleged but substantially unproven ‘therapeutic’ property of fluoridated water will be evident to readers. So any health professional or other official issuing the claim that fluoridation will benefit the community as a whole, or even any individual member of that community, instantly renders fluoridated water a medicine by ‘presentation’, and absolutely subject to full licensing and regulation as such.

What reliable scientific evidence is available suggests strongly that there is no benefit to those who are not the primary target of the medication, not least the toothless elderly! Therefore, the supply of the product cannot provide the 'expected benefit' to the community that the promotional 'representation' of the medicinal properties of fluoridation would lead the public to believe.

If fluoridation has any positive effect whatever, that effect is confined to a minority - the majority are at best not affected. In the real world, many assessments have identified a very significant proportion of all children exposed to fluoridated water go on to develop disfiguring dental fluorosis, but experience no consistently demonstrable beneficial effect on their susceptibility to dental caries. In August 2010 the European Commission's Scientific Committee on Health and Environmental Risk (SCHER) stated that

> *'Systemic exposure to fluoride in drinking water is associated with an increased risk of dental and bone fluorosis in a dose-response manner without a detectable threshold.'* [9]

This conclusion is significant, and should be read in the context of a statement in November 2010 the US National Center for Health Statistics (CDC) announcing that dental fluorosis was present in 41% of American adolescents[10]. In fact this 'study', which has been repeatedly cited around the world, was released as a Press Report, not a peer-reviewed research paper, and was grossly misleading. The data referred to exposure to fluoride of two groups of children during their early childhood in the early 1970s and late 1980s - it had no relevance to the level of risk of fluoride intoxication amongst American infants in 2010.

I exposed this scientific fraud in December 2010, when I adjusted the two data sets to reflect a more probable interpretation of prevalence amongst at-risk (and not all) American adolescents during the time in infancy when they were at highest risk of their exposure to fluoridated water leading to fluorosis. The proportion of American infants growing up in areas supplied with fluoridated water rose substantially during the period covered by this study. So adjusting the data to reflect this confounding factor revealed that the underlying trend in the percentage of children developing dental fluorosis in such areas has not been constant as would be expected, but increased significantly between the early 1970s and the late 1980s. If this trend has continued, then this suggests that almost all American infants born in fluoridated water areas are now at very high risk of developing some level of dental fluorosis, and also that they will have it to a worse degree of severity.[11]

Despite this exposure, even the scientific opponents of fluoridation continue to refer to the CDC Press Release as if it was a reliable source of information. It is significant that this CDC 'research', which was publicly funded but not peer-reviewed, was misreported in a manner that allowed the problem of dental fluorosis to appear to be a far less significant public health problem than is acknowledged by the State and Federal authorities. As I discuss below, the deliberate misuse of public funds for issuing biased propaganda in order to improperly influence public opinion is anti-democratic and unethical. It may even be unconstitutional, as the Irish government has recently discovered.

Arguing that fluoridation is not medication, but the justifiable fortification of a food.

It is a popular fallacy embraced by fluoridation advocates that fluoridated water is not a medicine. They then argue that the practice is merely 'the topping up of a deficiency of natural fluoride' in a food - drinking water. I will not expand here on the scientific and legal absurdity of this baseless claim. It is sufficient to note that under EU law drinking water is a food, and that it is prohibited to make any medicinal claim (in the wider interpretation of Article 1 of 2004/27/EC) for any food, food additive, food supplement, or any vitamin or mineral. Under national food legislation, issuing any such claim is a criminal offence. So if fluoridated water is indeed, still a 'food', then it is distributed in defiance of criminal law.

Is fluoridated water then a food or a medicine?

According to the European Food Safety Authority (EFSA)

> *Fluoride is not essential for human growth and development* [12]

But despite this, fluoride has been irrationally registered as a 'mineral' under EU legislation, permitting it to be added to human foods. However, the manner of its use is still closely regulated. Regulation (EC) No.1925/2006 *on the addition of vitamins and minerals and of certain other substances to foods* sets out the definitive list of minerals that can be added to foods. It also specifies exactly what source materials are permitted to be used for this purpose.

Only the fluorides of sodium and potassium are permitted sources of fluoride that can be added to foods, so the specification of fluorosilicic acid and its sodium salts in the enabling fluoridation law in the UK and Ireland is in violation of the Regulation. However if, as in Australia, sodium fluoride were to be used for this purpose then the UK and Irish fluoridation legislation would not be in breach of food law.

