Blue Ribbon Commission
On Health Care
Costs and Access

Supplement
Proposals
Submitted by Stakeholders
Proposals not included in revised web posting on September 28, 2006

Blue Ribbon Commission on Health Care Costs and Access

Supplement to Proposals

Proposals not included in revised web posting on September 28, 2006

List of Proposals

Tab 68 – American Academy of Pediatrics, Dr. Chris Olson, 509-489-5110, president@wcaap.org

Tab 69 – Senator Jim Kastama, Senator – 25th Legislative District, 360-786-7648, kastama.jim@leg.wa.gov

Tab 70 – Williamette Dental, Gary Allen, DMD, 503-526-4421, gallen@williamettedental.com

Tab 71 – Bill Osmunson, DDS, bill@teachingsmiles.com

Tab 72 – NARAL Pro-Choice Washington, Karen S. Cooper, Executive Director, 206-624-1990, karencooper@prochoicewashington.org

Tab 73 – SB&E, Inc., Gerene D. Schmidt, President, 509-892-9242, sdgerene@earthlink.net

Revised November 16, 2006: added Proposal Tab 73

Tab 68

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DEDICATED TO THE HEALTH OF ALL CHILDREN™

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September 21, 2006

TO: Blue Ribbon Commission of Health Care Costs and Access

FR: Dr. Chris Olson, President, WA Chapter American Academy of Pediatrics

SUBJ: Proposal to the Blue Ribbon Commission

The WA Chapter American Academy of Pediatrics is a member of the Health Coalition for Children and Youth, one of the organizations that submitted comments prior to your September 11th meeting. We would like, however, to take this opportunity to provide comments directly from the Chapter regarding two issues that are of significance to pediatricians in the State of Washington.

Provider Payments – Low Medicaid fee-for service reimbursement rates result in low physician participation in Medicaid. In Healthy Options, Medicaid Managed Care plans have not been given rate increases that keep pace with the cost of providing care to these patients. This hurts children by reducing their access to quality pediatric care.

When children are shut out of mainstream primary care, parents have no choice other than using expensive services in hospital clinics and emergency departments. In King County, Children's Hospital and Regional Medical Center's emergency room is clogged with children seeking primary care, and in their specialty clinics where wait times for appointments have skyrocketed for so many children who could have easily been cared for in primary care if they had a medical home.

Federal law requires states to reimburse physician services adequately so that it is just as easy for a Medicaid participant to see a physician as it is for the general population in the same geographic area. Unfortunately, Washington state has not raised the reimbursement rates for children covered by Medicaid since 1989. The rate (conversion factor) has been around $34.56/RVU for 17 years. This is about 65% of the average paid in this state by the major commercial insurance carriers. Practices cannot take the number of Medicaid patients in need or they go bankrupt. Pediatricians are forced to limit the number of Medicaid patients they accept. More calls from parents looking for a pediatrician are turned away.

When the state last increased reimbursement for services for children in 1989 there was a 90% decline in hospitalization rates for Medicaid children. These children had access to primary care in a medical home and their health care needs were met in a way that better preserved their health and was less expensive.

appears to be a significant cost to the state, all physician care accounts for less than 8% of Medicaid payments. Less than 3% of Medicaid payments are for physician services for children and adolescents under 21.

Medical Home – A medical home is an approach to providing health care services in a high-quality, comprehensive, and cost-effective manner. Provision of care is through a primary care physician in partnership with other allied health care professionals and the family. Through a medical home children and their families receive the care that they need from a pediatrician or other PCP whom they know and trust. The pediatric health care professionals and parents act as partners to identify and access all the medical and non-medical services needed to help children and their families achieve their maximum potential.

According to the American Academy of Pediatrics health care services provided through a medical home are:

- Accessible
- Family Centered
- Coordinated
- Comprehensive
- Continuous
- Compassionate
- Culturally Sensitive

Benefits of medical homes include:

- Increased patient and family satisfaction
- Establishment of a forum of problem solving
- Improved coordination of care
- Enhanced efficiency for children, youth and their families
- Efficient use of limited resources
- Increased professional satisfaction
- Increased wellness resulting from comprehensive care

Children in a medical home are half as likely to visit an ED or be hospitalized and are 30% more likely to be immunized. A recent study published in *Pediatrics*, the Official Journal of the American Academy of Pediatrics, concluded that a medical home provides better effectiveness of services as well as fewer disparities and more equity in health across population subgroups. "A concerted attempt to provide health insurance for all of the country's population as well as a medical home for everyone should be of high priority if the United States is to take its place among countries with the best health statistics. (Aug 7, 2006)

Recommendation -- It is the recommendation of the WA Chapter American Academy of Pediatrics that the Blue Ribbon Commission include in your final proposals an increase in the Medicaid reimbursement rate (to $50/RVU) and a commitment to ensure that children in the State of Washington have a medical home.

Thank you for your attention.

Tab 69

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September 15, 2006

The Honorable Christine Gregoire
Governor, State of Washington
Legislative Building
Post Office Box 40002
Olympia, WA 98504-0002

Dear Governor Gregoire:

Thank you for your consideration of alternatives to our current healthcare system. I am sorry that I have been unable to attend the Blue Ribbon Commission on Health Care Costs & Access meetings, however I hope to do so in the future.

Enclosed are two articles which outline a method of reform that I believe is feasible. One is from the Stanford Medical Magazine and the other is an article that appeared in Time Magazine entitled "Health Care Can Be Cured: Here's How" approximately two years ago. Both outline the need for an independent administrative body charged with overseeing healthcare decisions. They advocate a model similar to the Federal Reserve. In addition to these articles is legislation that I sponsored in 2005 that attempts to implement their recommendations. As you may remember, this was part of my powerpoint presentation that compares our nation's health outcomes and costs to other nations. This bill passed out of the Senate Health and Long-Term Care Committee, but failed to make it to the Senate floor for a vote.

I would ask that this concept be considered in your deliberations.

Sincerely,

Jim Kastama
Senate-25th Legislative District
State of Washington

Enc 4

CC Blue Ribbon Commission Members
Christina Hulet
Jonathan Seib

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And now for something completely different

A message to President Bush from a co-architect of the Clinton health plan

By PAUL ELLWOOD, MD

Illustration: Riccardo Vecchio

The American health system is crashing. We need to convince President Bush and the new Congress to put in place institutions and rigorous policies supporting health care that works for everyone. Confronting the system's failings is a challenge that only a powerful president in his second term can take on. The system is huge, devilishly complex, emotionally charged and filled with economic and professional snags.

First, the problem: Our domestic health expenditures are huge — greater than the entire Chinese economy and growing at a comparable rate. U.S. health spending is $1.6 trillion and is projected to reach $3.4 trillion in 2013. Yet the quality of U.S. health care is poor. For example, according to a 2003 study published in the New England Journal of Medicine (Beth McGlynn et al), patients receive the proper diagnosis and treatment only about 55 percent of the time.

The health system will continue to be out of control until we have an institution responsible for guiding it. No existing institution has the tools to manipulate the health system's performance or the clout to implement its goals. Indeed, most federal regulatory entities lack the degree of independence, refinement and scope to deal with something as complex and professionalized as health care. The lone exception is our venerable central bank — the Federal Reserve System.

A prototype for health care?

The Federal Reserve System has shown that a federal agency can achieve political

independence and endurance while deploying tools affecting the whole economy. The health system needs a similar steward. For purposes of this discussion, the new health oversight agency will be the “HealthFed.”

Why is such an intrusive, top-down proposal coming from the leader of the Jackson Hole Group, which arguably brought the United States its laissez-faire, market forces-based, HMO/managed-care health policies and worked to include them in the Clinton health plan? I learned much during 17 years of medical practice and 35 years of health policy work. But I didn’t really understand the health-care system until I depended on it as a patient. I am now a typical Medicare patient with the prerequisite five big-ticket chronic illnesses, plus a broken neck from a reckless ride on a young horse. The system does not work.

Tough lessons for reformers

Until recently I was convinced that consumers given adequate information about their choices could effectively influence both the cost of health insurance and the quality of health care. I was wrong! Studies show that despite the greater public access to sound health information, market forces, patient choices and professionalism do not exert sufficient influence over the quality of health services. But market forces can work to control the cost of health care if quality can be guaranteed by some other means. Quality and costs require different management strategies.

Another lesson: History teaches that restructuring the massive health enterprise requires decades of continuous and pragmatic leadership. In December 1970, President Nixon adopted the HMO approach as health policy, expecting that 1,500 HMOs would form and be available to 90 percent of the population within five years. The most predominant health plans were expected to be prepaid group practices. But legislation encouraging this market-based approach languished.

The promised impact of competition on health costs didn’t occur until the Clinton administration — 23 years after the original Nixon HMO policy proposal. Prepaid group practices never took off. And during the ’90s, when price competition became most effective, the seeds of managed care’s unraveling had already been planted. Providers and their patients were charging that cost containment meant skimping on needed care.

The HealthFed proposal

HealthFed needs effective tools for guiding the quality and value of health services if medical costs are to be justified and the system to be trusted. It will also need enough power to assure compliance with its policies. Let the market determine prices of health insurance and the structure of health-care organizations but have the HealthFed enforce adherence to evidence-based medical quality guidelines.

The source of HealthFed’s power comes from another page of the banking system playbook: federal insurance. The government extends guarantees to depositors in banks meeting Federal Reserve and Federal Deposit Insurance Corporation standards. The health system could benefit from similar insurance or reinsurance on high-cost cases. To be eligible for optional federally guaranteed reinsurance, patients, providers and insurers would have to meet the data collection and evidence-based quality standards of the HealthFed.

The HealthFed assures Americans that they are getting health care that is effective by

requiring its users and providers to rely on evidence-based guidelines. In return it gives access to federal health reinsurance thus obviating risk selection by insurers.

The new health guidance institution must become so effective that politicians and interest groups leave it alone. Currently, the medical industrial complex ruthlessly wields tremendous power, using it in ways that can harm the public. An example: In the early 1990s, the newly formed Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) issued a report on the most effective care for back pain. This drew political fire from a small group of threatened orthopedists and neurosurgeons who almost succeeded in killing the whole federal health services research program.

Our health system is out of control because each presidential administration, HHS secretary, Congress and Medicare/Medicaid administrator introduces new strategies for dealing with health care. Since 1979 Medicare has had 22 chief (or acting chief) administrators. Each has had to learn on the job how to run a $482 billion insurance company. Over this same period, the Fed has had only two chairmen, assisted by seven Federal Reserve Governors with 14-year terms, the presidents of 12 Federal Reserve Banks and large professional staffs. They have two major responsibilities — keep the economy moving forward at modest rates of inflation and assure the integrity of the banking system.

No one has analogous responsibilities or capabilities in health care. But someone should.

Paul Ellwood, MD, (SM'53), is president of The Jackson Hole Group and Healtru, two health-care reform Organizations. Send him HealthFed suggestions at pmellwood@earthlink.net.

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TIME

FROM THE MAGAZINE

Monday, Oct. 4, 2004

Health Care Can Be Cured: Here's How

Americans are burdened with a costly, hugely dysfunctional health-care system. In a new book, a pair of investigative reporters offers a fresh remedy based on a successful model we're all familiar with

By DONALD L. BARLETT; JAMES B. STEELE

This is the picture of health care in America. We spend more money than anyone else in the world — and yet have less to show for it than other developed countries. That's one reason we don't live as long. We don't adequately cover half the population. We encourage hospitals and doctors to perform unnecessary medical procedures on people who don't need them, while denying procedures to those who do. We charge the poor far more for medical services than we do the rich. We force senior citizens with modest incomes to board buses to Canada to buy drugs they can't afford in America. We clog our emergency rooms with patients because they can't get in to see their doctors. We spend more money treating disease than preventing it. We are victims of rampant fraud and overbilling. We stand a good chance of dying from a mistake if we are admitted to a hospital, and we kill more people with prescription drugs than with street drugs like cocaine and heroin. We have an endless choice of health-care plans, but most people have few real choices. We are forced to hold bake sales, car washes and pancake breakfasts to pay the medical bills of family members and friends when a catastrophic illness strikes.

Americans tend to believe they have the best health care in the world, but in truth it is a second-rate system and destined to get a lot worse and much more expensive.

It need not be this way.

The simplest and most cost-effective remedy is one that is considered untouchable in the U.S. because of the huge lobbying forces arrayed against it. Indeed, neither presidential candidate has come close to offering such a comprehensive solution. The remedy: provide universal coverage and create one agency to collect medical fees and pay claims. This would eliminate the staggering overlap, bureaucracy and waste created by thousands of individual plans. Under a single-payer system, all health-care providers — doctors, hospitals, clinics — would bill one agency for their services and

would be reimbursed by the same agency. Every American would receive basic health care, including essential prescription drugs and rehabilitative care. Anyone who needed to be treated or hospitalized could receive medical care without having to wrestle with referrals and without fear of financial ruin.

Radical? We already have universal health care and a single-payer system for everybody age 65 and over: it's called Medicare. For years, researchers and health-care professionals have advocated a similar plan for the rest of the population, but no plan has ever got far in the legislative process because of fierce opposition by the health-care industry. To discredit the single-payer idea, insurers, HMOs, for-profit hospitals and other private interests play on Americans' long-standing fears of Big Government. In truth, it is the private market that has created a massive bureaucracy, one that dwarfs the size and costs of Medicare, the most efficiently run health-insurance program in the U.S. in terms of administrative costs. Medicare's overhead averages about 2% a year. In a 2002 study for the state of Maine, Mathematica Policy Research Inc. concluded that administrative costs of private insurers in the state ranged from 12% to more than 30%. That isn't surprising because unlike Medicare, which relies on economies of scale and standardized universal coverage, private insurance is built on bewildering layers of plans and providers that require a costly bureaucracy to administer, much of which is geared toward denying claims.

What kind of agency would administer this Medicare-like plan for the rest of us?

The idea of a single-payer plan run by the U.S. government carries with it far too much political baggage to ever get off the ground. What's needed is a fresh approach, a new organization that is independent and free from politics. For in addition to covering the basic costs of all Americans, a new system would need to institute programs to improve America's overall health that focus on preventing illness and disease as well as on treatment and do so without breaking the bank. How does the U. S. come up with such a mechanism?

One possible answer: loosely copy and then expand on what already exists in another setting — the Federal Reserve System, which oversees the nation's money and banking policies. The Fed is one of America's most ingenious creations, a public agency that is largely independent of politics. The Fed's board members are appointed to 14-year terms by the President with the consent of the Senate, meaning that neither the White House nor Congress can substantively influence the Fed's policies.

Call this independent agency the U.S. Council on Health Care (USCHC). Like the Fed, the council would set overall policy for health care and influence its direction by controlling federal spending — from managing research grants to providing medical coverage for all citizens. Unlike the Fed, it would be funded by taxpayers. The money

could come from two taxes: a gross-receipts levy on businesses and a flat tax, as with Medicare, on all individual income, not just wages.

This would not represent an additional cost to society but would rather replace existing taxes and write-offs. It would cut costs for corporations and raise taxes slightly on individuals at the top of the income ladder. The council's mission: implement policies that improve health care for everyone, not just those suffering from certain diseases. In short, make the unpopular decisions that the market cannot make. The council could establish regions similar to those of the Fed.

The geographic subdivisions could take into account cultural and regional differences. That would allow for health-care delivery to be fine-tuned at the local level and ensure that regulations take into account the differences between metropolitan and community hospitals. That is not to suggest that a single-payer system overseen by a Fed-like independent organization would instantly correct everything that's wrong with market-driven health care. What it would do is provide the framework to reach that goal. For starters, it would:

Guarantee that all Americans receive a defined level of basic care, including a fixed number of visits to doctors, routine lab work, immunizations for children, coverage for all childhood illnesses and all hospital charges.

Establish flexible co-pays for basic care that would vary depending on income as well as usage. Those people who seldom seek medical attention could have their co-pays waived. So too could those at the bottom of the income ladder.

Pay all costs to treat any catastrophic illness, such as cancer and other devastating diseases.

Restore freedom of choice by allowing patients to choose their doctors and their hospitals.

Redirect health-care spending by allocating money for disease prevention as well as treatment.

Provide critically important drug information to consumers to balance the promotional hype of advertising.

Concentrate health-care spending on cost-effective areas, such as stemming the increased prevalence of diabetes in children.

Halt the existing practice by which insurers squeeze doctors through unrealistically

low reimbursement rates. The same for hospitals and nursing homes that squeeze nursing salaries and staffing levels.

Reverse the costly but seldom discussed health-care trend of overdiagnosis and overtreatment — something no market system will ever do. While many Americans suffer from a lack of health care, a growing number get too much.

Once the basic care package is in place, its scope could be expanded as the system realizes savings derived from standardization, more efficient computer technology and the end of market-based health-care management, with its required profits, stock options and generous executive compensation.

Individuals could supplement their basic government-supported coverage through private insurance. Wealthier citizens could continue to get whatever care they wanted and pay for it. But they would still be required to pay the earmarked taxes, just as everyone must contribute to Medicare and Social Security. Similarly, hospitals would be free to accept a certain percentage of cash-paying patients from outside the USCHC plan. As for prescription drugs, a good health-care system would strive to prescribe fewer pills, especially since the effectiveness of many drugs is questionable. The USCHC could negotiate the best possible drug prices, something that Medicare is forbidden to do by Congress.

Many Americans fear that a universal health plan would cost too much, even though the market system has already given the U.S. the world's most expensive health care. They fear the long waits they have heard about in Canada, even though comparable waiting times for tests and procedures are commonplace in many parts of the U.S. Lastly, they fear government-decreed rationing, even though health care is already rationed in the most inequitable of ways.

Despite all the fears, change will come, ultimately from two sources: working Americans who are disenchanted with ever rising costs and shrinking care, and U.S. corporations, which are increasingly refusing to pick up the added costs. They can't afford to, because America's privately funded system puts U.S. companies at a disadvantage to their competitors in the industrialized world, where health care is funded by government. GM says the cost of providing health care to its workers and retirees totals $1,400 for each vehicle sold in the U.S., more than the cost of steel.

America's health-care system is in critical condition, and we find ourselves at a turning point. We can continue to hold bake sales to finance it, or we can do what every other civilized nation on earth does — take care of our citizens.

S-0987.3

SENATE BILL 5748

State of Washington 59th Legislature 2005 Regular Session

By Senators Kastama, Keiser, Poulsen and Rockefeller

Read first time 02/04/2005. Referred to Committee on Health & Long-Term Care.

AN ACT Relating to creating the office of health information and planning; amending RCW 70.47.060; adding new sections to chapter 41.05 RCW; adding a new section to chapter 48.43 RCW; creating a new section; making appropriations; and providing an effective date.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature finds:

(1) Assuring the well-being of our state's residents through a viable, accessible health care system is one of our fundamental responsibilities. The current system, however, is broken and unsustainable. Medical expenditures threaten to overwhelm government budgets, displacing other essential public goods. Double digit cost increases have become routine, dampening our economy and denying an increasing number of people even their basic health care needs. Yet the product of these expenditures is too often poor; too much is spent on that which contributes little to quality or length of life;

(2) The state must be a leader in the development of an affordable, effective, and sustainable health care system, that acknowledges that resources are limited, and directs the use of those limited resources to those things that do the most to maintain and improve the health

status of our population as a whole. We cannot promise every service to every resident, but we can assure everyone's access to a basic level of care, and the best health outcomes given the resources available;

(3) The foundation of such a system is good information, and the use of that information by all to reduce the need and demand for medical treatment, and assure that when treatment is necessary, it provides the best expected result at the lowest possible cost; and

(4) Recent efforts in this state to collect, analyze, and act on information to improve health care decision making have not been sufficiently comprehensive or coordinated. Our continued reliance on incomplete information, and a lack of uniform standards, will only perpetuate current inefficiencies. A statewide, systematic approach is necessary to more clearly define the purpose of our health care system, and align its various components to serve that purpose.

NEW SECTION. **Sec. 2.** A new section is added to chapter 41.05 RCW to read as follows:

(1) The office of health information and planning is created within the authority to:

(a) Make systematic, long-term improvements in the quantity and quality of information and data used to make health care decisions in both the public and private sector in Washington state; and

(b) Where appropriate, promote and coordinate the use and application of that information and data on a statewide basis in support of:

(i) The proper allocation of financial and human resources within the health care system, including public health, to best maintain and improve the health status of all Washington residents;

(ii) Intelligent and informed purchasing and reimbursement decisions by state agencies, employers, health carriers, and others responsible for financing medical treatment;

(iii) Treatment decisions by health care providers that result in the best health outcomes at the lowest possible cost; and

(iv) Consumer choices to improve their own health, reduce the demand for medical treatment, and when treatment is necessary, receive only the most efficacious and cost-effective treatment available.

