Guiding the way through the darkness.

RADIO LIBERTY Host: "Dr. Stan" Monteith

Box 969, Soquel, CA 95073
1-800-544-8927 Fax: 831-464-8427
WWW.RADIOLIBERTY.COM

April 2005

THE COERCIVE POPULATION CONTROL AGENDA

Dear Friend of Radio Liberty,

"Prior to approval of Vioxx, a study was performed by Merck named 090. This study found nearly a 7-fold increase in heart attack risk with low-dose Vioxx. The labeling at approval said nothing about heart attack risks. In November 2000, another Merck clinical trial named VIGOR found a 5-fold increase in heart attack risk with high-dose Vioxx. The company said the drug was safe. . . ."

Dr. David Graham, Senate testimony, November 18, 2004 [1]

". . . we should facilitate, instead of foolishly and vainly endeavouring to impede, the operations of nature in producing . . . mortality; . . . Instead of recommending cleanliness to the poor, we should encourage contrary habits. In our towns we should make the streets narrower, crowd more people into the houses, and court the return of the plague. In the country, we should build our villages near stagnant pools, and particularly encourage settlements in all marshy and unwholesome situations."

Thomas Malthus, 1826 [2]

"I do not pretend that birth control is the only way in which population can be kept from increasing. There are others. . . . War . . . has hitherto been disappointing in this respect, but perhaps bacteriological war may prove more effective. If a Black Death could be spread throughout the world once in every generation survivors could procreate freely without making the world too full."

Bertrand Russell, 1953 [3]

"It's terrible to have to say this. World population must be stabilized and to do that we must eliminate 350,000 people per day. This is so horrible to contemplate that we shouldn't even say it. But the general situation in which we are involved is lamentable."

Jacques Cousteau, November 1991 [4]

"Population pressures on our planet are real and getting worse every day. Whether it is traffic congestion, urban sprawl, rain forest depletion, overfishing, global warming, pollution, famine, war, or terrorism - the problems are made worse, and more difficult to solve, by overpopulation. . . . We're heading on a collision course toward a population crisis that could deepen this nightmare - not only in the developing countries of Africa, Asia, and Latin America, but right here in the United States."

Zero Population Control, March 2005 [5]

What is being done to remedy the situation? The U.S. funds abortion, tolerates euthanasia, promotes sex education, finances wars, and lets pharmaceutical companies market lethal drugs. Merck Company recalled Vioxx on September 30, 2004, because of the concern over its safety. Eighteen days later Dr. David Graham, the associate director for science and medicine in the FDA's Office of Drug Safety, testified before the U.S. Senate, and revealed that Vioxx, and several other medications, have killed tens of thousands of people. [6] Following the testimony, the FDA appointed an independent advisory panel to evaluate Cox-2 inhibitors, and Congress promptly enacted legislation to protect Merck, Pfizer, and other drug companies from Class Action law suits in State Courts. [7]

The "independent advisory panel" met in February 2005, and voted 17-15 to allow Merck to market Vioxx, 17 - 13 (with two abstensions) to allow Pfizer to market Bextra, and 31 - 1 to allow Pfizer to market Celebrex. MSNBC reported:

> **"Ten members of the Food and Drug Administration advisory panel who voted that the group of powerful pain killers, including the controversial drug Vioxx, should continue to be sold had ties to the drug makers. . . . A study by the Center for Science in the Public Interest indicates that 10 of the 32 panel members had ties to either Pfizer Inc., or Merck & Co., ranging from consulting fees and speaking honoraria to receiving research support from the companies. . . . The Associated Press indicated that the 10 panel members in question voted 10 - 0 in favor of keeping Celebrex and Bextra available and 9 - 1 in favor of allowing Vioxx to be brought back onto the market."** [8]

How dangerous is Celebrex? *The New York Times* reports:

> **"The company has acknowledged that the 1999 study, which was intended to examine whether Celebrex could treat Alzheimer's disease, found that the number of Celebrex patients suffering heart attacks was almost four time that of those taking a placebo. Pfizer's own analysis found the difference statistically significant. But the study was never published and not submitted to the Food and Drug Administration until June 2001, four months after the F.D.A. conducted a major safety review of Vioxx and Celebrex's safety. Two doctors who participated in that review said they had not known about the 1999 study until yesterday. And one of them . . . said that if the safety panel had known about the study, the group might have recommended that both Vioxx and Celebrex be taken with greater caution. That panel decided to recommend that Vioxx, but not Celebrex, carry a warning about its cardiovascular risks. That difference is one of the main reasons Celebrex had greater sales than Vioxx."** [9]

Dr. David Graham claims Vioxx, Bextra, and Celebrex have produced over 100,000 heart attacks and strokes. The pertinent sections of his Senate testimony are reproduced below:

****

Introduction: My name is David Graham, and I am pleased to come before you today to speak about Vioxx, heart attacks and the FDA. By way of introduction, I graduated from the Johns Hopkins University School of Medicine, and trained in Internal Medicine at Yale and in adult Neurology at the University of Pennsylvania. After this, I completed a three-year fellowship in pharmacoepidemiology and a Masters in Public Health at Johns

Hopkins, with a concentration in epidemiology and biostatistics. Over my 20 year career in the field, all of it at FDA, I have served in a variety of capacities. I am currently the Associate Director for Science and Medicine in FDA's Office of Drug Safety. . . .

Vioxx: Let me begin by describing what we found in our study, what others have found, and what this means for the American people. Prior to approval of Vioxx, a study was performed by Merck named 090. This study found nearly a 7-fold increase in heart attack risk with low-dose Vioxx. The labeling at approval said nothing about heart attack risks. In November 2000, another Merck clinical trial named VIGOR found a 5-fold increase in heart attack risk with high-dose Vioxx. The company said the drug was safe and that the comparison drug naproxen was protective. In 2002, a large epidemiologic study reported a 2-fold increase in heart attack risk with high-dose Vioxx and another study reported that naproxen did not affect heart attack risk. About 18 months after the VIGOR results were published, FDA made a labeling change about heart attack risk with high-dose Vioxx, but did not place this in the "Warnings" section. Also, it did not ban the high-dose formulation and its use. I believe such a ban should have been implemented. Of note, FDA's label change had absolutely no effect on how often high-dose Vioxx was prescribed, so what good did it achieve?

In March of 2004, another epidemiologic study reported that both high-dose and low-dose Vioxx increased the risk of heart attacks compared to Vioxx's leading competitor, Celebrex. Our study, first reported in late August of this year, found that Vioxx increased the risk of heart attack and sudden death by 3.7 fold for high-dose and 1.5 fold for low-dose, compared to Celebrex. A study report describing this work was put on the FDA website on election day. Among many things, this report estimated that nearly 28,000 excess cases of heart attack or sudden cardiac death were caused by Vioxx. I emphasize to the Committee that this is an extremely conservative estimate. FDA always claims that randomized clinical trials provide the best data. If you apply the risk-levels seen in the 2 Merck trials, VIGOR and APPROVe, you obtain a more realistic and likely range of estimates for the number of excess cases in the U.S. This estimate ranges from 88,000 to 139,000 Americans. Of these, 30-40% probably died. For the survivors, their lives were changed forever. It's important to note that this range does not depend at all on the data from our Kaiser-FDA study: Indeed, Dr. Eric Topol at the Cleveland Clinic recently estimated up to 160,000 cases of heart attacks and strokes due to Vioxx, in an article published in the New England Journal of Medicine. This article lays out clearly the public health significance of what we're talking about today. . . . Today, in 2004, you, we, are faced with what may be the single greatest drug safety catastrophe in the history of this country or the history of the world. We are talking about a catastrophe that I strongly believe could have, should have been largely or completely avoided. But it wasn't, and over 100,000 Americans have paid dearly for this failure. In my opinion, the FDA has let the American people down, and sadly, betrayed a public trust. I believe there are at least 3 broad categories of systemic problems that contributed to the Vioxx catastrophe and to a long line of other drug safety failures in the past 10 years. Briefly, these categories are 1) organizational/structural, 2) cultural, and 3)scientific. I will describe these in greater detail in a few moments.

