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The FDA Exposed: An Interview With Dr. David Graham, the Vioxx Whistleblower

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The following interview with Dr. David Graham (senior drug safety researcher at the FDA) was conducted by Manette Loudon, the lead investigator for Dr. Gary Null. This interview contains jaw-dropping insights about the corruption and crimes that take place every day inside the Food and Drug Administration. This is no outside critic, either: these are the words from a top FDA employee who has worked at the agency for two decades. If you've ever wondered how the drug industry could pull off the greatest con of our time -- and turn the human [body](#) into a profit-generating machine -- you're about to learn the shocking answers in this interview.

This interview is reprinted here with permission from [Dr. Gary Null](#). Parts of this interview also appear in Dr. Gary Null's *Prescription For Disaster* [video](#) documentary, which is available at the Gary Null website and is a must-see video for anyone who wants to know the truth about the [pharmaceutical industry](#) and the FDA.

MANETTE: 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. 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 okay.

MANETTE: On November 23, 2004 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.

MANETTE: 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 five 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.

MANETTE: 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 one to two 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.

MANETTE: 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 lifesaving 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 lifesaving, but they get treated as if they were.

MANETTE: 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.

MANETTE: Do you think we should have any confidence in the FDA and if so, can you elaborate on what they do that you feel benefits the [American people](#)?

DR. GRAHAM: In terms of confidence in what the FDA does, there are two things that the FDA determines when it looks at a drug: it determines whether or not a drug is safe and it determines whether or not it's effective. Regarding the determination of drug effectiveness, I think the FDA does a pretty good job. If the FDA says that the drug will have a particular effect, probably for many of the [patients](#) who take the drug it will actually have that effect. If the FDA says a given drug will lower [blood pressure](#) and you're somebody who has [high blood pressure](#), there's a good chance that the drug will have an effect that lowers your [blood](#) pressure. That has to do with the rigor with which they force the drug [companies](#) to establish that the drug actually has an effect.

On the safety side, I think that the American public can't be very confident. They can have some confidence because it turns out that most drugs are remarkably safe. But, when there are unsafe drugs, the FDA is very likely to err on the side of industry. Rarely will they keep a drug from being marketed or pull a drug off the market. A lot of this has to do with the standards that the FDA uses for safety. When they look at efficacy, they assume that the drug doesn't work and the company has to prove that the drug does work. When they look at safety it's entirely the opposite. The FDA assumes the drug is safe and now it's up to the company to prove that the drug isn't safe. Well, that's a no-brainer. What company on earth is going to try to prove that the drug isn't safe? There's no incentive for the companies to do things right. The clinical trials that are done are too small, and as a result it's very unusual to find a serious safety problem in these clinical trials. Safety flaws are discovered after the drug gets on the market.

MANETTE: I read somewhere that a drug only has to be better than a [sugar](#) pill

DR. GRAHAM: Right. The standard that the FDA uses to approve a drug is primarily “does the drug work?” That's what they call efficacy. Most often, they'll compare the drug against something called a [placebo](#) or a sugar pill. It's basically something that doesn't have a medical effect. The assumption is that the drug will be no different than the sugar pill. The FDA puts the onus on the drug company to conduct a clinical trial to show that the drug is different from a sugar pill. The way the FDA's approval standards are, the drug does not necessarily have to have a very great effect in order to be approved. The drug might lower your blood pressure by just a few millimeters of mercury, but the FDA will say we can approve it because it does lower your blood pressure.

Now, would that be a benefit or are there other drugs out there – many other drugs – that patients could take instead that would lower their blood pressure by 10 or 15 or 20 millimeters? The FDA doesn't really care about that. What happens is the drug gets marketed. You've got two drugs that are out there – one drug that effectively lowers your blood pressure a substantial degree and another drug that barely lowers your blood pressure at all. The company that has that second drug markets it like it's this breakthrough [medicine](#). It lowers your blood pressure and they have all these glitzy ads, [direct-to-consumer advertising](#). Lots of patients and lots of doctors will use that [medication](#). What happens in the process is these patients are actually in a sense being denied a more effective treatment because the FDA doesn't require that drugs that come on to market be at least equivalent to, or better than, the drugs that are already there. All they have to do is be better than a sugar pill.

MANETTE: When you consider the financial impact your whistle blowing has had on the pharmaceutical industry do you have any fears that your [life](#) may be in jeopardy?

DR. GRAHAM: I have tried not to think about that. In the work that I've done I've never really thought about what the financial impact would be on any particular company. I put that out of my mind because my primary concern is whether or not the drug is safe. If it's not safe, how unsafe is it and how many people are being hurt by it? In terms of when I identify an unsafe drug, to me it doesn't really matter what drug company it is. I've helped to get ten different drugs off the market, and they're from ten different drug companies. It's not a vendetta against any particular drug company. I have to hope that the drug companies don't take it personally. I'm just a [scientist](#) doing my job and I have to leave the rest to [God](#) to protect me.

MANETTE: Has anyone tried to silence you and stop you from becoming a [whistleblower](#)?

DR. GRAHAM: Prior to my Senate [testimony](#) in mid-November of 2004, there was an orchestrated campaign by senior level FDA managers to intimidate me so that I would not testify before Congress. This intimidation took several forms. One attack came from our acting Center Director who contacted the editor of the Lancet, the prestigious medical journal in the United Kingdom, and intimated to the editor that I had committed scientific misconduct and that they shouldn't publish a paper that I had written showing that Vioxx increases the risks of [heart attack](#). This high-level FDA official never talked to me about this allegation. He just went directly to the Lancet.

The second attack was from other high level FDA officials who contacted Senator Grassley's office and attempted to prevent Senator Grassley and his staff from supporting me and calling me as a witness. They knew that if they could disarm Senator Grassley that would neutralize me.

The third attack came from senior FDA officials who contacted Tom Devine, my attorney at the Government Accountability Project, and attempted to convince him that he should not represent me because I was guilty of scientific misconduct; I was a bully; a demigod; and a terrible person that couldn't be trusted. These people were posing as whistleblowers themselves ratting on another whistleblower. Some of these senior level FDA officials were in my supervisory chain and are people I work for. They were involved in a coordinated attempt to discredit me and to smear my name and to prevent me from giving testimony.

There's one other thing that happened the week before I testified. The Acting Commissioner of the FDA invited me to his office and offered me a job in the Commissioner's Office to oversee the revitalization of [drug safety](#) for the FDA if I would just leave the Office of Drug Safety and come to the Commissioner's Office. Obviously he had been tipped off by people in the Senate Finance Committee who are sympathetic to the FDA's status quo that I was going to be called as a witness. To preempt that, he offers me this job, which basically would have been exile to a fancy title with no real ability to have an impact. This was a conspiracy and it was coordinated and there was collaboration among senior level FDA officials. What a mess!

MANETTE: All of these attacks backfired on them. Tell us a little bit about that.

DR. GRAHAM: Well, Senator Grassley and his staff quickly realized that what they were saying about me was fabricated. The editor of [The Lancet](#) also realized that what the high level FDA officials were saying to him was a pack of lies. He sent emails to them saying it looked to him as if they were trying to interfere with his editorial process. He was very savvy to what these people were doing. Tom Devine, as he said publicly, was very interested in doing the right thing. He said, "We don't want to protect somebody who's a lawbreaker and who really isn't representing the truth so produce your [evidence](#)." They had no evidence because there is no evidence. But I produced my evidence. I showed him all the documentation, all the emails, and the reports that I've written. They flunked every test and I passed every test.

In all of the criticism I have received relating to Vioxx and drug safety, they've never attacked the work or the [science](#) that I've done or the [results](#) that I've come to. What they've done is call me names. The ad hominem attack is the last refuge of the indefensible. They don't have an argument that's substantial. They know that they're vulnerable. They know that they've disserved the

American people. The FDA is responsible for 140,000 [heart attacks](#) and 60,000 dead Americans. That's as many people as were killed in the Vietnam War. Yet the FDA points the finger at me and says, "Well, this guy's a rat, you can't trust him," but nobody is calling them to account. Congress isn't calling them to account. For the American people, it's dropped off the radar screen. They should be screaming because this can happen again.

MANETTE: On CNN with Lou Dobbs you said that there was a certain "culture" that exists at the FDA. Can you explain what you meant by that?

DR. GRAHAM: The FDA has a very peculiar [culture](#). It runs like the army so it's very hierarchal. You have to go through the chain of command and if somebody up above you says that they want things done in a particular way well, they want it done in a particular way. The culture also views industry as the client.

They're serving industry rather than the public. In fact, when a former office director for the Office of Drug Safety criticized me and tried to get me to change a report I'd written on another drug – Arava – he said to me and to a colleague who was a coauthor on this report that "industry is our client." I begged to differ with him. I said, "No, industry is not the client, it's the American people, the people who pay our taxes. That's who we're here to serve." He said, "No! Industry is our client." I ended the conversation by saying, "Well, industry may be your client, but it will never be my client."

