Presented to the

National Toxicology Program (NTP)

A Response to the Board of Scientific Counselors (BSC) submission by
American Association for Dental Oral and Craniofacial Research (AADOCR)
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https://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2023/may/publiccomm/fox-vieira20230428_bsc_508.pdf

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by

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Introduction. I am a clinical dentist who treats cosmetic and functional dental fluorosis. For about 25 years I promoted fluoride ingestion and when I read the research for my self, I stopped promoting fluoride ingestion due to over exposure and lack of evidence of efficacy, safety, dosage, FDA CDER NDA, label, prescribing doctor, or freedom of choice.

The AADOCR claims to be the *"leading professional community for multidisciplinary scientists who advance dental, oral, and craniofacial research."[1]*

However, the AADOCR has had over 70 years to provide, call for, and certainly evaluate research on the efficacy and safety of dental products, such as the ingestion of fluoride with intent to mitigate dental caries. Instead, the AADOCR has failed to provide research or an FDA CDER NDA (US Food and Drug Administration Center for Drug Evaluation and Research New Drug Application) and expects the NTP to do the research and research evaluation at tax payer expense on one of several risks of excess fluoride exposure.

The AADOCR calls for a clear statement from the NTP. We all agree, clarity is important. For example, the FDA has had a warning on fluoride toothpaste for decades, "DO NOT SWALLOW," [1] referring to a quarter milligram of fluoride and the AADOCR has failed to understand the FDA warning. How much clearer could the FDA be? What about "DO NOT SWALLOW" lacks clarity?

Science is dynamic and should always grow and will always be "incomplete" and demand greater "clarity." However, before a drug (substance used with intent to prevent disease) is marketed, adequate research must be provided to the FDA CDER to gain NDA. Until the AADOCR provides quality studies and FDA CDER NDA, the NTP must discount AADOCR as without objectivity and promoting/protecting an unapproved drug.

1. AADOCR wants Clarity but Lacks Clarity.

"AADOCR supports NTP providing clear statements that define that the monograph cannot be used to draw any conclusions regarding low fluoride exposure concentrations, including those typically associated with drinking water fluoridation." [2]

a. **Concentration is not dosage.** Concentration is a good term when treating water but not when treating people.

b. **Not everyone drinks the same amount of water** and water is not the only source of fluoride. Therefore, AADOCR's term “exposure concentrations" instead of "dosage" or "total fluoride exposure" is misleading and lacks clarity.

c. Nor does the AADOCR add clarity to the word "typically." **What percentage of the population is "typical"?** Is the "statistical mean "typical"? Should more than the statistical mean not be protected from authority controlled over exposure? The EPA does not include the 10% (+20,000,000 people in the USA) drinking the most amount of water. Nor does EPA include infants or fetus, and about a third under 6 years of age in their dose response analysis or relative source contribution. [3] What percentage of the population does AADOCR consider typical and why should not everyone be protected and given freedom of choice?

d. **How much fluoride ingested is needed to be effective?** The first step when evaluating a drug, substance used with the intent to prevent or cure disease, is with efficacy. [4]

An effective dose or dosage has not been defined. Instead, concentration of 1 mg/L in water was claimed necessary, now 0.7 mg/L is presumed to be effective. However, research on the effectiveness at the lower concentration is seriously incomplete.

d. **The AADOCR does not define the term "low fluoride exposure."** Mother's milk is ideal for infants and could be considered "low fluoride exposure," ranging from not detected to about 0.01 mg/L depending on mother's exposure. **Low fluoride exposure for an infant would be 0.00 mg/L and “high fluoride exposure” would be about 0.01 mg/L . . . for infants.** Formula made with fluoridated water at 0.7 mg/L far exceeds mother’s milk which is in keeping with the FDA CDER’s guidance, “do not swallow.” The AADOCR lacks clarity.

d. **The AADOCR requests the NTP be more clear.** The argument of "clarity" can go on forever, delay, delay, delay. Meanwhile the public is harmed, certainly with dental fluorosis. If the AADOCR finds the FDA statement “DO NOT SWALLOW” hard to understand, NTP will never be able to be clear enough with the science for the AADOCR to understand unless the NTP evades the empirical evidence.

