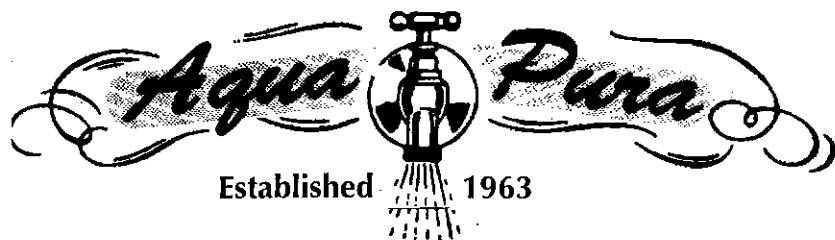


THE AUSTRALIAN FLUORIDATION NEWS



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Fluoride Poisoning of Horses from Artificially Fluoridated Drinking Water

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SUMMARY: On a farm in Pagosa Springs, Colorado, Quarter horses consuming artificially fluoridated water (up to 1.3 ppm F) for extended periods of time developed classical symptoms of chronic fluoride intoxication including dental fluorosis, crooked legs, hyperostosis and enostosis, hoof deformities, and microscopic evidence of reduced bone resorption. These symptoms began to appear about two years after fluoridation started in 1985 and gradually became more severe.

Representative postmortem F concentrations in dry matter bone were: 587 ppm in a 20-year-old gelding drinking F water for the last 10 years; 936 ppm in a 17-year-old gelding on F water for the last 11 years; and 757 ppm in a 21-year-old mare on F water all her life.

Blood serum thyroxin in a 19-year-old mare (T4) was "very low", and interference with reproduction was noted after five years. Radiographs of the third metacarpal bone revealed osteomegaly with thick lamellae from both ends extending throughout the medullary space.

The levels of F ingestion and the bone F concentrations of these horses are far below those claimed to cause F intoxication in cattle. After fluoridation was terminated on March 29, 2005, colic gradually ceased and other significant improvements have occurred.

Introduction

Although the literature on fluorosis in cattle is extensive, information about fluorosis in horses is almost nonexistent. A 1974 US National Academy of Sciences-National Research Council report on effects of fluoride in animals gave only one reference to horses in which dental and radiographic skeletal changes were described in horses grazing in areas where cattle and sheep had developed severe

fluorosis.¹ The report stated: "No carefully controlled studies have been conducted to determine the effect of excessive fluoride ingestion on horses."

Here we present evidence that artificial water fluoridation can cause serious fluorosis in horses.



Figure 1

Figure 1. Severe hoof deformity in left thoracic limb of 22-year-7-month-old Quarter horse mare on fluoridated water for 21 years.

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Materials and Methods

Background: Most of the horses in this study belong to the Justus Farm in Pagosa Springs, Colorado. Over the years this farm has included up to ten Quarter horses, numbering six in the year 2005. In 1985 artificial water fluoridation was introduced by the Pagosa Area Water and Sanitary District at a concentration ranging from 0.35 to 1.3 ppm F. This water was the only source of water for the horses on the farm. No other sources of fluoride were present; fluoride-containing phosphate fertilizer was not used on the pastures, nor were fluoride-containing mineral supplements ever fed to the horses.

Early sign of intoxication was seen in a regular incidence of colic in all the horses.

Clinical observations: An early sign of intoxication was seen in a regular incidence of colic in all the horses, which promptly disappeared when the affected horses were removed from the farm. After about five years, hoof deformities reaching the extreme shown in **Figure 1** were seen. Moreover, crooked legs were observed in some horses, as were exostoses in six horses, especially in the distal MCIII (thoracic leg third metacarpus = "cannon bone") but also in the back and rib bones. Also after about five years, low conception rates were noted, and one mare delivered a fetal monster with partial aplasia of the skull. In a 19-year-old mare the serum thyroxin (T4) was found to be "very low".

After many years, the farm owner, co-author CJ, suspected fluorosis, which, however, was not confirmed by local veterinarians. Remarkably, clinical examinations of the horses by the veterinarians apparently never included the teeth, since their records show nothing about dental conditions.

Over the years, five horses had to be sacrificed because of ailments that, in retrospect, appear to have been induced by fluoride.

"Colic among the horses entirely ceased when water fluoridation was terminated."

On March 29, 2005, water fluoridation of the Pagosa Springs area was terminated. Since then, colic among the horses has gradually entirely ceased, and other significant improvements have been noted.

Laboratory examinations: When the senior author LPK was engaged to investigate the problem, he requested photographs of the teeth of horses on the Justus farm as well as the most easily accessible MCIII bone specimens from any horse on the farm terminated for whatever reason. Dental photographs were supplied together with MCIII samples from three Quarter horses, one from the Justus farm and two from nearby farms using the same Pagosa Springs fluoridated water. One "control" MCIII sample was obtained from a "very old" thoroughbred horse, which had never consumed fluoridated water, at the necropsy laboratory of the Cornell University College of Veterinary Medicine. For the radiographs the MCIII samples were split longitudinally in the dorso-palmar midline and radiographed on fine screen Kodak Lanex Fine TML film at 300 mA and 62 kV for 0.1 sec.

