AFFIDAVIT OF MARK DIESENDORF, Ph.D.
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Country of Australia
City of O'Connor

Mark Diesendorf, Ph.D., being first duly sworn on oath and with personal knowledge of the information contained herein, respectfully states to the Court as follows:

BACKGROUND

1. I am presently Coordinator of the Global Change Program of the Australian Conservation Foundation, one of Australia's largest community-based environmental organizations. I also have a private consultancy, called Science in the Public Interest.

2. From 1988 to 1990 I was a Senior Research Fellow in the Australian Institute of Health, which is the Australian Government's health statistics institute, and leader of the Medical Services Group within that Institute. For part of that period I was also acting-head of the Health Services Division of the Institute.

During the period from 1985 to 1988 I was both a Visiting Fellow and a Lecturer in the Human Sciences Program at the Australian National University, Canberra.

From 1975 to 1985 I was a Senior Research Scientist and later a Principle Research Scientist in the Division of Mathematics and Statistics, Australian Commonwealth Scientific and Industrial Research Organization, known as CSIRO. In the early 1980s I was also leader of the Applied Mathematics Group within that Division.

From 1971 to 1975 I was first a Queen Elizabeth II Fellow and then a lecturing Fellow in applied mathematics at the Australian National University, Canberra.

3. I received my BSc with first class honours in physics from the University of Sydney in 1964, and my PhD in applied mathematics from the University of New South Wales in 1968.

4. Over the past 20 years, I have devoted considerable time to researching the safety and effectiveness of artificial water fluoridation. I have published a
number of articles in recognized journals and periodicals on the subject of fluoridation, including:


**EFFECTIVENESS OF FLUORIDATION**

5. Fluoride in milligram per day doses is not necessary for life or for sound teeth. Not a single person has ever been shown to have a genuine "deficiency" of fluoride.

6. There is now a substantial body of evidence that the mechanism of action of fluoride is on the surface of teeth, and that there is little or no benefit in swallowing fluoride. Thus the argument for fluoridating drinking water is weakened still further. (Exhibit____).

7. Over the past 20-30 years there have been large declines in tooth decay in both fluoridated and nonfluoridated communities in the western world. Today, 99.5% of people in western continental Europe, 91% in Britain, 34% in Australia and 50% in the USA, Canada and New Zealand do not consume fluoridated water. Still, there have been very large reductions in tooth decay in the nonfluoridated regions of all these countries. (Exhibits______).

8. Traditionally it has been claimed that there are scores of studies on fluoridated communities from around the developed world which prove or "demonstrate" that water fluoridation has enormous benefits. In practice, those studies which have been re-examined critically have been found to be very badly designed and/or executed.

9. At best these studies show that tooth decay has been declining in fluoridated regions, but the evidence also shows that there are over 20 studies showing that tooth decay has also been declining in unfluoridated areas. (Exhibits______).

10. The early cross-sectional surveys of tooth decay in naturally-fluoridated communities in the USA by Dean claimed to find an "inverse relationship" between fluoride concentration in drinking water and tooth decay (DMFT). But although Dean studied hundreds of communities, he published the results for only 21. (Exhibit______). Such highly selected data are unlikely to give unbiased results!

11. The early "trials" of artificial fluoridation in North America have been severely criticized in a detailed scientific monograph by Sutton (Exhibit______), on the grounds of major failings in experimental design,
statistical analysis and selective quoting of results. Most reviews of the alleged benefits of fluoridation still cite the early trials as if they were "gospel," and omit to cite Sutton's critique of them.

12. The design inadequacies of some of the well-known fluoridation trials conducted in various parts of the world are summarized as follows:
   a. In not one of the Australian fluoridation trials has there been simultaneous observation of changes over time in tooth decay in the test community and an appropriate nonfluoridated control population. (Exhibit____).
   b. In the two trials held in Anglesey, Wales, in the 1970s and 1980s, the "control" was chosen 19 years after fluoridation of Anglesey, from a known high-tooth-decay area. This negated the benefit of the blind examinations of teeth. Moreover, the test population was rural while the "control" was urban, and so they are not comparable. (Exhibit____).
   c. In the Hastings, New Zealand trial, the decline in tooth decay resulted mainly from instructions to dental therapists to find and fill fewer cavities. The instructions, which were never mentioned in published reports of the trial, were revealed in material obtained by Colquhoun by means of a request under the Official Information Act. (Exhibit____).
   d. In the Grand Rapids study, almost all the reductions in tooth decay occurred in the first year. The official results also imply that tooth decay was decreasing with increasing age or, in other words, that fluoridation was actually filling cavities. Since these results are impossible, they must reflect sampling errors.
   e. In the study of fluoridation at Tamworth, Australia, a large part of the reported reduction in tooth decay occurred too late in time to have been caused by fluoridation.