Another aspect to the culture at the FDA is that it overvalues the [benefits](#) of drugs and undervalues the [risks](#) of drugs. And so the FDA will always say to you, "Well, we're leaving this drug on the market because the benefits exceed the risks." Well, the FDA has never assessed the benefit of any drug that it's ever approved. It works on what's called efficacy. Does the drug work or not? Does it lower your blood pressure or does it lower your [blood sugar](#)? Not: Does it prolong your life? Does it prevent you from having a heart attack? Those are benefits. All they focus on is efficacy.

For example, ask the FDA why on earth they didn't [ban](#) high dose Vioxx after the VIGOR Study showed in early 2000 that it increased the risk of heart attack by 500 percent? High dose Vioxx was approved for the short-term treatment of acute [pain](#). What earthly benefit was there that exceeds a 500 percent increase in heart attack risk? Ask the FDA to produce its benefit analysis that shows that the benefits exceed the risks. It doesn't exist. The FDA has never looked at benefit. The FDA just says to the American people, "The benefits exceed the risks. Trust me. Believe me." If you held the FDA to its proof the American people would see how badly served they've been by the FDA and its culture that belittles safety in the drug companies' interest.

If the FDA were to pull a drug due to safety issues, it would hurt the marketing of the drug. It might also call into question why they approved the drug in the first place. Therefore, you get this culture of cover-up, this culture of suppression, this culture of denial, and this culture that demonstrates above all else that industry is the client and not the American people.

MANETTE: Have your peers turned against you?

DR. GRAHAM: No. I've been very fortunate. Tom Devine at GAP has told me that the experience of a typical whistleblower is that they'll have the support of their peers but the peers will be so afraid of retaliation that they won't express that support in public. I've had a very different experience. I've been basically embraced by my peers as someone who has said what they want to say and what they wished they had been able to say and that they recognize as the truth. They're really proud of the fact that I've said it and they're not afraid to be seen with me. They're not afraid to work with me. I've been pretty fortunate in that way.

Now with management it's been another story. Upper management avoids me and doesn't talk to me. I could be walking down the hall and I'll say hello, and they'll act like I'm not there. They don't give me interesting work assignments. They don't call me in to consult on things that I should be consulted on even though I am the senior epidemiologist in the Office of Drug Safety with more

experience than any of the other people there. I'm looked up to by the scientific staff because of that expertise. Basically, I feel like I'm in the Gulag.

MANETTE: How do you cope with that going to work each day?

DR. GRAHAM: It's difficult. It's a mind game. They're hoping that I'll just become very frustrated and disillusioned and leave or that I'll slip up in some way so that they can take some sort of action against me. As Tom Devine at GAP has said, I have to be Saint David. I can't afford to make any mistakes. That's very difficult and it is a little bit discouraging. But I've been a target of retaliation in the past. You take ten drugs off the market well, no good deed goes unpunished at the FDA. I've experienced retaliation with many of those other episodes but not as severe as what I've experienced with Vioxx. This is the first time that my job was actually in jeopardy and where the FDA actually intended to fire me. That was stopped only because Senator Grassley intervened. He put the heat on the FDA and told them, "Lay off. This guy has told the truth. He's helped America. Whose side are you on?"

MANETTE: Were there any warnings that Vioxx was a problem? Did you see the disaster coming?

DR. GRAHAM: I think that I was afraid that there would be a disaster, but I only became aware of this with the publication of the VIGOR Study, which was this large clinical trial that was done that showed that Vioxx increased the risk of heart attack five fold. That study was published in November of 2000. It was written, performed, and paid for by industry. What industry concluded was not that Vioxx increases the risks of heart attack, but that the drug they were comparing it against – Naproxen – decreased the risk of heart attack. I knew that was not a sustainable argument. There was no way that Naproxen was that protective against heart attacks. Clearly Vioxx was the problem. I knew that Vioxx was on the road to becoming a blockbuster drug (20 million users). All the ingredients were there for a disaster.

The FDA is responsible in so far as it could have prevented much of the damage, heart attacks, and [deaths](#) simply by banning the high dose Vioxx back in mid 2000 when they knew the results of the VIGOR Study. But the FDA did nothing for almost two years. They were "negotiating" with the company over a label. What did the label accomplish? Nothing! Before the label 17 or 18 percent of people who took Vioxx took the high dose. After the label change 17 or 18 percent were still taking the high dose. High dose use didn't change at all. People didn't read the label, and if they read the label they wouldn't know what to do anyway because it was very confusing. The right thing to do would have been to pull the high dose off the market because there is no benefit for short-term relief of acute pain that exceeds this risk. The FDA made bad decisions based on its culture and its institutionalized biases that favor industry, and as a result thousands of Americans died. Americans and Congress should be screaming bloody murder. They should be beating on the doors of the FDA demanding change.

MANETTE: It's estimated that over 200,000 people a year die from [prescription drugs](#). Do you see this as a serious problem and do you think many of these treatments are more dangerous than the disease itself?

DR. GRAHAM: Death from adverse drug reactions is one of the leading [causes](#) of death in the United States. It turns out that most of these adverse reactions are actually what are expected in the sense that they are an extension of the drug's action. For example, we know that drugs for diabetes can lower your blood sugar. If you're more sensitive to the drug than the normal person and it lowers your blood sugar too much, causing you to have a seizure while driving your [car](#) and you get killed, well, you died from an adverse drug reaction, but it wasn't something unexpected.

The blood thinner Coumadin is another example. That drug provides a benefit, but it is also responsible for probably more deaths than any single drug currently marketed. But it has a recognized benefit and there aren't other drugs to do what it does or to do what it does well. So [physicians](#) accept that there are patients who are in a serious situation and who might die without the drug, so they take it.

Yes, drugs cause a lot of harm. Unfortunately, we haven't quantified the benefits. For most of these drugs it's more belief. It's faith. We have faith that they'll confer a benefit, but the FDA hasn't demonstrated that they confer a benefit. We're getting much better at quantitating the risks. In the future what we need to do is just take the risks and look hard and dispassionately at what the real benefits are. If the benefits aren't there we shouldn't be having discussions about [labeling](#) the drug. You need to weed the garden patch of drugs that aren't doing what they're supposed to do. The FDA has not been very good about that; it likes to cultivate all these weeds.

MANETTE: In a perfect world what role do you see the FDA playing in our nation's [health](#)?

DR. GRAHAM: In a perfect world, I think the FDA would need to be restructured. If it were restructured properly, I think that it could actually provide a great benefit to the [public health](#). I would recommend several [changes](#). First, I would separate safety and post-marketing from the pre-marketing. I would create a separate center for product safety. Actually, Senator Grassley and Dodd have recently introduced [legislation](#) to create an independent center for post-marketing safety that would serve to protect the American people from unsafe drugs. This isn't happening now.

On the pre-marketing side, the FDA needs to pay greater attention to safety. They need to have larger clinical trials. They need to compare drug [products](#) against other drugs that treat the same indication rather than comparing a drug against a sugar pill. What we want in the end are drugs that actually have better benefit.

The FDA also needs to determine the post-marketing benefits of a drug. I've done that for several drugs. How many people are actually benefiting? How many people are living longer versus those who are having their lives shortened? Only when you have that kind of [information](#) can you make rational decisions about a medication. The times when I've done the benefit analysis, I've been chastised, criticized and suppressed by the FDA. These benefit analyses should be done as a matter of routine.

There is a lot that the FDA could do to improve, but the changes aren't going to happen on their own. Congress is going to have to make them happen. There's an expression, "the zebra doesn't change its stripes nor the leopard its spots." The FDA isn't going to change the way it does [business](#); changes will have to be imposed from outside.

MANETTE: How do you feel about direct-to-consumer [advertising](#)?

DR. GRAHAM: Direct-to-consumer advertising in general is a great disservice to the American people. We see wonderful ads of people demonstrating their health, whether they're skating across the ice or doing their Tai chi. Madison Avenue knows that a picture is worth a thousand words, so they convey an image, a message, and it makes an impression on patients and on physicians. It creates needs or desires where there really isn't a need or a desire.

There was a recent study in The Journal of The American Medical Association that showed that if patients mentioned a drug that they've seen on television to their physician they were much more likely to be prescribed that drug by the [doctor](#). Drug companies know this. That's why they do it. Would the Vioxx disaster have been as great and as large in the absence of direct-to-consumer advertising? I submit that the numbers would have been far lower than what they were. Direct-to-consumer advertising is part of what made Vioxx a blockbuster drug. It helped to rev the market up to get people to want to use the drug.

Clearly, direct-to-consumer advertising does not serve the American people well. Madison Avenue is smarter than the most intelligent American. That's why they make so much [money](#) and that's why the drug companies go to them to sell their products. We're not living in a neutral world where the information we're getting is objective and unbiased. It might be that the average American, given all the data, all the facts, and all the information in an objective way could make an intelligent, rational decision. But we don't live in that kind of world. We live in a world where what we're seeing is a visual image of these people being vital and [healthy](#) and cured of their illnesses. And it's all because

of this little pill that they're taking. A patient with that condition says, "I want to be just like that person." So they go to the doctor and say, "I want that pill." Are their lives changed? Maybe some people's lives are changed, but I think most aren't.

MANETTE: What do you think people hear when they're watching the ad and after the ad they list all the possible side effects?