(2) The office of health information and planning may receive gifts, grants, and endowments from public or private sources that may

be made from time to time, in trust or otherwise, for the use and benefit of the purposes of the office and spend gifts, grants, or endowments or any income from the public or private sources according to their terms.

(3) All state agencies shall cooperate with the office of health information and planning in the implementation of its duties.

NEW SECTION. **Sec. 3.** A new section is added to chapter 41.05 RCW to read as follows:

(1) The office of health information and planning shall develop and maintain a comprehensive plan for statewide health care information and data collection, distribution, and exchange. For each of the areas listed in section (2)(1)(b) (i) through (iv) of this act, the plan shall:

(a) Include an inventory and evaluation of public and private sources of information and data currently used to support the relevant health care decision making;

(b) Include an assessment of and strategies to overcome the organizational and structural barriers, including electronic telecommunications capacity, to the collection of data and information and its appropriate and timely distribution and exchange to and among the parties relevant to the various decisions;

(c) Identify individual and institutional incentives and disincentives to the consistent use of the best available information and data to improve decisions affecting the health of Washington residents, and means to create the incentives and eliminate the disincentives;

(d) Address plan implementation, including costs, a timeline, and the appropriate delegation of responsibility among public and private entities for the various components of the plan;

(e) Include recommendations to the legislature regarding any changes in law necessary to implement the plan;

(f) Be consistent with any relevant federal laws or guidelines, including the privacy provisions of the federal health insurance portability and accountability act; and

(g) Be developed in consultation with other state and federal health care agencies, and an advisory committee representing the

interests and expertise of affected parties in the public and private sector.

(2) Beginning December 2005, the office of health information and planning shall report to the legislature regarding plan development and implementation. The report shall be submitted again in December 2006, and biennially thereafter.

NEW SECTION. **Sec. 4.** A new section is added to chapter 41.05 RCW to read as follows:

The office of health information and planning shall design and implement a centralized technology assessment pilot project to strengthen the capacity of state health care agencies and others to obtain and evaluate scientific evidence regarding evolving health care procedures, services, and technology in support of appropriate coverage and medical necessity decisions and criteria. A preliminary evaluation of the project is due to the legislature by May 2007, with a final evaluation by March 2008.

NEW SECTION. **Sec. 5.** A new section is added to chapter 41.05 RCW to read as follows:

The office of health information and planning shall:

(1) Design and periodically update model health benefit plans reflecting the conscientious, explicit, and judicious use of current best evidence with regard to patient care. In designing the schedule of benefits and enrollee cost sharing, the office shall:

(a) Include preventive care services, based on the recommendations of the United States preventive services task force, with no enrollee cost sharing;

(b) Include other benefits determined to be the most efficacious and cost-effective use of the funds available within the limits established in this section. Any benefit otherwise mandated by state law, requiring coverage of certain types of providers, services, or conditions, shall not be included unless explicitly determined by the office to meet the requirements of this subsection; and

(c) Structure enrollee cost sharing to discourage demand for inappropriate or unnecessary treatment, encourage enrollee responsibility, including the use of efficacious and cost-effective

services and products, and promote quality care. Costs imposed on enrollees should not be a barrier to the appropriate use of necessary health care services;

(2) Develop at least three model plans: Plan A, with an actuarial value equal to that of the basic health plan as of January 1, 2006; plan B, with an actuarial value twenty percent less than that of the basic health plan as of January 1, 2006; and plan C, with an actuarial value twenty percent more than that of the basic health plan as of January 1, 2006;

(3) Develop contract standards for the administration of the model health benefit plans which address the role of the plan administrator in:

(a) Educating enrollees regarding proper health care decision making, engaging them in health promotion and wellness activities, and assuring their receipt of appropriate preventive services;

(b) Identifying and encouraging appropriate, efficacious, and cost-effective care by providers based on evidence of best practices, and promoting the use of quality providers by enrollees;

(c) Identifying enrollees with, or with the potential for, chronic or other high-cost conditions and providing them coordinated care through disease and demand management programs;

(d) Encouraging innovative, efficient, and patient-centered facility designs and service delivery methods that improve enrollee access to care and health outcomes; and

(4) Develop contract standards for the medical treatment of enrollees by providers in the model health benefit plans to assure the receipt of appropriate, efficacious, and cost-effective care.

NEW SECTION. **Sec. 6.** A new section is added to chapter 48.43 RCW to read as follows:

(1) By January 1, 2008, a carrier offering any individual health benefit plan in this state shall offer to all individuals at least one of the model health benefit plans designed by the office of health information and planning under section 5 of this act.

(2) By January 1, 2008, a carrier offering any small group health benefit plan in this state shall offer to all small groups at least one of the model health benefit plans designed by the office of health information and planning under section 5 of this act.

Sec. 7. RCW 70.47.060 and 2004 c 192 s 3 are each amended to read as follows:

The administrator has the following powers and duties:

(1) ((~~To design and from time to time revise a schedule of covered basic health care services, including physician services, inpatient and outpatient hospital services, prescription drugs and medications, and other services that may be necessary for basic health care. In addition, the administrator may, to the extent that funds are available, offer as basic health plan services chemical dependency services, mental health services and organ transplant services; however, no one service or any combination of these three services shall increase the actuarial value of the basic health plan benefits by more than five percent excluding inflation, as determined by the office of financial management. All subsidized and nonsubsidized enrollees in any participating managed health care system under the Washington basic health plan shall be entitled to receive covered basic health care services in return for premium payments to the plan. The schedule of services shall emphasize proven preventive and primary health care and shall include all services necessary for prenatal, postnatal, and well-child care. However, with respect to coverage for subsidized enrollees who are eligible to receive prenatal and postnatal services through the medical assistance program under chapter 74.09 RCW, the administrator shall not contract for such services except to the extent that such services are necessary over not more than a one-month period in order to maintain continuity of care after diagnosis of pregnancy by the managed care provider. The schedule of services shall also include a separate schedule of basic health care services for children, eighteen years of age and younger, for those subsidized or nonsubsidized enrollees who choose to secure basic coverage through the plan only for their dependent children. In designing and revising the schedule of services, the administrator shall consider the guidelines for assessing health services under the mandated benefits act of 1984, RCW 48.47.030, and such other factors as the administrator deems appropriate.~~)) To adopt as the basic health plan model plan A, and its corresponding contract standards, developed by the office of health information and planning under section 5 of this act. The model plan may be modified to include a separate schedule of benefits for those eighteen and younger. It may also be modified to include cost sharing appropriate

to the population served by the basic health plan, as long as other modifications in the benefits are made so that the actuarial value of the plan remains the same.

(2)(a) To design and implement a structure of periodic premiums due the administrator from subsidized enrollees that is based upon gross family income, giving appropriate consideration to family size and the ages of all family members. The enrollment of children shall not require the enrollment of their parent or parents who are eligible for the plan. The structure of periodic premiums shall be applied to subsidized enrollees entering the plan as individuals pursuant to subsection ((~~(11)~~)) (10) of this section and to the share of the cost of the plan due from subsidized enrollees entering the plan as employees pursuant to subsection ((~~(12)~~)) (11) of this section.

(b) To determine the periodic premiums due the administrator from nonsubsidized enrollees. Premiums due from nonsubsidized enrollees shall be in an amount equal to the cost charged by the managed health care system provider to the state for the plan plus the administrative cost of providing the plan to those enrollees and the premium tax under RCW 48.14.0201.

(c) To determine the periodic premiums due the administrator from health coverage tax credit eligible enrollees. Premiums due from health coverage tax credit eligible enrollees must be in an amount equal to the cost charged by the managed health care system provider to the state for the plan, plus the administrative cost of providing the plan to those enrollees and the premium tax under RCW 48.14.0201. The administrator will consider the impact of eligibility determination by the appropriate federal agency designated by the Trade Act of 2002 (P.L. 107-210) as well as the premium collection and remittance activities by the United States internal revenue service when determining the administrative cost charged for health coverage tax credit eligible enrollees.

(d) An employer or other financial sponsor may, with the prior approval of the administrator, pay the premium, rate, or any other amount on behalf of a subsidized or nonsubsidized enrollee, by arrangement with the enrollee and through a mechanism acceptable to the administrator. The administrator shall establish a mechanism for receiving premium payments from the United States internal revenue service for health coverage tax credit eligible enrollees.

((~~(e) To develop, as an offering by every health carrier providing coverage identical to the basic health plan, as configured on January 1, 2001, a basic health plan model plan with uniformity in enrollee cost-sharing requirements.~~))

(3) To evaluate, with the cooperation of participating managed health care system providers, the impact on the basic health plan of enrolling health coverage tax credit eligible enrollees. The administrator shall issue to the appropriate committees of the legislature preliminary evaluations on June 1, 2005, and January 1, 2006, and a final evaluation by June 1, 2006. The evaluation shall address the number of persons enrolled, the duration of their enrollment, their utilization of covered services relative to other basic health plan enrollees, and the extent to which their enrollment contributed to any change in the cost of the basic health plan.

(4) To end the participation of health coverage tax credit eligible enrollees in the basic health plan if the federal government reduces or terminates premium payments on their behalf through the United States internal revenue service.

(5) ((~~To design and implement a structure of enrollee cost-sharing due a managed health care system from subsidized, nonsubsidized, and health coverage tax credit eligible enrollees. The structure shall discourage inappropriate enrollee utilization of health care services, and may utilize copayments, deductibles, and other cost-sharing mechanisms, but shall not be so costly to enrollees as to constitute a barrier to appropriate utilization of necessary health care services.~~

~~(6)~~)) To limit enrollment of persons who qualify for subsidies so as to prevent an overexpenditure of appropriations for such purposes. Whenever the administrator finds that there is danger of such an overexpenditure, the administrator shall close enrollment until the administrator finds the danger no longer exists. Such a closure does not apply to health coverage tax credit eligible enrollees who receive a premium subsidy from the United States internal revenue service as long as the enrollees qualify for the health coverage tax credit program.

((~~(7)~~)) (6) To limit the payment of subsidies to subsidized enrollees, as defined in RCW 70.47.020. The level of subsidy provided to persons who qualify may be based on the lowest cost plans, as defined by the administrator.

((~~(8)~~)) (7) To adopt a schedule for the orderly development of the delivery of services and availability of the plan to residents of the state, subject to the limitations contained in RCW 70.47.080 or any act appropriating funds for the plan.

((~~(9)~~)) (8) To solicit and accept applications from managed health care systems, as defined in this chapter, for inclusion as eligible basic health care providers under the plan for subsidized enrollees, nonsubsidized enrollees, or health coverage tax credit eligible enrollees. The administrator shall endeavor to assure that covered basic health care services are available to any enrollee of the plan from among a selection of two or more participating managed health care systems. In adopting any rules or procedures applicable to managed health care systems and in its dealings with such systems, the administrator shall consider and make suitable allowance for the need for health care services and the differences in local availability of health care resources, along with other resources, within and among the several areas of the state. Contracts with participating managed health care systems shall ensure that basic health plan enrollees who become eligible for medical assistance may, at their option, continue to receive services from their existing providers within the managed health care system if such providers have entered into provider agreements with the department of social and health services.

((~~(10)~~)) (9) To receive periodic premiums from or on behalf of subsidized, nonsubsidized, and health coverage tax credit eligible enrollees, deposit them in the basic health plan operating account, keep records of enrollee status, and authorize periodic payments to managed health care systems on the basis of the number of enrollees participating in the respective managed health care systems.

((~~(11)~~)) (10) To accept applications from individuals residing in areas served by the plan, on behalf of themselves and their spouses and dependent children, for enrollment in the Washington basic health plan as subsidized, nonsubsidized, or health coverage tax credit eligible enrollees, to establish appropriate minimum-enrollment periods for enrollees as may be necessary, and to determine, upon application and on a reasonable schedule defined by the authority, or at the request of any enrollee, eligibility due to current gross family income for sliding scale premiums. Funds received by a family as part of participation in the adoption support program authorized under RCW

26.33.320 and 74.13.100 through 74.13.145 shall not be counted toward a family's current gross family income for the purposes of this chapter. When an enrollee fails to report income or income changes accurately, the administrator shall have the authority either to bill the enrollee for the amounts overpaid by the state or to impose civil penalties of up to two hundred percent of the amount of subsidy overpaid due to the enrollee incorrectly reporting income. The administrator shall adopt rules to define the appropriate application of these sanctions and the processes to implement the sanctions provided in this subsection, within available resources. No subsidy may be paid with respect to any enrollee whose current gross family income exceeds twice the federal poverty level or, subject to RCW 70.47.110, who is a recipient of medical assistance or medical care services under chapter 74.09 RCW. If a number of enrollees drop their enrollment for no apparent good cause, the administrator may establish appropriate rules or requirements that are applicable to such individuals before they will be allowed to reenroll in the plan.

((~~(12)~~)) (11) To accept applications from business owners on behalf of themselves and their employees, spouses, and dependent children, as subsidized or nonsubsidized enrollees, who reside in an area served by the plan. The administrator may require all or the substantial majority of the eligible employees of such businesses to enroll in the plan and establish those procedures necessary to facilitate the orderly enrollment of groups in the plan and into a managed health care system. The administrator may require that a business owner pay at least an amount equal to what the employee pays after the state pays its portion of the subsidized premium cost of the plan on behalf of each employee enrolled in the plan. Enrollment is limited to those not eligible for medicare who wish to enroll in the plan and choose to obtain the basic health care coverage and services from a managed care system participating in the plan. The administrator shall adjust the amount determined to be due on behalf of or from all such enrollees whenever the amount negotiated by the administrator with the participating managed health care system or systems is modified or the administrative cost of providing the plan to such enrollees changes.

((~~(13)~~)) (12) To determine the rate to be paid to each participating managed health care system in return for the provision of covered basic health care services to enrollees in the system.

Although the schedule of covered basic health care services will be the same or actuarially equivalent for similar enrollees, the rates negotiated with participating managed health care systems may vary among the systems. In negotiating rates with participating systems, the administrator shall consider the characteristics of the populations served by the respective systems, economic circumstances of the local area, the need to conserve the resources of the basic health plan trust account, and other factors the administrator finds relevant.

((~~(14)~~)) (13) To monitor the provision of covered services to enrollees by participating managed health care systems in order to assure enrollee access to good quality basic health care, to require periodic data reports concerning the utilization of health care services rendered to enrollees in order to provide adequate information for evaluation, and to inspect the books and records of participating managed health care systems to assure compliance with the purposes of this chapter. In requiring reports from participating managed health care systems, including data on services rendered enrollees, the administrator shall endeavor to minimize costs, both to the managed health care systems and to the plan. The administrator shall coordinate any such reporting requirements with other state agencies, such as the insurance commissioner and the department of health, to minimize duplication of effort.

((~~(15)~~)) (14) To evaluate the effects this chapter has on private employer-based health care coverage and to take appropriate measures consistent with state and federal statutes that will discourage the reduction of such coverage in the state.

((~~(16)~~)) (15) To develop a program of proven preventive health measures and to integrate it into the plan wherever possible and consistent with this chapter.

((~~(17)~~)) (16) To provide, consistent with available funding, assistance for rural residents, underserved populations, and persons of color.

((~~(18)~~)) (17) In consultation with appropriate state and local government agencies, to establish criteria defining eligibility for persons confined or residing in government-operated institutions.

((~~(19)~~)) (18) To administer the premium discounts provided under RCW 48.41.200(3)(a) (i) and (ii) pursuant to a contract with the Washington state health insurance pool.

NEW SECTION. **Sec. 8.** (1) The sum of one million dollars, or as much thereof as may be necessary, is appropriated for the fiscal year ending June 30, 2006, from the general fund to the health care authority for the purposes of this act.

(2) The sum of one million dollars, or as much thereof as may be necessary, is appropriated for the fiscal year ending June 30, 2007, from the general fund to the health care authority for the purposes of this act.

NEW SECTION. **Sec. 9.** Section 7 of this act takes effect January 1, 2008.

--- END ---

Dec. 18, 2005
Tacoma News-Tribune Op-Ed

Health care reform requires tough cost-benefit approach

By Sen. Jim Kastama

We've all heard about the problems with our health care system – 46 million people without insurance, skyrocketing costs, questionable quality and so on.

Simplistic solutions abound: socialized medicine, deregulation of the health insurance industry, medical savings accounts.

None of these gets at the heart of the health care problem: We simply spend too much money for our health care compared to other countries. To add insult to injury, our outcomes are worse. That's right, we are less healthy, yet we spend roughly twice as much per person as our competitors in Germany, Japan, England and France.

Before getting angry and looking for someone to blame, I suggest we examine how other countries achieve their savings.

First, they don't let politicians determine which services are covered in their health care plans, and which ones aren't. They know that politicians have a hard time saying "no" and often fall prey to the immediate, and sometimes irrational, desires of the public.

They also don't put these decisions in the hands of insurance companies or businesses – fearing that the focus will be on profits and not the public's health.

Instead, they create an objective, independent agency of health care experts whose sole focus is to design a health care plan that is both affordable and comprehensive.

Second, they live within a budget. Unlike our country, they do not have the luxury of doubling their health care expenditures every five to seven years. This leads them to make tough decisions. For example, there are longer wait times for surgeries and checkups, and waits for complex procedures can take months instead of weeks.

This also, however, leads them to make smarter decisions. New drugs and treatments are scrutinized to determine their effectiveness and whether the cost is worth the benefit to the public. If it is not, it is not included in their health care plan. Also, treatment protocols are standardized to ensure consistency and quality of care.

Contrast this with the United States. When a new drug is introduced, we hear about it first through media outlets such as newspapers, magazines and broadcast networks. Physicians are directly marketed by pharmaceutical companies and encouraged to prescribe their products. This is reinforced by a glut of advertising aimed at consumers. There is no rigorous cost-benefit analysis.

An example of this is the sale of the drugs Vioxx and Celebrex – both prescription pain relievers. For years it has been known that there is little statistical difference between the effectiveness of these drugs and the inexpensive, over-the-counter pain reliever called ibuprofen.

Yet sales for Vioxx and Celebrex totaled approximately $6 billion per year, with a marketing budget of nearly $100 million per year for Celebrex alone. Only after it was suspected that these drugs contributed to heart attacks, strokes and blood clots have their sales been curtailed or severely limited.

Third, and finally, other countries emphasize preventive care. It only makes sense. If you have limited dollars, you focus on preventing expensive illnesses rather than treating them. In the United States, 1 percent of our population consumes approximately 30 percent of the health care. We execute countless more expensive procedures than other countries. Consider coronary angioplasties, which we perform almost 800 percent more often than a country such as England.

If all these extra procedures meant that we were healthier, I'd be in favor of them. But they don't.

Estimates indicate that our infant mortality rate is 43rd, and our life expectancy rank is 35th among countries for which such data is available. The overall performance of our health system was ranked 37th by the World Health Organization as recently as 2000, and it seems unlikely to have improved since then.

To bring these three principles to Washington, I introduced the Health Care Recovery Act this past legislative session. Senate Bill 5748 would direct the state Health Care Authority to develop a health care plan using evidence-based medicine and a rigorous cost-benefit analysis.

This approach would result in a more affordable plan for small businesses and individuals – a plan focused on covering preventive services and only the most cost-effective treatments. To ensure continued affordability of the plan, the bill would limit premium increases to the Cost of Living Index, which would force the HCA to make tough decisions that, so far, no one has been willing to make.

The bill passed out of the Senate Health & Long-Term Care Committee but was never brought to the Senate floor for a vote. I intend to push this bill again in the 2006 session.

Its chance of passing in a meaningful form is slim under any circumstances. Interest groups – be they pharmaceutical companies, medical technology companies or health care providers, as well-meaning as they may be, and often supported by citizen advocates – all believe that their services would be threatened under a system of rigorous cost-benefit analysis and cost containment.

The truth is that they're probably right.

But someone, independent of the foibles of our political system and the profit orientation of the market place, with expertise in health care, has got to make the tough decisions to bring our health care system under control. If not, we could easily go broke. Or worse, fall victim to simplistic solutions that only further health disparities and inefficient spending.

We need these reforms.

State Sen. Jim Kastama (D-Puyallup) is a member of the Senate Health and Long-Term Care Committee.

Return to Senator Kastama's home page

Tab 70

WILLAMETTE DENTAL

Willamette Dental
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Administration • 503-644-6444
FAX • 503-644-2170

September 20, 2006

Governor Christine Gregoire
Senator Pat Thibaudeau
Co-Chairs
Blue Ribbon Commission on Health Care Costs & Access
State of Washington

Dear Governor Gregoire and Senator Thibaudeau:

Willamette Dental is an advocate of a system that provides accessible, affordable and quality health care to all Washingtonians. We are firmly committed to the idea that oral health care is an integral part of whole body health.