13. Results running counter to the alleged inverse relationship have been reported from time-independent surveys in naturally fluoridated locations in India, Sweden, Japan, the United States, and New Zealand. (Exhibit____).
14. In Australia in 1987, the prevalence of decay in the permanent teeth of elementary school children in the unfluoridated Australian state capital city of Brisbane was equal to or less than that in the fluoridated state capitals of Adelaide, Perth and Melbourne. (Exhibit____).
15. It should be noted that I am comparing similar populations: all are major cities by Australian standards, with similar socio-economic class. Many pro-fluoridation studies make inappropriate comparisons, such as comparing fluoridated large cities with unfluoridated small rural towns (which have different socio-economic and dietary patterns from the large cities, and hence different levels of tooth decay).
16. Colquhoun has reported on tooth decay in all 12- and 13-year-olds in the major cities of New Zealand in 1984 and 1986. He found that tooth decay in unfluoridated Christchurch is approximately the same as in all the other major cities in New Zealand, which are fluoridated. (Exhibit____).
17. The results from a 1986-1987 survey of US school children by the NIDR, with data from dental examinations of 39,207 children in 84 areas throughout the US, showed no significant reduction in tooth decay in fluoridated areas. (Exhibit____). This supported the findings of an earlier Missouri study (Exhibit____).
18. In animals, experiments are often much better designed and controlled than with humans. In the laboratory rat, which seems to be generally regarded as a good model for caries in humans, it was found that no decay reduction could be obtained from an implanted subcutaneous device which released
fluoride slowly into the bloodstream (and from there to the saliva).

(Exhibit____).

SAFETY OF FLUORIDATION

19. Most assessments and reviews of the "safety" (i.e. health hazards) of water fluoridation, which have been written from a pro-fluoridation perspective, have only considered the health implications for the "average person." This is a natural consequence of focusing on fluoride concentrations in drinking water rather than on the range of daily doses actually ingested by people.

20. The proper approach to risk assessment in toxicology protection is to identify the high-risk groups in the community and to set safety standards for daily doses with sufficient margin to protect them with a high degree of certainty. If only the risks to the "average" member of the community are known, a "safety factor" of 10 is normally used to allow for high-risk groups. Any other major uncertainties are compensated for by increasing the "safety factor". (Klaassen, C.D., Principles of Toxicology (1986)).

21. Such an approach has not been followed for water fluoridation, which was introduced long before the growth in awareness of environmental chemical and physical health hazards of the 1970s.

22. By estimating the fluoride intake of some of the high-risk groups and by reviewing the published scientific literature, it is found that there can be no safety margin for members of some of these groups if they consume water fluoridated at 1 ppm.

23. The most obvious high-risk groups are those which consume large daily doses of tapwater, such as infants who are fed on powdered formula reconstituted with fluoridated water, long-distance runners and other sportspeople, outdoor labourers and diabetics. People with malfunctioning kidneys are also at high risk, since the kidney is responsible for excreting fluoride.

24. The fluoride intake from the major contributors to the fluoride dose (tapwater in the home and that used in commercial processing of food and beverages) can be estimated from a recent survey of "total water" and "tapwater" intake by 26,000 people in the USA. (Ershow & Cantor, National Cancer Institute, 1989. (Exhibit____).

25. In the Ershow survey, the average daily intake of all participants was 2.07 (plus or minus 0.80) liters of "total water", including 1.19 (plus or minus 0.70) liters of tapwater. The large value of the standard deviation demonstrates the importance of determining the high-consumption groups rather than simply focusing on the averages.

26. The percentile distribution shows that 5% of participants had a daily "total water" intake greater than 3.55 liters, and 5% had a "total water" intake of less than 1.01 liters. This wide range shows the difficulty of trying to medicate a whole community safely and effectively through the water supply.

27. For estimating the risk of diseases such as skeletal fluorosis, it may be more appropriate to consider the top 1% of water drinkers. This group has a daily "total water" intake of greater than 4.65 liters. For adult males aged 20-64, the average intake is 2.5 liters, but 1% consume 5.5 liters or more of "total water."

28. For water fluoridated at 1 ppm, 1 liter contains 1 mg of fluoride. Natural fluoride in raw food could add daily another 0.3-0.8 mg, while other items such a fluoride tooth pastes and tea drinking add still more.

29. In summary, based on the comprehensive US survey, it is likely that about 1% of the adult population in a fluoridated area ingest daily about 6-7.5 mg.
fluoride, excluding fish and tea. (Exhibit____). These results are similar to the earlier estimates of the Royal College of Physicians, which gave "maximum" daily intakes of 6 mg excluding tea. (Royal College of Physicians, 1976).