In an apparent anomalous ruling, in EU law water is regulated as a food only after it emerges from the consumers' taps. EC Regulation No 178/2002 *on the general principles and requirements of food law* states

> ***'Article 2**. 'food' (or 'foodstuff') means any substance or product [. . .] intended to be, or reasonably expected to be, ingested by humans. 'Food' includes drink [. .].It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC* [the EU drinking water Directive]

(The 'point of compliance' is the consumers' taps. Directive 65/65/EEC was the original version of the Medicines for Human Use Directive - it has now been replaced by 2004/27/EC)

But the Directive then goes on to make this crucial proviso:

> *Food shall not include [. . .](d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;*

This is echoed in article 3.1(b) of 98/83/EC, which also excludes medicinal waters from regulation under this Directive. So a medicinal water is not 'water for human consumption', but an entirely different and legally distinct product, a 'medicinal water'. This has profound implications for all persons whose public water supply has been substituted by this medicinal product, since none of the quality standards that must be complied with when real 'water for human consumption' is supplied need to be complied with if public water supplies are fluoridated. The legal implications for suppliers should a fluoridated public water supply become dangerously contaminated by the accidental or deliberately malicious action of a third party or from unexpected natural causes appear not to have been appreciate by public authorities.

When does potable water become a medicine?

This raises the interesting question, precisely what class of product is fluoridated municipal water before it emerges from consumers' taps? Quite simply, it is a medicine within the water treatment works itself, and within the entire distribution system, and remains so once delivered into the premises of the consumer.

Adding fluorosilicic acid (or even sodium fluoride) to potable water within the premises of a drinking water treatment works instantly converts that drinking water - 'water for human consumption' in the European law - to a medicinal water. It is therefore no longer a food at the treatment works itself, but a medicine. It cannot be magically converted back to a food by allowing it to pour through an orifice in domestic plumbing in the consumer's kitchen!

So once again we come back to the simple fact that fluoridated water, no matter how prepared, is a medicine, and not a food. In fact the entire unsound foundation on which fluoridation rests in all countries where it is practised relies on the deliberate refusal to acknowledge this crucial distinction. As Shaw recently confirmed,

> *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.*[13]

In fact substituting this therapeutic good for the food 'potable water' before it arrives at the taps of the consumer constitutes the decidedly risky practice of 'product substitution' and may be in violation of the contract between the State, the water supplier, and the consumer.

'Functional drinks' - nutritious perhaps, but legally medicines.

If a final verdict on this distraction into irrelevant food law is required, then the decision of the ECJ on the classification of any drink that is claimed to have a medicinal property is definitive.[14] It ruled that where two different sets of rules appear to apply to any drink, medicinal legislation must take precedence, and the product must be regulated as a medicine. It emphasised that medicines regulators in Member States do not have the authority to exercise their discretion on the classification of such dual-function products - they must regulate them as medicines.

So under European law, the claim that fluoridated water prevents tooth decay instantly renders it a 'functional drink', and as such a medicine. And since it is a medicine, its administration to the public in a form that is effectively unavoidable is indeed 'mass medication'.

Decisions that establish that fluoridated water is subject to medicinal law.

The last word on 'mass medication may be shared between Australia's Mr Justice Gillard and the UK's Lord Justice Jauncey. In 1964 Gillard decided that

> *"The power to introduce this process must be found apart from its powers in its role as a water utility. On the evidence before me, at the most, fluoridation can be described as a public health measure. The justification for its introduction by the council must, therefore, be found in the powers of the municipality with respect to health rather than in its function as the controller of the town water supply* [15]

In other words, fluoridation law specifies how this therapeutic good is to be manufactured, but it does not thereby constitute authority to over-ride or supersede the requirement for its actual supply to the public to comply with medicinal law. As Gillard implied, the 'powers of the municipality with respect to health' refer to Councils' responsibility to ensure that their duty in protecting public health rests within the remit of medical practice, and not that of the provision of safe drinking water.

This decision was supported by Judge Biscoe in Oshlack v Rous Water[16] recently, when he ruled that New South Wales fluoridation law cannot be 'unfettered' - when both water and/or fluoridation law and medical law apply and do not compete with each other (as they do not), then water providers are legally required to comply with both arms of the law.

And almost thirty years after Gillard delivered his verdict in Australia, it was echoed by Lord Jauncey in the Scottish Court in 1983, when he ruled that

> *"Section 130 [of the Medicines Act 1968] defines "medicinal product" and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within the definition."* [17]

Although this action was heard before the Scottish Court of Session, the Medicines Act under which the action was brought is an Act passed by the English Parliament that applies throughout the whole of the UK, including Scotland. Since the definition of a medicine in English law corresponds closely to that in Australian law, Jauncey's view indicates that it would be irrational to refuse to recognise the status of fluoridated water as a therapeutic good under the existing Australian Therapeutic Goods Act.