This proposal, submitted to the Blue Ribbon Commission on Health Care Costs & Access, provides information about Willamette Dental's involvement in the Oregon Health Plan as a Dental Care Organization (DCO) Contractor. The final section of the proposal includes an outline of the services we feel should be considered in any health care system.

WILLAMETTE DENTAL HISTORY

Willamette Dental was established in 1970 and is the largest staff-model dental plan in the western United States. The company employs more than 1200 people in Oregon, Washington and Idaho. Twenty-six (26) of Willamette Dental's sixty (60) dental offices are in Washington, providing oral health services to more than 150,000 citizens located throughout the state.

WILLAMETTE DENTAL & THE OREGON HEALTH PLAN

Willamette Dental has been a participant in delivery of Medicaid services to Oregonians since the inception of the Oregon Health Plan in 1994. The Oregon Health Plan was created under the visionary leadership of then Governor and Doctor John Kitzhaber. The Oregon Health Plan is a unique Medicaid program that was designed to approach health care on a holistic basis through a prioritized list of medical, dental and mental health services. Even before studies began to emerge to clearly link oral health to whole body health, Governor Kitzhaber, state officials and Oregon's citizens put a premium on fully integrating oral health services into the prioritized list of services.

The intent of the Oregon Health Plan is to control costs and increase access through a state-approved prioritized list of services. This "prioritized list" was created through an open process of public community meetings, hearings and a survey of Oregon citizens. The initial list consisted of 709 condition-treatment pairs. Services are ranked from most important to least important, with preventive services positioned near the top. The list of actual covered services is determined by available funding.

The legislature initially determined that funding was available to afford 587 of the 709 condition-treatment pairs. The cut-off line has continued to be adjusted by subsequent legislatures. Dental services are fully merged with medical services in the Oregon Health Plan and are not to be selectively eliminated in times of reduced state revenues. This approach has been effective in preserving, as a minimum, preventive and urgent dental care services for eligible adults.

Prior to the Oregon Health Plan, adult dental services were optional under Oregon Medicaid, as they are under federal law. The Oregon Health Plan did nothing to change entitlement to adult dental services, but it did set a precedent to establish oral health as an important prioritized component of whole body health. Even during the troubled times of a prolonged state-wide recession, Oregon's legislature and Governor's office have responded to the voice of Oregonians and dental stakeholders to continue funding of an adult dental health care package.

Another unique aspect of the Oregon Health Plan was the development of a state-wide managed health care network of dental care organizations to deliver dental benefits. Reimbursement for approved services is made through capitated monthly payments to the dental care organizations. This reduces administrative costs to the state as well as the burden on state officials to monitor and investigate fraud and abuse.

OREGON'S INITIATIVE TO COVER UNINSURED

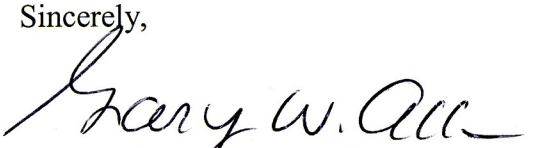
Oregon's elected and appointed leaders continue the commitment to the Oregon Health Plan to make access to health care affordable for all Oregonians. To this end, Oregon has convened a special interim Senate Commission on Affordability and Access to Health Care. The Oregon Commission has goals very similar to the Blue Ribbon Commission in Washington. In keeping with the initial spirit and intent of the Oregon Health Plan, dental representatives have been appointed to the Commission as equal partners. A group of dental stakeholders have responded to the Commission's tasking and vision in order to:

- Develop a basic dental benefits package that would be available to all Oregonians.
- Develop a list of fundamental guiding principles for oral health services in addition to the basic benefit plan.

These guiding principles are attached and respectfully submitted for consideration by the Blue Ribbon Commission on Health Care Costs & Access. The proposed dental benefits plan developed by the stakeholders can also be made available if it would be helpful in your deliberations.

Thank you for the opportunity to submit this proposal to the Blue Ribbon Commission. Representatives from Willamette Dental are available, at your convenience, if you would like additional information about our experiences with managed care, the Oregon Health Plan and the Oregon Senate Commission on Affordability and Access to Health Care.

Sincerely,



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OREGON SENATE COMMISSION
On Access And Affordability to Health Care

Oral Health Care

Oral health is an intrinsic part of whole body health and must be included in a basic health care reform plan for all Oregonians. Tooth decay and periodontal problems compose the majority of oral disease problems and they are largely preventable diseases. Any oral component of health care reform must include the following components.

1. Prevention. Disease prevention must be supported, including programs to provide fluoride in public water supplies.

2. Personal Responsibility. Patients have to be educated and motivated to assume responsibility for preventing oral disease.

3. Utilization of Expanded Function. Dental Assistants, Dental Hygienists, and health aides can, with modification to our current Board of Dentistry rules, fulfill the oral health care education function.

4. Treatment. Customized oral health care coverage for diverse populations, utilizing evidence-based assessments and risk profiles, to account for differences based on age, socio-economic, cultural, geographic, and other factors must be developed. This customized coverage should include pregnant mothers, infants and children.

   The Oregon Health Plan is a good model for integrating and prioritizing basic oral care health services into a medical model. The state's professional dental organizations should be encouraged to work together to develop workforce models that take advantage of the skills and experience of the dental workforce. In particular, training and certification programs should be developed for employment of dental assistants and dental hygienists to perform restorative services in dental offices

5. Access. Many in Oregon have limited access to oral health care and can benefit from preventive care delivered in schools and other settings. Programs should be encouraged to train, certify and utilize mid-level practitioners, LAP Hygienists and Expanded Function Dental Assistants, to provide non-invasive treatment, such as assessing and placing sealants, outside of dental office settings.

6. Cost Shift. Ultimately, an employer-based system must address the cost-shift of uncovered and publicly financed care. A new approach must be developed to equitably finance whole body health coverage, including dental, for all citizens of Oregon.

Tab 71

To the Blue Ribbon Commission on Health Care Costs and Access in Washington State.

Bill Osmunson DDS, MPH 9/29/06

Fluoridation

Summary: The "Stake holders" promoting fluoridation should be required to provide scientific evidence as to the efficacy, toxicology, ethics, total intake, total dosage and legality of adding hydrofluorsalicic acid to water.

Our total intake of fluoride from all sources is too much and needs to be reduced. Most of the world has rejected fluoridation because it no longer appears to reduce dental decay[1], is not safe, and individual dosage is increasing from increases in foods, beverages, and medications. Without benefit, with increasing risks, and dosage from all sources too high, most prudent reduction of fluoride intake is a cessation of water fluoridation. The National Research Council 2006 outlines concerns, "Some say Fluoridation has serious problems with no benefits:

Infringement on freedom of choice Hilman 1988; Cross and Carton 2003
Causes adverse health effects which outweigh benefits (Colquhoun 1997)
Safety of the Chemicals are in question
Toxicity database on silicofluorides is sparse (Coplan and Masters 2001)
Individual variations in exposure
Major benefits are topical, not systemic. (Zero 1992; Rolla 1996; Featherstone 1999; Limeback 1999; Clarson 2000; CDC 2001; Fejerskov 2004" [2]

Although the CDC suggested fluoridation was one of the 10 great public health achievements of the 20th century, the CDC then continues "fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children."[3] Topical benefits of fluoride require higher concentrations than found in fluoridated water.

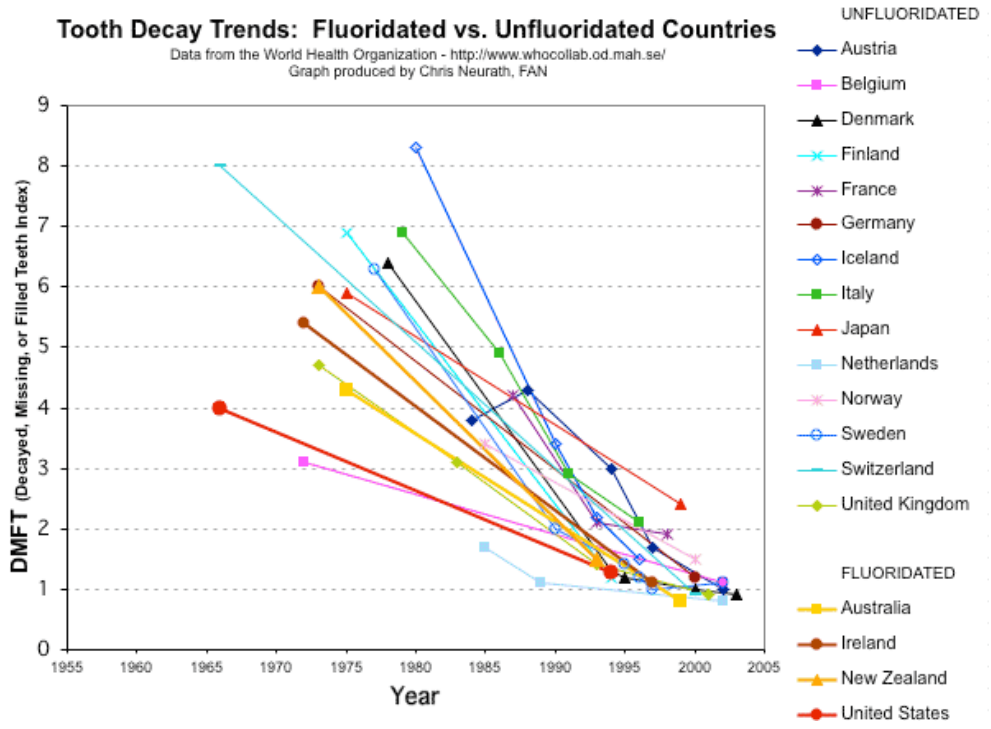
The source of fluoridation is not medical grade fluoride and contains contaminants such as lead, arsenic, beryllium, vanadium, cadmium, mercury, radium radionuclides, silicon, and bauxite. Although these other contaminants are in small quantities, even these small amounts are significant. Lead levels are elevated in the blood of those drinking silicofluoride treated water.[4] The EPA has maximum contaminant level goals for lead and arsenic at "0 ppm" and fluoridation contaminates our water above EPA MCL goals. Naturally occurring fluoride as calcium and magnesium fluorides are relatively insoluble, while sodium fluorosilicates and hydrofluorosilicic acids are highly soluble.

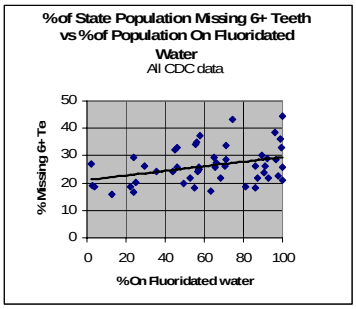
Fluoride benefits appear to be topical, not systemic.[5]

1. "In summary, we hold that fluoridation is an unreasonable risk. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small – if there are any at all – that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments." EPA scientists and lawyers.[6]

2. Excellent scientists in most developed countries world wide have rejected, banned or suspended fluoridation: China, Austria, Belgium, Finland, Germany, Denmark, Norway, Sweden, Netherlands, Hungary, Japan, and June 21, 2006 Israel suspended mandatory fluoridation until the issue is reexamined from all aspects. Ontario reduced fluoridation from 1 ppm to 0.6 ppm.

3. Most industrialized countries have never fluoridated nor have they used significant fluoride from other sources, yet they have reduced dental decay just as much as the USA. The graph below shows 14 countries who on good scientific grounds have said "NO" to fluoridation and 4 countries which have fluoridated. Over a 30 year period, all countries have reduced decay about the same amount. Some have given the option of fluoridated salt (freedom of choice) and the option is often refused. The American Dental Association continues to blindly assert, *"studies prove water fluoridation continues to be effective in reducing tooth decay by 20-40%."*[7] If the ADA were correct, we should see a benefit for fluoridating countries, but we do not. The references provided by the ADA show up to a 0.6 out of 88 to 128 tooth surface reduction in tooth decay (about half a percent) if confounding factors are not included. If confounding factors are included we may actually be experiencing an increase in the life time incidence of decay in fluoridated areas.





4. When the percentage of fluoridated people in each state increases (graph on the left), so does the percentage of people with six or more missing teeth. There appears to be no life long reduction in dental decay with fluoridation and possibly an increase in tooth loss from fluoridation.

5. In 2003, the ADA awarded Kentucky with a "50 Year Award" for virtually 100% fluoridation for 50 years. In 2002 the CDC reported Kentucky with the highest percentage of people without any teeth, 42%.[8] Fluoridation does not benefit those without teeth and does not appear to have helped prevent their tooth loss.

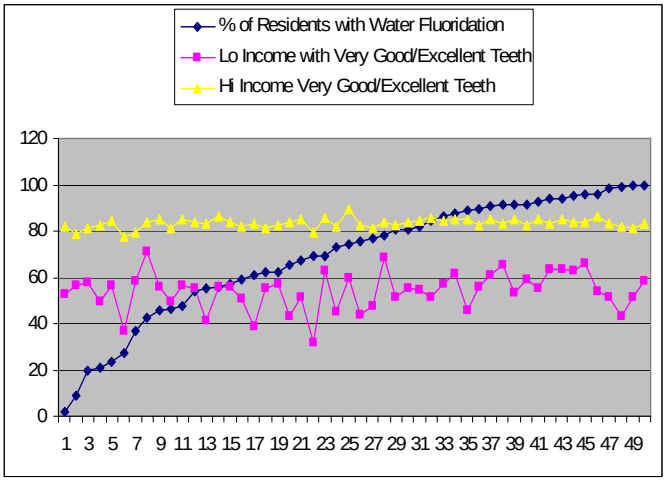
6. A number of recent cessation studies show that stopping fluoridation does literally nothing to increase overall dental decay.[9]

7. Scientific studies are mixed, some showing an increase in dental decay with fluoridation[10] and others showing a decrease.[11] Socioeconomics, a huge variable,

is seldom included. "Not taking into account delayed tooth eruption makes early fluoridation studies "over-estimates of the benefits".... Fluoride added to drinking water may have simply delayed caries in the past." Hardy Limeback DMD, PhD Even those flawed studies found 0.6 ppm fluoridation was better than 1.0ppm. Edward & Strickler

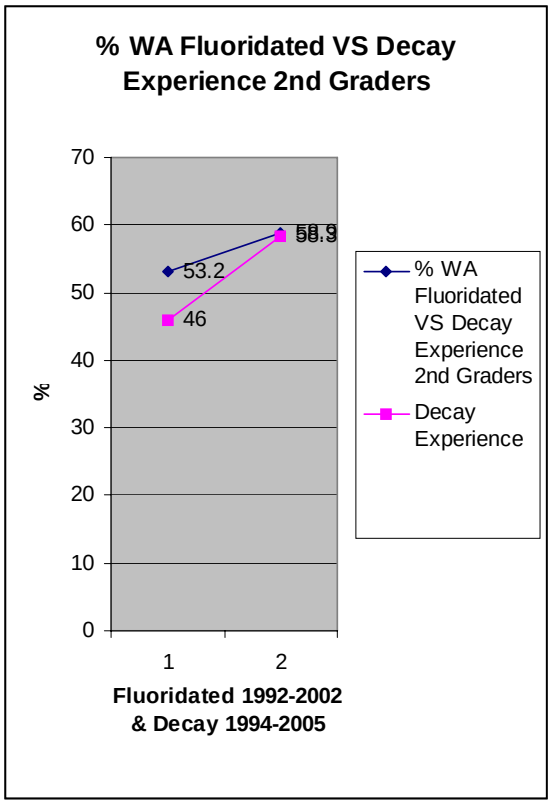
8. The graph below[12] has all 50 US states listed in order of the percentage of residents on public water who are fluoridated, the least at 3% and the greatest at 99+% (black line). The pink line represents the percentage of poor children's parents who report their child to have very good/excellent teeth. The yellow line represents the same for wealthy children. A state could fluoridate at 3% or 99% and have the same dental health.

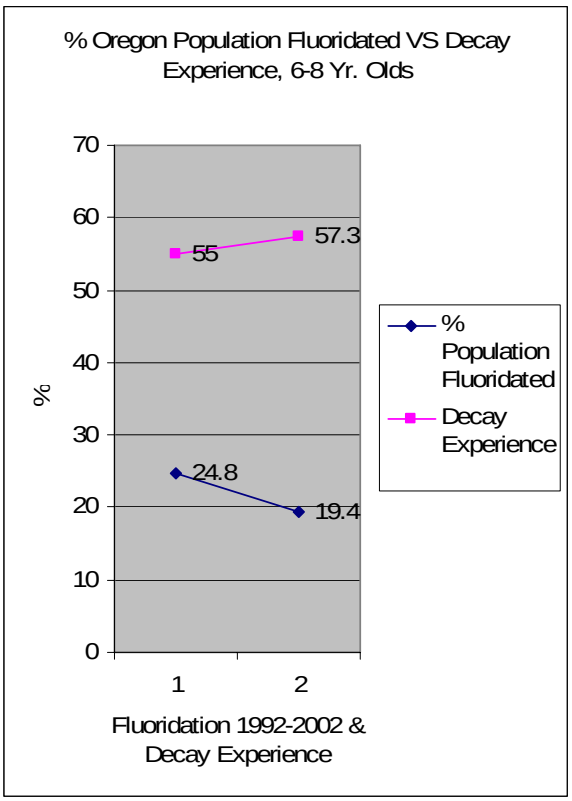
What are your goals for the percentage of children with healthy teeth? Suppose you choose 55% of the poor and 82% of the wealthy? Now look on the chart to find how much you need to fluoridate to achieve these results. Consistent with published studies, fluoridation does not appear to improve dental health. Without benefits, mass medication makes no sense.



9. The next two graphs compare Washington and Oregon and the change in fluoridation and dental decay, 1992 and 2002[13]. Both states have similar confounding factors of language, elevation, race, education, except Washington has about a 12% higher mean socioeconomic level and thus should have better Oral Health. Washington has three times the percentage of residents fluoridated than Oregon and even with higher socioeconomics has now surpassed Oregon's decay rate.

Where is the "20-40% proven benefit"[14] with fluoridation suggested by the American Dental Association? Other studies by Spencer, de Liefde, Angelilo, Clark, Ismail, Slade, Kumar, Armfield, and Spencer have found clinically meaningless results and benefits with fluoridation. Biostatisticians Rek et.al, in 2005 reported, "Our analysis shows no convincing effect of fluoride-intake on caries development. A Bayesian analysis of multivariate doubly-interval-censored dental data"[15] Other studies actually found Increases in tooth decay with elevated fluoride levels and indeed consistent with the trend now experienced in Washington.[16]





When comparing fluoridated and non fluoridated groups of people, several confounding factors must be included which promoters of fluoridation seldom consider. A couple huge factors include: Poor people have more decay and socioeconomics must be considered. Bellingham's decay rate cannot be reasonably compared to Seattle's decay rate because Seattle has three times the mean income level. Another major factor is the delay in tooth eruption found in fluoridated areas which skews the data.[17] For a life time benefit, studies must consider how long the teeth have been exposed in the mouth, not just the age of the subject. A 13 year old on fluoride with exfoliating primary molars and unerupted second molars will have a lower incidence of decay than a non-fluoridated child of the same age who has had their teeth for a year.

It makes no sense to mass medicate people with a drug which no longer shows any benefit.

10. Fluoride is not a nutrient, it is a drug. Read a fluoridated toothpaste label. The absence of fluoride does not cause any disease. Decay is not the result of fluoride deficiency.[18]
11. "Fluoride works topically" not systemically CDC 2001[19]
12. The evidence for fluoride varnish (topical application) reducing decay is "fair". The evidence for the benefits of fluoride ingestion is "incomplete." NIH Consensus Development Conference 2001.
13. Fluoridation does not prevent bottle decay, pit and fissure decay, or decay from bad habits such as soda pop, diet, poor hygiene or meth. At best, fluoride was thought to simply reduce one of the symptoms of poor diet and oral hygiene.
14. Sometimes promoters of fluoridation will show emotional pictures of little children with decayed front teeth. This "bottle decay" is due to juice/milk in a bottle at night and naps and is not prevented with fluoridation.
15. For 25 years I observed patients from fluoridated areas who had good teeth and non-fluoridated areas with bad teeth. I was convinced with my own eyes I clinically "saw" the benefits of fluoridation. With a more studied evaluation, I was seeing the effects of socioeconomics rather than fluoridation.