30. Breastmilk has one-hundredth of the fluoride content of artificially fluoridated drinking water. Therefore, infants who are fed on powdered formula reconstituted with fluoridated water receive at least 100 times the fluoride intake of breastfed babies. This is accepted as a fact by both sides of the fluoridation debate.

31. In my view, to deliver such an unnaturally high fluoride intake to the most sensitive age-group of human beings is a violation of the principles of toxicology and of medical ethics.

32. The fluoride intakes of 6-month old infants, who are fed on powdered formula reconstituted with fluoridated water, are typically 4-6 times the daily doses recommended by US pro-fluoridation pediatricians for fluoride supplements in nonfluoridated areas. (Exhibit____).

33. The very low traditional estimates of fluoride consumption in fluoridated areas must be discarded as being unrealistic, and contrary to the evidence.

Dental Fluorosis

34. Dental fluorosis is a particular type of mottling of teeth which is caused only by the ingestion of fluoride during early childhood. In its milder forms, which are ranked as grades 1 and 2 on Dean's classification index, dental fluorosis comprises opaque white patches which cover less than 50% of the enamel surface. The more severe grades, 3 and 4, can involve dark brown staining and pitting of the fluorosed enamel.

35. On the basis of controlled-dose studies, it is stated that a substantial proportion of children suffer dental fluorosis of grades 1 and 2 when doses exceed 0.1 mg/kg of body weight/day. (Exhibit____). It is claimed that the "Optimal" dosage to reduce subsequent tooth decay is 0.05-0.07 mg/kg/day, though as Leverett has pointed out, there is little direct evidence to support this claim (Exhibit____).

36. Even if this were true, the safety margin between 0.07 (beneficial) and 0.1 (harmful) is very small. Indeed, the wide variation in dose from drinking fluoridated water makes it inevitable that a significant proportion of children in fluoridated areas will have dental fluorosis.

37. In the 1930s, in naturally fluoridated areas where fluoride concentration was about 1 ppm, Dean observed dental fluorosis of grades 1 and 2 in about 10% of children, but none of greater severity. Recent evidence shows that the prevalence and severity of dental fluorosis have increased in both fluoridated and nonfluoridated areas, but these increases are generally much greater in fluoridated areas.

38. In several recent American studies, the prevalence of all grades of dental fluorosis ranged from 26% to 51% in fluoridated areas, while the more "objectionable" grades 3 and 4 affected 1% - 2% of children. (Exhibits______).

39. Dental fluorosis is generally believed to be a result of disturbance or damage to the ameloblasts, the cells which are responsible for the development of the dental enamel. As such, it is an indicator of physiological damage or disease, rather than simply a "cosmetic effect."

Skeletal Fluorosis
40. When fluoride is ingested by adults, about 50% is excreted by the kidneys (provided that they are working normally) and almost all the remainder is stored in the bones. In infants and young children, there is evidence that considerably more than 50% is stored in the bones.

41. Skeletal fluorosis is a disease involving changes in the structure of bones and calcification of ligaments, which results from the chronic intake of fluoride over a period of years. Early clinical stages resemble arthritis, with patients experiencing pain and stiffness in bones and joints. Restriction of movement occurs in the spine, mainly in the cervical region, but also in the lower back, shoulder joint, hip and knee.

42. The conventional wisdom on skeletal fluorosis, in reports which have a pro-fluoridation perspective, is that there are no osteosclerotic changes in "temperate countries" when the fluoride concentration in drinking water is below 4 ppm, and there are no "clinically significant" changes, except for dental fluorosis, below 8 ppm.

43. It should be noted that fluoride doses are not usually specified in the conventional wisdom, only concentrations. However, the EPA and other regulatory agencies have stated that crippling skeletal fluorosis results from intakes of fluoride of 20 mg/day over periods of 20 years or more. But these agencies do not justify this figure, nor do they give a figure for the dose causing crippling skeletal fluorosis over a lifetime, which is surely lower.

44. In addition, they do not give a figure for skeletal fluorosis which produces clinical symptoms but is not crippling. Such pain and stiffness in bones and joints is simply ignored.

45. The "conventional wisdom" -- that there are no osteosclerotic changes when the fluoride concentration in water is below 4 ppm and no "clinically significant" changes below 8 ppm -- is wrong. Skeletal fluorosis with clinical indications has been reported for over 25 years in the refereed medical literature from at least 4 countries (including USA) from places where the fluoride content of drinking water is less than 2.5 ppm. Given the lack of training western doctors receive on skeletal fluorosis, it is very likely that early stages of the condition (including pain and stiffness) are being misdiagnosed as arthritis in artificially fluoridated areas. (Exhibit____).

46. In India there have been several reports of skeletal fluorosis with serious complications where fluoride concentrations in drinking water were below 1.5 ppm.