2. AADOCR claims, *"There is a large body of research – over 7 decades' worth – pointing to the safety and effectiveness of fluoride to prevent tooth decay."* [2]

a. **No. The FDA CDER notified fluoride manufacturers that the evidence of fluoride ingestion efficacy was incomplete. [5]** The AADOCR provides endorsements, and lower quality research, to support their claim of "effective" and does not have or provide safety studies at the as yet undetermined effective dosage.

b. **The AADOCR lacks clarity.** Is the AADOCR referring to topical fluoride which does have FDA approval and does show effectiveness with a label warning, "Do Not Swallow," referring to a quarter milligram. Or is the AADOCR referring to systemic fluoride where about 2 out of 3 children show signs of harm [6] from over exposure, [7] lacks FDA CDER NDA, lacks freedom of choice, lacks Randomized Controlled Trials on efficacy, lacks evidence of safety and lacks a clear mechanism of action?

c. As researchers, the AADOCR must be aware that **first "efficacy" must be determined at a specific dosage with randomized controlled trials.** Once "effective" is determined at a specific dosage only then can "safety" be determined with a label and the product taken to the FDA CDER for an NDA.

d. The AADOCR has not provided the **mechanistic studies** on how fluoride gets from the blood, through the tooth to where the caries are developing. The enamel and dentin are highly resistant to the flow of fluoride. Research has not shown saliva with extremely low fluoride concentrations, 50 to 100 fold less than food, will help prevent dental caries.

e. The AADOCR uses the word, **"pointing."** If all the believers are "pointing" at something, pretty soon most will start seeing what is being pointed at regardless of reality. Pointing is not empirical evidence. The AADOCR lacks clarity.

3. The AADOCR suggests, *"fluoridated water is a simple, equitable, and effective strategy that can help millions of people.*"

In support, the AADOCR references a position paper by like minded believers and the CDC which has no authority to approve the safety or efficacy of any substance and has not published quality RCT studies on the equity, efficacy, dosage or safety of fluoride ingestion. Failing to gain FDA CDER NDA promoters circumvented the designated authorities and went to the CDC for an endorsement.

a. A Cochrane Database Systematic Review, 2015, [8] without RCTs, made a rather unusual exception and used prospective observational studies to evaluate the fluoride drug. The study reported benefit for children. More than 2 out of 3 studies were historical, not at current fluoridation concentrations and historical at 1 mg/L prior to 1975, finding *"There is insufficient information to determine whether initiation of a water fluoridation programme results in a change in disparities in caries across socioeconomic status (SES) levels. There is insufficient information to determine the effect of stopping water fluoridation programmes on caries levels. No studies that aimed to determine the effectiveness of water fluoridation for preventing caries in adults met the review's inclusion criteria. . . Over 97% of the studies were at high risk of bias and there was substantial between-study variation."*

The Cochrane authors concluded: *"There is very little contemporary evidence, meeting the review's inclusion criteria, that has evaluated the effectiveness of water fluoridation for the prevention of caries. . . Our confidence in the size of the effect estimates is limited by the observational nature of the study designs, the high risk of bias within the studies and, importantly, the applicability of the evidence to current lifestyles. . . . There is insufficient evidence to determine whether water fluoridation results in a change in disparities in caries levels across SES. There is a significant association between dental fluorosis (of aesthetic concern for all levels of dental fluorosis) and fluoride level. The evidence is limited due to high risk of bias within the studies and substantial between-study variation."*

The Cochrane authors did not consider any adverse health effect other than dental fluorosis with a 12% chance people may have a concern about how their teeth look. No functional risks were considered. "*There is a lack of evidence for other postulated harms. . . Opponents have raised concerns about ethical issues and its potential harms* (Cheng 2007)*"*

b. The Cochrane review has been criticized for being too restrictive, suggesting Cochrane reviews primarily evaluate RCTs *"for new drugs and clinical interventions for use with individuals, not public health initiatives targeted at populations." [9]*

Indeed, fluoride is a drug, unapproved, dispensed to millions without individual consent, without a known effective dosage, without quality safety studies, and without a single government agency accepting jurisdiction.