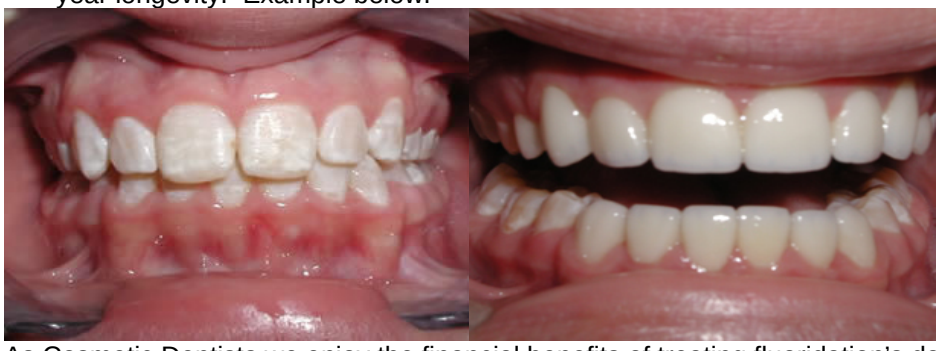
B. Risks from Fluoridation appear to be significant:

1. When presented to impartial Courts[20], the finding of fact has consistently found fluoridation to be hazardous and Governments even in time of war have restrictions on medicating people.[21] The FDA has never approved any substance for water fluoridation and in 1974 agreed under the SDWA that the EPA is responsible for drinking water because water is not a food.[22] The EPA is involved with the removal of fluoride, not the addition of fluoride and in US House Hearings, 2001, provided the position the EPA is prohibited and lacks authority to require the addition of anything for the treatment of humans.[23] The circle leaves no one at the switch, monitoring all sources of fluoride intake, monitoring efficacy, monitoring side effects and risks.

Anyone who claims the 2006 NRC report has nothing to do with water fluoridation, has not read the NRC report. The scientists' advice to the EPA that 4ppm fluoride in water is too high means the level needs to be reduced theoretically somewhere between 0 and 3 ppm. The margin of safety between 1 ppm and 4 ppm was not significant and lowering MCLG below 4 ppm provides no margin of safety for sensitive individuals on fluoridation. Read the NRC report (Footnote #2).

2. Fluoridation does cause harm to the Public Health. Fluoride at fluoridation levels does indeed cause damage to teeth and bones and is an enzymatic reactor, a contributing factor in various pathologies.

   a. Dental fluorosis has significantly increased and no one disputes the damage fluoride and fluoridation causes to teeth. Two thirds of children show some signs of too much fluoride.[24] Life time costs for repairs can exceed $100,000 per person. Parents often pay about $14,000 for treatment of dental fluorosis with expected 10-15 year longevity. Example below.



   As Cosmetic Dentists we enjoy the financial benefits of treating fluoridation's damage. If children on fluoridation had a reduction in decay, the benefits might outweigh the risks. No Dentist disagrees with the risks of fluoridation and the tremendous cosmetic costs, coverage born for retreatment by Dental Insurance.

   b. Increased bone fractures, especially in the elderly[25]. NRC 2006

   c. Evidence is fair that fluoridation decreases thyroid activity (thyroxin the 4th most common Rx and increases obesity), decreases intelligence[26], increases mental retardation[27], increases violent behavior[28], increases bone cancer, increases kidney damage and much more. Not everyone has the same risks.[29]

The National Research Council (2006 p. 26) reports: (inserted comments)

"Endocrine Effects: The chief endocrine effects of fluoride exposures in experimental animals and humans include

a decreased thyroid function,
(synthyroid is the1st to 5th most common Rx; low BMR, obesity, skin disorders)

b. increased calcitonin activity,
(opposite parathyroid, reduces Calcium in blood, enhances Ca excretion)

c. increased parathyroid hormone activity,

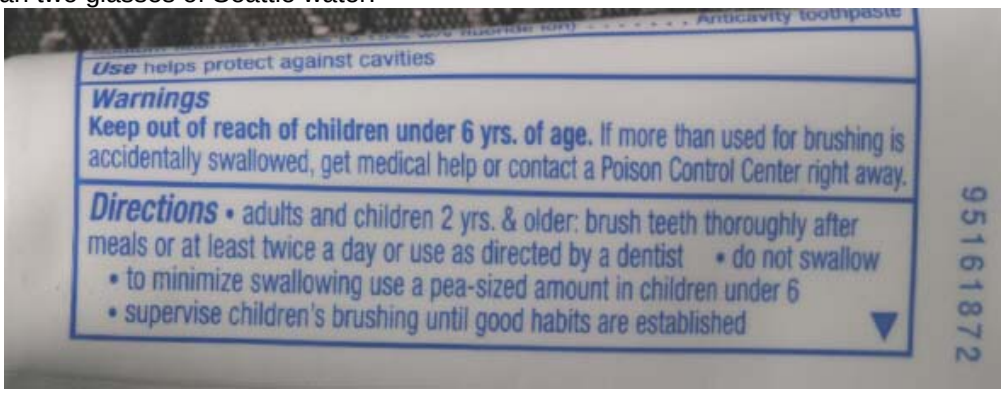
(increases blood Ca level, from bone & kidney)

d. secondary hyperparathyroidism,
(When Ca blood level too low due to low Vit D or low Ca absorption)

e. impaired glucose tolerance, and
(Diabetes, 7%, sixth leading killer. Six fold increase since 1958, $132 B)

f. possible effects on timing of sexual maturity." NRC 2006 p.26

3. Read the Crest toothpaste label, flexible wording required by the FDA. "Drug Facts. Do not swallow. If more than used for brushing (a pea size) is accidentally swallowed, get medical help or contact a poison control center right away." A pea size of Crest contains 0.5mg or less of fluoride. The same amount of fluoride as two glasses of Seattle water. Certainly fluoridated water districts should at least warn young residents not to drink more than two glasses of Seattle water.



4. Household water filters do not remove fluoride.
5. As with all medications, some individuals have very little tolerance and significant side effects. Mass medication of everyone regardless of their need, tolerance, side effects or desire makes no sense.
6. Last weeks National Academy of Science 550 page report on fluoride, lists numerous studies which should and have not been done to determine fluorides risk/safety.[30] We have failed to have due diligence and precaution.

C. Recommended Dose and Dosage:

1. There is NO recommended Daily Allowance for Fluoride because fluoride is a drug, not a nutrient. "AI" or the American Dental Associations suggested "Adequate Intake" to reduce dental decay:[31]

a. Infant's AI is 0.01 mg/day through six months. This would be one hundredth of a liter (10 ml) of Seattle water mixed in formula. A tablespoon of Seattle water contains about 0.02mg of fluoride, twice the AI. The Washington Department of Health should warn parents not to use Seattle Water to mix infant formula. Soy Formula also contains fluoride. (Even water from reverse osmosis contains 0.05 ppm) Nature provided an infant with significant protection, 100 to 200 times less fluoride than formula mixed with Seattle water. Why are not Public Health agencies, water districts and those responsible for fluoridating providing parents with warnings? For children 6 mo to 3 years, one cup of Seattle Water provides the AI of 0.25mg/da. 3 years to 6 years AI is two cups of water. Why are parents not being warned to stop their children from drinking water/beverages/foods/soups in excess of these levels? Who is at the switch?

b. The American Academy of Pediatrics in May 1998 Pediatrics, recommended no prescription fluoride before the age of 6 months and only one cup of water (0.25 mg) from 6 mo. to 3 yr. of age.[32] If a child is thirsty and has had their glass of fluoridated water/beverage/soup, what does a parent tell their child?

Do not drink more water, this water is not safe? The wealthy can afford bottled water, the poor find it an expensive burdon.

c. Adults from foods and beverages without fluoridated water frequently, if not usually exceed AI levels by two and three times. Examples can be provided.

d. The total fluoride intake from all sources is almost never considered and hard to determine.

i. Almost all foods contain fluoride.

ii. Recent increases in pesticides such as Cryolite (52% fluoride) for example in lettuce from 7mg/Kg residue to 180 mg/Kg residue and make testing of foods in the past incomplete.

iii. Post Harvest fumigants (2004 and 2005) permitting huge amounts of sulfurylfluoride residue (Profume, i.e. Vikane) in most foods. For example up to 900 ppm residue in dried egg[33] almost the same concentration as toothpaste. No credible estimates have been made on total fluoride ingestion with these new increases and sources of fluoride.

iv. Medications[34] and several have had to be taken off the market.[35] Toothpaste and dental visits, add significant fluoride intake and significant economic gain for most dental offices. (Twice a year for 500 people generates over $30,000.) The topical use of fluoride varnish does have fair evidence of benefit in reducing dental decay.

v. Even the National Organic Standards permits over 1,000 ppm in bone meal.[36]

Fluoridation is controversial. Remember, the people who claim fluoridation is safe are also the people who tell us the mercury we place in our teeth is too toxic for the sewers and trash, yet is safe implanted in our bodies three inches from our brains. Although their claim is to protect the public health, please note that when asked in court, the American Dental Association represents, "Dissemination of information relating to the practice of dentistry does not create a duty of care to protect the public from potential injury."[37] I am proud of my Profession, but in just a few instances our pride and profit stand in the way of good science and ethics. Fluoridation is a moment in Public Health history which we will not remember with pride.

Sincerely,

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[1] SDWA Section 1412 (b)(11)
[2] http://www.nap.edu/catalog/11571.html, Fluoride in Drinking Water: A Scientific Review of EPA's Standards
[3] CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22.
[4] Masters, R.D. et al, Association of Silicofluoride Treated Water with Elevated Blood Lead, NeuroToxicology 2000
[5] Brunelle, Angelilo, Clark, Ismail, Slade, Kumar and in Australia by Armfield JM. Spencer AJ 2004, a very large study found No difference in dental decay in permanent teeth.
[6] Dr. J. William Hirzy, Sr. VP, Headquarters Union, USEPA, March 26, 2001.
[7] http://www.ada.org/prof/resources/positions/statements/fluoride_community_effective.asp 7/13/06
[8] 2002 CDC Mortality Weekly Report.
[9] Komarek et al, A Bayesian analysis of multivariate doubly-interval-censored dental data, Biostatistics 2005 6 pp 145-155
[10] Binbin W, Baoshan Z, Hongying W, Yakun P, Yuehua T. (2005). Dental caries in fluorine exposure areas in China. Environ Geochem Health. 27(4):285-8. See: http://tinyurl.com/765m2
[11] www.ada.org
[12] http://mchb.hrsa.gov/oralhealth/portrait/1cct.htm National Survey of Children's Health. U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau.
The National Survey of Children's Health 2003. Rockville, Maryland: U.S. Department of Health and Human Services, 2005
http://www.cdc.gov/oralhealth/waterfluoridation/fact_sheets/states_stats2002.htm
[13] Fluoridation 2002 = 58.9% http://www.cdc.gov/fluoridation/fact_sheets/states_stats2002.htm
Washington Fluoridation 1992 = 53.2%
http://www.fluoridationcenter.org/papers/2002/cdcmmwr022102.htm
http://www.doh.wa.gov/cfh/Oral_Health/Documents/SmileSurvey2005FullReport.pdf
http://www.oregon.gov/DHS/ph/oralhealth/docs/databook.pdf#search='Oregon%20Decay%20experience'
http://quickfacts.census.gov/qfd/states/41000.html
[14] http://www.ada.org/prof/resources/positions/statements/fluoride_community_effective.asp 7/13/06
[15] *ARNO˘ST KOMA´ REK∗, EMMANUEL LESAFFRE Biostatistical Centre, Katholieke Universiteit Leuven, Kapucijnenvoer 35, B-3000 Leuven, Belgium arnost.komarek@med.kuleuven.ac.be TOMMI HA¨ RKA¨ NEN National Public Health Institute, Mannerheimintie 166, FIN-00300 Helsinki, Finland DOMINIQUE DECLERCK School of Dentistry, Katholieke Universiteit Leuven, Kapucijnenvoer 7, B-3000 Leuven, Belgium JORMA I. VIRTANEN Institute of Dentistry, University of Helsinki, PO Box 41, FIN-00014 Helsinki, Finland*
Biostatistics (2005), 6, 1, *pp.* 145–155 doi: 10.1093/biostatistics/kxh023
[16] A few recent studies: Awadia AK, et al. (2002). Caries experience and caries predictors - a study of Tanzanian children consuming drinking water with different fluoride concentrations. *Clinical Oral Investigations* (2002) 6:98-103) Binbin W, et al. (2005). Dental caries in fluorine exposure areas in China. *Environmental Geochemistry and Health* 27:285-8.) Budipramana ES, et al. (2002). Dental fluorosis and caries prevalence in the fluorosis endemic area of Asembagus, Indonesia. *International Journal of Paediatric Dentistry* 12(6):415-22. Ekanayake L, Van Der Hoek W. (2002). Dental caries and developmental defects of enamel in relation to fluoride levels in drinking water in an arid area of sri lanka. *Caries Research* 36(6):398-404. Grobleri SR, et al. (2001). Dental fluorosis and caries experience in relation to three different drinking water fluoride levels in South Africa. *International Journal of Paediatric Dentistry* 11(5):372-9.
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See also: Nadler GL. (1998). Earlier dental maturation: fact or fiction? *Angle Orthod*. 68(6):535-8.
[18] Aoba T, Fejerskov O. (2002). Dental fluorosis: chemistry and biology. *Critical Review of Oral Biology and Medicine* 13: 155-70.
[19] CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22.
[20] J and Morin, P, Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies, J. Land Use & Envtl.L. Vol. 14.2, Spring 1999, p.195-248 Contact Jack Grahm for details, 418.888.5049, graham@megaquebec.net Graham
[21] The Court ruled even under emergency conditions of war the Government cannot force an individual to be medicated with a substance which has not been specifically approved for the purpose and manor it is intended. Case regarding AVA, a non FDA approved anthrax drug. Doe v. Rumsfield 2003 U.S. Dist. LEXIS 22990
[22] http://www.ada.org/public/topics/fluoride/facts/fluoridation_facts.pdf Summary p. 22
[23] SDWA Section 1412 (b)(11)
[24] Heller, K et al, Dental Caries and Dental Fluorosis at Varying Water Fluoride Concentrations, NIDR, 1997, Vol 57, No 3. p.135
[25] Danielson, C, et al, Hip Fractures and Fluoridation in Utah's Elderly Population, JAMA Aug 12, 1992
[26] The lowering of IQ by 8 to 10 points 1 Lu Y, Sun ZR, Wu LN, Wang X, Lu W, Liu SS. Effect of high-fluoride water on intelligence in children. Fluoride 2000; 33:74-8.
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[27] Tianjin, Fluoride Vol. 33 No. 2 49052 2000, Editorial 49 Fluoride 33 (2) 2000
[28] Jay Seaveya Manchester, NH, USA Fluoride 2005;38(1):11–22 Research report 11 http://homepages.ihug.co.nz/~spittle/381%2011-22.pdf
[29] "Existing data indicate that subsets of the population may be unusually susceptible to the toxic effects of fluoride and its compounds. These populations include the elderly, people with deficiencies of calcium, magnesium, and/or vitamin C, and people with cardiovascular and kidney problems... Because fluoride is ubiquitous in food and water, the potential for human exposure is substantial (ATSDR, p 112, 153)." The Agency for Toxic Substances and Disease Registry (ATSDR) stated in 1993:

[30] *Excerpts from: "Fluoride in Drinking Water: A Scientific Review of EPA's Standards" (National Research Council, 2006)*

NRC's RESEARCH RECOMMENDATIONS:

"Fluoride should be included in nationwide biomonitoring surveys and nutritional studies; in particular, analysis of fluoride in blood and urine samples taken in these surveys would be valuable." p9

"To assist in estimating individual fluoride exposure from ingestion, manufacturers and producers should provide information on the fluoride content of commercial foods and beverages." p71

"The concentrations of fluoride in human bone as a function of exposure concentration, exposure duration, age, sex, and health status should be studied." p9

"Information is particularly needed on fluoride plasma and bone concentrations in people with small-to-moderate changes in renal function as well as in those with serious renal deficiency." p9

"More research is needed on the relation between fluoride exposure and dentin fluorosis and delayed tooth eruption patterns." p9

"A systematic study of clinical stage II and stage III skeletal fluorosis should be conducted to clarify the relationship between fluoride ingestion, fluoride concentration in bone, and clinical symptoms. " p10

"More studies of communities with drinking water containing fluoride at 2 mg/L or more are needed to assess potential bone fracture risk at these higher concentrations." p10

"Carefully conducted studies of exposure to fluoride and emerging health parameters of interest (e.g., endocrine effects and brain function) should be performed in populations in the United States exposed to various concentrations of fluoride." p10

"Better characterization of exposure to fluoride is needed in epidemiology studies investigating potential effects. Important exposure aspects of such studies would include the following: collecting data on general dietary status and dietary factors that could influence exposure or effects, such as calcium, iodine, and aluminum intakes." p72

"To permit better characterization of current exposures from airborne fluorides, ambient concentrations of airborne hydrogen fluoride and particulates should be reported on national aregional scales, especially for areas of known air pollution or known sources of airborne fluorides. Additional information on fluoride concentrations in soils in residential and recreational areas near industrial fluoride sources also should be obtained" p71-72

"The possibility of biological effects of SiF_6 , as opposed to free fluoride ion, should be examined." p72

"The biological effects of aluminofluoride complexes should be researched further, including the conditions (exposure conditions and physiological conditions) under which the complexes can be expected to occur and to have biological effects." p72

"Thus, more studies are needed on fluoride concentrations in soft tissues (e.g., brain, thyroid, kidney) following chronic exposure." p83

"Research is needed on fluoride plasma and bone concentrations in people with small to moderate changes in renal function as well as patients with serious renal deficiency. Other potentially sensitive populations should be evaluated, including the elderly, postmenopausal women, and people with altered acid-base balance." p83

"More work is needed on the potential for release of fluoride by the metabolism of organofluorines." p83

"More research is needed on bone concentrations of fluoride in people with altered renal function, as well as other potentially sensitive populations (e.g., the elderly, post-menopausal women, people with altered acid-balance), to better understand the risks of musculoskeletal effects in these populations." p147

"the relationship between fertility and fluoride requires additional study." p161

"Two small studies have raised the possibility of an increased incidence of spina bifida occulta in fluorosis-prone areas in India; larger, well-controlled studies are needed to evaluate that possibility further." p164

"More research is needed to clarify fluoride's biochemical effects on the brain." p186
"The possibility has been raised by the studies conducted in China that fluoride can affect intellectual abilities. Thus, studies of populations exposed to different concentrations of fluoride in drinking water should include measurements of reasoning ability, problem solving, IQ, and short- and long-term memory." p187

"Studies of populations exposed to different concentrations of fluoride should be undertaken to evaluate neurochemical changes that may be associated with dementia. Consideration should be given to assessing effects from chronic exposure, effects that might be delayed or occur late-in-life, and individual susceptibility." p187

"Further effort is necessary to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and the factors that determine the response, if any, in a given individual. Such studies would address the following...

