## **OPINION**

- 1. I have been asked by Mr. Paul Carr on behalf of a group of water consumers in Cumbria to give my opinion on the legal position concerning the correct characterization of fluoridation in relation to medication.
- 2. In particular my attention has been directed to a Conclusion to a Report presented by a Working Party (the Task and Finish Group) to a meeting on 24 November 2021 of the Scrutiny Management Board of Cumbria County Council where it was stated (at page 46):

"Legal status of water fluoridation: Members were assured that fluoridation is not classified as a medicine under UK legislation:

I was informed that a County Councillor summed up the position by stating that:

"the legal position on water fluoridation is very clear – it is not a medicine".

- 3. These statements evince a misunderstanding of the legal position. Fluoridation is the act or process of artificially adding a chemical to the public water supply to create a specified concentration of fluoride to it. It is thus an additive to the water and the fluoride is carried by the water acting as a vehicle or mode of transport until some of the fluoride ions reach their intended destination when they chemically react with, and bond to, another substance such as some form of human tissue e.g. teeth. The input chemical most commonly used to fluoridate the water is hexafluorosilicic acid (H<sub>2</sub>SiF<sub>6</sub>). Water fluoridation schemes set a maximum permissible fluoride concentration, in the UK of 1p.p.m. (1mg/l).
- 4. It is easy for non-lawyers to become confused over legal terminology, including definitions of legal words. In law the definition of a term, used as a legal term, is subject-specific and context-dependent. Confusion has arisen in the present case because of the particular narrow definition of medicine

used by the statutory draftsman in connection with the control, licensing and prescription of certain types of medicinal products for individual patient use under domestic legislation formulated for this purpose in the U.K. Thus, in the famous case of McColl v. Strathclyde Regional Council [1983] SC 225 Lord Jauncey, held that (a) dental caries was not a fluoride-deficiency disease (i.e. dental decay was not caused by lack of fluoride in the water supply) but (b) that the particular scheme of fluoridation which he considered did not involve a breach of the Medicines Act 1968.

- That is a far cry from saying that fluoride is not a medicine and it is not legally correct to extrapolate from Lord Jauncey's decision to such a general principle.
- 6. The appropriate legal analysis is to follow the established approach taken in fields of law such as landlord and tenant law where the nature of a legal concept such as a "tenancy" does not depend on the labels used or on artificial drafting considerations but on the reality and core conceptuality of the matter in question.
- 7. In determining what is and is not a "medicine" in terms of reality and core conceptuality one looks at the purpose, nature, and effects of the substance that is being used.
- 8. Starting with the purpose, this is readily ascertained because fluoridation is not an accidental occurrence but a deliberate policy-driven process whose purpose is stated by its sponsors. Its sponsors are health ministries and health authorities and dental bodies. In the current case the promoter is Public Health England (now replaced by UK Health Security Agency and Office for Health Improvement and Disparities) which describes it as "a public health measure" and "one of a range of interventions available to improve oral health". (See: Public Health England, "Improving Oral Health —

- A community water fluoridation toolkit for local authorities, October 2020 at page 8).
- 9. Turning to its nature, the mechanism involved is using a substance to transmit a chemical to enter the human body in order to produce a chemical reaction with existing bodily tissues, most notably to harden the surface enamel of teeth. The objective of this is to prevent or mitigate dental disease (Ibid, pages 14-15).
- 10. The substance being used for fluoridation is not a substance found naturally-occurring but one artificially-produced by chemical/industrial manufacturing processes and tested for its consistency and non-adulteration with other chemicals and its strength (concentration).
- 11. It is not contended by any of the official proponents of fluoridation in the U.K. that fluoride is a food (nutrient) or vital trace element like a vitamin whose absence would interfere with normal bodily functions or, on the other hand, that it is chemically non-reactive or inert. In high doses it is an acknowledged poison. But its proponents state that this is not so at the levels they recommend. We are therefore looking for a category that is pharmacologically-active yet not a nutrient, vital element, or poison. The main remaining category which appears to create the best fit is "medicine".
- 12. The inherent attributes and nature of the fluoridation process and its purpose (what it is designed to achieve) therefore need to be matched against the standard criteria in medical science connoting what a "medicine" is.
- 13. Starting with Stedman's Medical Dictionary, a medicine has the primary meaning of a drug and a drug is defined as "a therapeutic agent" and as "any substance, other than food, used in the prevention, diagnosis,