Present Findings

Dental disturbances: Figures 2-4 illustrate dental changes observed in the F-exposed horses with increasing age.

Figure 2 shows the incisor teeth of a Quarter horse foal 2 years and 10 months old. The foal came to the Justus farm at age 7 months. The photo shows the permanent central pair of incisors with extensive enamel defects in the maxillary teeth.

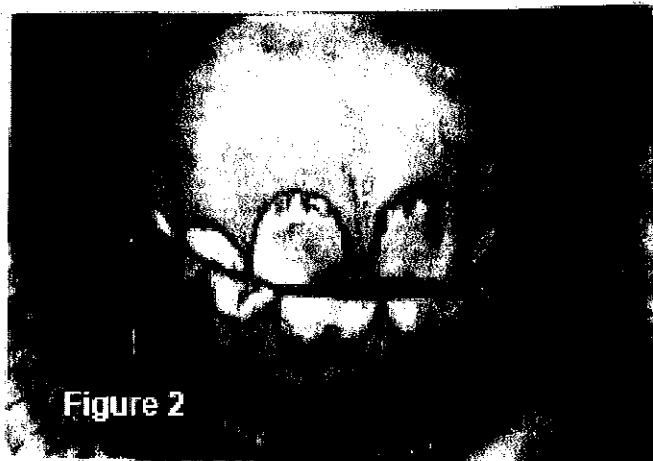


Figure 2. Incisor teeth of 2-year-10-months-old Quarter horse foal introduced to farm with fluoridated water at 7 months of age. Erupted permanent central incisors have extensive enamel defects distally of the maxillary teeth.

Figure 3 shows the incisor teeth of a 6-year-8-months old Quarter horse gelding that drank fluoridated water from birth. All teeth have severe brown discoloration, and the enamel of these areas is thinner and has receded from the surrounding less-disturbed enamel. The maxillary gingiva is recessed, and the exposed distal enamel exhibits extensive defects. The mandibular gingiva has receded and is bulging. The entire masticatory surface of the mandibular teeth has a severe brown coloration.

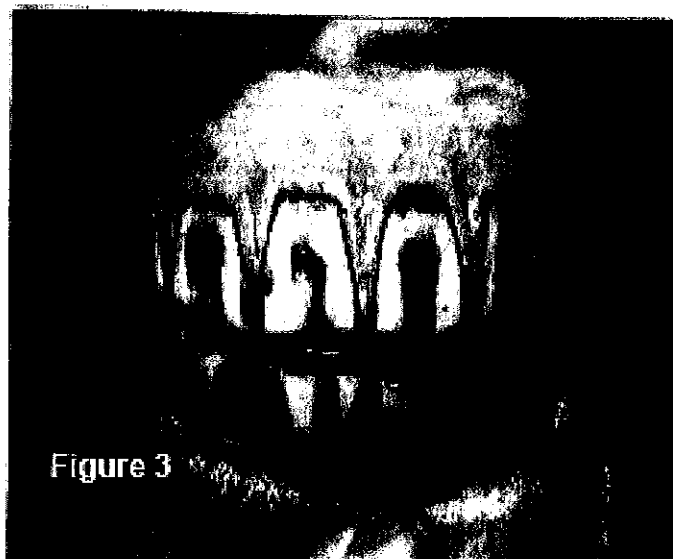


Figure 3. Extensive enamel defects of incisor teeth of quarter horse gelding, age 6-years-8-months, that drank fluoridated water from birth.

Figure 4 shows the incisor teeth of a 23-year-8-months old Quarter horse mare that has been on fluoridated water for 21 years. Brown discoloration of the enamel and extensive defects of the distal enamel of the maxillary teeth are present. A severe loss and recession of apical alveolar bone resulted in exposure of the distal clinical crown and the upper part of the roots of the maxillary teeth along with recession and bulging of the gingiva of the mandibular teeth.

Bone fluoride and radiographs: Three MCIII (thoracic leg third metacarpus = "cannon bone") samples were submitted for fluoride analysis by CJ from terminated Quarter horses (QH) at the Justus farm. A control MCIII sample was obtained by LPK from a "very old" thoroughbred gelding at routine necropsy at the Cornell University College of Veterinary Medicine. Fluoride in dried bone tissue was determined by the fluoride ion electrode method for measurement of F ion activity in standard and sample solutions. The analytical results for these samples are tabulated below.



Figure 4

Figure 4. Severe loss and recession of apical bone; extensive enamel defects and severe brown discoloration.

Table. MCIII bone fluoride analysis of four deceased horses performed in 2005

Horse	Age (years)	Fluoridated water	Dry bone F (ppm)
QH mare	21	All her life	757.1
QH gelding	20	Last 10 years	587.1
QH gelding	17	Last 11 years	936.1
Thoroughbred	"Very old"	Never	162.2

The radiographs of MCIII bone samples from the thoroughbred "control" horse and the 17-year-old Quarter horse gelding in the Table above are presented in Figure 5.