DR. GRAHAM: I don't think it registers. You have the visual image that conveys one message. Then you have the voice that's speaking over this pictorial being shown telling you what this drug is good for. Then at the end the auctioneer gets on and says, "You know this drug could cause..." and they rattle off 25 different things in three seconds. You're lucky if you hear anything. I don't think that people come away with it and they certainly don't come away with any sense of how likely it is to happen because the visual image overpowers anything that gets said.

It's the same with the ads that appear in magazines. Companies are required to put some of the labeling in the ad. You have the ad on the one side – that's the picture. It shows this person being healthy because they take this pill. The fine print is all on the next page. People aren't going to read the fine print. It's the same thing with labeling for physicians. Physicians don't read product [labels](#). Where do they learn about drugs? They learn about drugs from the detail person from the drug company or from other colleagues who have used the drug. They're not learning it from the labeling.

MANETTE: Do you think there is a criminal cover-up going on between the FDA and [Big Pharma](#) to approve dangerous drugs that sicken and kill Americans?

DR. GRAHAM: I have no knowledge of criminal activity and I'm sure there are legal standards for what's criminal and what's not. I do think that there is an institutional [bias](#) at the FDA that says we will look for a way to say "yes" to the approval of any drug that comes down the pipe. If a drug is so bad that they can't find a reason to approve it, they won't. But, if there is any way that they can approve the drug, they will. The way this is done is by what's called the "indication." Why is it that you're going to take the drug? Maybe you're going to take it because you have high blood pressure. Maybe you'll take it because you have high [cholesterol](#). That's the indication. A company may come in with a drug and want to get it approved for five different indications. One of them is a really insignificant indication that affects a very small number of people. The main indication might affect millions of people. The drug doesn't show efficacy for that major indication, but they're able to somehow or another approve the small indication.

So the drug gets approved for this narrow indication, but the FDA and the drug company both know that it's going to be used for that other indication. It's going to be used "off-label." Then, the FDA turns around and says that they don't regulate the "off-label" use of drugs. No. But, they aid and abet it. They allow it to happen and in many instances "off-label" use of a drug product is a public health threat. The FDA has a responsibility to protect the public health. The FDA should be intervening, but they don't. In my own experience I have seen multiple examples where I've heard people say, "We can't ask a company to put that in the labeling because the company will say no." Or, "We can't do that because that will decrease their marketing. We've got to try to approve this drug. Let's see if we can give them this small indication. At least it's giving them something. You've got to find a way to say yes."

That is the typical attitude of the FDA culture. I think Congress is partially responsible for that because when they issued the PDUFA, the Prescription Drug User Fee Act, what they were really saying was, "We want you to review these drug applications more quickly because you're keeping lifesaving medicines from the American people." That's the line they were fed by Big Pharma. So they pressure the FDA and the FDA gets the message. It's a really pernicious system. I think it's unfortunate. There are many people from the FDA who have examples that they unfortunately can't talk about. They'd lose their job and maybe get thrown in prison because you can't discuss confidential and trade secret information. But the fact is these things happen at the FDA and there

have been multiple examples in the past where one could see evidence of that.

MANETTE: Did your faith as a devout Roman Catholic play any role in the decisions you made to put your career on the line to report the truth?

DR. GRAHAM: It did in so far as my faith forms my conscience. It's sort of my sense of what's right and what's wrong and what I am and am not responsible for. I was in a situation here with Vioxx where I was invited by Senator Grassley's office to testify. I could have told them no, but then they would have subpoenaed me. So of course I went peaceably. I was faced with this dilemma. Should I lay it on the line and tell them the way it really is or do I kind of downplay it? There are ways of doing that.

What I concluded was that I'm now being given the opportunity to tell the truth to the people who are in a position to actually make a difference. I can't make a difference. I can't change the FDA, but Congress can. If I don't tell them the truth, then I'm now responsible, in part, for future deaths. I don't want to become a co-conspirator with the FDA in what happens with Vioxx because tens of thousands of people were injured or killed because of the FDA's disregard for safety. If I keep quiet about that, now I'm part of the problem. I'm one of them, and at that point then my conscience asks me, "You know what the truth is, are you going to speak it or aren't you?"

So I went ahead and did that and prayed that it all works out well for me personally. That I have a job and I'll be able to support my family, that I'm protected from retaliation, that maybe some good will come out of that. My faith plays a role, but it wasn't a direct teaching of the church. You have to do x, y and z, but it's the faith as I've internalized it. My conscience is formed by the voice of Christ speaking internally to me. That's what the conscience is; it's the voice of God speaking to each and every one of us about what's right and what's wrong. I knew what was right. If I walked away from that nobody else would have to do anything. I'd be beating myself up because my conscience would condemn me. So yes, faith plays a part in every thing that I do. It's not saying I'm a saint, because I'm not. But I can't separate who I am from my religious faith. It's all part of the same person.

MANETTE: Do you think Congress genuinely wants to fix the problems at the FDA or are too many politicians influenced by the pharmaceutical industry?

DR. GRAHAM: I don't know what Congress will do in the end. My hope is that they will act decisively to [reform](#) the FDA and make the American people safer by having strong post-marketing. Will that happen or not? I don't know. I think there are many people in Congress who see this as a serious problem and who very much want to see a change. I think at the same time there are other people who don't think it's such a bad problem, and many of those people honestly believe that. For those people I'd say they haven't seen the evidence so they don't really understand how bad the problem is. There are undoubtedly some people who are influenced by industry. Does that influence their judgment in the end? I don't know. They'd probably say no, it doesn't. Maybe at a conscious level it doesn't. But we have the same phenomenon in the scientific world where we look at [research](#) studies that are funded by industry and [studies](#) that are funded by [government](#), by National Institutes of Health or the Medical Research Council in the United Kingdom. Multiple studies have been done that have shown that if your study is funded by industry you are much likelier – about five times more likely – to come up with the result that's favorable to the drug company than if your study on the same subject is funded by an independent body unrelated to the company.

Now, are the researchers who did this study biased? Are they consciously cheating and manipulating the data and everything else? No. I don't think that's happening at all, but the fact is if the study is funded by industry it's much more likely to be favorable to industry. Without attributing bad motivations to the scientists doing those studies all I can do is point to a strong correlation.

With Congress I would be concerned that there could be a strong correlation there because Pharma is very bright. They fund as many politicians as they can. They get to the [Republicans](#) and the Democrats. Look at the funding on the major committees, the Health, Education, Labor and Pension Committee in the Senate or the Oversight and Investigations Subcommittee in the House. The Wall

Street Journal reported recently that many people on these committees are funded by industry to a substantial degree. Industry knows how to [exercise](#) influence. What we have to do is overcome that influence with evidence, and then rely on the fact that at the end of the day the Congress will do what's best for the American people.

Will that happen? I don't know because then it gets embroiled in politics. You know, Republicans versus [Democrats](#), the left versus the right, conservatives versus liberals. Yet, what we're talking about is public health and public health is nonpartisan. I can say this with certainty. For every member of the House of Representatives somebody in their district died because of Vioxx. Somebody in their district had a heart attack because of Vioxx. For every Senator in the Senate, many more people in their state died because of Vioxx or had a heart attack because of Vioxx. It doesn't matter whether it's a red state or a blue state. Those are human beings and what we're talking about is public health. What I'm hoping is that Congress will respond. There is a problem and the evidence is overwhelming, but we'll just have to wait and see.

MANETTE: What are your thoughts on President Bush's attempt to pass tort reform, which would protect most pharmaceutical companies from lawsuits except in the most egregious cases?

DR. GRAHAM: I think it's dangerous and wrong for the following reasons. We already have an FDA that's been neutralized by industry and sees industry as its client. The Center for Drug Evaluation and The Office of New Drugs dominates drug safety so that the drug safety is not independent. Drug safety can't protect the American people. So government now isn't going to protect the average citizen from the consequences of unsafe drugs. The only alternative they have left is the legal system – the tort system. It's not a wonderful system. It would be much better if we had effective post-marketing regulation so that we could get bad drugs off the market before they hurt more people, but that's been neutralized. All that's left to people now is the [courts](#). That's the only way we have of getting companies to change their [behavior](#).

What tort reform will do is remove that threat as well. It's basically giving companies immunity because now the people who are injured by the drugs can't recover damages that might actually mean something to industry. I mean \$250,000 for damages; they blow that in one ad campaign. To them that's nothing. But a [lawsuit](#) for multiple millions of dollars has more of an impact. Now, is that optimal? No. But the fact is that since we have a regulatory agency that doesn't regulate and we have a public health agency that doesn't protect the public, we have thousands of people who are being injured by products that the FDA knows are unsafe. The FDA knew there was a problem with Vioxx. They knew it was a big problem back in mid 2000 yet did nothing about it.

There has to be a system in place that reins companies in. If the FDA isn't going to exercise control over companies, then who will? How will it happen? I don't think that working through the courts and lawsuits is a particularly effective way of doing it; but it's the only recourse we have now, and that will be removed as well. You can demonize the trial lawyers but I think that there are patients who are severely injured by drugs. The defense is, "It's on the labels so we're protected." The problem is that nobody reads the labels so how do they protect anyone? The FDA should be making those decisions.

MANETTE: What can you tell us about all the [antidepressants](#) on the market that millions of [children](#) are taking?