My Vioxx experience at FDA: To begin, after publication of the VIGOR study in November 2000, I became concerned about the potential public health risk that might exist with Vioxx. VIGOR suggested that the risk of heart attack was increased 5-fold in patients who used the high-dose strength of this drug. Why was the Vioxx safety question important? 1) Vioxx would undoubtedly be used by millions of patients. That's a very large number to expose to a serious drug risk. 2) heart attack is a fairly common event, and 3) given the above, even a relatively small increase in heart attack risk due to Vioxx could mean that tens of thousands of Americans might be seriously harmed or killed by use of this drug. If these three factors were present, I knew that we

would have all the ingredients necessary to guarantee a national disaster. The first two factors were established realities. It came down to the third factor, that is, what was the level of risk with Vioxx at low- and high-dose.

To get answers to this urgent issue, I worked with Kaiser Permanente in California to perform a large epidemiologic study. This study was carefully done and took nearly 3 years to complete. In early August of this year, we completed our main analyses and assembled a poster presentation describing some of our more important findings. We had planned to present these data at the International Conference on Pharmacoepidemiology, in Bordeaux, France. We concluded that high-dose Vioxx significantly increased the risk of heart attacks and sudden death and that the high doses of the drug should not be prescribed or used by patients. This conclusion triggered an explosive response from the Office of New Drugs, which approved Vioxx in the first place and was responsible for regulating it post-marketing. The response from senior management in my Office, the Office of Drug Safety, was equally stressful. I was pressured to change my conclusions and recommendations, and basically threatened that if I did not change them, I would not be permitted to present the paper at the conference. One Drug Safety manager recommended that I should be barred from presenting the poster at the meeting, and also noted that Merck needed to know our study results.

An e-mail from the Director for the entire Office of New Drugs, was revealing. He suggested that since FDA was "not contemplating" a warning against the use of high-dose Vioxx, my conclusions should be changed. CDER and the Office of New Drugs have repeatedly expressed the view that ODS should not reach any conclusions or make any recommendations that would contradict what the Office of New Drugs wants to do or is doing. Even more revealing, a mere 6 weeks before Merck pulled Vioxx from the market, CDER, OND and ODS management did not believe there was an outstanding safety concern with Vioxx. . . .

There were 2 other relevatory milestones. In mid-August, despite our study results showing an increased risk of heart attack with Vioxx, and despite the results of other studies published in the literature, FDA announced it had approved Vioxx for use in children with rheumatoid arthritis. Also, on September 22, at a meeting attended by the director of the reviewing office that approved Vioxx, the director and deputy director of the reviewing division within that office and senior managers from the Office of Drug Safety, no one thought there was a Vioxx safety issue to be dealt with. At this meeting, the reviewing office director asked why had I even thought to study Vioxx and heart attacks because FDA had made its labeling change and nothing more needed to be done. At this meeting a senior manager from ODS labeled our Vioxx study "a scientific rumor." Eight days later, Merck pulled Vioxx from the market. . . .

Finally, we wrote a manuscript for publication in a peer-reviewed medical journal. Senior managers in the Office of Drug Safety have not granted clearance for its publication, even though it was accepted for publication in a very prestigious journal after rigorous peer review by that journal. Until it is cleared, our data and conclusions will not see the light of day in the scientific forum they deserve and have earned, and serious students of drug safety and drug regulation will be denied the opportunity to consider and openly debate the issues we raise in that paper.

Past experiences. My experience with Vioxx is typical of how CDER responds to serious drug safety issues in general. This is similar to what Dr. Mosholder went through earlier this year when he reached his conclusion that most SSRIs should not be used by children. I could bore you with a long list of prominent and not-so-prominent safety issues where CDER and its Office of New Drugs proved to be extremely resistant to full and open disclosure of safety information, especially when it called into question an existing regulatory position. In

these situations, the new drug reviewing division that approved the drug in the first place and that regards it as its own child, typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues. The second greatest obstacle is often the senior management within the Office of Drug Safety, who either actively or tacitly go along with what the Office of New Drugs wants. Examples are numerous so I'll mention just a few.