In the control horse the subchondral bone plate is well differentiated from the lamellar epiphyseal bone. The



Figure 5

Figure 5. Radiographs of lower two-thirds of left thoracic third metacarpus (MCIII) cut longitudinally at the dorso-palmar midline (palmar is to the left).

Left: From an old thoroughbred horse (routine necropsy at Cornell College of Veterinary Medicine) which had never consumed fluoridated water. The subchondral bone plate is well defined from the lamellar epiphyseal bone. The metaphyseal lamellae become gradually thinner and disappear at the lower half of the picture. The cortex is sharply demarcated from the medullary cavity.

Right: From a 17-year-old Quarter horse gelding on fluoridated water for the last 11 years. The subchondral bone plate blends diffusely with the epiphyseal bone. The metaphyseal trabeculae remain thick and extend throughout the entire medullary cavity. The cortical surface facing the medulla is less sharply defined, most eloquently so at the upper palmar cortex.

metaphyseal lamellae become gradually thinner and disappear well below the midshaft. Especially noteworthy is the sharp demarcation of the cortex from the medullary cortex. By contrast, the radiograph of the MCIII sample from the fluoride-exposed 17-year-old QH gelding shows that the subchondral bone is blended diffusely with the epiphyseal bone. The metaphyseal trabeculae remain thick and extend through the entire medullary cavity. The cortical surface of the medulla is less sharply defined than in the control, most strikingly at the upper palmar cortex.



Figure 6. Photo of the left MCIII of 21-year-old Quarter horse mare on fluoridated water all her life. The bone is cut lengthwise in the dorso-palmar midline with the lower end, not including the joint cartilage, at the bottom. The dorsal contour is to the left. The dorsal cortex of the wall bulges severely into the marrow space, beginning just proximal to the epiphysis, creating endosteal hyperostosis "enostosis". The added bone is less dense than the original cortex; the contour of the original cortex is well defined.

Figure 6

As seen in Figure 6 for the 21-year-old Quarter horse mare in the Table, the poor definition of the inner surface of the MCIII cortex reaches a more extreme degree than in the 17-year-old Quarter horse gelding depicted in Figure 5. In the 21-year-old mare, the inner surface of the dorsal wall of the left MCIII bulges severely in the narrow space, beginning just proximally to the metaphysis. The bone of this endosteal hyperostosis is less dense than the original cortex, the contour of which is obvious.

Examination of microscopic sections of MCIII samples of lamellar as well as compact bone of the fluoride-exposed horses shows retarded activity of resorbing osteocytes, and the normal basophilia of the adjacent matrix has receded into sharply defined bands giving the field a mosaic appearance. Failure of normal resorption also caused osteosclerosis as seen radiographically in Figure 6. Likewise, the endosteal hyperostosis was evidently the result of failure of normal maturation of the lamellar bone which, instead, is piled up in multiple layers.

Discussion

The foregoing clinical and morphological observations, together with the bone fluoride analyses, establish the diagnosis of chronic fluoride intoxication of horses in this

study caused by consumption of artificially fluoridated drinking water.

The curled hoof of one horse seen in **Figure 1** mimics the hoof lesions found in 88 (57.9%) of 152 cows fed fluoride-containing phosphate mineral supplements.² The same report also provided conclusive proof that F interferes with thyroid function in cows, since lowered serum T3 and T4 hormones correlated significantly with urinary F concentrations. The "very low" serum T4 found in one of the horses in the present study further supports the diagnosis of chronic fluorosis.

Diagnosis of chronic fluoride intoxication of horses caused by consumption of artificially fluoridated drinking water.

Also beyond question are the pathognomonic indications of dental fluorosis lesions seen in *Figures 2-4*.

As noted earlier, the F concentration in the fluoridated water ranged from 0.35 to 1.3 ppm. The later 1978 NAS report on "Nutrient Requirements of Horses"³ states that the need for water intake in horses is 2 to 4 times that of dry matter intake, and the F tolerance levels are all based on dry matter intake. The equivalent ppm F in the dry matter would then be $4 \times 1.3 = 5.2$ ppm. The same report³ continues: "Work may increase the water need about 20-30 percent, and lactation may increase it 50-100 percent above maintenance."

If we consider the most extreme situation with the Pagosa horses, their intake of F in ppm of dry matter would be only a small fraction of the so-called "tolerance level" of **SIXTY** (60) ppm F of dry matter, cited by NAS.¹ This 60-ppm figure first appears in a 1974 article by Shupe and Olson titled: "Clinical Aspects of fluorosis in Horses"⁴ and concerns "breeding and lactation animals". The same figure is then repeated in the 1974 NAS-NRC publication *Effects of Fluorides in Animals*¹ this time as the "tolerance level" for "performance" defined as "Levels that, on the basis of published data for that species, could be fed without interference with normal performance". That publication further informs: "Analyses of pastures in these [fluorosis] areas (Shupe, 1972a, b) suggests that 60 ppm F is the tolerance levels for this species [horses]." The "Shupe, 1972a" is reference 5 of the current paper, but it contains no mention whatsoever to support the above NAS-NRC statement.¹ Shupe's reference 1972b is reference 6 of the current paper. It too presents the same vacuum of its claimed support for the NAS-NRC 60-ppm figure.