DR. GRAHAM: In early 2004, [SSRI](#) antidepressants and [suicidal behavior](#) was a big safety issue. The FDA had suppressed a report written by a colleague of mine in drug safety and had prevented him from presenting this information in an advisory committee meeting. That information leaked to the media, embarrassing the FDA because it had been caught suppressing very important information – that most of the antidepressants don't work for treating children. Someone in my supervisory chain initiated a criminal [investigation](#) to identify the person who had leaked this information to the media. It turns out that the investigation ordered by these FDA officials was illegal. They broke federal laws – at least two or three federal laws – in ordering this investigation.

I think it's well established that [depression](#) is very common in adolescence. With the antidepressants that we have on the market right now only one of them has been shown to work in children and that's Fluoxetine or Prozac. All the other SSRI antidepressants are no better than sugar pills. However, if you were to read the labeling for these drugs it doesn't point that fact out so patients think one SSRI is as good as another. This is another way that the FDA has betrayed the American public and has betrayed the public health.

With the SSRI and antidepressants what the FDA should have insisted on was a signed informed consent at the time a [child](#) was going to be treated. That informed consent would say three things. One, these are the antidepressants that are available. Only Fluoxetine has been shown to work for depression in children. All the other drugs are no better than placebo. That's point two. No better than placebos. No better than sugar pills. Third, all of these drugs appear to have the ability to increase the risk of suicidal behavior. As a parent, if I see that in writing and the psychiatrist or GP is going to write the prescription and put my child on some drug other than Fluoxetine, I can say, "Doc, why are you putting my child on a drug that doesn't work in kids."

The FDA didn't want patients to have that information so they refused to have signed informed consent. The companies didn't want the patients to have that information because all of a sudden the "off-label" use of these drugs would dry up. So whose interest was being served there?

MANETTE: How do you feel about taking the approval process out of the hands of the FDA?

DR. GRAHAM: Well, where would you put it? If you put it somewhere else they're going to eventually become co-opted the way the FDA has been co-opted. I think the most that we could probably hope for is to try to disassociate the industry pressures from the approval decision. You have to change the culture of the organization, and you have to change the incentives in the organization. The culture and the incentives that the FDA operates by would have to be changed, and Congress can do that through legislation and by establishing different standards for how a drug gets approved. Not only do you have to show that the drug is effective, but you've got to show that it works as well or better than other drugs that treat that indication. You've got to prove to me that the drug is safe, not that the drug is harmful because you're never going to prove to me that the drug is harmful. You set up stringent standards of evidence that might [lead](#) to the approval of safe drugs that actually have benefits to the population.

Then pair that up with an independent post marketing regulation. Currently, the pre-market people who approve the drug decide what happens after it's on the market. If the drug needs to come off the market, they're the ones who have to say yes at the end of the day. The people at the FDA who approved the drug, the Office of New Drugs, they are the single greatest obstacle when it comes to removing unsafe drugs from the market. I can vouch for that from personal experience. What you have to do is you have to take that responsibility and power away from them and put it with the group who sees their mission as serving the public and protecting the public health from unsafe drugs. I think if you do those two things you'd be a long way towards getting the FDA on the right footing.

Also, it would probably be beneficial not to have the FDA's funding come from industry. He who pays the piper calls the tune, and we now have a captured agency. Industry underwrites more than 50 percent of the Center for Drug Evaluation's budget. When industry yanks the chain whose neck is going to get tugged? The Center for Drug Evaluation! If industry isn't happy with them and the funding dries up what are we going to do? We're going to have to let half our people go. The program is going to shrink. Congress is going to be jumping up and down on our back. So it's a captured agency and America is not well served when industry is calling all the shots. Yes, industry has a right to make a legitimate profit from marketing products that help the American people. But you shouldn't have a situation that just basically leaves the American public defenseless. And that's what we have right now. We're virtually defenseless.

MANETTE: Are there other Vioxx's out there? Do you think this will repeat itself at this high

profile level?

DR. GRAHAM: At this current moment I don't think there are other drugs out there that are as bad as Vioxx in terms of the enormous numbers of people that were hurt. During my Senate testimony I did mention that there were five other drugs that I thought the FDA really needed to reevaluate because in my estimation the benefit to risk was misjudged. After I named those five drugs the FDA was in the media saying that I did junk science and that these drugs were safe and effective and that I was a crackpot. However, recently the FDA announced that they were going to take Bextra off the market. Well, Bextra was one of the five I mentioned. They announced that with Acutane they were going to impose a restricted distribution system. Well, I had recommended a restricted distribution system 15 years ago. The major problem with Acutane is that it's just so widely overused that it causes an enormous amount of potential harm to pregnancy exposure. If we restricted the use of the drug to the small number of women who really need it each year, the problem would be pretty much resolved. But the FDA didn't want to do that because it would interfere with company profits. If you restrict the distribution and only one-tenth of the people who are getting it now are getting it tomorrow, profit will drop 90 percent. Of course companies aren't going to go along with that and the FDA isn't going to do anything that's going to harm corporate profit.

After my Senate testimony the FDA announced that they can look at other drugs – not only the other three of the five that I mentioned. There are other drugs on the market that I prefer not to talk about that the FDA knows are killing people. Ten or 100 people a year are dying because of the use of a particular drug or being hospitalized. Hundreds or maybe thousands of people are being hospitalized each year. For some of those drugs the benefits do exceed the risks. For others, it's clear that more could and should be done and maybe that means restricting the distribution of the drug's use or maybe it means banning an indication for the drug saying the drug should not be used for particular indications. Maybe it would be something like with the SSRI's where I believe there should be signed informed consent so that parents will know that the drug the doctor is prescribing for their son or daughter actually doesn't work in children.

I think that there are many things that can be done that haven't been done. There are other unsafe drugs out there, and the nature of our business is that a drug could be approved tomorrow that turns out to be the next Vioxx and we won't know until it happens. Then the question is, how quickly do we identify the problem and how quickly do we take effective action against it? We're pretty good at identifying these problems quickly. Where the FDA falls flat on its face is that there is a long period of time in which it does nothing. Then what it normally does is woefully inadequate and ineffective and as a result the body count mounts and that needs to be changed. Maybe Congress will change that.

MANETTE: Let's talk about incentives. When you say incentives what do you mean? For example, working at the FDA, is their pay somehow based on how many drugs they approve?

DR. GRAHAM: Currently, the performance evaluations for managers at the FDA are built around the drug review. How many reviews did they get done? Did they meet their PDUFA deadlines? It looks bad if you miss your PDUFA deadlines. The unspoken mores – what's the expected – is that you're going to approve as many of these drugs as you can. There has to be an overwhelming reason for you not to approve. Frequently what will happen is that these medical officers in their review will recommend that a drug not be approved and they get overruled by the higher ups because the higher ups are answering to a different set of incentives. You have to change that. A lot of that comes from the leaders. What I want to see is does the drug really make a difference? Is it beneficial?

There are many classes of drugs where we've got 10 or 15 members of that class. They all lower your blood pressure. They all lower your cholesterol. Another one comes along and the FDA feels its obligation to approve it. Why? Maybe the standard should be that for the drugs that come later in a class, they've got to show that they're actually better than the drugs on the market because we've already got these other drugs that work. That would create incentives maybe within industry to

develop drugs that are better than the ones that are already there. Currently, the way the incentives are for industry, it's safer to do a "me too" drug, another drug in the same class.

MANETTE: Do you think that the FDA should not be partially funded by industry?

DR. GRAHAM: I think that PDUFA funding for the FDA is a mistake.

MANETTE: Can you explain that a little more clearly because most people don't know what PDUFA funding is?

DR. GRAHAM: The drug companies pay a substantial amount of money to the FDA at the time that they bring a drug application for approval in order for the FDA to review the drug. Basically it's a tax. It's a fee. Industry pays the fee, and the FDA will review the drug application. But the real expectation is from the company: "We've paid our money, now approve our drug." That's basically how the FDA reacts as well. I think that the funding for the FDA should be independent of the industry that it's regulating and I think in the scientific field there's good evidence to support this notion. Industry money is influencing the decisions that get made, and it creates this incentive structure. You have this culture, you have these expectations, you have pressure from Congress. All of them come to a head at the FDA and all of those incentives are in the direction of "approve the drug." That's what happens so I believe that the FDA is unduly influenced by industry and that undue influence is in part the result of industry money funding the FDA operations.

MANETTE: Dr. Graham, thank you for your commitment to your convictions and for sharing insights that drove you to save many lives.

DR. GRAHAM: You're welcome. I hope I've helped.

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The great direct-to-consumer prescription drug advertising con: how patients and doctors alike are easily influenced to demand dangerous drugs

Sunday, July 31, 2005 by: Dani Veracity

A cute, animated ball bounces around very sadly until he takes a magic potion; suddenly, it becomes happier than ever. No, that isn't the plot of a new children's movie. On the contrary, it's the storyline of a Zoloft commercial – yes, Zoloft, a powerful antidepressant drug. In the 1990s, direct-to-consumer advertising like this increased at a compounded-annually rate of 30 percent, according to Ian Morrison's book, *Health Care in the New Millennium*. In fact, by 1995, drug companies had tripled the amount of [money](#) they formerly allotted to consumer-directed [advertising](#), writes to Gary Null in *Death by Medicine*. Since then, pharmaceutical advertising has grown to an entirely new, pop culture-savvy level.