However, public health interventions should be even **more** protective than clinical interventions. A clinician making a mistake can harm that individual patient. An authority controlled and administered public health initiative can harm millions. Getting a public health initiative correct should have stronger evidence of safety.

The AADOCR is now seeking protection of fluoridation by requesting further delay and clarity. That is precisely the job AADOCR has failed to do decades ago. The AADOCR references are mostly cherry picked “endorsements" by like minded believers and lack the high quality efficacy and safety studies the AADOCR expects of the NTP.

c. I treat dental fluorosis, both cosmetic and functional, and fluoride exposure damaging teeth costs more than the caries allegedly mitigated.

The US Environmental Protection Agency funded a study [11] (1987) evaluated the cost of treating dental fluorosis, reporting:

> *“A mean cost for all consultants shows that the estimated costs for restoring function exceeds the cosmetic costs in all categories except the minimum later costs. This represents a new finding and raises an issue that has been overlooked or ignored by previous investigators and the profession. i.e . that repair of the cosmetic discoloration was the only cost involved; or that repair of dysfunction was never considered to be a problem.”*

All consultants do not appear to have been cosmetic dentists nor did they estimate lifetime costs. “Damage is the cost, not the repair.”

Another study [10] of adolescents at 12 years of age reported 52% with dental fluorosis at a fluoride concentration in water of 0.7 mg/L. Of the subjects, 95% wished to remove the spots. In contrast to the subjects reported concern, only 14.5% had professionally diagnosed mild, moderate or severe dental fluorosis. Patients are more concerned with cosmetics than dentists. Dentists tend to treat the functional damage but seldom diagnose the etiology.

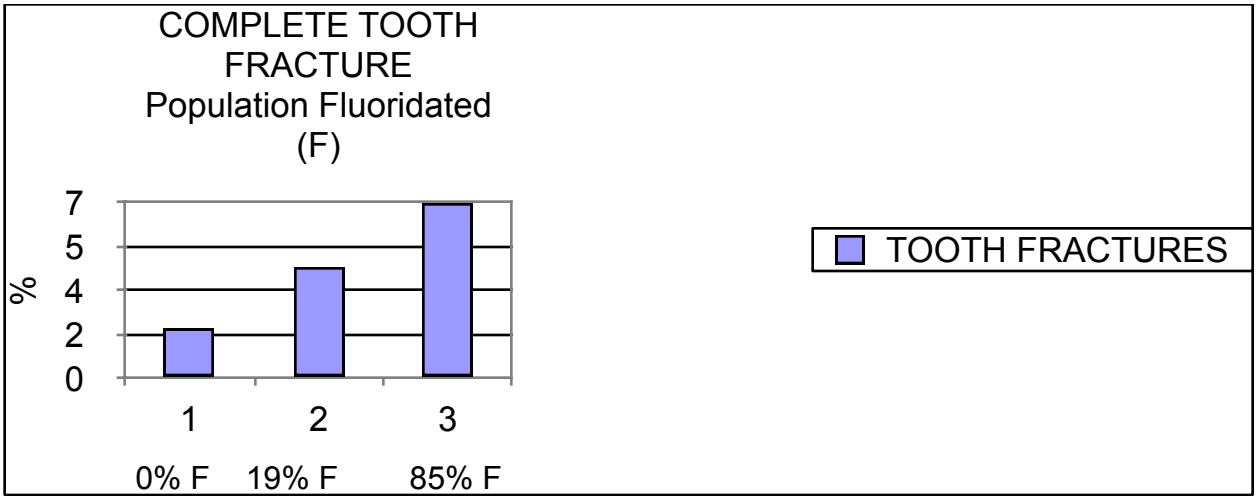
The AADOCR has failed to consider research that fluoride is not safe for teeth, dismissing fluorosis as "cosmetic." And when is cosmetic damage not damage? If someone scratched your car, the scratch is damage. Dentists placing black mercury fillings have not always been the best at determining cosmetic damage. Lack of evidence is not proof of safety.