"No carefully controlled studies have been conducted to determine the effects of excess fluoride ingestion in horses."

U.S. National Academy of Sciences Report

Thus there is no justification for NAS to state that the "tolerance level" for F in horses is 60 ppm on a dry matter basis. On page 52 of its NRC Committee on Animal Nutrition report,¹ we read: "No carefully controlled studies have been conducted to determine the effects of excess fluoride ingestion in horses." Yet, three pages later, Table 4 in the report lists a "tolerance level" of 60 ppm F in horses as based on published data for that species. The second statement contradicts the first, and, as seen here, is in obvious conflict with the truth.

As is well known, when sufficient circulating F is present it promptly changes the mineral phase of hard tissue by replacing hydroxyl ions in calcium hydroxyapatite to form calcium fluoroapatite. The F so trapped is toxic to the

respective cells of the hard tissues. In acting on the enamel ameloblasts F causes the dental fluorosis lesions shown in **Figures 2 and 3**. In acting on bone tissue F first affects the bone resorbing cells, resulting in osteomegaly.

Over time and/or with greater F exposure, bone-forming cells are also affected, resulting in osteopenia.⁷ Since the metabolic rate is higher in alveolar bone than in skeletal bone tissue at other sites,⁸ the alveolar bone first shows evidence of a very important sign of chronic F poisoning, seen in recession of the alveolar bone and gingival so eloquently depicted in *Figure 4*.

"The second statement (Table in report) lists a "tolerance level" of 60 ppm F in horses based on published data. The second statement is in obvious conflict with the truth."

Although enamel changes in dental fluorosis are acknowledged by NAS-NRC, its report¹ advocating a 60-ppm F tolerance in horses overlooks and fails to recognize that "The tooth should not, during clinical and morphological examinations, be considered as only a tooth, but as part of a functional unit, a unit which, in addition to the tooth, includes the supporting tissues such as the Sharpey's fibers, the transeptal fibers, the gingiva and, above all, the alveolar bone."⁹ Thus, loss of alveolar bone with recession of gingiva tissue as observed here is a sign of far more advanced fluoride intoxication than enamel changes only.

"Loss of alveolar bone with recession of gingiva tissue . . . is a sign of far more advanced fluoride intoxication than enamel changes only."

In closing, it must be asked: How could the Subcommittee on Fluorosis, appointed by a US Federal authority, convey such blatant misinformation on F tolerance in horses and fail to note a critically important aspect of dental fluorosis? The subcommittee consisted of four biochemists and one veterinarian, at least four of whom had financial support from F polluting industries, and it was on the basis of "research" sponsored by these industries that the tolerance levels of F for cattle and horses were proposed by the committee. By sending out the skeletal material for description by a pathologist,¹⁰ the subcommittee acknowledged its inability to examine the most important expression of F intoxication in animals.

It seems that the only beneficiaries of NAS-NRC (mis)information on fluorosis in animals are the F polluting industries by which and for which it was evidently written.

REFERENCES

1. National Academy of Sciences-National Research Council Committee on Animal Nutrition, Subcommittee on Fluorosis. Effects of fluoride on animals. Washington, DC; US National Academy of Sciences; 1974.
2. Hillman D, Bolenbaugh D, Convey EM. Fluorosis from phosphate mineral supplements in Michigan dairy cattle. East Lansing, MI: Research Report 365. Michigan State University Agricultural Experimental Station; 1978; 23 pp. See by the same authors: Hypothyroidism and anemia related to fluoride in dairy cattle. J. Dairy Sci 1979; 63: 416-23.
3. National Academy of Sciences-National Research Council Committee on Animal Nutrition, Subcommittee on Horse Nutrition, Board on Agriculture and Renewable Resources. Nutrient requirements of horses. Washington, DC: US National Academy of Sciences; 1978.
4. Shupe JL, Olson AE. Clinical aspects of fluorosis in horses. J Am Vet Med Assoc 1974; 158:167-74.
5. Shupe JL, Clinical and pathological effects of fluoride toxicity in animals. In: Carbon-fluorine compounds: chemistry, biochemistry and

biological activities. A Ciba Foundation Symposium. Amsterdam: Associated Scientific Publishers; 1972; p 357-88. Cf. Shupe JL, Olson AE, Sharma RP. Fluoride toxicity in domestic and wild animals. Clin Toxicol 1972;5;195-213.

6. Shupe JL. Fluorosis: Equine medicine and surgery. Wheaton, IL: American Veterinary Publications; 1972; p 215-24.
7. Krook L, Maylin GA. Industrial fluoride pollution: Chronic fluoride poisoning in Cornwall Island cattle. Cornell Vet 1979;69(Suppl 8):1-70.
8. Baumhammer A, Stallard RE, Zander, HA. Remodeling of alveolar bone. J Periodont 1965;36:439-42.
9. Krook L, Maylin GA, Lillie JH, Wallace RS: Dental fluorosis in cattle.