47. What is the prevalence of people of average mass who live in fluoridated areas and are in the top 1% of water drinkers throughout their lives? They may be at risk of skeletal fluorosis because as infants they were formula-fed, as children they drank water-based beverages rather than cow's milk, and as adults they had strenuous outdoor jobs or exercised heavily.

48. In the pro-fluoridation literature, there is a strong tendency to regard people who are at high risk of adverse effects from fluoridation as abnormal and somehow unworthy of protection by the same standards which are applied by toxicologists as a matter of course to other chemicals.

49. There have been no properly conducted scientific studies to investigate the prevalence of skeletal fluorosis within the high-risk groups -- only reassuring anecdotes from medical researchers and dentists with vested interests in the use of fluoride for therapy or as a preventive medicine.

50. Skeletal fluorosis is a well-known public health problem in several naturally fluoridated areas of the world. Most artificially fluoridated areas were only fluoridated in the 1960s and 1970s. In such regions it is still too early to expect to see enhanced levels of skeletal fluorosis in epidemiological surveys of the general population. A survey of subsets of the population which are at high risk might be useful. Unfortunately, such surveys have not
been performed scientifically.

**Hip Fractures**

51. Clinical trials have shown that fluoride therapy for osteoporosis increases bone fracture rates, contrary to the previous belief. (Exhibit____).
52. There is now evidence that this hazard may extend down to the much lower fluoride doses received from fluoridated drinking water. Since 1990, four epidemiological studies have been published from the USA and Britain, showing that there is an increased rate of bone fractures (notably hip fractures) in older people in fluoridated areas. (Exhibits__________). 
53. Proponents of fluoridation point out that the increase in fracture rates is fairly small. But I believe that it will inevitably become greater with time, until people have become exposed to fluoridation from birth to old age. Hip fracture is fatal in about 25% of cases.

**Hypersensitivity**

54. Clinical reports of hypersensitivity to 1 ppm fluoride in drinking water or 1 mg/day in fluoride tablets have been published by Waldbott, Feltman, Shea, Grimbergen and Petraborg (Exhibits_________).
55. These reactions include some of the following symptoms:
   - gastrointestinal upsets;
   - skin rashes (also after bathing in F- water);
   - mouth sores;
   - migraine-like headaches;
   - arthritic-like pains;
   - dryness of the mouth;
   - excessive water consumption;
   - chronic fatigue;
   - depression;
   - nervousness; and
   - respiratory difficulties.

   These symptoms subside after discontinuation of exposure to fluoride. In many cases the association has been confirmed by blind and double blind-challenges. (Exhibits________).
56. The standard response of proponents of fluoridation and pro-fluoridation reports has been to quote a statement by the Executive Board of the American Academy of Allergy that: There is no evidence of allergy or intolerance to fluorides as used in the fluoridation of communal water supplies.

   Dr. Waldbott, a Fellow of that same Academy, has responded that: Curiously, none of these prominent scientists had carried out research on the health effects of fluoride; no hearings were held on the subject and no inquiries were made of the members of the Academy regarding fluoride poisoning among their patients.... The Bibliography did not include any of my original publication on chronic fluoride poisoning... (Waldbott, Fluoridation: the Great Dilemma, 1978).

   Clearly the statement by the Executive Board cannot be regarded as a scientific refutation of the published reports of hypersensitivity.
57. Waldbott also pointed out that the Academy's statement was apparently made at the request of the pro-fluoridation USPHS and that most of the members of the Executive Board of the Academy had received grants from the USPHS. Four members of the Board actually received grants around the time that their statement was published. Therefore, at least several members of the Executive Board were in a situation of potential conflict of interest.

58. Another response to reports of fluoride hyper-sensitivity has been to take the position that the reports should be ignored until those making them can produce a theoretical mechanism to explain their observations. This position appears to be inconsistent with modern scientific method which places empirical observation before theories.

CONCLUSION

59. The fluoridation of drinking water delivers an uncontrolled dose of a chronically toxic substance to consumers. In artificially fluoridated areas the prevalence and severity of dental fluorosis is increasing. Reports of hypersensitivity reactions in the medical and dental literature have not been refuted scientifically.

60. Skeletal fluorosis has been reported in naturally fluoridated areas of at least 4 countries where the fluoride concentration ranges from 0.7 to 2.5 ppm. In Britain and the USA, there is a much higher rate of hip fractures in older people in fluoridated than in nonfluoridated areas. Both skeletal fluorosis and hip fractures are likely to become prevalent among high-risk groups (people with malfunctioning kidneys and/or high water intake) in artificially fluoridated areas in people who have been exposed to 1 ppm fluoridated water from infancy to old age.

61. It is my best judgment, reached with a high degree of scientific certainty, that fluoridation is invalid in theory and ineffective in practice as a preventive of dental caries. It is dangerous to the health of consumers.

62. I make this Affidavit in support of the Plaintiff’s Motion for Summary Judgment.