- identification of those factors, endogenous (e.g., age, sex, genetic factors, or preexisting disease) or exogenous (e.g., dietary calcium or iodine concentrations, malnutrition), associated with increased likelihood of effects of fluoride exposures in individuals.
- consideration of the impact of multiple contaminants (e.g., fluoride and perchlorate) that affect the same endocrine system or mechanism." p223

"The effects of fluoride on various aspects of endocrine function should be examined particularly with respect to a possible role in the development of several diseases or mental states in the United States. Major areas for investigation include the following:

- thyroid disease (especially in light of decreasing iodine intake by the U.S. population);
- nutritional (calcium-deficiency) rickets;
- calcium metabolism (including measurements of both calcitonin and PTH);
- pineal function (including, but not limited to, melatonin production); and
- development of glucose intolerance and diabetes." p224

"Studies are needed to evaluate gastric responses to fluoride from natural sources at concentrations up to 4 mg/L and from artificial sources." p. 258

"Additional studies should be carried out to determine the incidence, prevalence, and severity of renal osteodystrophy in patients with renal impairments in areas where there is fluoride at up to 4 mg/L in the drinking water." p. 258

"The effect of low doses of fluoride on kidney and liver enzyme functions in humans needs to be carefully documented in communities exposed to different concentrations of fluoride in drinking water." p258

"In addition, studies could be conducted to determine what percentage of immunocompromised subjects have adverse reactions when exposed to fluoride in the range of 1-4 mg/L in drinking water." p259

"It is paramount that careful biochemical studies be conducted to determine what fluoride concentrations occur in the bone and surrounding interstitial fluids from exposure to fluoride in drinking water at up to 4 mg/L, because bone marrow is the source of the progenitors that produce the immune system cells." p 259

"Further research on a possible effect of fluoride on bladder cancer risk should be conducted." p288

"in vivo human genotoxicity studies in U.S. populations or other populations with nutritional and sociodemographic variables similar to those in the United States should be conducted." p288

[31] The American Dental Association 1994, Institute of Medicine 1997, and recently the American Dietetic Association

[32] Pediatrics May 1998 Vol. 95, Number 5 RE9511

[33] http://www.epa.gov/fedrgstr/EPA-PEST/2005/July/Day-15/p13982.htm In response to industry requests, Dow AgroSciences has developed ProFume gas fumigant (Sulfuryl fluoride) as an alternative to methyl bromide for the control of stored product insect pests in mills, warehouses, storage structures, transportation vehicles, and many commodities and foods stored within them. Sulfuryl fluoride, marketed as Vikane* Specialty Gas Fumigant, has provided over 40 years of effective control of structural insect pests such as termites and wood boring beetles.
http://mbao.org/2004/Proceedings04/064%20WelkerJ%20UPDATE%20ON%20THEWelkerJ%20DEVELOPMENT%20AND%20COMMERCIALIZATION%20OF%20PROFUME.pdf

[34]

Drug	generic name	Use	potential max. dose (mg/d)	empirical formula	MW gm/mol	F wt. gm/mol	% F	F release if 10% of the drug is defluorinated (mg/d)
Arava	leflunomide	anti-arthritic	100	C12H9**F3N**2O2	270.2	57	21.1	2.1
Celebrix	celecobix*	anti-arthritic	200	C17H14**F3N**3O2S	381.8	57	14.9	2.9
Ciproa	ciprofloxacin	anti-anthrax	500	C17H18**FN**3O3.HCl.**H**2O	385.8	19	4.9	2.5
Maxaquin	lomefloxacin	antibiotic	500	C17H19**F2N**3O3**.HCl**	387.8	38	9.8	4.9
Avelox	methoxyfloxacin	antibiotic	500	C21H24**FN**3O4**.HCl**	437.9	19	4.3	2.2
Diflucan	fluconazole	anti-fungal	400	C13H12**F2N**6O	306.3	38	12.4	5.0
Tambocorb	flecainide	anti-arythmic	400	C19H23**F6N**2O5	473	114	24.1	9.6
Luvox	fluvoxamine maleate	anti-depressant	100	C15H21**F3O**2N2**. C**4H4O4	434.4	57	13.1	1.3

Paxil	paroxitine	anti-depressant	100	C19H20**FNO**3.**HCl.1/2H**2O	374.8	19	5.1	0.5
Prozac	fluoxitine HCl	anti-depressant	100	C17H18 **F3NO.HCl**	345.8	57	16.5	0.33
Prolixin	fluphenazine	schizophrenia	40	C22H26 **F3 N**3OS**.2HCl**	510.4	57	11.1	4.4
Stelazine	trifluoperazine	schizophrenia	40	C21H24**F3N**3S•2HCl	480.4	57	11.9	4.8
Dalmane	fluorazepam	anxiolytic	30	NA	460.8	19	4.1	0.12
Lipitor	atorvastatin Ca*	lower cholesterol		(C33H34**FN**2O5)2Ca•3H2O	1209.4	38	3.2	0.26
Flonase	fluticasone proprionate	anti-allergy	0.2	C25H31**F3O**5S	500.6	57	11.4	0.0023

[35] **Fluoroquinolones (a recent antibiotic)**
Flosequinan withdrawn 1993 (higher hospitalization rate than placebo)
Fenfluramine and Dexfenfluramine withdrawn 1997 (cardiac)
Temafloxacin (Omniflox) withdrawn 1992 (deaths, liver dysfunction)
Grepfloxacin withdrawn 1999 (serious cardiac events)
Fen-Phen withdrawn
Astemizole (allergy drug), Tolrestat (anti-diabetic)
Cisapride (Propulside) withdrawn 2000 (Cardiac)
Mibedrafil (Posicor) withdrawn 1998 (heart failure)
[36] http://www.apfn.org/apfn/fluoride.htm
[37] The Superior Court of the State of California Case No. 718228, Demurrer (October 22, 1992).

CHAPTER VIII. JUDICIAL FINDINGS

Forensic science and medicine is the art of presenting scientific and medical facts to a judge or jury in a court of justice. As such it is a specialized field in the law of evidence and trial advocacy. It should come as no surprise that this art has been used to deal with a question so controversial as artificial fluoridation of public water supplies, which may be defined as a public imposition upon human beings, seeking to alter the level of fluoride in public drinking water from a natural level, usually 0.2 to 0.4 parts per million, to a desired level, usually 0.9 to 1.2 parts per million, as directed by statutes, regulations, and ordinances.

Many substances, including fluoride, can be used to serve medicinal, nutritional, or poisonous purposes, depending of dosage, administration, and other considerations. And if the objective of artificial fluoridation of public water supplies were distribution of claimed medical or dental benefits, it is obvious enough that a pure pharmaceutical grade of fluoride would be used, the same as when a physician or dentist prescribes fluoride tablets for patients in a clinical setting. Fluoride is a part of nature, in that sense like many substances refined for use as medications, and physicians or dentists should be trusted in dealing with the ailments of their individual patients, in regulating dosage and administration according to acquired expertise and judgment, in monitoring progress, and in making proper adjustments along the course of treatment.

But there is a telling fact, revealing that human health has never been the real objective of artificial fluoridation of public water supplies. The process consists in most cases of machine-regulated dripping of hydrofluoselicic acid into public drinking water. But hydrofluoselicic acid is an industrial waste product which would never be prescribed by a physician or dentist for a patient in a clinical setting, because it contains, aside from low-grade fluoride as a primary component, secondary trace amounts of arsenic, lead, and other impurities. In all remaining cases, the process consists of machine-regulated infusion of sodium silicofluoride in public drinking water. But sodium silicofluoride is hydrofluoselicic acid, only neutralized by sodium hydroxide or caustic soda, then transformed into a powder which likewise contains low-grade fluoride as a primary component, together with secondary trace amounts of arsenic, lead, and other impurities. And this alternative would never be prescribed by a physician or dentist for a patient in a clinical setting. It so happens that no more convenient and economical way to dump these highly toxic industrial waste protects has ever been devised than artificial fluoridation of public water supplies.

It is, therefore, obvious that the real purpose of artificial fluoridation of public water supplies has, from the beginning, been nothing other than a cost-effective method of dumping an industrial waste product, otherwise difficult and expensive to dispose of, all done on false pretenses, behind an elaborate façade of

public relations gimmicks. When people learn this cynical reality, they naturally react with indignation, for their intelligence has been insulted, not to mention adverse effects on their health. And so over the course of many decades, there has developed an enormous corpus of litigation undertaken to defend against forced imposition upon protesting citizens, or brought by protesting citizens to enjoin it by injunction.[1] The courts have generally sided with governments pushing, and corporations benefiting from artificial fluoridation of public water supplies, but more needs to be said.

We shall attempt to accomplish several objectives here:

We shall first distill the key judicial decisions on applicable principles of law from a large corpus of reported cases both American and Canadian. We shall then expound these decisions in broad philosophical terms.

We shall next consider the forensic evidence that has been or can be used in court to prove that artificial fluoridation of public water supplies actually induces large-scale cancer in man.

From there, we shall focus upon critical phases of the two most important court trials cases on the adverse impact of artificial fluoridation of public water supplies on human heath.

We shall then review the express findings of American judges after hearing the foremost experts in the world on both sides. Three judges have condemned

artificial fluoridation of public water supplies as an important causal factor in inducing large-scale cancer and other ailments in human populations. We shall here consider two of these three cases, from which we have ample trial records.

Finally, we shall discuss the legal and political fallout from these judicial findings. We shall also look into the approaching future.

We begin with a decision still frequently cited and argued whenever questions arise concerning rights unenumerated, yet protected by constitutional provisions. In *Meyer v. Nebraska*, 261 U. S. 390 (1923), the United States Supreme Court struck down a law which forbade the teaching of German in the primary grades of public schools. The guiding formula was stated with graceful clarity on pages 399-400 of the opinion:

> While this court has not attempted to define with exactness the liberty thus guaranteed, the term has received much consideration, and some of the included things have been definitively stated. Without doubt, it denotes, not merely freedom from bodily restraint, but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, to establish a home and bring up children, to worship God according to the dictates of conscience, and, generally, to enjoy privileges long recognized at common law as essential to the orderly pursuit of happiness by free men

In this connection, Sir William Blackstone listed as among the "absolute rights of individuals" at common law the "preservation of a man's health from such practices as may prejudice and annoy it."[2]

It should be evident from these authorities that legislation protecting public health, while generally valid so long as fair and reasonable, is always subject to the right of citizens to prove in a satisfactory manner that application to them would seriously threaten life and health and would thus be unlawful.

The seminal judicial decision on regulation of public health, never overruled and frequently cited, is *Jacobson v. Massachusetts*, 197 U. S. 11 (1905). A citizen challenged the constitutionality of a statute imposing mandatory smallpox vaccinations to deal with a threatened epidemic. At the time there was, and ever since there has been responsible dissent in the medical profession concerning the efficacy and safety of this practice. Even so, respectable opinion in the medical profession, right or wrong, has long regarded the practice as an important means of protecting public health. The United States Supreme Court held that, under these circumstances, the law was on its face a legitimate exercise of legislative authority. The court reasoned on page 35 of its opinion that the possibility dissenters might finally be proven right did not render the statute invalid, because the legislature had authority to enact laws based on reasonable belief to prevent the spread of contagious disease.

The court then went on to qualify its holding on page 39 of the opinion, saying the statute could never be interpreted to compel a vaccination whenever it

could be shown "with reasonable certainty" that application to any objecting citizen "would seriously impair his health or probably cause his death."

The court did not define exactly what was meant by the phrase "with reasonable certainty." Yet the phrase has long been a term of art in the law of damages in civil proceedings, for judges have traditionally said that a plaintiff cannot recover unless he proves harm "with reasonable certainty." The meaning is that a plaintiff cannot rest his case on speculation or guess, yet it will be enough for him to show the approximate degree of harm by fair preponderance of the evidence, or balance of probabilities, adduced from competent and material evidence in a judicial hearing.[3] And in such case, injury may be proved by the opinions of experts who have demonstrated that they are well informed on the subject under investigation, as such opinions are applied to the facts of the case.[4]

Gallant attempts have been made to distinguish *Jacobson v. Massachusetts* by argument that artificial fluoridation of public water supplies does not address contagious disease. But the great weight of judicial decisions since handed down all apply the rule of *Jacobson* to any regulation of public health, whether or not addressed to contagious disease. The contrary might be devoutly wished or intelligently supposed, yet the law remains that any regulation of public health imposed by legislative authority is valid *on its face,* notwithstanding responsible dissent in science and medicine, so long as such regulation has been approved by

legislative authority, and is based on respectable opinion in the established health professions.

Even so, if *in a particular case* it is proved beyond speculation and guess, by fair preponderance of the evidence based on expert testimony, that application of the regulation would create a likely danger to health or life, then in such case the regulation in question *may not be enforced* over the protest of those endangered, and in such event citizens affected may have an injunction or other remedy to protect their interests.

Another important qualification to *Jacobson* is found in the judgment of the Supreme Court of Canada in *Toronto v. Forest Hill*, [1957] S. C. R. 469, in which the majority held that a statute regulating public health should be strictly construed so as not to authorize mandatory medical treatment of human beings, not unless the language of the statute is unmistakable. Therefore, the court held, an organic law allowing municipal regulations to make public drinking water "pure and wholesome" did not in and of itself authorize fluoridation.

And the Supreme Court of Canada has very recently held in *Chaoulli v. Quebec*, [2005] 2 S. C. R. ---, that the right of citizens to preserve health and life must be given such solicitous judicial protection that a government monopoly in medical care, established to assure equal access to all, may not be allowed to interfere with individual exercise of such right in securing care urgently necessary.

Chaouli thus serves to reinforce the qualification in *Jacobson* that, although the legislative power has broad discretion in enacting laws to regulate public health, such laws must give way to the "absolute rights of individuals" to protect health and life. Whenever individuals can show "with reasonable certainty" that the execution of such laws would tangibly endanger health or life, the courts may and should intervene to protect the individuals adversely affected.

In this light it is easier to appreciate the proper scope and meaning of the leading case on artificial fluoridation of public water supplies. In *Paduano v. New York*, 257 N. Y. S. 2d 531 (S. Ct. N. Y. County 1965), subsequently affirmed or left standing in all appellate tribunals, the court cited and *Jacobson* with approval, then said at page 542 of its opinion,

> *Until the scientific evidence as to the deleterious effects of fluoridation reaches beyond the purely speculative state now existing*, decisional law mandates holding that the controversy should remain within the realm of the legislative and executive branches of government. While the courts do not have a right to impose fluoridation on anyone, judicial restraint requires us to adhere to the uniform decisions holding that the executive and legislative branches of government do -- *at least until some proof is adduced that fluoridation has harmful side effects* and therefore is not in the interests of the community." [Emphasis added]

In 1965 when *Paduano* was decided, fluoridation enjoyed immense prestige in the United States. Since 1950, it had been endorsed by the United States Public Health Service, the American Dental Association, and many other prestigious organizations, and at the time, so far as then known and understood by most

physicians and dentists, the weight of the evidence seemed to support the measure as an effective and economical way to reduce dental caries without danger to the general public. And so the court dismissed a suit seeking an injunction prohibiting fluoridation in New York City.

The same reasoning has resulted in a mountain of precedent so that citizen protests have been overwhelmed in the most cases. Today 170 million people drink fluoridated water in the United States, nor has Congress ceased to make large appropriations every year to continue promoting this program through the United States Public Health Service. In Canada, fluoridation has also been aggressively promoted, so that now about 7 or 8 million drink fluoridated water.

It is now known that the glowing reputation of fluoridation in 1965 was not deserved, but at the time of *Paduano* the facts were not yet known, in part because important evidence had not yet been gathered and reported by competent scientists, and in part because telling evidence then existing had been covered up by corrupt bureaucrats.

The claim of cover up may seem extravagant, but can be illustrated easily enough, for examples are abundant and significant. Probably the most important of these episodes concerns the work of Dr. Alfred Taylor, a fellow in the Clayton Biochemical Institute at the University of Texas.

In the early 1950s, Dr. Taylor undertook a series of preliminary experiments in which it appeared that cancer-prone mice consuming water containing sodium fluoride at concentrations as low as 1.0 per million had shorter life spans than such mice drinking distilled water. Because the mice ate chow containing measurable fluoride, probably combined with calcium, as he learned after his initial runs, Dr. Taylor replicated his earlier work, this time using chow containing negligible fluoride. He ran twelve experiments using 645 cancer-prone mice, a very large study including enough data to assure meaningful results. He found that cancer-prone mice drinking water containing fluoride at 1.0 and 10.0 parts per million had significantly shorter life spans than such mice drinking distilled water. His work was peer reviewed and published in a learned journal when the dental profession was becoming excited about the possibility of fluoridation as a universal public health program across the United States and Canada.

Dr. Taylor's article, *Sodium Fluoride in the Drinking Water of Mice*, 60 Dental Digest 170 (1954), was historic and important. For mice are mammals like human beings, and their susceptibility to cancer from drinking water containing water containing fluoride even at concentrations as low as 1.0 per million, artificially introduced as ions freed when sodium fluoride dissociates, is a clear warning that human beings might also be susceptible to contracting cancer when public water supplies are treated with hydrofluoselicic acid or sodium

silicofluoride, likewise releasing free ions to achieve a fluoride level of about 1.0 part per million.

Dr. Taylor's article in the Dental Digest was published at a politically sensitive time, because the last stages of the boasted surveys in Newburgh and Kingston, New York, were then underway. These surveys were expected to demonstrate that fluoridation would dramatically yet safely reduce tooth decay. An elaborate and comprehensive report on anticipated results was planned for publication under prestigious circumstances as the beginning of a giant public relations campaign. Soaring hopes were rudely blunted by the bad news from Dr. Taylor, because the obvious meaning of his results was that widespread implementation of fluoridation would have to be delayed until further time-consuming investigation could be done to clarify the situation.

The official reaction to the crisis induced by Dr. Taylor is seen in the *Newburgh/Kingston Caries-Fluorine Study: Final Report*, 52 Journal of the American Dental Association 290 (1956). Since the facts were inconvenient, a "policy decision" was made, and the truth was thus grossly misrepresented on page 313 of the *Final Report*:

> The reports by Alfred Taylor, a biochemist at the University of Texas, on the increased incidence of cancer in mice drinking fluoride-treated water have been show to be unfounded, since the food that he was giving the mice had many times the fluoride content of the drinking water, and the food was supplied both to the control and experimental groups. Subsequent tests did not confirm the differences.

Ever since those words were printed, officials of the United States Public Health Service have insisted, contrary to known facts, that Dr. Taylor's reruns were never done, that his results were never confirmed, that his work was never peer-reviewed, that his work was never published, and that no other qualified scientists have ever reported comparable results. Hence, in a standard history of the National Institute of Dental Research, published thirty-five years after Dr. Taylor's work first appeared in a refereed journal, it was said, "Alfred Taylor, an investigator with a doctorate in biochemistry, indicated that he would not publish his findings, because he was unable to confirm those results in a second experiment," and further, "A literature search of scientific journals failed to show any publication of this work by Dr. Taylor -- an indication that it was not subjected to review by his peers."[5]

The importance of Dr. Taylor's work is best measured, all things considered, by the strenuous efforts of the United States Public Health Service to conceal it.

After his first study, Dr. Taylor and his wife Nell, who also held a doctorate in biochemistry, published the results of yet another large-scale study in a peer-reviewed journal. The article appeared as *Effect of Sodium Fluoride on Tumor Growth*, 119 Proc. Soc. Exptl. Biol. & Med. 252 (1965), and reported 54 runs with 991 laboratory mice implanted with malignant tumors. As compared with control mice, experimental animals were exposed to sodium fluoride in varying

concentrations by injection into implanted tissue, in drinking water, and by subdermal injection. In all runs, mice exposed to fluoride experienced significantly faster growth in tumors. A rapid and pronounced increase in the weight of tumors was observed in mice exposed to fluoride in drinking water at concentrations of 1.0 and 2.0 parts per million, comparable to amounts artificially introduced into the drinking water of man, but the rise began to level off as concentrations of fluoride increased to 5.0 and 20.0 parts per million and higher. Such leveling off is typical of biomedical data, for nature does not invariably move in straight lines.

Far from being isolated results, the work of Dr. Taylor has been confirmed many times by many scientists publishing in flag ship journals.[6] Even so the United States Public Health Service still pushes an official line that artificial fluoridation of public water supplies is perfectly safe, and has no tendency whatever to cause or contribute to the cause of cancer in man.

The work of Dr. Taylor and those confirming his results raises the question whether, in keeping with *Jacobson* and *Paduano*, it can now be proved by a fair preponderance of the evidence in judicial proceedings that fluoridation is dangerous to human health by causing large-scale cancer and other ailments in man.

The answer to this question is that, not only can such danger be so proved in courts of justice, it has already been thus proved, and eminent trial judges, after

hearing the evidence over many days of strenuous adversarial combat, have found that fluoridation in fact causes cancer and other ailments in man. And certainly such proof can be offered again, and, if adequately presented by qualified witnesses examined by well-prepared counsel, and the judges hearing such evidence are independent and upright, such judicial findings based upon a fair preponderance of the evidence can again be secured. The fulfillment of this possibility depends on determination, intelligence, knowledge, skill, discipline, character, and resources.

Two kinds of information can be presented by experts properly qualified, guided by counsel skilled in forensic science and medicine.

Laboratory studies enable us to view a disease at the molecular and cellular levels, and to consider reactions in living plants, insects, and animals. The advantage of laboratory studies is that precise experimental conditions can be designed and controlled for known and unknown variables. The work of Dr. Taylor has been done, peer-reviewed, published, and confirmed by others. And the same work can be rerun and reconfirmed.

The disadvantage of laboratory studies is that caution is required in extrapolating results to human beings. In order to remedy the need to speculate from laboratory studies, epidemiology must come into the picture. Epidemiology is the branch of medicine which studies the human diseases in human populations

and environments with an view to finding causes. If controls in epidemiological surveys cannot in the nature of things be as precise, the results are more pertinent to human experience. Therefore, both laboratory studies and epidemiological surveys should be considered together, and, when parallels between them become striking, causal relationships between agents in the environment and human disease can more readily be identified by scientists and proved up in courts.

Thus the question: Has the carcinogenic potential of fluoride observed in laboratory studies also been observed in human experience? The answer, based on very extensive epidemiological data, is certainly in the affirmative, and this fact has removed the speculative character of objections expressed by certain physicians and scientists against fluoridation as a public health practice.

The leader among scientists gathering pertinent epidemiological data and organizing it in usable form was Dr. Dean Burk, who retired in 1974 as the head of the cytochemistry section of the National Cancer Institute of the United States. In his time, he was one of the most famous and decorated cancer research scientists in the world. He was a pioneer in both chemotherapy and metabolic therapy for the treatment of cancer. And from his retirement in 1974 to his death in 1988, he directed the retrieval of data and analysis of the relationship between water fluoridation and human cancer, particularly as expressed by the cancer death rates set forth in Tables 1A and 1B in Chapter IV.[7]

All necessary data, including everything required for demographic adjustments in Dr. Burk's later work, can be obtained from published reports of the United States Census Bureau, the National Center for Health Statistics, and the United States Public Health Service. All analysis has been done according to orthodox methods.[8] And so the main corpus of Dr. Burk's epidemiological work can be recapitulated by anyone willing and able to retrieve the data from published government records and apply standard techniques of medical statistics.