Seriously, if the AADOCR dismisses fluorosis as only cosmetic and not damage; clear, visible, undisputed effect of excess fluoride exposure, reported by NHANES in about 2 out of 3 children, then the AADOCR can't be trusted to be objective for a non "dental" effect, not visible, not treated in the dental office, of excess fluoride.

When I first started looking at possible adverse effects of fluoride I understood that fluoride made teeth harder, which might make them more brittle. Searching in Epubmed for office visits due to complete cusp fractures, I found 3 historical studies [13] in three different communities by two authors. Note: the following evidence is not intended to be "proof." These graphs are my double checking the NRC 2006 report for the EPA and those opposed to fluoridation. I provide them as simple evidence easy for the AADOCR to find so they could call for more research.

As the percentage of the population fluoridated increases, the percentage of office visits for complete cusp fractures increases. More research is needed.

The photos are an illustration of a complete cusp fracture. Research needs to be done to see if and how much fluoride increases complete cusp fractures.



4. The AADOCR claims fluoridation is cost effective, *"The Oral Health in America: Advances and Challenges report affirms that community water fluoridation (CWF) is "a cost-effective community-based mode of prevention, benefits everyone, including children in low-income families."* The reference is for children younger than 5 years of age, not "everyone."

Fluoridation is not cost-effective [12] when all costs of operations and the costs to treat dental fluorosis, both cosmetic and functional, are included. If any risk of IQ is added, excess fluoride exposure is one of public health's greatest blunders.

The AADOCR states, *"As recent as December 2021, the United States Preventative Services Task Force (USPSTF) continued to recommend that primary care clinicians prescribe*

oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride."

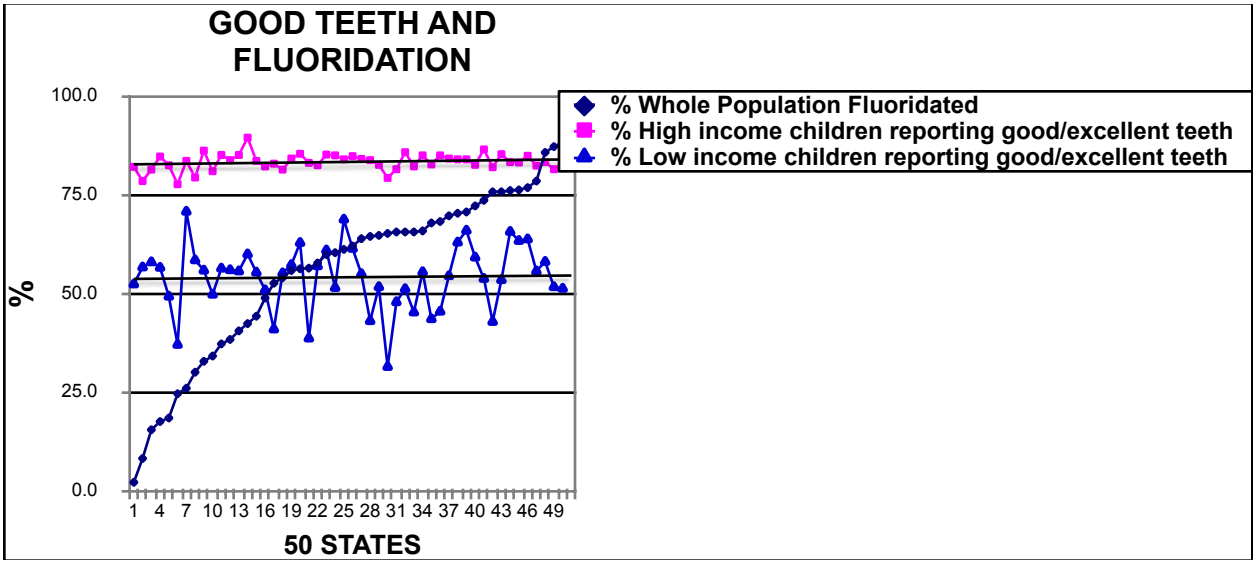
a. What about **infants** on formula made with fluoridated water? Are infants to be ignored?

b. The term **"Deficient"** is not clear, especially for infants and pregnant women. Dental caries is not a fluoride "deficiency" disease.

c. Efficacy must be determined first, then dosage, then safety with label. Simply claiming "deficient" is not scientific and makes no sense. For example, is the child swallowing fluoride toothpaste?

d. Enough evidence exists when considering all streams of evidence, to determine fluoride is a known developmental neurotoxic and is lethal. The question is at what dosage? To date, the evidence provides a presumed confidence of developmental neurotoxicity with no obvious threshold. Until further research is provided that fluoride ingestion is indeed effective at an approved dosage, safe, label, and FDA CDER NDA approved, authority administered fluoride exposure should be suspended.