Cornell Vet 1983;73:340-62.

10. Johnson LC. Histogenesis and mechanisms in the development of osteofluorosis. In: Simons JH, editor. Fluorine chemistry. Vol. IV. New York and London: Academic Press; 1965; p. 424-41.

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EDITORIAL

HORSES AND MAN

The severe long term impact on the health of horses from consuming artificially fluoridated water for much of their lives is not only disturbing evidence of the toxic nature of the chemicals used in artificial fluoridation of public water supplies, but another damning indictment of the whole artificial fluoridation of public water supplies process.

The study shows that being "as strong as a horse" is no protection for these servants of man from the devastating impact on the health of horses if small amounts of an extremely potent poison are consumed over a long period of time.

But there are other equally disturbing aspects.

This is probably the first detailed long term study on the health of a group of horses consuming artificially fluoridated water. Public authorities who should be responsible to man and animal for knowing the impact of a scheme which they helped introduce, have apparently failed to undertake any properly conducted investigation into the outcome of the measure during over 50 years of the experiment. Why?

But for the concerns of the owner of the horses and engagement of a thoroughly qualified independent expert in the field to investigate the problem, the damning evidence that has emerged would still not be known.

A second concern is either the extreme incompetence of the members of the U.S. Government's Sub-Committee on Fluorosis, supposedly a leading body to investigate fluorosis, or worse, extreme bias by the majority of members of the sub-committee. It appears that their so-called "research" was intended to mislead the scientific community while concurrently avoiding finding and revealing evidence that would indict the fluoride producing industries which provided their financial support.

The implications for human health are abundantly clear. The concentration of fluoride in the water which the horses consumed was between 0.35 and 1.3F parts per million. By comparison, concentrations of the fluoride (F) ion in artificially fluoridated public drinking water supplies in N.S.W. is required by government regulation to be between 0.9 and 1.5F ppm, an increase of 157% at the lower concentration and 15% at the highest concentration. The implications for man are obvious, particularly as the majority of the human population in artificially fluoridated communities in Australia ingests an even larger dose of toxic fluorides from other sources such as the widespread use of fluoridated toothpaste.

Student of chemistry well know that the fluoride chemicals used in artificial fluoridation are extremely toxic. A public illustration was the excruciating death of three well-performed Sydney racehorses and the severe illness of fourteen others which were accidentally given a salt drench containing sodium fluoride, one of the poisons used for artificial fluoridation and still used in some fluoride toothpastes. *Sydney Daily Telegraph* 19 March; *Sydney Morning Herald* 21 March, 1966; reported in *The Australian*

Fluoridation News-Aqua Pura, (AFN), Vol. 3, No. 10, March 1966.

A photo of a five-year-old thoroughbred mare reproduced in *AFN, Vol. 16, No. 7, Feb. Mar. 1980*, was taken by J.L. Shrupe and A.E. Olson, Utah State University, reproduced from *Public Interest Report* by Mary Caldwell. The poor condition of the mare was caused by grazing on fodder affected with fluoride fallout from nearby factories.

At Tomago, near Newcastle, NSW, the owner of a small property claimed the stunted growth of a thoroughbred horse was caused by fluoride fallout from the Tomago aluminium smelter commissioned nearby several years before. The property was within the buffer zone of the smelter fallout area and although the smelter was obliged to purchase the property, several years of strained negotiations preceded the purchase. Trees in the area were dying at an alarming rate, with 20% dead or dying. *Newcastle Herald*, 3 May 1985, reported in *AFN, Vol. 21, No. 5, Sept.-Oct. 1985*.

A similar case occurred years before in Canada. The *Toronto Globe and Mail*, 23 Oct. and 2 Nov. 1967, recorded that both residents and their dairy herds were severely affected by fluoride fallout from the nearby Dunville factory. Cattle stopped eating and became weak, the veterinarian diagnosed fluorosis and large herds had to be destroyed. Over \$200,000 was awarded to the farmers in compensation. Reported in *AFN, Vol. 5, No. 10, March 1968*.

Australia's fluoridated "Death Valley" was featured in a special edition of *AFN, Vol. 26, No. 2, March-April 1990*. Fluoride chemicals leaked out of a drain from the council's fluoridation plant onto Sylvia and John Braim's farm just south of Hobart, Tasmania. Pastures died, sheep, young lambs and cattle died and some developed deformed hoofs. The Supreme Court of Tasmania ordered that the Rivers and Water Supply Commission pay the Braims \$65,000 compensation and over \$50,000 in costs, demolish the fluoridation plant and clean up the site.

The harm suffered by horses from consuming artificially fluoridated water, the innocent victims of the folly of man, should be a lesson to governments, public authorities and the people of Australia. Neither man nor animal can be immune to a toxic cumulative poison.

