Secrets of the FDA Revealed by Top Insider Doctor

According to the Journal of the American Medical Association (JAMA), "Adverse drug reactions are the fourth leading cause of death in America. Reactions to prescription and over-the-counter medications kill far more people annually than all illegal drug use combined."

Annually, drug companies spend billions on TV commercials and print media. They spend over $12 billion a year handing out drug samples and employing sales forces to influence doctors to promote specifically branded drugs. The drug industry employs over 1,200 lobbyists, including 40 former members of Congress. Drug companies have spent close to a billion dollars since 1998 on lobbying. In 2004, drug companies and their officials contributed at least $17 million to federal election campaigns.

To get a full diagnosis of this provocative story, highly acclaimed health guru Gary Null sent his lead investigator and director of operations, Manette Loudon, to Washington, D.C. to interview Food and Drug Administration (FDA) employee and Vioxx whistleblower Dr. David Graham. What you are about to read may leave you questioning the safety of all drugs, but it is a story that must be told. Unless Congress steps up to the plate and changes policy at the FDA, millions more will become unwitting victims of adverse drug reactions from unsafe drugs.

Loudon: Dr. Graham, it's truly a pleasure to have the opportunity to interview you. Let me begin by asking you how long you've been with the FDA and what your current position is?

Dr. David Graham: I've been with the FDA for 20 years. I'm currently the Associate Director for Science and Medicine in the Office of Drug Safety. That's my official job. But when I'm here today I'm speaking in my private capacity on my own time, and I do not represent the FDA.

We can be pretty certain that the FDA would not agree with most of what I have to say. So with those disclaimers, you know everything is OK.

Loudon: On November 23, 2004 (during the) PBS Online News Hour Program, you were quoted as making the following statement: "I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx. Simply put, FDA and the Center for Drug Evaluation Research (CDER) are broken." Since you've made that statement, has anything changed within the FDA to fix what's broken and, if not, how serious is the problem that we're dealing with here?

Dr. Graham: Since November, when I appeared before the Senate Finance Committee and announced to the world that the FDA was incapable of protecting America from unsafe drugs or from another Vioxx, very little has changed on the surface and substantively nothing has changed.

The structural problems that exist within the FDA, where the people who approve the drugs are also the ones who oversee the post marketing regulation of the drug, remain unchanged. The people who approve a drug when they see that there is a safety problem with it are very reluctant to do anything about it because it will reflect badly on them. They continue to let the damage occur. America is just as at risk now as it was in November, as it was two years ago, and as it was five years ago.

Loudon: In that same PBS program, you were also quoted saying, "The organizational structure within the CDER is currently geared towards the review and approval of new drugs. When a serious safety issue arises at post marketing, the immediate reaction is almost always one of denial, rejection and heat. They approved the drugs, so there can't possibly be anything

wrong with it. This is an inherent conflict of interest."

Based on what you're saying it appears that the FDA is responsible for protecting the interests of pharmaceutical companies and not the American people. Do you believe the FDA can protect the public from dangerous drugs?

Dr. Graham: As currently configured, the FDA is not able to adequately protect the American public. It's more interested in protecting the interests of industry. It views industry as its client, and the client is someone whose interest you represent. Unfortunately, that is the way the FDA is currently structured. Within the Center for Drug Evaluation and Research, about 80 percent of the resources are geared towards the approval of new drugs and 20 percent is for everything else. Drug safety is about 5 percent. The "gorilla in the living room" is new drugs and approval. Congress has not only created that structure, they have also worsened that structure through the PDUFA, the Prescription Drug User Fee Act, by which drug companies pay money to the FDA so they will review and approve its drug. So you have that conflict as well.

Loudon: When did that go into effect?

Dr. Graham: The Prescription Drug User Fee Act came into play in 1992. It was passed by Congress as a way of providing the FDA with more funds so that it could hire more physicians and other scientists to review drug applications so that drugs would be approved more quickly.

For industry, every day a drug is held up from being marketed, represents a loss of 1 million to 2 million dollars of profit. The incentive is to review and approve the drugs as quickly as possible, and not stand in the way of profit-making. The FDA cooperates with that mandate.

Loudon: And what about those new drugs? Are they any better than what already exists on the market?

Dr. Graham: It's a myth that is promulgated not only by industry but also by the FDA itself. It's a misperception that our lawmakers in Congress have as well and they've been fed this line by industry.

Industry is saying there are all these lifesaving drugs that the FDA is slow to approve and people are dying in the streets because of it. The fact is that probably about two-thirds to three-quarters of the drugs that the FDA reviews are already on the market and are being reviewed for another indication. So, for example, if I've got a drug that can treat bronchitis and now it's going to be used to treat a urinary tract infection, well, that's a new indication. But it's the same drug and we already know about the safety of the drug. There is nothing life-saving there. There is nothing new. There is nothing innovative.

A very small proportion of drugs represent a new drug that hasn't been marketed before. Most of those drugs are no better than the ones that exist. If you want to talk about breakthrough drugs -- the ones that really make a difference in patients' lives and represent a revolution in pharmacology -- we're talking about maybe one or two drugs a year. Most of them aren't breakthroughs and most of them aren't life-saving, but they get treated as if they were.

Loudon: Are you at liberty to discuss some of the problems your colleagues are finding with other drugs and if so, how widespread is the problem?

Dr. Graham: I'm really not at liberty to talk about things that pertain to my official duties at the FDA. I can talk in my private capacity, but I can't talk about material that would be confidential.

What I can say is that there are a number of other scientists within the FDA who have also worked with drugs that they know are not safe, even though the FDA has approved or allowed them to remain on the market. They face some of the same difficulties that I do. The difference is that either the problem isn't as serious in terms of the numbers of people that were injured or that it's a fatal reaction -- they're not willing to expose themselves to retaliation by the FDA -- and retaliation would surely follow.

Loudon would like to thank Manette Loudon and Pam Klebs for their help in putting this interview with Dr. David Graham together.