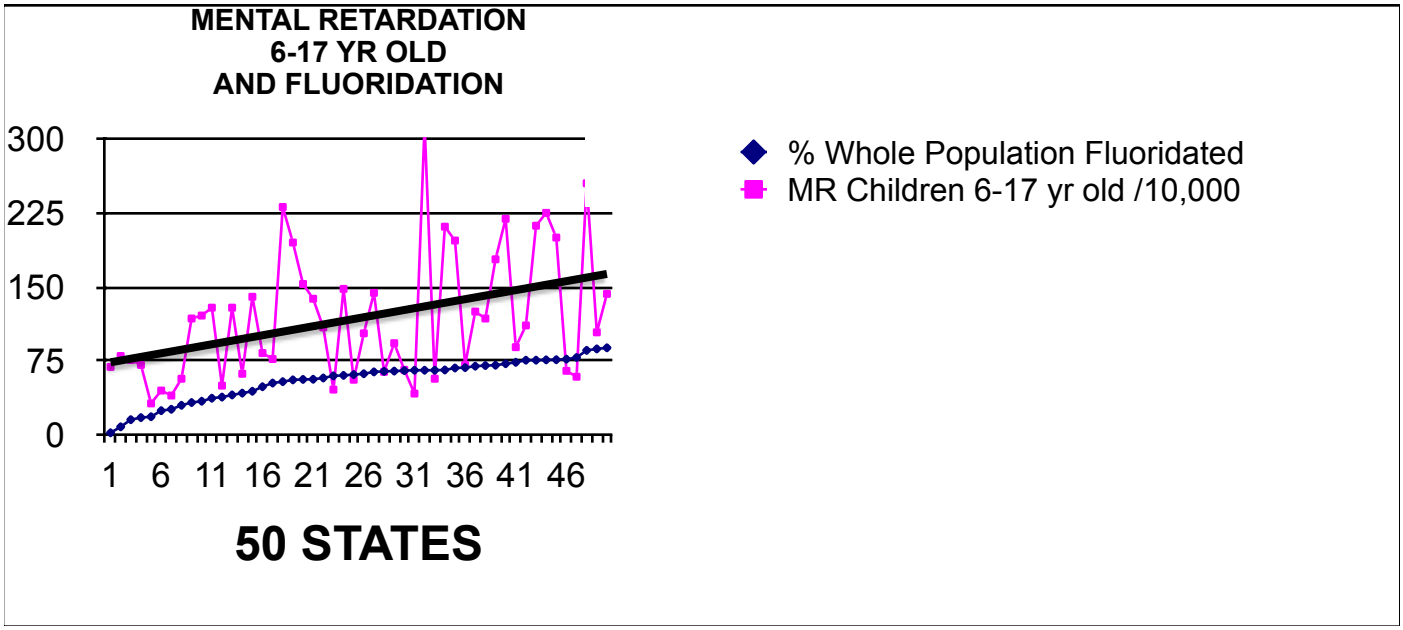
AADOCR's hesitation to support the NTP original recommendation of fluoride as a "presumed" developmental neurotoxin is in part because they have not done their homework. Almost two decades ago, I wanted to see if there was any evidence linking fluoride to developmental neurotoxicity in the USA. I ranked the 50 USA states on their whole population fluoridated. and plotted the parental reported "good teeth."



No common cause is apparent. I had been promoting fluoridation yet there did not appear to be a clear benefit and yet the poor did not have as good teeth. It struck me that I had been comparing the poor vs the rich patients in my practice and giving fluoridation credit for the difference. Actually, I was comparing the rich in the city with the poor living in the woods.