No to fluoride toothpaste

Once again the Freedom From Fluoridation Federation of Australia, the Safe Water Association of N.S.W. and the Anti-Fluoridation Association of Victoria wish to make it perfectly clear that we do not endorse statements still being made by people that fluoride is OK except in water. Some are conveying to communities that fluoride tooth paste is safe.

We do not agree with such claims and recommendations. The eternal tooth paste flame of their promotion of the use of fluoride in toothpastes, is in reality the hot air coming from their erroneous dogma.

Water Fluoridation does not comply with European Community Food and Drugs standards

Extracts of Summary Report by Doug Cross, Forensic Ecologist

After studying European Community (EC) standards for medicines, foods, water and cosmetics, Doug Cross concludes that fluoridation of public drinking water supplies in UK and Ireland does not comply with EC standards.

He points out that legislation in member states (such as UK and Ireland) is required to be compatible with the objectives set out in EC legislation. EC *Regulations* set out the principles that apply to specific regulatory sections, whilst EC *Directives* then detail specific requirements for the various distinct fields within the over-all umbrella. While *Directives* are not of themselves laws, they establish the basis on which National legislation must be implemented under the individual Member States' own legislative systems.

EC Regulations and Directives on Medicine Legislation

"Fluoridated water must be classified as a medicinal product under the definitions in the current EC Medicines Directives. 2004/27/EC incorporates earlier European Court of Justice decisions and judgements relating to the classification of medicinal substances, and establishes the central role of intent to medicate as the criterion by which medicinal substances should be classified. Medication includes prophylactic intervention such as fluoridation. There is no requirement that the product should actually be effective as a medicine in order for it to be classed as such - the key issue is the existence of the intent to medicate.

"Fluoridated water meets both of the core definitions of a medicinal product as set out in 2004/27/EC - it is medicinal by presentation and medicinal by function. In addition, the Jauncey decision in McColl v Strathclyde (Fluoridation Trial, the High Court of Edinburgh, 1980) clearly supports the view that the public water supply is an unusual but nevertheless clearly identifiable mechanism for distributing a substance for which medical claims are made to the target recipients."

Fluoridation Contrary to Requirements of EC Medicines Directives

National regulators normally decide to authorize or refuse medicinal marketing authorization for any medicine. "Such authorizations must be issued with regard to the framework laid down under 726/2004 and 2004/27/EC. National regulators normally decide not to issue an authorization because the evidence submitted by an applicant relating to their safety or efficacy is unconvincing or incomplete. In the case of fluoridated water, however, there appears to have been no format application for the product to be specifically submitted to the regulators by a manufacturer..."

"In the UK, the legality of fluoridation should have been subject to scrutiny on the formation of the private water

companies in 1991. It should certainly have been considered in the formulation of the Water Act 2003 - the fluoridation clauses are the only clauses dealing with medication. Fluoridation is clearly contrary to the requirements of the EC medicines *Directives* existing at that time. The new water companies should have taken precautions to ensure that they were not permitting such incompatibilities to continue, not least because of the implications for their shareholders.

"However, legal review in the UK has been driven by Government policies aimed at merely reinforcing national policy in dentistry, regardless of the over-riding EC framework, to the extent that 'retrospective indemnity' for claims by the public against water companies has been proposed to cover liability before the most recent imposition of mandatory fluoridation under the Water Act 2003.

"Such indemnity has no legal foundation. The continuation of the practice of fluoridation has been based on extremely uncertain precedent, but is now clearly incompatible with the legal framework of the European Community. The decision by the Irish Medical Board (IMB) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK that fluoridated water is not a medicinal product is open to challenge in the Courts."

"Fluoridation ... is now clearly incompatible with the legal framework of the European Community."

Medicines Packaging and Advertising

"It is prohibited to advertise any medicinal product that does not have a marketing authorization. This applies equally, across the board, to national Health Administrations, professional medical or dental organizations, and to any private organization promoting the alleged medicinal properties of fluoridated water. This prohibition equally applies personally to any health professional, or any other person that the public might reasonably be led to believe can be relied upon for medicinal (including, of course, dental) advice.

All medicines must be packaged in dose form, and labelled clearly according to the medicinal regulations. They cannot be administered indiscriminately to the general public in a form for which there is no control over dosage, or irrespective of each recipient individual's personal medical need. All such products must be capable of being recalled using a batching test, labelling and recall system in the event of a defect in the product. **The only way that fluoridated water might be legally marketed in the EC is by first subjecting it to scrutiny for efficacy and safety, and then securing a legal marketing authorization. It could then be supplied only in bottles, clearly labelled according to the requirements of the medicines *Directives*."**

Drinking Water Directive

Quality of water intended for human consumptions in *Directives* 98/83/EC.