These days, it's hard to tell the difference between pharmaceutical commercials and [car](#) commercials. Both are almost always intended to look "cool." Car and pharmaceutical commercials use the same hooks -- popular music, good acting and lofty promises -- to hook [consumers](#) and reel them in. Falling prey to car commercials [results](#) in little more than hefty car payments; however, becoming seduced by [pharmaceutical companies](#) can result in the consumer willingly taking powerful [drugs](#), at the risk of serious illness and even [death](#). In spite of this tremendous risk, pharmaceutical [advertisements](#) are becoming increasingly common and, unfortunately, increasingly effective.

In 2000, pharmaceutical [companies](#) spent \$2.5 billion on [mass media](#) pharmaceutical advertisements, according to Mike Fillon in *Ephedra: Fact or Fiction*. This number increased to over \$3 billion in 2003, according to Dr. John Abramson's book *Overdosed America*. In his book,

Death by Prescription, Ray D. Strand looks at these high figures and poses the question: "Why?" Why do pharmaceutical companies spend billions of dollars on [direct-to-consumer advertising](#), when consumers can only obtain [prescriptions](#) for these drugs through a [doctor](#)? Wouldn't it seem that consumers have no influence whatsoever on the success of a [prescription drug](#), so advertising should be directed entirely toward [doctors](#)?

That makes sense, but it's not the way things work. Pharmaceutical companies wouldn't spend billions of dollars on direct-to-consumer advertising if it didn't work. In fact, the advertisements *are* working ... too well. Fillon writes, "The average number of prescriptions per person in the [United States](#) increased from 7.3 in 1992 to 10.4 in 2000. Along with this increase in demand, there has been a shift towards the use of more expensive [medications](#). It's more than a coincidence that many of the most expensive medications happen to be those medications that are most heavily advertised." In fact, between 1999 and 2000, prescriptions for the 50 most heavily advertised drugs rose six times faster than prescriptions for all other drugs, according to Katharine Greider's book, *The Big Fix*. So, how is direct-to-consumer advertising so effective in a system in which doctors write out the prescriptions?

Telling clever stories with [misleading ads](#)

Well, first, let's explore direct-to-consumer advertising, namely the [television](#) commercial. Most prescription [drug](#) commercials follow the same script progression: First, the commercial shows how bleak [life](#) was for a person or character before taking whatever prescription [medicine](#) the commercial is advertising. Then, the protagonist demonstrates or tells how wonderful life is while on the drug. Finally, a voiceover obligingly lists the [side effects](#), often speaking as quickly and inaudibly as possible.

Take, for example, a [Paxil](#) commercial that was recently popular. At the beginning of the commercial, the typical 30-something-year-old woman is standing outside a house, looking through the window at the happy [party](#) going on inside. She looks so lonely and depressed that it must break nearly every consumer's heart. "What's wrong with her?" we compassionate humans gasp in unison. The voiceover answers our question as we think it: The woman has social anxiety [disorder](#), a condition that can be treated with the prescription drug Paxil.

Suddenly, the now-medicated woman rings the doorbell and, with a huge smile on her face, joins the party. We see how much fun she is having and we are so happy for her! Of course, the voiceover quickly goes through the list of Paxil's potential side effects, but how can we concentrate on that, when we're so busy rejoicing at the woman's new happiness? Whoever wrote that commercial should write Hallmark movies. After seeing it a few times, I was convinced that most of my non-immediate family had social [anxiety](#) disorder and I even called one relative up to suggest that she take Paxil. I'm not even a gullible person, yet I was persuaded by [pharmaceutical company](#) advertising.

Doctors prescribe whatever the patient names

We are what Strand calls a "self-medicated" society. Consumers do not actually write their own prescriptions, but they practically do, based on whatever drugs they see advertised on television. Strand writes, "Surveys reported in our [medical literature](#) reveal that when a patient comes into a doctor's office and requests a specific drug that he has seen advertised in the media, the doctor writes the exact prescription the patient requested more than 70 percent of the time!"

So, let's say that a consumer who has been feeling a little sad lately sees a commercial for the [antidepressant drug](#) Zoloft. The commercial demonstrates the symptoms for [depression](#) and the consumer identifies with them. Suddenly, he or she thinks, "I'm not just sad. I'm depressed, which is

a 'medical condition that can be treated by the prescription drug [Zoloft](#).'" With this in mind, the consumer goes to a medical doctor and says, "I've been really depressed a lot lately. I've been [*the consumer recites the depression [symptoms](#) listed in the Zoloft commercial*]. I think I need Zoloft." So, according to Strand, there's a 70 percent chance the doctor will prescribe Zoloft, the exact prescription the consumer requested. That's how pharmaceutical commercials really work. They directly influence consumer behavior, yet [drug companies](#) claim they only "educate" [patients](#), but don't persuade them to do anything.

Doctors are easy to manipulate, drug companies discover

You may be wondering why doctors base their prescriptions on the requests of their patients, who usually have no medical [training](#) whatsoever. That's a good question with a simple answer. The pharmaceutical-advertising machine seduces doctors, too.

According to Burton Goldberg's book, *Alternative Medicine*, paid pharmaceutical advertisements are the main source of the Journal of the American Medical Association's revenues. The American Psychological Association is equally under the pharmaceutical companies' spell, as 15 to 20 percent of the American Psychological Association's (APA) income comes from pharmaceutical advertisements in its journals.

In *Innocent Casualties*, Elaine Feuer calls these advertisements "intentionally misleading" because they promote the pharmaceutical by "exaggerating a drug's [benefits](#) while downplaying its hazards in small print in the addendum." This is very similar to the obligatory "side effects" voiceover recited at the end of a pharmaceutical television commercial; neither consumers nor doctors pay much notice to the "final voiceover" or "fine print."

Just in case advertisements in the [Journal of the American Medical Association](#) (JAMA) haven't properly seduced doctors, pharmaceutical companies take an extra promotional step by aggressively "detailing" doctors, which involves promoting drugs through door-to-door giveaways of free [information](#) and samples, according to *Health Care in the New Millennium*. Morrison writes that "Pfizer alone has 4,500 people in its sales force," but these employees' salaries are small change compared to the increased revenue they encourage.

The next time you watch television or read a magazine, pay special attention to pharmaceutical advertisements. Notice their promotional hooks and be grateful that you, unlike most consumers, are no longer susceptible to their influence. That's what knowledge, unlike naiveté, brings you.

The [experts](#) speak on pharmaceutical advertising:

In the pharmaceutical area, DTC advertising has been increasing in the late 1990s at a rate of around 30 percent compounded annually. Once prevented by regulation from advertising aggressively, pharmaceutical companies now see DTC advertising as a major source of stimulating demand for their product; they spent \$1.3 billion on DTC advertising in 1998 alone. This has had two key effects: (1) it has built brand [awareness](#) and product awareness in the minds of end users (consumers), who are increasingly taking medications for chronic [conditions](#) in increasingly crowded and competitive therapeutic categories—cholesterol management, cardiovascular diseases, asthma, allergy, and other forms of respiratory ailments; and (2) more directly, it has encouraged users to visit their doctors and ask for the product by name.

Health Care in the New Millennium by Ian Morrison, page 44

In order to reach the widest audience possible, drug companies are no longer just targeting medical doctors with their message about [antidepressants](#). By 1995 drug companies had tripled the amount of money allotted to direct advertising of [prescription drugs](#) to consumers. The majority of the money is spent on seductive television ads.

Death By Medicine by Gary Null PhD, page 13

In 2000, pharmaceutical companies spent \$2.5 billion on mass media ads for prescription drugs. Admittedly, this is a small portion of the \$101.6 billion spent on advertising of mainstream consumer [products](#) in the United States.

Ephedra Fact And Fiction by Mike Fillon, page 75

The stage could not have been set more perfectly for prescription [drug advertising](#) to become a major force in American medicine. And so it did. In 1991 the drug companies spent a paltry \$55 million on advertising drugs directly to consumers. Over the next 11 years, this increased more than 50-fold to over \$3 billion in 2003. The ads appeal to viewers as independent decision makers—capable of forming their own opinions about which drugs they need—and resonate with the growing concern that HMOs and managed care plans tend to withhold the best care to save money.

Overdosed America by John Abramson MD, page 81

While \$3 billion in advertising may seem like an awful lot, rest assured that the drug companies aren't worried. Why? Americans are expected to spend over \$500 billion on drugs this year—not including the extra \$100 billion estimated for the Medicare drug benefit program. Spending on prescription drugs is now the fastest growing portion of [healthcare](#) spending in the United States.

Ephedra Fact And Fiction by Mike Fillon, page 176

Many of us don't find the amount of money spent on [marketing](#) prescription drugs to [physicians](#) surprising, but when considering the billions of dollars spent on marketing prescription drugs to the public, don't you wonder why? After all, you can obtain prescriptions only through a doctor. Pharmaceutical companies are willing to spend this kind of advertising money on only their most recently approved [medication](#).