alleviation, treatment or cure of disease". The British Medical Association A-Z Family Health Encyclopedia defines a drug as "Any chemical substance that ... changes the process of a disease" and explains that "Drugs act on cells in the body ... by stimulating or blocking chemical reactions". It defines "medication" as "any substance prescribed to treat disease". There are numerous definitions to like effect across the range of medical literature in the U.K., the U.S.A., and more generally. These accord with the general public definition of a medicine, as given in Chambers Etymological Dictionary, as "any substance used (especially internally) for the treatment or prevention of disease".

- 14. Putting the above analysis of what water fluoridation is side-by-side with what a medicine is there is a close match. Fluoridation is the act of medicating the water supply to transmit a chemically-reactive therapeutic substance (i.e. a medicine) to create a chemical reaction with human tissue with the intention of trying to treat or prevent oral disease.
- 15. The purpose, nature and design of fluoridation is thus to use the public water supply as a means of delivering a medicine to the human population. This is why it is described by its proponents as a public health measure.
- 16.As with all medicines there are concerns about the integrity of the manufacturing process, the technical specification of the product, the potential side effects, the efficacy of it, and the problems of accidental overdose. Like most medicines the dose is crucial hence the concern to try to ensure that the fluoride concentration in the water supply is kept within specified levels.
- 17. The Statements referred to in Paragraph 2 of this Opinion do not reflect the current legal position. They confuse the narrow question of what counts as a licensed medicinal product (which is what the Medicines Act was

concerned with) with the important broader question of what counts in law as a medicine and as medication in the context of a fluoridation scheme. The view which I have formed as set out in this Opinion is in accord with and supported by the decision of the Supreme Court of Canda in Municipality of Metropolitan Toronto v. Village of Forest Hill (1957) 9 D.L.R. (2d) 113 which held that the fluoridation of the water supply was using the water for a medicinal purpose and Cartwright J. in that case (at page 124) described fluoridation of the water supply as "compulsory preventive medication of the inhabitants of the area" – very similar language to that which I have used in this Opinion. In the McColl case Lord Jauncey held that fluoridation was medical treatment by means of the water supply designed to have an effect on the body of the consumer equivalent to taking fluoride pills.

- 18. Some definitions of medicine narrow it to substances "prescribed" by a medical practitioner. That is too narrow for most legal purposes since there is a large and increasing number of over-the-counter medicines which do not require a prescription. Those are available for purchase by individuals from chemists and general retailers. Likewise, it is possible to deliver a medicine through the tap to the populace generally as with fluoridation.
- 19. However, the earlier reference to prescription is significant because it draws attention to the potency and side-effects of medicines and the need for correct diagnosis, and the consideration of appropriate treatment for each particular individual.
- 20. Fluoridation is not prescribed for any individual by any medical practitioner. It does not involve any prior diagnosis or consideration as to whether the person needs or would benefit from any treatment. It constitutes mass medication without reference to the diversity of the people affected by it, without any individual consultation, and without the consent of the person

(the patient) receiving it.

21. The fact that the fluoride is not being prescribed for individuals and the fact that most unusually this form of medical treatment is being delivered to, and imposed upon, individuals by being put in the public water supply does not mean they are not receiving medicine and being medicated, it merely means that this medicine is one that in practical terms is virtually compulsory for them. That is the real legal position that every member of the public will be put in where a fluoridation scheme comes into operation. The law in the U.K. sets great weight on precedents. Fluoridation sets the precedent that the public water supply is to be used for the purpose of mass delivery of a chemical designed for a medical treatment of one part of the body (teeth). The precedent sets the stage for the future use of other chemicals for the treatment of other parts of the body or mind on a mass scale through the water supply. I note that Lord Jauncey in the McColl case came to the same

conclusion as I have and that he stated that it caused him "considerable

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anxiety".

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