"The objective of the drinking water *Directive* and EC and

We thank Doug Cross for supplying us with his excellent summary, "The implications of the European Community legislation on medicines, foods, water and cosmetics with respect to the practice of water fluoridation in the UK and Ireland". The EC legislation clearly does not support compulsory mass medication.

national water quality standards is that the quality of water should be the highest possible, not the worst permissible. The establishment of a standard for any parameter in drinking water is not a licence to add that substance up to its maximum permitted level - this is made clear in the Preamble to the *Directive*. Water that has no added medicinal ingredient (and this includes water that has naturally-occurring fluoride in it) is a food, as such its quality is regulated under the drinking water *Directive* and national water quality legislation. However, if any substance (and this would even include 'natural' fluoride) is added to it, **with the intent to medicate the recipient**, it is no longer regulated under the food and water *Directives*, but becomes irrevocably a medicinal product, regulated solely under the *medicines Directive* and requires a marketing authorization before being sold to the public.

"If any substance is added to water with the intent to medicate the recipient . . . it becomes irrevocably a medicinal product."

"Originally there was a loophole in the 1980 drinking water *Directive* that allowed Governments to claim that fluoridated water was not a medicinal product, by refusing to recognise it as a 'medicinal water'. However, this was closed in the *1998 Directive*, and from then on any water that was marketed with any medicinal claim was automatically required to be licenced as a medicinal product, and subject to the constraints for marketing and presentation set out in the *medicines Directive*. **Since dental fluorosis may appear in children subject to exposure to fluoridated water after only a few years of consuming this product, the seven year delay since this loophole was removed is quite long enough for many children to have developed this disfigurement after the loophole was removed. They would therefore be eligible to claim against those ordering their exposure, and those marketing and advertising or promoting the product.**"

Food Legislation

"Water is a food, unless any substance is deliberately added to it with the intent to medicate any human disease condition, in which case it becomes a medicine.

"All foods containing permitted supplements must be packaged and labelled clearly, indicating the name of the supplement. No health claims may be made for any food, or food supplements - if such are made, then the product is automatically regulated as a medicinal product and requires an appropriate medicinal marketing authorization. Therefore, promoting the product as a food having prophylactic dental properties would be entirely illegal. This prohibition also applies to all individually packaged vitamins and minerals. Supplements of essential vitamins and minerals are permitted, but must be disclosed on the packaging of the food so treated without any accompanying health or medicinal claim.

"There is no 'fluoride deficiency disease' any more than there is a deficiency of mercury or cadmium"

"The inclusion of fluoride as a 'mineral' in 2002/46/EC is anomalous. It is the only substance for which there is no biochemical requirement; there is no 'fluoride deficiency disease' in humans, any more than there is a deficiency of mercury or cadmium. There is therefore no medical or scientific validity in 'supplementing' its presence in drinking water. Such action would not be tolerated in the case of other toxic substances."

Cosmetics

"Cosmetics may contain any of 20 forms of fluoride, including four fluorosilicates, but not fluorosilicic acid, the most widely used fluoridating chemical. No cosmetic product may be consumed unless it also has a medicinal purpose, in which case the medicines, medicines marketing and medicines packaging and labelling regulations apply.

"Proponents of fluoridation frequently dismiss complaints of dental fluorosis as a mere 'cosmetic effect', and imply (or even explicitly claim that) fluoridated water is regulated under 'cosmetic regulations'. **Dental fluorosis is a disfigurement, not a cosmetic effect, and this product is entirely incompatible with EC Directives relating to cosmetic products. The cost of remedial action such as tooth veneers is attributable to the manufacturers of the product.**"

"Dental fluorosis is a disfigurement, not a cosmetic effect."

Fluoride Carcinogenicity and its Implications

"Bassin's suppressed research at Harvard School of Dentistry has revealed a substantial increase in the incidence of osteosarcoma in young boys growing up in fluoridated areas. It is therefore extremely unlikely that a medicinal licence could be issued for this product. For the same reason, existing authorizations for the use of other fluorides as medicines, food 'supplements', additives in special foods, and in oral hygiene products also needs to be reviewed urgently.

"But there are other implications of this finding within the EC legislation relating to wastes that are apparently not appreciated by the UK or Irish Governments. If fluoride is declared to be a carcinogen, then sewerage works effluents will have to be classed as discharges of hazardous *Special Waste* if they contain more than 0.1% of the threshold value for its carcinogenicity.

"Bassin's work clearly implies that the carcinogenic threshold is well below 1mg/litre of fluoride, so any effluent containing even as much as 1 microgram/litre would require treatment as a *Special Waste*, and cannot be discharged to the environment. The US Environmental Working Group's call for the maximum admissible level of fluoride in drinking water to be reduced to zero on this basis. This is a problem for water suppliers and sewerage treatment authorities presently operating in fluoridated areas, but the widespread contamination of foods and drinks by fluoride may mean that sewerage authorities in other areas may also fall foul of the special waste regulations.