Death By prescription by Ray D Strand, page 48

The average number of prescriptions per person in the United States increased from 7.3 in 1992 to 10.4 in 2000. Along with this increase in demand, there has been a shift toward the use of more expensive medications. It's more than a coincidence that many of the most expensive medications happen to be those medications that are most heavily advertised.

Ephedra Fact And Fiction by Mike Fillon, page 77

According to a report prepared by the National Institute for Health Care Management, a nonprofit [research](#) foundation created by the Blue Cross Blue Shield [health insurance](#) plans, the fifty most-advertised prescription [medicines](#) contributed significantly last year to the increase in the nation's spending on drugs. The increases in the sales of the fifty drugs that were most heavily advertised to consumers accounted for almost half the \$20.8 billion increase in drug spending last year, according to the study. The remainder of the spending increase came from 9,850 prescription medicines that companies did not advertise, or advertised very little. The study attributed the spending increase to a boost in the number of prescriptions for the fifty drugs, and not from a rise in their price.

Ephedra Fact And Fiction by Mike Fillon, page 77

Pharmaceutical companies are in [business](#) to make money; with the exception of over-the-counter medications that will be sold in great numbers, the only way a pharmaceutical company can make lots of money is by developing medications that can be patented. Natural [herbs](#) and foods as well as medications that can no longer be patented won't be "pushed" in advertising because there's no real money to be made on them.

Attaining Medical Self Efficiency An Informed Citizens Guide by Duncan Long, page 11

Not surprisingly the "super [aspirin](#)" have received lots of favorable press on the TV since there's money to be made. With the dollars pharmaceutical companies make, translating into greater

advertising revenues for broadcasters and publishers, the rush is push the super aspirin and play up the "dangers" of common aspirin.

Attaining Medical Self Efficiency An Informed Citizens Guide by Duncan Long, page 13

The cheap-but-effective medications that can't be patented are also kept out of the limelight by the big companies paying for advertising and the mass media intent on making money through advertising.

Attaining Medical Self Efficiency An Informed Citizens Guide by Duncan Long, page 19

When you go into a pharmacy to get a prescription filled, you can often pay considerably less by choosing a "generic" drug over a brand name. The generic drugs are often made by the same manufacturer as the name-brand medication — the extra price is in the packaging and advertising. Even when a different company makes the generic medication, it is every bit as good as the brand name because it is required to meet certain standards before it can be sold in the US.

Attaining Medical Self Efficiency An Informed Citizens Guide by Duncan Long, page 183

In contrast, most physicians are unaware of the considerable [risks](#) and limited benefits of commonly used prescription cholesterol-lowering agents. In addition, since [niacin](#) is a widely available "generic" agent, no pharmaceutical company stands to generate the huge [profits](#) that the other lipid-lowering agents have enjoyed. As a result, niacin does not enjoy the intensive advertising that the HMG CoA reductase inhibitors and gemfibrozil enjoy. Despite the advantages of niacin over other lipid-lowering drugs, niacin accounts for only 7.9 percent of all lipid-lowering prescriptions.

Encyclopedia Nutritional Supplements by Michael T Murray ND, page 90

In addition, since niacin is a widely available "generic" agent, no pharmaceutical company stands to generate the huge profits that the other cholesterol-lowering drugs have enjoyed. As a result, niacin is not intensively advertised like the other drugs. Despite the advantages of niacin over the cholesterol-lowering drugs, niacin accounts for only 7.9 percent of all lipid-lowering prescriptions.

Encyclopedia Of Natural Medicine by Michael T Murray MD Joseph L Pizzorno ND, page 352

In 1996 Russia spent about \$1.75 million on testing. But 1997 opened with a smaller HIV/AIDS budget, unpaid doctors and nurses countrywide, and [hospitals](#) with empty pharmaceutical shelves. Far from being able to afford \$10,000 to \$40,000 a year to treat [HIV](#) patients in ways that met U.S. standards, or to continue a nearly \$2 million testing program, Russia couldn't even find the wherewithal to buy television advertising time on national television to promote [AIDS](#) education.

Betrayal Of Trust By Laurie Garrett, page 205

According to the study, Vioxx, an [arthritis drug](#) sold by Merck & Company, was the most-heavily advertised prescription drug and also accounted for more of last year's increased drug spending than any other single drug. [Merck](#) spent \$160.8 million to promote [Vioxx](#) to consumers—more than PepsiCo spent to advertise [Pepsi](#) or Budweiser spent to advertise its beer, the study said. With the help of the advertising, Vioxx sales quadrupled to \$1.5 billion last year from about \$330 million in 1999.

Ephedra Fact And Fiction by Mike Fillon, page 77

And if that weren't enough, the British pharmaceutical company GlaxoSmithKline spent more on consumer advertising than any other company. It spent \$417 million on advertising last year—an increase of 40 percent from the previous year.

Ephedra Fact And Fiction by Mike Fillon, page 178

Hundreds of millions of dollars are spent by pharmaceutical companies to research and then advertise their patented medical drugs to physicians and consumers. No such bankroll exists for [nutritional supplements](#). That's because nutritional [supplements](#), based on vitamins, minerals, herbs, and [natural](#) substances such as [MSM](#), are not patentable.

The Miracle Of MSM by Stanley W Jacob, page 13

The reason drugs cost more in America than in any other country boils down to one simple factor:

the pursuit of maximum profit. The [pharmaceutical industry](#) has taken every opportunity, used every ploy, to deceive the American people. To derail efforts at making pharmaceutical benefits an integral part of Medicare, they spent tens of millions of dollars on an advertising campaign to discredit the Canadian system, and even created a bogus organization, "Citizens for Better Medicare," to try to lend credibility to their efforts. And now they are introducing piecemeal discount card programs in an effort to defuse efforts for more comprehensive change.

Health Care Meltdown by Robert H Lebow MD, page 263

But Canada's system has borne the brunt of negative advertising campaigns in the U.S., campaigns which have been successful in coloring Americans' perceptions of the Canadian system. The [American Medical Association](#) spent several million dollars in the early '90s to discredit the Canadian system and create doubts in the mind of the American public about a government-managed system for universal coverage. And in 2000, in a somewhat less successful ad campaign that cost perhaps \$60 million, the American pharmaceutical [industry](#) tried to discredit the Canadian system. A ubiquitous "bus from Canada" appeared in a plethora of TV spots and full-page newspaper ads across the U.S. The goal was to derail efforts to make pharmaceutical benefits an integral part of Medicare.

Health Care Meltdown by Robert H Lebow MD, page 149

Most, but not all, megasites support themselves with ads for prescription drugs, [vitamins](#), and medical sundries, as well as laptops, life [insurance](#), and books — typical Internet commerce. Therefore, advertisers may influence the information you find on the site.

Healthcare Online for Dummies by Howard and Judi Wolinsky, page 23

With annual U.S. revenues of about \$100 billion and worldwide revenues of \$300 billion, the pharmaceutical industry is one of the largest, most powerful industries, producing some of the most sophisticated marketing and advertising anywhere. Marketing is the economic equivalent to waging war—sizing up your own forces, your enemy's (the competition), and emphasizing your own strengths and your enemy's weaknesses. Marketing strategy meetings are akin to war rooms where generals map out their plans for attack and defense.

Syndrome X by Jack Challem Burton Berkson MD and Melissa Smith, page 55

The reason that prescription drugs are not recognized as one of the biggest killers in America is complex. Drug companies who make huge profits from the sale of drugs spend more than \$10 billion a year promoting drugs, and spend next to nothing warning the public about potential risks. Drug companies also engage in misleading advertising campaigns which make outright false or unrealistic claims, but which convince that vast majority of the public that most or all prescription drugs are not only safe, but the key to better [health](#) and a better life. The doctors themselves are also a part of the problem. Doctors chronically under-report and even ignore the deaths or adverse reactions to the drugs they prescribe because it is not in their professional self interest to raise public awareness to the [danger](#). Doctors are afraid of being sued, they maintain a [culture](#) of denial, and they also profit from their relationships with the big drug companies. The [government](#) is also part of the problem because it does not have the resources or the political will to do more about the dangers of prescription drugs. Also, powerful members of the American government, from the President on down, are all lobbied heavily by the cash rich drug companies.

Prescription Medicines, Side Effects and Natural Alternatives by American Medical Publishing, page 16

First of all, consider the fact that the American prescription [drug industry](#) - the giant pharmaceutical companies — is the most profitable industry in the world. Drug companies make more money than banks, more money than [oil](#) companies, more money than [Ford](#) or GM, more money than anybody. Drug companies spend billions of dollars on advertising and promotion -- some \$10 billion every year. This advertising is directed at both doctors, and directly to the public.

Prescription Medicines, Side Effects and Natural Alternatives by American Medical Publishing, page 11

The United States is currently the only country in the world that allows drug companies to advertise prescription drugs directly to the consumer. It used to be that prescription drugs could only be touted to physicians. But now consumer ads on TV tantalize you with great promises of health and well-being, skim through the side effects as quickly as possible and then suggest you contact your physician or a drug company hotline for more information. The drug companies are also responsible for the expensive, slick, four-color ads you now see in consumer magazines and newspapers. You are bombarded with \$3 billion worth of advertising for prescription and over-the-counter drugs every year. That should give you an idea of how valuable you are as a drug consumer and of the staggering profits the drug companies rake in every year.