The difference between public health measures and a clinical intervention

It is often claimed that Local Authorities and Councils have a duty to protect 'public health' through the imposition of fluoridation as a 'public health intervention'. For this reason, in some States they are said to be responsible for water fluoridation. This is a dangerously misleading assumption. Local Authorities do indeed have responsibility for the prevention of health risk to the public, but this is confined to what may be termed 'environmental health' issues, such as sanitation, rubbish collection, and the control of contamination of foods and consumer products.

But the administration of a medicinal product or therapeutic good to the public is an entirely different matter. Fluoridation not a permissible 'environmental health' intervention, but an invasive clinical intervention carried out without the protocols demanded for all clinical interventions, including medication.

As a clinical intervention relying on the administration of a potentially lethal substance to entire communities, without regard to individual need nor personal consent, it is entirely beyond the bounds of acceptable medicinal practice. This form of intervention is the sole prerogative of qualified prescribing health professionals, and such procedures are rigidly regulated under universal codes of medical practice and ethics.

Since fluoridated water is a medicine or therapeutic good, if it were to be appropriately licensed it could be made available as an over-the-counter medicine, in the same fashion as fluoridated toothpaste. Remarkably, few advocates of fluoridated toothpaste and fluoridation appear to be aware that such toothpastes are themselves subject to medicinal licensing! But Local authorities are not licensed to practice medicine, and their collusion with proponents of fluoridation to supply (or even permit the supply) of this unlicensed medicine to the public for whom they have a legal duty of Care, in a process of mass medication, may render them liable to challenge on a number of legal grounds in both the civil and the criminal courts.

State-sponsorship - using public money to influence public opinion on mass medication

The decision to fluoridate public water supplies invariably originates within the field of State-managed public health management As I have indicated above, any such form of invasive clinical intervention lies solely within the prerogative of licensed prescribing health practitioners under consent from their patients, and there are clear legal prohibitions on the general administration of this product to the public.

Yet despite these absolute obstacles, public sector health authorities still attempt to circumvent resistance amongst the public by engaging in spurious public consultations campaigns. And in every case, considerable sums of public finance are diverted into producing promotional materials that are little short of propaganda aimed at securing positive support for the imposition.

The universally unreliable epidemiological evidence claiming that fluoridation is both safe and effective is presented as if it carries substantial scientific credibility, when it does not. Yet at the same time far more scientifically respectable evidence in the fields of toxicology, physiology and biochemistry, revealing the uncertainties and risks of the practice, is subjected to far more stringent, and often entirely improper, censure, in order to persuade the public that there are far greater grounds for supporting fluoridation that is actually the case.

The use of public funds to issue such biased propaganda is one of the most offensive aspects of the deliberate misdirection of the public. Indeed, it may also be unlawful. In an apparently unrelated judgment that is actually of great relevance to the issue of public funding of misleading propaganda, in November 2012 the Irish Supreme Court ruled such actions to be in violation of the Irish Constitution. Judge Fennelly said that the use of public funds to try to influence public opinion over its proposed *Children's* Referendum was improper. Referring to material published by the government commented:

> *It is patent, in my view, that the web site and booklet were written with a view to providing support for the objectives of the referendum proposal. The material is not fair, equal or impartial. It is advocacy. It is compounded by the presence of a serious misstatement in the booklet of the effect of the referendum proposal.*[18]

The Court's decision in McCrystal implies that in any case in which the government seeks to obtain public support for even a legitimate action, it is fundamental to the concept of democracy that decision-making on any intervention that impinges on personal rights must be taken by the public.

The public's right to self determination and personal autonomy must not be evaded by a deliberate attempt by the State to mislead the public about the potential consequences of denying the intervention. The power of the State to over-rule public opinion on such issues is absolutely subservient to the right of the public to provide an informed opinion. A binding 'Code of Good Practice on Referendums' is now recognised within the EU, and states that

> *2.2 Equality of opportunity must be guaranteed for the supporters and opponents of the proposal being voted on. This entails a neutral attitude by administrative authorities, in particular with regard to … public funding of a campaign and its actors. [. . .] 25. There must be no use of public funds by the authorities for campaigning purposes in order to guarantee equality of opportunity and the freedom of voters to form an opinion.* [19]

Conclusions

Fluoridated water therefore is a medicine, it is supplied with the intent to medicate entire communities, and it does constitute mass medication, even if few - or even no - members of those communities are actually in need of the intervention, or are capable of benefiting from it.

Since fluoridated water is a medicinal water, it is not 'water intended for human consumption', and the water quality criteria applied to drinking water do not apply to fluoridated water, leaving the public legally unprotected against non-compliance with any other parametric water quality standard.

And since its supply, in the absence of a relevant licence, to individuals who do not consent to what is effectively State-imposed coercion or recruitment, it is in violation of the fundamental right of individuals to control their physical autonomy, this form of mass medication incompatible with the fundamental principles of human rights legislation and in gross breach of medical ethics.

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