Conclusion

"There is serious incompatibility between the EC legislative framework and the National legislations implemented by the British and Irish governments. Authorization of any public medication with unlicensed fluoridated water by national governments is entirely incompatible with the European *Directive* on medicinal products. It is also a violation of Article 3 of the European *Directive* on medicinal products. It is also a violation of Article 3 of the European Convention on Human Rights. The situation is identical on both the UK and Ireland. **The decisions of the IMB and MHRA may be subject to challenge through the Courts as an issue of public interest. In the event that the Courts find that fluoridated water is a medicinal product according to the definitions of the EC Directives and the judgement of the ECJ, then potential further actions may be eligible under criminal law, and private actions for damages under the civil codes.**"

The article "Does not discuss the additional issues raised under the Human Rights Convention, nor of Professional codes of Conduct and Medical Ethics, by the indiscriminate administration of an unlicensed medical substance to the general public, irrespective of individual need, personal medical supervision or informed consent. These inevitably arise from the findings of this analysis, and should be seen as a necessary additional field of legal analysis for any person exposed to this controversial State-imposed medicinal intervention."

Relevant EC Directives

- 65/65/EEC on medicinal products (OJ No 22 of 9.2.1965, p. 369/65.)
- 75/319/EEC Guide to Good Manufacturing Practices for Medicinal Products' (OJ No L 147 of 9.6.1975, p. 13)
- 75/440/EEC on standards for surface water for the abstraction of drinking water (OJ L 194, 25.7.1975, p. 34)
- 76/768/EEC on cosmetic products (OJ L 262, 27.9.1976, p. 169)
- 79/112/EEC on the labelling, presentation and advertising of foodstuffs (OJ L 33, 8.2.1979, p. 1)
- 80/778/EEC on quality of water intended for human consumption (OJ L 229, 30.8.1980, p. 11)
- 89/107/EEC on food additives authorised for use in foodstuffs for human

- consumption (OJ L 40, 11.2.1989, p. 27).
- 89/398/EEC on foodstuffs for particular nutritional uses (OJ L 186, 30.6.1989, p. 27)
- 92/28/EEC on advertising of medicinal products (OJ L 113, 30.4.1992)
- 92/73/EEC on homeopathic medicinal products (OJ L 297, 13.10.1992)
- 98/83/EC on the quality of water intended for human consumption (OJ L 330, 05/12/1998 p. 0032 - 005)
- 1999/21/EC on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29)
- 2000/13/EC on labelling, presentation and advertising of foods (OJ L 109, 6.5.2000, p. 29)
- 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (OJ L 052, 22.2.2001, p. 0019-0025)
- 2001/20/EC good clinical practice in clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34)
- 2001/82/EC on veterinary medicines (OJ L 311, 28.11.2001, p. 1)
- 2001/83/EC Codified Directive on human medicines (OJ L 311, 28.11.2001, p. 67)
- 2002/46/EC on Food Supplements (OJ L 183, 12.7.2002, p. 51)
- 2003/15/EC amending Council Directive 76/768/EEC on cosmetic products (OJ L 66, 11.3.2003, p. 26)
- 2004/27/EC on human medicines (OJ L 136, 30.4.2004, p. 34)
- 2004/28/EC on veterinary medicines (OJ L 136, 30.4.2004, p. 58)

TENTERFIELD, NSW

"Seven to One" Vote Against Fluoridation

But Department of Health say:-

THIS IS A VOTE IN FAVOUR OF FLUORIDATION!

Residents of Tenterfield, NSW, have yet again voted overwhelmingly against artificial fluoridation of their water supply, for the third time.

Opposition to fluoridation has escalated at successive referenda. The current resounding condemnation of the scheme by the people of Tenterfield is the clear message, "We do not want a toxic fluoride chemical added to our water supply!"

Following the strong "7 to 1" vote against fluoridation in November 2005, in April 2006 the NSW Department of Health directed Tenterfield Shire Council to fluoridate its water supply! The council is now asking the Department of Health for an urgent review of the directive.

Mayor Toby Smith says the department has reinterpreted the 2005 voluntary poll result, suggesting that the 60% of the community who did not vote supported fluoridation. The Mayor said this interpretation is incorrect.

"The people that really did care voted and they voted seven to one against," he said. "Now in local government if you are a councillor at a meeting and you abstain from voting, it's automatically declared a negative vote.

"So if the Health Department want to go that way, that was a local government poll ... so I'm saying then that the people who abstained they'd have to be recorded as a negative and therefore 90 per cent of people were against fluoridation."

- The first referendum, held in 1962, was nearly a 3 to 1 vote against fluoridation (999 against, 381 in favour). At this referendum, large press advertisement quoted the once "Australia's most respected medical researcher", Dr.

William McBride, Medical Director of Foundation 41, as claiming no harmful effects of artificial fluoridation and that it eliminated more than 60% of tooth decay in children. McBride was later found to have fudged research results and medically disgraced. No evidence of any research into artificial fluoridation carried out by Dr. McBride has ever been produced. A whistleblower has advised of no knowledge of any research into artificial fluoridation undertaken at Foundation 41.

- The second referendum, held on 20th September 1980, increased this margin to nearly 4 to 1 against fluoridation (1465 against, 382 in favour).
- The 12 November 2005 referendum was 4 to 1 against fluoridation (789 against fluoridation, 199 in favour).

This latest example of jiggery-pokery by the NSW Health Department is disturbingly typical of disregard for the will of the people, trifling with the truth and the "big brother" tactics used by promoters of artificial fluoridation of public drinking water supplies.

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