With Lotronex, even though there was strong evidence in the pre-approval clinical trials of a problem with ischemic colitis, OND approved it. When cases of severe constipation and ischemic colitis began pouring into FDA's MedWatch program, the reaction was one of denial. When CDER decided to bring Lotronex back on the market, ODS safety reviewers were instructed to help make this happen. Later, when CDER held an advisory committee meeting to get support for bringing Lotronex back on the market, the presentation on ways to manage its reintroduction was carefully shaped and controlled by OND. When it came to presenting the range of possible options for how Lotronex could be made available, the list of options was censored by OND. The day before the advisory meeting, I was told by the ODS reviewer who gave this presentation that the director of the reviewing office within OND that approved Lotronex in the first place came to her office and removed material from her talk. An OND manager was "managing" an ODS employee. When informed of this, ODS senior management ignored it. I guess they knew who was calling the shots.

Rezulin was a drug used to treat diabetes. It also caused acute liver failure, which was usually fatal unless a liver transplant was performed. The pre-approval clinical trials showed strong evidence of liver toxicity. The drug was withdrawn from the market in the United Kingdom in December 1997. With CDER and the Office of New Drugs, withdrawal didn't occur until March 2000. Between these dates, CDER relied on risk management strategies that were utterly ineffective, and it persisted in relying on these strategies long after the evidence was clear that they didn't work. The continued marketing of Rezulin probably led to thousands of Americans being severely injured or killed by the drug. And note, there were many other safer diabetes drugs available. During this time, I understand that Rezulin's manufacturer continued to make about $2 million per day in sales.

The big picture. The problem you are confronting today is immense in scope. Vioxx is a terrible tragedy and a profound regulatory failure. I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless.

It is important that this Committee and the American people understand that what has happened with Vioxx is really a symptom of something far more dangerous to the safety of the American people. Simply put, FDA and its Center for Drug Evaluation and Research are broken. . . . The corporate culture within CDER is also a barrier to effectively protecting the American people from unnecessary harm due to prescription and OTC drugs. The culture is dominated by a world-view that believes only randomized clinical trials provide useful and actionable information and that post-marketing safety is an afterthought. This culture also views the pharmaceutical industry it is supposed to regulate as its client, over-values the benefits of the drugs it approves and seriously under-values, disregards, and disrespects drug safety. . . ."

****

The FDA claims Vioxx is relatively safe because the risk of heart attack and stroke is minimal, so Bextra, Celebrex, and Vioxx are sold throughout the world, and hundreds of people die from the medications every day.

Many people believe the FDA authorizes dangerous drugs because key officials have been promised high paying jobs when they retire from government service, but I believe some government officials are Malthusians. The sixth edition of Thomas Malthus's Essay on Population states:

> **". . . we should facilitate, instead of foolishly and vainly endeavoring to impede, the operations of nature in producing . . . mortality. . . . Instead of recommending cleanliness to the poor, we should encourage contrary habits. In our towns we should make the streets narrower, crowd more people into the houses, and court the return of the plague. In the country, we should build our villages near stagnant pools, and particularly encourage settlements in all marshy and unwholesome situations."** [10]

Bertrand Russell wrote:

> **"I do not pretend that birth control is the only way in which population can be kept from increasing. There are others. . . . War . . . has hitherto been disappointing in that respect, but perhaps bacteriological war may prove more effective. If a Black Death could be spread throughout the world once in every generation survivors could procreate freely without making the world too full."** [11]

Jacques Cousteau stated:

> **"It's terrible to have to say this. World population must be stabilized and to do that we must eliminate 350,000 people per day. This is so horrible to contemplate that we shouldn't even say it. But the general situation in which we are involved is lamentable."** [12]

A recent letter from the Zero Population Growth organization warns:

> **"Population pressures on our planet are real and getting worse every day.**
>
> **Whether it is traffic congestion, urban sprawl, rain forest depletion, overfishing, global warming, pollution, famine, war, or terrorism - the problems are made worse, and more difficult to solve, by overpopulation. . . . We're heading on a collision course toward a population crisis that could deepen this nightmare - not only in the developing countries of Africa, Asia, and Latin America, but right here in the United States."** [13]

One in six American children has a neurodevelopmental abnormality and/or behavioral problem, over a third of the veterans of Desert Storm have Gulf War Illness, over a million Americans have chronic fatigue-fibromyalgia, over a million Americans have chronic Lyme Disease, the incidence of Alzheimer's Disease is increasing, half a million Americans have died from AIDS, and almost a million Americans are HIV infected because the CDC, the National Institute of Health, and the U.S. Public Health Service blocked the use of standard public health measures to stop the epidemic. [14]

What can you do? Distribute this letter, and encourage your friends to listen to Radio Liberty. Dr. David Graham risked his job and his future when he revealed Cox 2 inhibitors are killing people. What are you willing

to risk to help save America? The complete text of Dr. Graham's testimony is available on the Internet, or from Radio Liberty. [15]

Most people would like to live their lives and raise their families, but our enemies won't let that happen. I close with Patrick Henry's plea to the Virginia Convention after a group of Americans were murdered by the British military:

> **". . . The gentlemen may cry, Peace, peace! but there is no peace. The war has actually begun!. . . . Our brethren are already in the field! Why stand we heare idle? What is it that the gentlemen wish? What would they have? Is life so dear or peace so sweet as to be purchased at the price of chains and slavery? Forbid it, Almighty God. I know not what course others may take, but as for me, give me liberty or give me death!"** [16]

I appreciate your support, and your prayers.

Yours in Christ,

Stanley Monteith

*** Since I started writing this letter, Bextra has been recalled; however, there is talk of returning Vioxx to the market.

REFERENCES

1. Dr. David Graham's November 18, 2004 Senate testimony. www.healthcoalition.ca/vioxx-sp.pdf
2. Allan Chase, The Legacy of Malthus, University of Illinois Press, Urbana, IL, p. 6.
3. Bertrand Russell, The Impact of Science on Society, Simon and Schuster, New York, 1953, p. 103.
4. Bahgat Elnadi et al, "Interview: Jacques-Yves Cousteau," The UNESCO Courier, November 1991, pp. 8-10.
5. Population Connection letter, March 2005, 1400 Sixteenth Street, NW, Suite 320, Washington, DC, 20036. Copy available from Radio Liberty.
6. David Graham, op. cit.
7. Gardiner Harris, "F.D.A. To Create Advisory Board on Drug Safety," The New York Times, February 16, 2005, p. A1. See Also, David Rogers et al, "Bush Set to Sign Landmark Bill On Class Actions," The Wall Street Journal, February 18, 2005, p. A1.
8. www.msnbc.msn.com/id/7031927
9. Alex Berenson et al, "Pfizer Says 1999 Trials Revealed Risks With Celebrex," The New York Times, February 1, 2005, p. C1.
10. Allan Chase, op. cit.
11. Bertrand Russell, op. cit.
12. Bahgat Elnadi, op. cit.
13. Population Connection letter, op. cit.
14. www.MedSciMonit.com/pub/vol_11/no_4/6630.pdf
    See Also, Stanley Monteith, AIDS: The Unnecessary Epidemic, Covenant House, 1991, available from Radio Liberty
    See Also, CDC's HIV AIDS Surveillance Report, Vol 15, 2003, p.16.
    See Also, Scientific Progress in Understanding Gulf War Veterans' Illnesses: Research Advisory Committee on Gulf War Veterans' Illnesses, September, 2004, p. 28.
    See Also, www.alzheimers.org/nianews/nianews59.htm
15. Dr. Graham's testimony, op. cit., copies available from Radio Liberty at (800) 544-8927.
16. John Bartlett, Bartlett's Familiar Quotations, Little, Brown and Company, Boston, 1980, p. 383.