Prescription Alternatives by Earl Mindell RPh PhD and Virginia Hopkins MA, page 531

Pharmaceutical companies spent \$2.5 billion in 2000 promoting prescription drugs, an increase of nearly 45 percent over 1999. These advertisements contribute to rising costs by inducing consumer demand for newer, higher-priced drugs, when the older ones may work just as well.

Prescription For Dietary Wellness by Phyllis A Balch, page 285

Claritin, a formerly prescription antihistamine used to control allergic symptoms, was far and away the most heavily advertised prescription drug in the two years following the FDA's 1997 rules change. They resisted the idea that there were equally good and perhaps even better ways to relieve their allergy symptoms than a new (and therefore less well tested) drug. Moreover, they were unconcerned about Claritin's cost (more than \$2.10 per day): most had prescription drug coverage as part of their health insurance. With an advertising budget greater than that of Budweiser beer or Coca-Cola, Claritin took off: sales grew from \$1.4 billion in 1997 to \$2.6 billion in 2000.

Overdosed America by John Abramson MD, page 153

Thus, it is not surprising that direct-to-consumer prescription drug advertising is expected to increase to \$7.5 billion by 2005, a 1,200% increase over a decade, as drug manufacturers decide, as Vodra put it, to "fight fire with fire in the marketplace. It's only a small step from that to the adoption of an 'offense is the best defense' policy as marketing pressures intensify."

Overdose by Jay S Cohen, page 162

The medication marketplace is a very competitive world. At pharmaceutical companies, doctors usually don't make the final decisions—business people make them. In order to sell medications, good and bad, elaborate marketing and advertising strategies are necessary, and impressive rates of effectiveness are essential.

Overdose by Jay S Cohen, page 35

A self-medicated society

Not only are we an overmedicated society, we are a self-medicated one. It's true, physicians are prescribing more drugs than ever before, but not only is the pharmaceutical industry effective in advertising prescription medications, it has overwhelmingly persuaded the American public to buy tons of over-the-counter medications.

Death By prescription by Ray D Strand, page 169

Surveys reported in our medical literature reveal that when a patient comes into a doctor's office and requests a specific drug that he has seen advertised in the media, the doctor writes the exact prescription the patient requested more than 70 percent of the time!

Death By prescription by Ray D Strand, page 49

But, again, there is a problem. While TV ads for drugs do indeed list potential harmful side effects, the slickly produced ads gloss over them so fast, and with such finesse, it creates an overwhelming impression among the public that these potential dangers are all but nothing to worry about. Also, TV ads do not list all of the potential side effects, but rather, just the most common side effects. So in effect, advertisements for prescription drugs on television are literally lying by omission.

Prescription Medicines, Side Effects and Natural Alternatives by American Medical Publishing, page 13

30 percent of consumers reported having talked with their doctor about a drug they'd seen advertised. Nearly half of those who asked for an advertised drug—13 percent of all consumers—came away with a script. In another Kaiser study, co-sponsored by The NewsHour with Jim Lehrer, nearly half of American consumers said they trust advertisements to provide them with accurate information. But perhaps most telling are these results of a recent NIHCM study: Between 1999 and 2000, prescriptions for the fifty most heavily advertised drugs rose at six times the rate of all other drugs. Sales of those fifty intensively promoted drugs were responsible for almost half the increase in Americans' overall drug spending that year. Makers of the new [arthritis](#) drug Vioxx spent \$160 million pushing it to consumers in 2000, more advertising dollars than were dropped on Pepsi Cola, Budweiser beer, Nike shoes, or Campbell's soups. Vioxx sales shot up 360 percent.

The Big Fix by Katharine Greider, page 30

Only the United States and New Zealand permit advertising of prescription medicines to consumers.

Ephedra Fact And Fiction by Mike Fillon, page 255

This practice of massive advertising campaigns for drugs in order to convince us and our doctors that we "need" various drugs and specifying which drugs we do need should be a great concern for us. CONSUMER REPORTS discussed this issue at length in two articles which ran concurrently in the February and March 1992 issues entitled "Pushing Drugs to Doctors" and "Miracle Drugs or Media Drugs?" They estimate a figure of 5 billion dollars was spent in 1991 for this type of advertising and add, "Though doctors insist their scientific training, high intelligence, and sophistication enable them to resist manipulation, the truth is that skillful marketers can influence M.D.s just as easily as they can sway the rest of us." The pharmaceutical companies spend more on this advertising than they spend in research and development of products.

PROZAC Panacea or Pandora by Ann Blake Tracy PhD, page 43

Merrell Dow pharmaceuticals mounted a massive advertising campaign admonishing, "If you want to quit [smoking](#) for good, see your doctor. . . . Now your doctor can provide a [treatment](#) to help control nicotine withdrawal symptoms." The smoking industry is too vast and the number of smokers wishing to quit too lucrative for smoking to be overlooked as a medical problem.

Diseasing Of America by Stanton Peele, page 119

The unnecessary [surgery](#) figures are escalating just as prescription drugs driven by television advertising. Media-driven surgery such as gastric bypass for obesity "modeled" by Hollywood personalities seduces obese people to think this route is safe and sexy. There is even a problem of surgery being advertised on the Internet. A study in Spain declares that between 20 and 25% of total surgical practice represents unnecessary operations.

Death By Medicine by Gary Null PhD, page 19

Since the mid-1990s, pharmaceutical companies have tripled the amount of money they spend on direct-to-consumer advertising prescription drugs. From 1996 to 2000, totals rose from \$791 million to nearly \$2.5 billion. And despite the huge increase, drug companies spend even far more dollars in advertising their products to physicians, not consumers. The \$2.5 billion figure for consumer ads is concentrated on a relatively small handful of medications.

Ephedra Fact And Fiction by Mike Fillon, page 176

Eli Lilly's advertisements in the general media for [Prozac](#) specifically state: "Like other antidepressants, it isn't habit forming." No wonder so many patients are not informed either about serious withdrawal syndromes or dependence. Obviously such statements by pharmaceutical companies and drug advocates are attempts to "educate" the public out of their healthy concerns about drugs in general, including Prozac-type medications. Although aggressively advanced, such pronouncements are at odds with the clinical reality for many patients on the drugs.

Prozac Backlash by Joseph Glenmullen MD, page 89

Yet the healthcare industry — as with most other industries — is slow to recognize the Internet's

potential business opportunities and threats. In addition, there is strong and irrational Internet resistance from physicians, who control about 80 percent of healthcare resources. Not surprisingly, pharmaceutical companies are switching their advertising budgets to target consumers rather than physicians in an attempt to influence how consumers determine their [medical treatment](#) needs.

Future Consumer com by Frank Feather, page 190

The pharmaceutical companies have been quick to realize the potential of this expanding market and are beginning to target advertising for prescription medicines directly to consumers, on television and in print. These developments can be positive, but they do require more effort and responsibility from all of us.

Graedons Best Medicine by Joe Graedon & Dr Terasa Graedon, page 111

Among the wealthy nations that support the global pharmaceutical industry, the United States is by far the most permissive in its regulatory scheme. As other countries move to control prices and sharply limit advertising, the industry increasingly turns to American consumers for its profits.

The Big Fix by Katharine Greider, page 172

The Kaiser Family Foundation reports that with thousands of drugs on the market, 60 percent of DTC spending in 2000 went to plug just twenty products. This intensive exposure creates what ad people call "brand awareness." A recent survey by [market research](#) firm Insight-Express found that, for example, 74 percent of respondents knew Claritin by name. More than half recognized Paxil, 45 percent knew the cholesterol-lowering Zocor, and nearly 80 percent were aware of the pharmaceutical phenomenon Viagra. All have been among the most heavily advertised drug products.

The Big Fix by Katharine Greider, page 91

This translates to a likelihood that prescriptions are being given for drugs that are more dangerous and less effective than patients—or even doctors—realize. Until changes are made, both physicians and patients will be harmed by prescribing decisions based on all-too-frequently generalized and misleading information from advertisements.

Ephedra Fact And Fiction by Mike Fillon, page 178

Pharmaceutical companies have overcome the obstacles of managed care. They have sophisticated pharmacoeconomic teams to negotiate the presence of their products on the formulary, and they have understood how to use both legislative action and sophisticated marketing to ensure that their products are not cut out of either [Medicaid](#) or private sector formularies. They have been significantly investing in DTC advertising as well as expanding their sales forces for detailing physicians. This is the business model for the pharmaceutical industry in the late 1990s, and industry leaders anticipate that these good times will continue rolling into the future.

Health Care in the New Millennium by Ian Morrison, page 48

Yet the mainstream media operate with somewhat of a double standard. They are willing, even eager, to use the video news releases from the pharmaceutical and [medical technology](#) industry. The morning talk shows are full of medical [technology](#) miracles; they cover the wonders of new drugs and medical devices and technology using the canned television images provided by the industry. More recently the media have been given further conflicting incentives with the enormous explosion of direct-to-consumer advertising; page after page of pharmaceutical industry supplements appear in popular media. For example, pharmaceutical giant Pfizer purchased all of the advertising space in an entire issue of Time magazine on the "Future of Medicine." Similarly, Johnson and Johnson purchased the advertising space of an entire issue of Newsweek.