The year-by-year average cancer death rates (so many cancer deaths for all sites per 100,000 persons) in ten large central cities (corporate limits, excluding suburbs) of the United States, which served as the control group and remained unfluoridated from 1940 through 1968,[9] were compared for the years 1940 through 1968 with corresponding year-by-year average cancer death rates in ten large central cities of the United States which served as the experimental group and remained unfluoridated from 1940 through 1951, but fluoridated from 1952 through 1956, and remained fluoridated through 1968 and thereafter.[10] The experiment came to an end in 1968 ironically because the United States Public Health Service, the American Dental Association, and other allied organizations were so successful in promoting fluoridation by persuading city councils to go along, or coercing them to submit by force of law. From and after 1969 control cities began to fluoridate their respective public water supplies.[11] Even so, by 1968

it had been possible to gather enough data from impeccable public records, and the unmistakable truth was established, never to be erased from the eyes of scientific history.

Not enough data were available to construct rates for 1951 and 1952, but rates could be constructed for all twenty cities in all other years from 1940 through 1968.

In order to assure comparable cancer experience in both groups before fluoridation began in the experimental cities, it was stipulated that every city in both groups had to have a cancer death rate in 1953 of at least 155 cancer deaths per 100,000 persons.

The aggregate population of the control cities was about 5.3 million in 1940, about 6.3 million in 1950, about 7.l million in 1960, and about 7.3 million in 1970. The aggregate population of the experimental cities was about 11.0 million in 1940, about 11.9 million in 1950, about 11.5 million in 1960, and about 10.8 million in 1970. The size of this survey was, therefore, enormous, covering cancer mortality for 16-18 million people in twenty large central cities spread out across the United States over thirty years. There has hardly ever been a published epidemiological study using so much data, over so long a period of time, and arranged in such powerful experimental design.

The cancer deaths for each city were taken as reported each year.[12] The populations figures for census years were taken as reported, and population figures between census years were estimated by linear interpolation in relation to census years. This procedure postulates that population increases or declines year by year in equal increments between census years.

The cancer death rates for each group of cities were expressed both as unweighted averages, giving each city equal weight regardless of population size, or weighted averages, giving each city weight according to population size. The use of weighted averages means in effect that all cancer deaths and all populations in all ten cities in each group must be pooled for each into one gross fraction which is then reduced a common denominator of 100,000 for purposes of comparison. The pattern of the data is virtually same whether unweighted or weighted averages are used, and the differences between the two is trivial, as should be visually evident from Figures 1A and 1B in Chapter IV. In this particular case, it is of no practical consequence whether unweighted or weighted averages are used for causal inference, statistical treatment, or any other technical purpose. And since weighted averages are mathematically more convenient to use, and were preferred by Dr. Burk and his critics alike, the discussion here will be confined to weighted averages, which are set forth and analyzed in Tables 1B and 2B in Chapter IV.

These basic data, gathered and organized under the supervision of Dr. Burk, are arranged in standard experimental design, comparing like with like along a base line from 1940 in which weighted-average cancer death rates grew equally, then continuing the comparison after fluoridation was introduced in the experimental cities. After fluoridation began, a pronounced and rapid acceleration in human cancer mortality in the experimental group (+F), as compared with the control group (-F).

The resulting association between fluoridation and cancer can be conveniently quantified by linear regression, which is a standard statistical technique for characterization of a field of points on a two-dimensional graph as a straight line which is called a line of best fit. The line is so drawn that the sum of the squares of the distances of the several points to the line is the lowest possible number. Such lines were drawn through the data for observed weighted-average cancer death rates (CDRo) from 1940-1950 to achieve values for 1940 and 1950, both for control (-F) cities and experimental cities (+F), and again through such data for 1953-1968 then extended to achieve values for 1950 and 1970. Hence, the figures in Table 2B in Chapter IV:

	1940	1950	1950	1970
CDRo (+F)	154.2	181.8	186.3	222.6
CDRo (- F)	153.5	181.3	183.6	188.8

The size of the association can then be calculated: [(222.6 – 188.8) – (186.6 – 183.6)] + [(154.2 – 153.5) – (181.8 – 181.3)] = 31.3 excess cancer deaths per year per 100,000 persons exposed after 15-20 years from the introduction of fluoridation in the experimental cities. The epidemiological data closely parallel and thus confirm the laboratory studies, and establish a causal relationship between artificial fluoridation of public water supplies and dramatic increases in human cancer mortality.

Consequently, there now exists and long has existed enough evidence to make out a prima facie case in courts of justice that fluoridation causes a dramatic increase in human cancer. And not only can a prima facie case be made out, but attempted rebuttal can be refuted.

In this connection it is important to keep in mind that judges must be instructed in scientific conventions, for the mentality of the law properly rests upon conventional standards in dealing with virtually any subject. And in this setting, attention should be given to principles of inductive logic which are properly used in weighing empirical evidence and identifying causal relationships in the natural sciences.[13]

A *first rule of right reason* is that, in order to find cause, it is necessary to control for known and unknown variables.

Thus Dr. Taylor compared identical strains of mice under identical laboratory conditions, then observed the results when sodium fluoride was introduced into the drinking water of identified groups, as compared to mice drinking distilled water. And Dr. Burk observed the similar cancer mortality of two similar groups of cities over many years, then noted the striking rise in cancer mortality when fluoridation was introduced in one group of cities as compared to the unfluoridated cities.

A *second rule of right reason*, often called Ockham's razor, is that, in dealing with empirical facts which display characteristic trends, assign the simplest and most fitting explanation as the cause, whether the mechanism is fully understood or not, and take such explanation is the cause. And that cause remains established unless and until the contrary be demonstrated.

Especially in light of Dr. Taylor's work on mice, the simplest and most fitting explanation for the sharp rise in human cancer mortality in the fluoridated cities is that the artificial addition of fluoride is the cause of the increased cancer, and such conclusion should be deemed established unless and until the contrary be demonstrated.

It is true that human cancer is influenced by countless demographic, environmental, dietary, socio-economic factors, some causing cancer incidence and mortality to increase, others causing cancer incidence and mortality to decease. Older people generally experience more cancer, for example, yet proper diet and

exercise, or a better environment, can significantly offset the adverse impact of aging. Applying Ockham's razor to Dr. Burk's basic data, it is proper to conclude, unless and until the contrary be demonstrated, that all cancer-influencing factors counterbalanced each other during the long base line period before 1950; that all these factors continued to counterbalance each other after 1950, except for the one factor known to be new, viz., fluoridation; and, therefore, that the entire association between fluoridation and cancer, i. e., 31.3 excess cancer deaths per 100,000 after 15-20 years, is attributable to fluoridation as the cause.

And a *third rule of right reason* is that, once a causal relationship is properly established from empirical facts at a certain time and place, subject to necessary controls and precautions, it is proper, unless and until the contrary be demonstrated, to generalize the same causal relationship throughout all like situations at all times and places in the universe.

Thus the causal relationships established in the laboratory at the University of Texas and the epidemiological survey of 20 American central cities from 1940-1968 may be generalized to all parts of the world whenever and wherever fluoridation is implemented. Let us say, then, that at least 130 million Americans have been drinking fluoridated water for at least 15-20 years. That number is steadily increasing as time rolls by. It is reasonable to reckon the casualty in the early years of the 21st Century as 31.3 excess cancer deaths per 100,000 multiplied

by 130 or more million Americans ever year, which works out to a stupefying figure of at least 40,000 excess cancer deaths in the United States every year. A casualty of some thousands of excess cancer death caused by fluoridation can properly be reckoned for Canada.

Dr. Burk memorably expressed such a conclusion in a hearing before Congress on April 6, 1976:

> Oliver Wendell Homes Sr., M. D., of Civil War medical fame, and professor of anatomy at Harvard University, in 1843 and 1855 described then prevailing treatment of puerperal fever in lying-in hospitals as criminal manslaughter. It was only manslaughter, however, not murder, because the physicians of that day did not have, and could not have had a sufficiently knowledgeable idea of the bacteriological basis of the doctor-nurse-patient transmission of the disease until the work of Pasteur and Lester decades later.
>
> The scientific and medical status of artificial fluoridation of public water supplies has now advanced to the stage of the possibility of socially imposed mass murder on an unexpectedly large scale of literally tens of thousands of cancer deaths of Americans annually.[14]

In order to illustrate how this causal relationship can be proved up as a prima facie case in a court of justice, we shall draw from actual testimony given in two of three famous trials in which the presiding judges found that fluoridation is causally related to large-scale human cancer.

One of these cases was tried in segments of days from March through July 1978 before Hon. John Flaherty, then President Judge of the Civil Division of the Allegheny County Court of Common Pleas and Chairman of the Board of the

Pennsylvania Academy of Science, later Associate Justice then Chief Justice of the Pennsylvania Supreme Court. The case was entitled Paul Aitkenhead et al. v. Borough of West View, filed of public record as No. GD-4585-78 on the docket of the Allegheny County Court of Common Pleas in Pittsburgh.

The other case was tried in January 1982 before Hon. Anthony Farris, Judge of the District Court of Texas in Houston. The case was entitled Safe Water Foundation of Texas v. City of Houston, No. 80-52271 on the docket of the District Court of Texas in Harris County, 151st Judicial District.

In proceedings before Judge Flaherty, a famous physician and scholar laid the foundation of the plaintiffs' case. Dr. George Waldbott was asked whether, from his general knowledge of medicine, he believed that fluoridation can cause cancer in man. Dr. Waldbott answered affirmatively, then said,

> There are three reasons why I go for this opinion. One, contrary to former views which held that fluoride accumulates only in bones and teeth, we know that fluoride is and can be present in every single cell of the body. The second point is that fluoride is that fluoride is by far the most active of all chemicals in the body with the exception, perhaps, of hydrogen. Number three, since it is present in every cell, it is liable to produce damage in every cell, and if that damage continues as long-term damage, it is bound to produce cancer in certain individuals. -- Transcript, April 11, 1978, pages 288-289.

In proceedings before Judge Farris, inquiry was made of Dr. Pierre Morin who had served as director of medical research at major university hospital, on how fluoride could injure human cells and cause cancer:

THE COURT: Doctor, do you have an opinion as to whether fluoride can damage chromosomes?

DR. MORIN: Yes, your Honor. For quite some time now the actual damage being done to the chromosomes of cells by fluoride was based on laboratory studies. Mohamed's work and some other work were good indications that something was happening with the cells. And the latest publication, a very recent publication by Emsley has added a degree of confidence to the fact that fluoride, due to its very strong hydrogen bonding capacity, is capable of either distorting chromosomes or even breaking them, and this a subject which I believe might need a small additional explanation.

In biology what we call active substances need to retain their characteristic spatial arrangement, which means that, if a structure is winding around three times in a certain length of time, and if some reason due to chemical reaction or some such thing, that structure is not winding this time, it may have lost all biological activity. An example of this would be insulin, which can be denatured by exposure to about fifty percent oxygen for a period of a few hours. It becomes denatured in the sense that, if the substance is injected inside the body, it will not do its biological function. This is due to a very, very minute change on what, in biology, we call the active site of the substance. I think that the work of Emsley points to the fact that, through hyrdorgen bonding of fluoride, the double helixes of DNA are entering into a chemical reaction which tends to break some of the bridges, and, therefore, to interfere with the total structure. Therefore, it is not surprising to find that, as the cell replicates itself and this structure replicates itself into the next generation, there has been a change in the global characteristic of the cell. And this is what we call a teratogenic effect. In other words, we create an effect which is carried out in cells from then on.

And another thing, too, which is very important, is that some of the reasons why fluoride interferes with enzymes were not understood. Enzymes have active sites, and these are usually animo acids, and these, if they do hydrogen bonding, will lose their biological activity. So this is why I am really quite relieved to find that Emsley has published his work, because it is really the clinching work necessary to understand the process of fluoride toxicity for a living cell. -- Transcript, pages 542-545 (January 15, 1982).

In the same case, Dr. Morin was asked by counsel to explain the meaning of the laboratory studies and epidemiological surveys, taken together as an intelligible whole:

> Q. Doctor, is the work of Taylor that you have just discussed consistent with the work of Mohamed on mutagensis?
>
> A. Yes, it is.
>
> Q. Why is that?
>
> A. You see, Taylor is working on complete structures, transplanted tumors and complete organisms, and the other studies are individual cells, and it is, I would say, a continuous step-by-step process of trying to understand what is happening, so that each one adds to the other, and adds comprehension to the mechanism of what is going on.
>
> Q. Is there a relationship between carcinogenesis and mutagenesis?
>
> A. Mutagenesis, being a random process, affects all different aspects of the cell. Therefore, in a very large number of substances, I would say up to ninety percent of the substances known to be mutagenic turn out to be carcinogenic.
>
> Q. Is the work of Taylor and Mohamed consistent with the work of Emsley?
>
> A. Yes, Emsley did the work on what I would call the molecular level, and enables one to understand how the mechanism from beginning to end.
>
> Q. Is the work of Taylor and Taylor, of Emsley, and of Mohamed and Chandler consistent with the work of Burk and Yiamouyiannis at the epidemiological level?
>
> A. Yes.

Q. How is it consistent?

A. It is a progression from the molecular level to the human being. So we go up from the molecular level to the cellular and animal level, then to the human level. -- Transcript, pages 837-839 (January 20, 1982).

Upon this foundation, the epidemiological data can be better understood. In the proceedings before Judge Flaherty, Dr. Burk described the meaning of the basic data gathered and organized under his direction. He testified,

> There is a principle in science known as Ockham's razor. Now he lived at the time of Chaucer in 1400, and this principle is almost as well known and important as Newton's law of gravity. It says that, if you are trying to assess cause and effect, you must take the most probable cause as the first best judgment. Now if somebody thinks that there is some better cause, it is up to him not only to say what he thinks it is, but to show that it is. He's got to show that it's better than the first cause. So here we have, in our opinion, an almost self-evident demonstration that fluoridation is causing a tremendous increase in cancer death rate." -- Transcript, April 10, 1978, pages 132-133.

In proceedings before Judge Farris, Dr. Burk amplified his position,

> Q. Doctor, you have already testified that, in your opinion, the basic data, when construed in light of Ockham's razor and general principles of science, yields a fair inference that fluoridation of public water supplies is causing cancer. Do you have an opinion, based on a reasonable degree of scientific probability, as to why fluoride could have such a carcinogenic effect?
>
> A. Yes, I do.
>
> Q. What is the opinion?
>
> A. But I would give it far less weight in my thinking than the mere fact that those are the facts, but fluoride is the most electronegative element, or to put it in more understandable terms, it is known to inhibit at least fifty enzyme reactions in the body and the enzymes, of course, are like

the governors on a car, they control the direction and extent of reactions. So it is no mystery to me that fluoride should have such a violent effect, all adding up to cancer and death. Now as a biochemist, that is all I really wish to talk about as to an explanation of the cause. It is facts of the matter set forth in this graph which, I consider, have the deepest and most profound meaning.

Q. Do you have an opinion to a reasonable degree of scientific probability as to whether the fluoride ion is an enzyme inhibiter?

A. It has been widely published as inhibiting at least fifty known enzymes, you could look up which in fifty in standard books, all at relatively low concentrations that are involved in the fluoridation of public drinking water.

Q. Would that be consistent or inconsistent with this graph picturing your basic data?

A. It would certainly be consistent with it and a potential explanation for it if you are interested in explanations. -- Transcript, pages 46-48 (January 13, 1982).

When asked in proceedings before Judge Farris whether the crude cancer death rates in his basic data might be misleading if not adjusted for age, race, and sex, Dr. Burk made himself clear:

Q. Which figures do you think more closely represent reality, the adjusted or unadjusted?

A. In this instance it is my opinion that the unadjusted are.

Q. Will you explain to the court why you think the unadjusted more closely represent reality?

A. Well, first of all, they are reality. They are the actual numbers, which is about as close to reality as you can get. Now you wish to add an explanation for understanding those figures. That immediately goes into the world of hypothesis and so forth, and, while there are times

> when those hypothetical considerations are most important, in my judgment and experience this is not one of those times, for the reason that cancer deaths, as I indicated yesterday, are clearly a function of many variables, some of which can be shown very clearly and numerically and some of which are more nebulous, but there can be anywhere from fifty to several hundred that one could without much trouble list of his head. So, when you are going to correct for three factors such as age, race, and sex, you obviously, by any system of logic, are being incomplete. You should be correcting for all the others, which you should do more or less by the same logic, as you have proceeded to do with those three.
>
> The only thing that can be said in mitigation of that is, if you think one of those factors, or two of them, is more important quantitatively than all the others put together, then what I was just saying was not as pertinent as might be. But I can only say from experience in the cancer field that all those other factors could easily be more important than any one, two, or three of the ones commonly used, which are used mainly because they are the data available, not because they are really the best ones. -- Transcript, pages 105-107 (January 14, 1982).

When asked in proceedings before Judge Farris about the fairly short latency period in his basic data -- the noticeable increases in cancer mortality after only five years following the introduction of fluoridation --, Dr. Burk answered,

> It is a very popular myth spoken by the unknowing that cancer always takes fifteen to thirty years to develop after the inciting agent was provided. Those unsophisticated people in that sense were thinking of, quite accurately, cancer produced by cigarette smoking and asbestos. But if they knew anything about the literature in the field of cancer, they would know that far shorter induction periods have been reported in human beings. -- Transcript, page 46 (January 13, 1982).

Dr. Burk then listed several examples of substances inducing human cancer within five years, including nickel, aniline dyes, benzene, and atomic radiation, among others.

And it ought to be expected from Dr. Taylor's work on mice that fluoridation should have impact mainly upon older human beings who are more prone to cancer, and that such impact should be relatively rapid at first, then eventually level off. While Dr. Burk always believed that there was no scientific need for demographic adjustments of his basic data for age, race, and sex in this particular case, he and several colleagues actively investigated demographic variables as a concession of conventional thought.[15]

He and Dr. John Yiamouyiannis discovered that race and sex had no impact, that age was the only demographic variable of any importance, even if immaterial in and of itself, and that the primary rapid impact of fluoridation on human cancer mortality is evidently upon individuals in more cancer-prone age groups, in some degree those over 45, and especially those over 65. The parallels between laboratory experiments and epidemiological data, therefore, are quite striking.

In any event, Dr. Burk concluded his testimony before Judge Farris with powerful emphasis:

> Q. In assessing the total percentage of cancer increase in the United States, do you have an opinion, based on a reasonable degree of scientific probability, as to what percentage would be associated with fluoridation?
>
> A. Not in terms of percentage. That would be estimated, but it is my firm opinion that fluoridation contributes very materially to the increase that is observed. I have had that opinion for quite a few years now. In other words, we wouldn't see by any means as much increase in cancer but for this fluoridation, or, to look at it the other way around, I know of

> absolutely no, and I mean absolutely no means of prevention that would save so many lives as simply to stop fluoridation, to not to start it where it otherwise is going to be started. There you might save 30,000 or 40,000 or 50,000 lives a year, cancer lives. That is an awful lot of lives a year.
>
> Q. At any expense?
>
> A. No, it would save money.
>
> Q. And, at any great effort?
>
> A. No, you just wouldn't bother to put it in the water. And why people don't fully appreciate it, or take action to oppose it, I cannot understand without going into the root of all evil and those things. But scientifically I can't understand any basis. -- Transcript, pages 234-236 (January 14, 1982).

The same kind of prima facie case was made out for the plaintiffs in both Pittsburgh and Houston. The defense in both trials was similar. A series of witnesses showed up, each with impressive credentials and unctuous speech. Some knew whereof they spoke. Others did not.