Some have suggested perhaps parental reported good teeth is not accurate. Maybe. However, I would usually ask parents, "do you have any concerns about your child?" Parents would either answer, "no, but that is why I'm here to make sure there are no problems." Or parents would answer, "yes, my child has problems, can you help?" Parents were usually correct for the overall oral health.

Then I plotted the reported percentage of mentally retarded in each state. [14] A more than doubling of mentally retarded with more fluoridation. That would represent close to half a SD or maybe 5 IQ point difference. Another doubt in fluoridation's safety.



And what about confounding factors? Income and poverty do not show a common cause when ranking the states. Eduction dose show a slight decrease with fluoridation. However, CHD, diabetes, and obesity do have a significant common cause with fluoridation. Research is needed.

The AADOCR raises questions of confidence of NTP's lack of support for fluoridation; however, the AADOCR has selectively picked evidence on one side of the controversy.

The NTP's original monograph determining fluoride exposure is a "presumed" developmental neurotoxin is correct.

Sincerely,
Bill Osmunson DDS MPH

References

[1] See all fluoridated toothpaste labels. Variable wording permitted.

[2] American Association for Dental Oral and Craniofacial Research (AADOCR) public comment presented to Christopher Fox DMD, DMSc CEO; Alexandre Vieira DDS, MS. PHD President
https://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2023/may/publiccomm/foxvieira20230428_bsc_508.pdf

[3] https://www.epa.gov/sdwa/fluoride-risk-assessment-and-relative-source-contribution

[4] www.fda.gov

[5] Letter to 35 Drug Companies as published in Drug Therapy 1975. *". . .there is no substantial evidence of drug effectiveness as prescribed, recommended or suggested in its labeling. . . marketing is in violation of the new drug provisions of the Federal Food, Drug, and Cosmetic Act; they have, therefore, requested that marketing of these products be discontinued."*

[6] Dong H, Yang X, Zhang S, Wang X, Guo C, Zhang X, Ma J, Niu P, Chen T. Associations of low level of fluoride exposure with dental fluorosis among U.S. children and adolescents, NHANES 2015-2016. Ecotoxicol Environ Saf. 2021 Sep 15;221:112439. doi: 10.1016/j.ecoenv.2021.112439. Epub 2021 Jun 22. PMID: 34166938. [PubMed]

[7] Neurath C, Tooth Trends for 12 Year Olds in Nonfluoridated and Fluoridated Countries. Fluoride 38(4)324-325. November 2005. Fluoride https://www.fluoridealert.org/wp-content/uploads/neurath-2005.pdf

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[9] Rugg-Gunn, A., Spencer, A., Whelton, H. *et al.* Critique of the review of 'Water fluoridation for the prevention of dental caries' published by the Cochrane Collaboration in 2015. *Br Dent J* 220, 335–340 (2016). https://doi.org/10.1038/sj.bdj.2016.257

[10] Moimaz SA, Saliba O, Marques LB, Garbin CA, Saliba NA. Dental fluorosis and its influence on children's life. Braz Oral Res. 2015;29:S1806-83242015000100214. doi: 10.1590/1807-3107BOR-2015.vol29.0014. Epub 2015 Jan 13. PMID: 25590503. [PubMed]

[11] Collins, E., V. Segreto, H. Martin, AND H. Dickson. ANALYSIS OF COSTS FOR THE TREATMENT OF DENTAL FLUOROSIS. U.S. Environmental Protection Agency, Washington,

D.C., EPA/600/5-87/001 (NTIS PB87170817), 1987. Revised 2005. [EPA Link], However, Data Revised 08/02/2022 . EPA Science Inventory Accessed Dec. 27, 2022

[12] Ko L, Thiessen KM. A critique of recent economic evaluations of community water fluoridation. Int J Occup Environ Health. 2015;21(2):91-120. doi: 10.1179/2049

[13] See: Geurtsen Quintessence 2003 and Patel Prim Dental Care 1995 Bader Com Dent Oral Epi 1996 and 2001 and JADA 2004 Vieira Eur J Oral Sci 2006 and Fennis Int J Prosth 2002

[14] 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 http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html