In the latter category fell the director of public health for the City of Houston. She held the degrees of doctor of medicine and master of public health, and was a member of many learned societies. Her appearance was very agreeable. Her background and credentials were impeccable. In an erudite and poised manner she testified in proceedings before Judge Farris. Her demeanor naturally commanded confidence and respect. She had enthusiastically recommended, for the good of little children, especially those in lower socio-economic groups, that the city

"adjust the fluoride in the municipal water supply to the optimum level for reduction of dental caries." Then came cross-examination:

> Q. Doctor, have you read a report which has been marked as plaintiff's exhibit 23, entitled Fluorides, Fluoridation, and Environmental Quality, a translation of a report prepared for the minister for the environment for the Province of Quebec by an advisory committee for the fluoridation of public water supplies?
>
> A. No.
>
> Q. Doctor, I am showing you what has been marked as plaintiff's exhibit 3, an article by Dean Burk and John Yiamouyiannis, published in the journal Fluoride, entitled Fluoridation and Cancer: Age Dependence of Cancer Mortality Related to Artificial Fluoridation. Have you read that before?
>
> A. No.
>
> Q. Doctor, I am showing you what has been marked plaintiff's exhibit 7, a book by George Waldbott, M. D., and Professors Bergstahler and McKinney, University of Kansas, entitled Fluoridation: the Great Dilemma. Have you read that book?
>
> A. No.
>
> Q. Doctor, showing you what has been marked plaintiff's exhibit 8, a publication by the National Research Council of Canada, entitled Environmental Fluoride 1977, by Dyson Rose and John Maurier, have you read that report?
>
> A. No.
>
> Q. Doctor, I am showing you what has been marked plaintiff's exhibit 13, a paper entitled Cytological Effects of Sodium Fluoride in Mice by Aly Mohamed and Mary Chandler of the Biology Department at the University of Missouri in Kansas City. Have you read that report?
>
> A. No.

Q. Doctor, showing you what has been marked plaintiff's exhibit 20, a translation of an article in the original German, the translation being entitled Fluoridated Water and Teeth by Rudolf Ziegelbecker in Austria, published in the journal Fluoride, have you read that report?

A. No.

Q. Doctor, showing what has been marked plaintiff's exhibit 9, a paper by Dr. Alfred Taylor in 1954 in the journal Dental Digest, entitled Sodium Fluoride in the Drinking Water of Mice, have you read that report?

A. No.

Q. Doctor showing you want has been marked plaintiff's exhibit 15, a paper by Danuta Jachimczak and others of the Department of Biology in the Institute of Biostructure in the Pomeranian Medical Academy, published in volume 19 of Genetica Polonica, entitled the Effect of Fluorine and Lead Ions on the Chromosomes of Human Leukocytes in Vitro, have you read that report?

A. No.

Q. Doctor, showing you what has been marked plaintiff's exhibit 10, a paper published in the journal Genetics, volume 48, in 1963, by Herskowitz and Norton, entitled Increase Incidence of Melanotic Tumors in Two Strains of Drosophila Melanogaster Following Treatment with Sodium Fluoride, have you read that paper?

A. No.

Q. Doctor, showing you what has been marked as plaintiff's exhibit 24, a paper by John Lee, M. D., entitled Optimal Fluoridation: the Concept and its Application to Municipal Water Fluoridation, it is reprinted from the Western Journal of Medicine, have you read that report?

A. No.

Q. Doctor, showing you what has been marked plaintiff's exhibit 25, a paper by George Waldbott, M. D., Fluoridation: a Clinician's Experience, in volume 73 of the Southern Journal of Medicine, published in March 1980. Have you read that study?

A. No.

Q. Doctor, I am showing you what has been marked as plaintiff's exhibit 26, a paper done by John Emsley, published in the Journal of the American Chemical Society, entitled An Unexpectedly Strong Hydrogen Bond: Ab Initio Calculations and Spectroscopic Studies of Amide-Fluoride Systems. Have you read that paper?

A. No.

Q. Doctor, showing you what has been marked plaintiff's exhibit 12, a paper in Plant Physiology, volume 43, by Dr. Chong Chang of the United States Department of Agriculture, entitled Effect of Fluoride on Nucleotides and Ribonucleic Acid in Germinating Corn Seedling Roots. Have you read that report?

A. No.

Q. Have you read anything in the literature by Ionel Rapaport?

A. No. -- Transcript, pages 960-965 (January 20, 1980).

As is said in Texas, counsel "passed the witness." The assistant city attorney then asked.

Q. You are not an expert in fluoride, are you?

A. No.-- Transcript, page 965 (January 20, 1980).

It is a melancholy fact that most advocates of fluoridation know much less than this witness. In her community, the good doctor was considered an authority,

held in awe and respect. And civic leaders obediently followed her recommendations.

The technical particulars of defense in Pittsburgh were presented by a distinguished group of witnesses representing the National Cancer Institute and the National Academy of Sciences in the United States, and the Royal Statistical Society and the Royal College of Physicians in the Great Britain. They were all formidable, polished, and sophisticated. The greatest trial lawyer in the world would have been powerless against them if their case had been solid.

As it was, their case was built upon a report presented at a hearing in Congress on October 12, 1977, under the signature of Dr. Arthur Upton, Director of the National Cancer Institute. The report was introduced to Congress by Dr. Guy Newell, Deputy Director, who had supervised the preparation of the document.[16] And this so-called "Upton Statement" was confirmed as to methodological and mathematical correctness in a paper published by the Royal Statistical Society in England.[17] It all seemed very impressive at the time.

The Upton Statement remains to this day the official reply of the United States Public Health Service to the basic data gathered and organized under the supervision of Dr. Burk.[18] And the Upton Statement was put on trial before Judge Flaherty and Judge Farris, and in both cases was found wanting. More

important than these particular judicial condemnations are the reasons why the Upton Statement cannot stand up before any impartial tribunal.

The Upton Statement claims that the basic data used by Dr. Burk must be adjusted for age, race, and sex, and that, when properly adjusted, any difference in cancer mortality between the fluoridated and unfluoridated cities is completely wiped away. In effect, the argument was that, among 16-18 million people in twenty large central cities over 30 years, it so happens the experimental cities grew older faster precisely a the time they initiated and continued fluoridation, and this aging occurred precisely to the extent necessary to create a shocking appearance of a huge association between fluoridation and cancer. But this association was said to be an illusion deceiving the ignorant. If the population figures in the two groups are considered over thirty years, and it is assumed changes in population size are an inverse index of population aging, it is reasonable to suppose adjusted figures might display a somewhat smaller association than the crude data. But given the enormous corpus of data involved, and the great size of the numbers generated, this claim is far-fetched. And truth to tell, it was worse than far-fetched.

The Upton Statement used the so-called indirect method, an orthodox procedure for adjustment of the basic data, which Dr. Burk eventually conceded as a proper tool of adjustment, and used himself in his last published papers.

When this procedure is used, two populations are compared, usually in terms of a ratio of the observed cancer death rate (CDRo) to the "index" or "expected" cancer death rate (CDRe).

In deriving an "expected" cancer death rate, it necessary first necessary to determine the number of persons in each demographic category of each observed population for which an adjusted rate is undertaken. In working up the Upton Statement, the staff at the National Cancer Institute used forty such categories, viz., age groups 0-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, and 85+, each divided into while male, white female, nonwhite male, and nonwhite female.

The next step is selection of a "standard population," drawn from vital statistics and census figures for a certain territory in a certain year: this standard population consists of a set of known cancer death rates for each category of each population for which an adjusted rate is undertaken. The choice of such a standard population requires sound judgment. In this case the staff at the National Cancer Institute the United States in 1950, which is not unreasonable, because it represents a fair estimate of what cancer experience would be, category by category, in the absence of anything tending to make cancer deaths higher or lower than usual. It serves as a standard of normal cancer mortality.

In each population and year considered, the number of persons in each category is multiplied by the corresponding rate in the standard population. Expected cancer deaths are then added up, then divided by the total population, and reduced to a common denominator of 100,000. The resulting "expected" cancer death rate will then represent what may be anticipated for the population in view of its demographic composition under normal circumstances.

The fraction CDRo/CDRe is called a standardized mortality ratio or SMR. If based on all available and pertinent data and sound judgment, it will indicate the extent to which the observed cancer death rate is higher or lower than what should be expected under normal circumstances, given its demographic structure. It is also possible to express an adjustment in terms of, not a fraction or ratio, but a difference, CDRo – CDRe, which can be more meaningful because it helps quantify adjusted cancer mortality in terms of cancer deaths, instead of a vague percentage.

In any event, the Upton Statement set forth a purported adjustment of the basic data expressed as weighted averages. The SMRs were as follows:

	1950	1970	Change
CDRo/CDRe (+F)	1.23	1.24	+.01
CDRo/CDRe (- F)	1.15	1.17	+.02

Using these figures, the National Cancer Institute asked Congress to believe that, relative to what might be anticipated in light of the demographic structure of the control and experimental groups compared in the basic data, cancer mortality actually grew *1.0% faster in the unfluoridated cities*.

The difficulty was that the CDRo values for 1950 and 1970 in the Upton Statement were simply the rates reported for those years. In 1950, fluoridation had not begun in the experimental group. In 1970, fluoridation was being started in the control group. The data causing all the concern were the CDRo values in both groups as reported for 1953-1968. Without data for 1953-1968, nobody would have suspected a linkage between fluoridation and cancer. Having left out all available and pertinent data in their adjustment, it is not surprising that the National Cancer Institute came up with the wrong answer.

The data for 1953-1968 can and must be included in the adjustment, as can easily be done by standard statistical method. For the control cities, then the experimental cities, a line of best fit can be drawn through 1953-1968, then extended to obtain CDRo values for 1950 and 1970. These CDRo values for 1950 and 1970, it is true, will be artificial because based on assumptions inherent in linear regression, but the whole of the indirect method, including even the choice of a standard population, is based on like assumptions. And here these

CDRo values for 1950 and 1970 represent a proper, conventional, and rational expression of *all available and pertinent data*.

Moreover, the change occurring after 1950 when fluoridation was started in the experimental cities is both a change *in trends after 1950* and a change *from trends before 1950*. Hence linear regression should also be used in reference to data for 1940 through 1950 to obtain CDRo values for 1940 and 1950, both for control cities and for experimental cities.

The resulting CDRo values can then be compared with CDRe values which can be established for 1940, 1950, and 1970. In this way, all available and pertinent data can be used for a comprehensive adjustment of the basic data for age, race, and sex. When this procedure is followed -- using weighted averages for CDRo values and the United States in 1950 as the standard population, exactly like the National Cancer Institute --, striking results are obtained:

	1940	1950	1950	1970
CDRo (+F)	154.2	181.8	186.3	222.6
CDRe (+F)	128.1	146.9	146.9	174.7
CDRo/CDRe (+F)	1.204	1.238	1.268	1.274
CDRo-CDRe (+F)	26.1	34.9	39.4	47.9
CDRo (- F)	153.5	181.3	183.6	188.8
CDRe (- F)	140.3	155.5	155.5	166.0
CDRo/CDRe (-F)	1.094	1.166	1.181	1.137
CDRo-CDRe (-F)	13.2	25.8	28.1	22.8

These figures can be transformed into coefficients which reflect an association between fluoridation and cancer death rates adjusted for demographic variables, as such association developed from 1940 to 1970:

The cumulative change in terms of CDRo/CDRe = [(1.274 – 1.137) – (1.268 – 1.181)] + [(1.204 – 1.094) – (1.238 – 1.166)] = +.088, which means that, relative to what might have been anticipated in light of demographic structure of the populations compared, adjusted cancer mortality grew by *8.8% faster in the fluoridated cities*, not 1.0% less than the unfluoridated cities as the Upton Statement claimed.

The cumulative change in terms of CDRo-CDRe = [(47.9 – 22.8) – (39.4 – 28.1)] + [(26.1 –13.2) – (34.9 – 25.8) = 17.6 excess cancer deaths per 100,000 persons exposed after 15-20 years, an *increase of 9.3%* (17.6/188.8) relative to the highest cancer death rate reached in the unfluoridated cities. This adjusted excess of 17.6 per 100,000, multiplied by 130 million Americans or more drinking fluoridated water 15-20 years, works out to something on the order of 23,000 or more excess cancer deaths in the United States every year.

Consideration could be given to certain variations of technique in using the indirect method to deal with this particular case, but the analysis has gone far enough to show that, whether adjusted or observed cancer death rates are preferred,

the human casualty caused by artificial fluoridation of public water supplies is huge and tragic. It is almost indecent to quibble over the numbers.

Why did the National Cancer Institute leave out all available and pertinent data in adjusting the basic data for age, race, and sex? It is obvious that, if observed cancer death rates for 1940-1950 and 1953-1968 were to be adjusted for age, race, and sex, all data for those years should be used, otherwise the adjustment would not be of the basic data, but of something else. And linear regression is a procedure taught in elementary courses on statistics in our colleges and universities, nor is there anything which might make it inappropriate in dealing with this problem.

The reasons for this omission was brought out during proceedings before Judge Flaherty on the cross-examination of Dr. *David* Newell, principal author of the paper published by the Royal Statistical Society in support of the Upton Statement, which had been prepared at the National Cancer Institute under the supervision of Dr. *Guy* Newell:

> Q. You adjusted essentially for the years 1950 and 1970 did you not?
>
> A. 1950 and 1970, yes.
>
> Q. There are a good many years between 1950 and 1970 on the graph. Why didn't you adjust for the other years as well?
>
> A. The main and simple reason is that we were sent data for 1950 and 1970.

Q. By whom?

A. This by the Royal College of Physicians, certainly the death figures we got from there.

Q. From where?

A. The Royal College of Physicians sent them.

BY THE COURT:

Q. Did the doctor say the main reason was they sent the data?

A. That's right.

Q. For those things?

A. Yes.

THE COURT: Thank you.

A. These are the two years we had the data for.

Cross-examination by counsel continued:

Q. In other words, you weren't sent any other data?

A. No, it was I recall for the individual years. I mean we were sent this graph, but not the data upon which it was based.

Q. Why didn't you request the rest of it?

A. Well, what we were asked to investigate were the figures which were being sent by the Royal College of Physicians, they asked us to investigate those figures and we looked a little further. There is a second reason, of course. The figures between census years are not as accurate.

Q. Not what?

A. Not as accurate, because you have a census only every ten years, so you have to figure, say, from 1960 to 1970.

BY THE COURT:

Q. Excuse me. The doctor says that the intermediate figures are not as accurate?

A. That's right.

Q. As accurate as what?

A. As the 1950 and 1970 figures, because the intermediate figures are based on the national census which takes place every ten years.

Cross-examination by counsel continued:

Q. In other words, we didn't have the actual census figures for the years between '50 and '60 and between '60 and '70?

A. You had no census.

Q. So the figures between census years had to be estimated?

A. They had to be estimated.

Q. How were they estimated?

A. I think Burk and Yiamouyiannis just plotted these points on a graph and read off on a straight line. -- Transcript, May 8, 1978, pages 72-72A and 73-74.

The witness objected to linear interpolation to estimate population figures between census years in working up observed cancer death rates between census years.

The procedure can be illustrated: in all ten experimental cities there were 21,485 reported cancer deaths in 1950, and 22,678 reported cancer deaths in 1955. The aggregate population (in thousands) of the ten experimental cites was 11,886,000 in 1950, as reported by the United States census. The aggregate population (in thousands) of the ten experimental cities was 11,500,000 in 1960, as reported by the United States census. Because there was no census in 1955, the aggregate population of those cities must be estimated for that year = 11,886,000 – [(11,886,000 – 11,500,000/10) x 5] = 11,693,000. The observed cancer death rate in 1950 for those cities as a weighted average is 21,485/11,886,000 = 180.8 cancer deaths per 100,000 population. And for 1955, 22,678/11,693,000 = 193.9 cancer deaths per 100,000 population. The difference between the two CDRo values is that for 1950 the common denominator is reduced from the reported census figure, while in 1955 the common denominator is reduced from an interpolated estimate.

Dr. Newell of the Royal Statistical Society insisted that this procedure is improper, and that all intercensal cancer death rates are too unreliable and should be disregarded. This urging effectively meant that we should close our eyes to the basic data as if they did not exist, and hope for the best.[19]

But Ockham's razor obliges us to take as established, unless the contrary should appear, that, if a population grows or declines by a certain number between census years, the change occurs in approximately equal increments in each

intervening year. A short-term boom and bust in a local economy may cause irregular growth or decline in a local population. And internal migrations within even a large country like the United States may under some circumstances cause irregular growth and decline in the population of a particular city. And such irregular growth and decline can sometimes weaken the accuracy of an interpolated estimate. But the basic data, as expressed in weighted averages, pool ten major central cities situate in different regions of a great continent in each of two large groups. It is irrational to suppose such an aggregate population will grow or decline so irregularly that interpolated estimates will be materially in error.

Dr. Newell admitted that he received the data he used from the Royal College of Physicians. The more ultimate source of his data is even more interesting, as was revealed in further cross-examination before Judge Flaherty:

> Q. Doctor, you've mentioned that you used the data that were given to you by the Royal College of Physicians. Do you know where they got it?
>
> A. It came, it must have come from the National Cancer Institute of the United States.
>
> Q. So you concede that the data did come from the National Cancer Institute. Then there is no question about it?
>
> A. No question. -- Transcript, May 8, 1978, pp. 75-76.

This ultimate source is important, because, in proceedings before Judge Farris, none other than Dr. *Guy* Newell, who had supervised preparation of the Upton

Statement for the National Cancer Institute, testified against the plaintiffs, this time appearing as a Professor of Epidemiology in the Medical School at the University of Texas. On cross-examination, this Dr. Newell was questioned about the use of linear regression and linear interpolation as they applied to the basic data which the other Dr. Newell had claimed were so improper upon data gathered by Dr. Burk. And on these fine points, the whole case turned. Due to the importance of this part of the trial, the courtroom was tense and silent as questions were asked and answers were given:

> Q. If you wanted to demonstrate the true trend of the field of points, as pictured on this graph, would you draw a line from one end point to the other, or would you use a line of best fit, going through the entire field of points?
>
> A. You would do both. If you had only two points, you would draw a line from one to the other and then extrapolate. If you had a field of points, you would do a best fit regression. -- Transcript, page 1649 (January 26, 1982)
>
> Questioning continued:
>
> Q. For the field of points, would you use the best fit line?
>
> A. If the data are accurate.
>
> Q. If the data are accurate. Let me ask you another question, Doctor. Isn't it quite regular in cancer epidemiology to ascertain cancer death rates for years between census years by a procedure called linear interpolation?
>
> A. Yes. -- Transcript, page 1651 (January 26, 1982).

So the question was clearly raised whether the interpolated estimates in the basic data used by Dr. Burk were reliable enough for epidemiological use, or rendered the data inaccurate and meaningless. Then came the crucial moment of the trial:

> Q. In Vital Statistics we have the number of cancer deaths in every city and county of the United States for every year. Isn't the problem that, in order to get cancer death rates for those year between the census years, we have to work up a data base by linear interpolation?
>
> A. For the denominator.
>
> Q. For the denominator, isn't that correct?
>
> A. But there is nothing bad with that, you understand.
>
> Q. I understand.
>
> A. It is accepted procedure.
>
> Q. It is accepted procedure.
>
> A. Yes. -- Transcript, pages 1653-1654 (January 26, 1982).

Without going into all the technical motions, pleas, demurrers, and arguments, it will be well here to consider the express findings of fact entered Judge Flaherty and Judge Farris, each formally on the record and never overturned:

> Judge Flaherty began his discussion of the evidence,
>
> Over the course of five months, the court held periodic hearings, which consisted of extensive expert testimony from as far as England. At issue was the most recent time-trend study of Dr. Burk and Dr. Yiamouyiannis which compared cancer mortality in ten cities which fluoridated their water systems with ten which did not fluoridate over a

> period of twenty-eight years from 1940 to 1968. The study concluded that there was a significant increase in cancer mortality in the fluoridated cities. -- Opinion, November 16, 1978, page 6.

Judge Flaherty then defined the question before him:

> The sole question before him is whether fluoride may be a carcinogen. -- Opinion, November 16, 1978, page 6.

He then found:

> Point by point, every criticism made of the Burk-Yiamouyiannis study was met and explained by the plaintiffs. Often the point was turned around against the defendants. In short, this court was compellingly convinced of the evidence in favor of the plaintiffs. -- Opinion, November 16, 1978, page 9.

Judge Farris found upon a fair preponderance of the evidence:

> That artificial fluoridation of public water supplies, such as is contemplated by Houston City Ordinance No. 80-2530, may cause or may contribute to the cause of cancer, genetic damage, intolerant reactions, and chronic toxicity, including dental mottling, in man; that said artificial fluoridation may aggravate malnutrition and existing illnesses in man; and that the value of said artificial fluoridation is in some doubt as the reduction of tooth decay in man. -- Findings of Fact and Conclusions of Law, May 24, 1982, pages 1-2.

Now for the legal aftermath, political fallout, and historical significance:

Appellate courts in Pennsylvania and Texas did not react well to these powerful judicial findings, which is regrettable, but only a temporary setback in the unrelenting march of scientific and legal history. Sir John Elliot died in prison following his arrest for a speech he delivered in Parliament. But thirty-seven years after his death, the wrong against him was acknowledged by the House of Lords in

England, and today legislators enjoy an important immunity from arrest for what they say in the course of legislative business. We all owe a debt to Sir John Elliot. Sometimes the law is tardy, but the law cannot forever deny justice, and in those cases in which the law has spoken after much delay, the law often speaks so memorably that a monument to legal tradition is established. In due course others will be able to build upon the foundations laid in the courtrooms of Judge Flaherty and Judge Farris.

Jurisdiction to enter the findings entered on November 16, 1978, was expressly sustained on appeal in *Aitkenhead v. West View*, 397 Atl. 2d 878 (Pa. Cmwlth. 1979). Then on a rather contrived technicality of administrative law, defying traditional principles of equity jurisdiction, it was held in *Aitkenhead v. West View*, 442 Atl. 2d 364 (Pa. Cmwlth. 1982), that the court of first instance could proceed no further. By then, in any event, Judge Flaherty was sitting on the Pennsylvania Supreme Court. The findings of Judge Flaherty were left undisturbed on appeal.

As appears in *Safe Water Foundation v. Houston*, 661 S. W. 2d 190 at 192 (Tex. App. 1983), the findings of Judge Farris were expressly sustained on appeal as having been supported by sufficient testimony and exhibits to prove harm by fair preponderance of the evidence, yet for reasons impossible to reconcile with

good sense and sound law it was held that such evidence was still not enough to justify an injunction enjoining legislative power.

The Safe Water Foundation of Texas relied on an old case from a golden age. In *Houston & T. C. Ry. v. Dallas*, 84 S. W. 648 at 653-654 (Tex. 1905), it was held that, where an exercise of general legislative power rests on assumed facts, those facts may be judicially examined, and if, upon inquiry it fairly appears that the means chosen are disproportionate to the end desired, the statute or ordinance should be declared unconstitutional. Obviously, given this rule, the City of Houston could not cause cancer and other ailments in a dubious attempt at reducing tooth decay. But this old case was disregarded. Nothing but the passing of time can remedy such an irrational error.

Even so, there have been good developments which have helped redeem confidence in human nature.

Among other things, the findings of Judge Flaherty have inspired spirited debates in the British House of Lords in which the Earl of Yarborough, Lord Douglas of Barloch, and the Earl Baldwin of Bewdley have delivered grand speeches against artificial fluoridation of public water supplies.[20]

And not long after Judge Flaherty entered his findings, a suit arose of public record as Sandra Green et al. v. Rockland County Department of Health, No. 57/79 on the docket of the Supreme Court of New York in Rockland County. The

complaint pleaded that a county board of health should be enjoined from imposing artificial fluoridation of public water supplies, because fluoride so delivered to the general public is "tumorogenic, mutagenic, teratogenic, and carcinogenic, causing or contributing to widespread cancer in humans," etc. A motion to dismiss was filed and argued. On April 30, 1980, Justice Robert Stolarick noted the judicial findings in Pittsburgh, and held that, if the same facts could be proved again in his court by fair preponderance of the evidence, the proposed imposition of fluoridation would be unconstitutional under the established standard of *Paduano v. New York.* The motion to dismiss was, therefore, denied. Thereupon county health authorities reflected upon their determination to impose fluoridation, and repealed their regulation, whereupon the cause became moot.

The decision of Justice Stolarick is important because it shows that, given scientific evidence already in existence in a form which has been presented before and can be presented again, it should be possible under established law in the United States, and probably also in Canada, to win injunctions enjoining artificial fluoridation of public water supplies.

In November 1979, an interdisciplinary committee led by Dr. Benoît Bundock returned a comprehensive report on artificial fluoridation of public water supplies, in which they advised the Environment Minister for the Province of Quebec in Canada that the findings of Judge Flaherty were scientifically correct.[21]

Again, in April 1980, Dr. Brian Dementi returned an official report on artificial fluoridation of public water supplies to the Virginia Department of Health, in which he advised the Commonwealth that the findings of Judge Flaherty were scientifically correct.[22]

Finally, on June 29, 2000, the professional union at the national headquarters of the United States Environmental Protection Agency appeared through its senior vice president before a subcommittee of the United States Senate, and advised the government of the United States that the judicial findings Judge Flaherty and Judge Farris were scientifically correct. A copy of this remarkable statement is attached as an appendix to this chapter. It speaks to the future.

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1 - Two comprehensive law review articles covering reported judicial decisions on artificial fluoridation of public water supplies are by Douglas Balog, *Fluoridation of Public Water Systems: Valid Exercise of State Police Power or Constitutional Violation?*, 14 Pace Envtl L. Rev. 645 (Pace University 1997), and J. R. Graham and Pierre Morin, *Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies*, 14 Jour. Land Use & Envtl. L. 195 (Florida State University 1999). In the latter article, the trials before and findings of three American judges are discussed in some detail, including ample context in legal history.

2 - *Commentaries on the Laws of England*, Edward Christian, London, 1765, Bk. I, p. 134.

3 - *Bigalow v. RKO Radio Pictures Inc.,* 327 U. S. 252 at 264-265 (1946).

4 - *Julian Petroleum Corp. v. Courtney Petroleum Co*., 22 F. 2d 360 at 362 (9 Cir. 1927).

5 - Ruth Roy Harris, *Dental Science in a New Age: a History of the National Institute of Dental Research*, Montrose Press, Rockville, Md., 1989, pp. 112 and 396.

6 - These many studies have been discussed in Chapter IV. But among some of the most outstanding examples of work confirmatory of Dr. Taylor's results are the contributions of Dr. John Emsley and others at the University of London, reported in their article *An Unexpectedly Strong Hydrogen Bond: Ab Initio Calculations and Spectrospopic Studies of Amide-Fluoride systems*, 103 Jour. Am. Chem. Soc. 24 (1981), and the work of Dr. Takeki Tsitsui and others at Nippon Dental University, reported in their article, *Sodium Fluoride-Induced Morphological and Neoplastic Transformation, Chromosome Aberrations, Sister Chromatid Exchanges, and Unscheduled DNA Synthesis in Cultured Syrian Hamster Embryo Cells*, 44 Cancer Res. 938 (1984). Important papers on the related phenomenon of mutagenesis induced by fluoride are Aly Mohamed and Mary Chandler, *Cytological Effects of Sodium Fluoride on Mice*, 15 Fluoride 110 (1982), and Takeki Tsitsui and others, *Induction of Unscheduled DNA Synthesis in Cultured Oral Keratinocytes by Sodium Fluoride*, 140 Mutation Res. 43 (1984). Much inferior in quality is a study authorized by the government of the United States: John Bucher and others, *Results and Conclusions of the National Toxicology Program's Rodent Carcinogenity Studies with Sodium Fluoride*, 48 Int. Jour. Cancer 733 (199l). It appears almost as if the study was designed to show no carcinogenic potential of fluoride, yet it showed a dose-dependent, statistically significant trend of osteosarcomas of bone in male rats, which was actually confirmed by independent epidemiological studies: Perry D. Cohn, *A Brief Report on the Association of Drinking Water Fluoridation and the Incidence of Osteosarcoma Among Young Males*, New Jersey Department of Health, 1992, and John Yiamouyiannis, *Fluoridation and Cancer: the Biology and Epidemiology of Bone and Oral Cancer Related to Fluoridation*, 26 Fluoride 83 (1993). Dr. Bucher and his colleagues conceded the findings in eleven published studies on the mutagenic potential of fluoride, recommended further work on fluoride and osteosarcomas, and noted the importance of revisiting epidemiological surveys on fluoridation and cancer. The official reaction at the United States Public Health Service was to stop further investigation.

7 - The epidemiological work of Dr. Burk in the form which he considered most satisfactory at the time of his death, and related scientific particulars, was comprehensively explained by John Remington Graham in a deposition given by him on December 8, 2003. The testimony was given under oath in reference to a full battery of exhibits marked and introduced. The deposition, including testimony and exhibits, is a matter of public record in Shirley Macy et al. v. City of Escondido et al., No. GIN 015280 on the docket of the Superior Court of California in San Diego County.

8 - See, e. g., Sir Austin Bradford-Hill, *Short Text on Medical Statistics*, Hodder & Stoughton, London, 1977, especially pp. 161-198 on the measurement of correlation, linear regression, calculation and statistical significance of the correlation coefficient, the direct and indirect methods for standardization of death rates, etc.

9 - Los Angeles, Boston, New Orleans, Seattle, Cincinnati, Atlanta, Kansas City (Missouri), Columbus (Ohio.), Newark, and Portland.

10 - Chicago, Philadelphia, Baltimore, Cleveland, Washington D. C., Milwaukee, St. Louis, San Francisco, Pittsburgh, and Buffalo.

11 - Starting with Atlanta and Seattle in 1969 and other control cities thereafter.

12 - With the exception of Boston for the years 1953-1954 and 1956-1958. In those years, cancer deaths for were estimated by linear interpolation. The estimates are certainly very close to accurate, and it was believed better to include Boston with estimates for these years, than to exclude the city altogether, lest the association between fluoridation and cancer be exaggerated. The objective of Dr. Burk and his co-workers was not to overstate the case, but to supply the facts as accurately and fairly as possible.

13 - The principles here discussed are drawn from the aphorisms in the first book of the *Novum Organum* by Sir Francis Bacon, and the rules of reason set forth at the beginning of the third book of the *Philosophiae Naturalis Principia Mathematica* by Sir Isaac Newton.

14 - As appears in *Hearings before a Subcommittee of a Committee on Appropriations, House of Representatives, 94th Congress, 2nd Session, Labor and HEW Appropriations, Part 7,* U. S. Government Printing Office, Washington D. C., 1976, pp. 1064-1065.

15 - In proceedings before Judge Farris, Dr. Burk gave extended testimony on adjustments for age, race, and sex, including reference to both direct and indirect methods. His testimony on demographic adjustments appears in the trial transcript on pages 48-105 (January 13-14, 1982). His active attention to the question of demographic adjustments is reflected in a series of articles published in two sets. The first set, representing his earlier views, was published as Dean Burk and John Yiamouyiannis, *Fluoridation of Public Water Supplies and Cancer Death Rates*, 35 Fed. Proc. Am. Soc. Biol. Chem. 1707 (1976), and *Fluoridation and Cancer: Age-Dependence of Cancer Mortality Related to Artificial Fluoridation*, 10 Fluoride 123 (1977). The second set, representing his matured views, was published as Dean Burk and J. R. Graham, *Lord Jauncey and Justice Flaherty: Opposing Views on the Fluoridation-Cancer Link*, 17 Fluoride 63 (1984), and Dean Burk, J. R. Graham, and Pierre Morin, *A Current Restatement and Continuing Reappraisal Concerning Demographic Variables in American Time-Trend Studies on Water Fluoridation and Human Cancer*, 61 Proc. Pa. Acad. Sci. 138 (1988).

16 - Reprinted in *Hearings before a Subcommittee of the Committee of Government Operations, House of Representatives, 95th Congress, lst Session, Government Operations and Human Resources, Part 2, Fluoridation of Public Water Supplies, September 21 and October 12, 1977*, U. S. Government Printing Office, Washington D. C., 1977, pp. 104-120.

17 - Reprinted ibid., pp. 219-230. This paper was by Drs. Peter Oldham and Davis Newell, and published by the Royal Statistical Society as *Fluoridation of Water Supplies and Cancer -- A Possible Association?*, 26 Applied Statistics 125 (1977).

18 -The prepared statements of Dr. Yiamouyiannis, controverting the Upton Statement on September 21 and October 12, 1977, are reprinted op cit. *Hearings, 95th Congress*, pp. 3-17 and 310-318.

19 - Dr. Newell of RSS actually helped convince Lord Jauncey, a British judge, to adopt this fabulous proposition, as appears in the opinion in causa Catherine McColl v. Strathclyde Regional Council, handed down in the High Court of Sessions in Edbinburgh, June 1983, pp. 148-154. But see the commentary of Dr. Burk et al. in op. cit. *Lord Jauncey and Justice Flaherty*, pp. 68-69.

20 - *Hansard's Parliamentary Debates*, House of Lords, November 15, 1979, pp. 1446-1450 (Yarborough), and 1461-1468 (Barloch); December 16, 1998, pp. 1394-1399 and 1427-1429 (Bewdley).

21 - Benoît Bundock, et al., *Les fluorures, la fluoruration, et la qualité de l'environnement*, Ministère de l'Environnement, Gouvernement du Québec, Ste-Foy, Novembre 1979, pp. 1-2, 103-104, 107-108, 116-117, 197-200.

22 - Brian Dimenti, *Fluoride in Drinking Water*, Department of Health, Commonwealth of Virginia, Richmond, April 1980, pp. 29-34.

Tab 72

Improving Women's Health in Washington: Caring for Women Suffering Pregnancy Loss

Early pregnancy loss is a common occurrence in a woman's reproductive life; an estimated one in four women will experience a miscarriage of pregnancy.[1] There are 126,910 women who become pregnant in Washington each year.[2] Fifteen percent will experience miscarriage.[3] When women lose their pregnancies, they should be given the highest quality of health care. The most efficient way to improve health is to target improvements in residency training, where you can reach large numbers of both patients as well as doctors in training.

Traditionally miscarriage has been treated in the operating room, often under general anesthesia; in many cases this incurs unnecessary cost and time for the physician, hospital, and patient. Using expensive space in the operating room, combined with the need to employ providers to deliver anesthesia, adds time and cost to a simple medical procedure. Current medical research indicates that treating every patient's early pregnancy loss in the operating room is not always the most appropriate treatment plan.[4]

Moving the treatment of miscarriage out of the operating room and into a procedure room or office-based practice is often more suited to the patient, physician and hospital. By offering treatment for early pregnancy loss outside of the operating room, hospitals and physicians are able to adopt a model that emphasizes patient-centered care, better efficiency, and substantial resource and cost savings.[5]

The Benefits to Patients, Residents, Hospitals, and Health Care Payers

Providing the resources to enable hospitals and their residency programs to move miscarriage treatment outside of the operating room has many benefits to doctors, patients, the hospital, and health care payers.

- *Patients*: There are multiple factors that determine a patient's preferences when in need of miscarriage treatment; traditional treatment in the operating room assumes that a woman's main priority is to be unconscious. Current data show that this assumption is not true. The main objectives of many women are to remain conscious and retain the most privacy with minimal waiting time. For these women, office-based procedures enable them to have more of their needs addressed.
- *Residents and Attending Physicians*: Physicians in training want to learn procedures that will help them treat their patients well. Teaching residents the skills they will need to treat patients experiencing miscarriage in their private office provides them with the opportunity to provide timely and efficient care
- *Hospitals*: Moving the treatment of miscarriage out of the operating room makes the operating rooms and anesthesiologists available for other procedures that are greater emergencies and result in post-operative admission, both of which are more lucrative for the hospital.
- *All Health Care Payers*: By making it possible for much of the treatment of miscarriage to be managed outside of the operating room, health care payers will experience savings on miscarriage expenditures. Moving the procedure out of the operating room also encourages an efficient, patient-centered model for healthcare provision. For example, office-based vacuum aspiration is 40% less expensive than procedures performed in the operating room.

- **How to Achieve a More Patient-Centered and Cost Efficient Model of Care**

In order for miscarriage treatment to be moved out of the operating room, residency programs need to integrate office-based procedures into their training and ensure educational opportunities for their residents on healthy pregnancy. The Governor is poised to quickly effect change in the area of miscarriage treatment and education, demonstrating a commitment to women's health and health care improvement and efficiency.

Initiative Launch Meeting:

To ensure commitment from residency programs across Washington, we propose that the Department of Health sponsor an initiative launch meeting that convenes national experts on the topic of pregnancy loss together with the leaders in Washington graduate medical education. This meeting will present a forum to discuss the benefits of moving to an office-based model for miscarriage treatment to residency Program Directors and Department Chairs.

Seed Grants:

The initiative to encourage residency programs to institute change in their training on miscarriage treatment will take financial commitment from the State. We estimate this initiative will provide technical assistance to thirteen programs over three years. Based on our estimates, the total cost of this initiative would be $2.8 million over three years. The $100,000 grants to each residency program would cover the cost of training and equipment. We will identify a public residency program that has already moved a large portion of their treatment of miscarriage out of the operating room and can serve as a model for the proposed service-delivery changes. This program will receive a sizable portion of the state grant to be the administrator of the initiative, responsible for coordinating a request for proposal process to all of Washington residency programs in Family Medicine and distributing the money to those programs that participate. Funding will be provided for expert assistance in the implementation of the initiative and for an external monitor to record progress over the three-year implementation period.

Conclusion

Healthy pregnancies can be an indicator of a population's overall health status. This initiative, using $2.8 million over three years, presents a comprehensive model to ensure residency training in order to impact pregnancies across Washington.

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[1] Creinin MD, Schwartz JL, Guido RS, et al. *Early pregnancy failure—current management concepts*. Obstet Gynecol Surv 2001; 56(2): 105-113.
[2] Guttmacher Institute. *Contraception Counts*. http://guttmacher.org/pubs/state_data/states/washington.html (August 17, 2006)
[3] Guttmacher Institute.
[4] Geyman JP, Oliver LM, Sullivan SD. *Expectant, medical, or surgical treatment of spontaneous abortion in the first trimester of pregnancy?* J Am Board Fam Pract 12(1): 55-64, 1999.
[5] Dalton VK, Harris L, Weisman CS, Guire K, Castleman L, Lebovic, *Patient Preferences, Satisfaction, and Resource Use in Office Evacuation of Early Pregnancy Failure.* Obstet Gynecol 108 (1): 103-110, 2006.

Tab 73

TO: Governor's Blue Ribbon Commission on Healthcare Costs and Access

Date: Tuesday, November 14, 2006 © November 14, 2006
From: Gerene D. Schmidt, Pres/Founder
SB&E, Inc. (Science, Business & Education)
Certified, woman-owned business by OMWBE, No. W2F7519449

Title: "How to Get Patients to Put Skin in the Game"
Subtitle: Method and Process for Engaging Patients to Take Responsibility to Access Available Healthcare Resources and Use Appropriately

SUMMARY

Some of the discussion around the table at the Governor's Blue Ribbon Cmsn on October 26, 2006, viewed on WTV, was about how to get patients involved in using available healthcare resources and use them appropriately.

SB&E appreciates the opportunity to submit this proposal to explore the depth of what underlies the notion that there is a way to "get patients to put skin in the game."

A recent five year study, conducted by an Associate Professor at the University of Washington in the Department of Psychiatry and Behavioral Science, focused on the different styles patients demonstrated in interacting with the healthcare delivery system. The findings revealed that some people have more difficulty than others in attaching to and cooperating with healthcare professionals. In other words, an individual's history of attaching to others in their environment over a lifetime influences how they also attach and cooperate with the healthcare team.

SB&E is installing a pilot system for diabetes types 1 and 2 at Evanston Northwestern Healthcare in Chicago in the Patient Education Center. The go live date is scheduled for the week of January 15th, 2007.

PROPOSED SOLUTION

SB&E offers a solution to working with patients with attachment difficulties. Supporting the patient in the home through an automated telephone-based, voice-interactive reporting, tracking and monitoring system holds promise to address the issue of getting the patient to put skin in the game and access available healthcare.

Rationale:
Many studies have been conducted on patients' perception of control and the relationship to taking responsibility for one's personal health. Findings were that unless there is a perception of control, responsibility doesn't happen.

Goal

The goal of SB&E's solution is to support the patient, in the home, to gain confidence and self-understanding as the underpinning for a perception of control. This perception, according to the studies, is accompanied by taking responsibility for problem identification and strategies for problem solving of personal health issues.

SB&E's home-based patient information management service is intended to support patients with chronic conditions and their healthcare team in real-time via automated telephone communication and information exchange.

Each patient has a personalized history file that asks questions pertinent to their particular condition, i.e., diabetes, to which the patients respond in a conversational style. This is accomplished by the advanced speech recognition technologies integrated with SB&E's diabetes software. The technology affords a dynamic, interactive conversation with the patient albeit automated.

If the patient reports information or symptoms that indicate destabilization, a change in progress or potential for an adverse event, the healthcare team is alerted immediately. The SB&E system sends a flag alert that can be accessed through the computer.

Value of Telephone Communication for Patients with Attachment Problems

Studies on the use of telephone systems, conducted over the nineties, demonstrated increased truth telling and patient confidence as opposed to sitting with a healthcare professional in a clinic setting. Patients were more open and communicative given the privacy of the telephone.

SB&E proposes a pilot to test its patient reporting, tracking and monitoring system, a low-cost home-based patient information management service, as a bridge and gateway to patients who are difficult to reach with the goal of obviating attachment issues and gaining cooperation with the healthcare team. This may be a solution to patients putting skin in the game and taking responsibility to access available health care resources and use them appropriately.

SB&E History:
A product prototype test was conducted with 1515 patients at The Heart Institute of Spokane several years ago. An additional prototype test for home health assessment was conducted with 20 home health nurses at Adventist Health System Sunbelt, Orlando, FL. A 41-page report of the data demonstrating accuracy, performance and patient acceptance is available.