Health Care in the New Millennium by Ian Morrison, page 79

Another issue associated with the cultural view of menopause has to do with issues of [youth](#) and femininity. As Dr. Andrew Weil writes in his Self Healing newsletter, "there is an unstated selling point that is quite clear in pharmaceutical company advertisements: that it is a chemical fountain of youth offering persistent beauty, attractiveness, and satisfying sexuality in the face of advancing

age.

Herbal Defense by Ralph T Golan ND, page 210

Anyone who watches television cannot but help notice a new trend in the past couple of years — suddenly our TV programs are flooded with advertisements for dozens of new prescription drugs. And they seem to promise everything. Night after night, television commercials paid for by drug companies are promising to fix or cure everything from depression and sleeplessness, to arthritis and allergy problems. You name it, they've got a drug for it, be the problem as serious as cancer, or as trivial as baldness and unattractive toenails.

Prescription Medicines, Side Effects and Natural Alternatives by American Medical Publishing, page 12

The 1997 change unleashed an unprecedented onslaught of commercials. By 1999, the average American was exposed to nine prescription drug advertisements on television every day. The number of television ads increased 40-fold between 1994 and 2000. Suddenly it became a normal part of our everyday experience to be confronted with the idea that we or a loved one might be suffering from ED (erectile dysfunction, for those not in the know), arthritis pain, high [cholesterol](#), nasal congestion, [osteoporosis](#), heartburn, or even the heartbreak of toenail fungus. In the "teachable moments" created by these skillfully raised concerns, consumers are "educated" about readily available drugs to solve the problem.

Overdosed America by John Abramson MD, page 152

Pharmaceutical advertising in [medical journals](#) and though 'detailing' seduces doctors

By 1900, there were 22 homeopathic [medical schools](#) and nearly 100 homeopathic hospitals in the U.S. In fact, 15% of all American physicians practiced [homeopathy](#) at the turn of the century, according to Trevor Cook, Ph.D., D.I.Horn., President of the British Homeopathic Medical Association." However, by the same time, the bond between [the AMA](#) and the pharmaceutical companies was firmly established. Paid advertisements from pharmaceutical companies in the AMA's journal were the AMA's main source of revenue (as it is today). Prominent physicians were paid to endorse proprietary drugs and doctors were deluged with free samples of pharmaceutical drugs. Through a series of maneuvers including a new rating system for medical [schools](#) aimed at eliminating [homeopathic](#) colleges, the practice of homeopathy had nearly disappeared as a force in American medicine by 1930.

Alternative Medicine by Burton Goldberg, page 520

Drug company money influences every aspect of modern-day psychiatry. The American Psychiatric Association is literally built on a foundation of drug money: millions of dollars of pharmaceutical advertising money are poured into the APA's publications, conferences, continuing education programs, and seminars. In return, the APA bends over backward to help drug companies promote their products. And 15 to 20 percent of the APA's income in recent years has come directly from drug company advertising in APA journals—another means of guaranteeing good press for new drugs.

A Dose of Sanity by Sydney Walker III MD, page 230

Pharmaceutical ad campaigns and the distribution of free samples usually determine the drugs doctors use to treat patients with. Advertisements in prominent medical journals are intentionally misleading, exaggerating a drug's benefits while downplaying its hazards in small print in the addendum. Although [the FDA](#) requires advertisers to present a "fair [balance](#)," Cheryl Graham, Acting Director of the FDA's Marketing Division, admits that one-half of the journal ads violate this standard. And since the [FDA](#) screens only 10 to 20 percent of all drug promotions, physicians are forced to take drug companies at their word.

Innocent Casualties by Elaine Feuer, page 73

Direct-to-consumer marketing increased 30 percent in 1998 alone. Through TV, magazine, and newspaper advertising, pharmaceutical companies are taking their message directly to the public. If

it weren't for pharmaceutical advertising supplements, Newsweek would be only three pages long. Similarly, pharmaceutical companies have focused on "detailing" physicians very aggressively (that is, promoting products through sales calls to doctors to provide information and free samples). Pfizer alone has forty-five hundred people in its sales force. Bristol-Myers Squibb and Hoffman-La Roche, for example, added over one thousand salespeople over the last couple of years. Drug companies know that putting sophisticated detailing teams in the field to promote their products to doctors makes a difference in prescribing [behavior](#). Doctors may find this offensive, but detailing works.

Health Care in the New Millennium by Ian Morrison, page 30

The FDA's [bias](#) is further shown by its selective implementation of policy directives. Its duty, by law, is to set standards for drug advertisements. Yet, according to a study conducted at the University of California and published in The Wall Street Journal, 60% of the pharmaceutical ads from medical journals violated FDA guidelines. But the FDA, to this day, has done nothing about these violations.

Alternative Medicine by Burton Goldberg, page 48

Such results can be reported by medical journalists—which are also hired by these PR firms—in unsuspecting medical journals. Healthcare PR firms also undertake conventional lobbying strategies, such as opposing restrictions on "direct-to-consumer" advertising, which allows companies to market prescription and OTC drugs using the same techniques as toiletry items. They can also move very quickly and deftly to "squash" any negative news about their clients, as well as to promote damaging news about others. Could it be this is a strategy being deployed against the dietary [supplement](#) industry?

Ephedra Fact And Fiction by Mike Fillon, page 146

Furthermore, physicians who abide by a conventional Western medical perspective are more likely to publish papers and be on editorial boards of scientific journals than their peers who hold to different philosophies. "There is kind of a self-selection process where physicians who are against [alternative medicine](#) end up being on the editorial boards of the journals," Dr. Gaby says. It's important to bear in mind that many medical journals receive a substantial amount of revenue from the advertising dollars they get from the pharmaceutical industry, whose interests would not be served by articles and [studies](#) that recommended the use of alternative medicine over drugs and surgery.

Alternative Medicine by Burton Goldberg, page 51

We are fully aware that what stands in the way of change are powerful pharmaceutical companies, medical technology companies, and special interest groups with enormous vested interests in the business of medicine. They fund medical research, support medical schools and hospitals, and advertise in medical journals. With deep pockets they entice scientists and academics to support their efforts. Such funding can sway the balance of opinion from professional caution to uncritical acceptance of a new therapy or drug. You only have to look at the number of invested people on [hospital](#), medical, and government health advisory boards to see conflict of interest. The public is mostly unaware of these interlocking interests. For example, a 2003 study found that nearly half of [medical school](#) faculty, who serve on Institutional Review Boards (IRB) to advise on clinical trial research, also serve as consultants to the pharmaceutical industry.

Death By Medicine by Gary Null PhD, page 10

Yet doctors repeatedly make new drugs bestsellers within months. Drug reps fill doctors' cabinets with "free" samples, knowing that if patients do well on them, they won't want to switch. Drug advertising seizes upon any difference, no matter how trivial, to sway doctors to prescribe expensive new drugs with no track records, and doctors readily oblige. You'd think that after recent disasters with Baycol, Rezulin, Lotronex, Duract, Redux and Fen-Phen, doctors would learn, but they keep prescribing new drugs like Clarinex, Nexium, and Bextra at greater [risk](#) and cost. These repeated problems compelled Drs. Marcia Angell and Arnold Relman, another former editor of the

New England Journal of Medicine, to warn, "Few Americans appreciate the full scope and consequences of the pharmaceutical industry's hold on our [health care](#) system."

Disease Prevention And Treatment by Life Extension Foundation, page 725

At first, pharmaceutical companies stepped up advertising, some of which ran for four pages, in the medical journals and weekly magazines sent to doctors' offices. Soon, such ads constituted the medical journals' major source of funding, and while they continue to deny it, publishers are influenced by the pharmaceutical industry in choosing which articles to print. Articles concerning alternative treatments, such as the use of nutritional supplements, are few in number in clinically oriented journals, and usually are routinely rejected in favor of articles extolling the virtues of a prescription drug or surgical procedures.

Health And Nutrition Secrets by Russell L Blaylock MD, page 344

Recently, pharmaceutical companies have launched an even cleverer plan. Whereas, in the past they depended on frequent visits to the doctors' offices by [drug reps](#) to convince doctors to use their drugs, now they've bypassed doctors altogether and advertise directly on television and the radio, urging people to tell their doctors they want to try the advertised drug.

Health And Nutrition Secrets by Russell L Blaylock MD, page 366

If you scan most clinical journals, you will see that they are filled from cover to cover with ads from pharmaceutical companies and medical supply dealers. These are very expensive ads. In addition, many of these companies give grants to the journals in which they advertise. Unfortunately, this is also true of many [nutrition](#) journals as well. Doctors tend to read the articles that deal with new drugs being developed, new surgical techniques, and advances in diagnosis. The scattered nutritional or biochemical articles are rarely read.

Health And Nutrition Secrets by Russell L Blaylock MD, page 367

This subtle type of bias sometimes becomes more blatant. For example, a former editor of the Journal of the American Medical Association ([JAMA](#)) alleged that Pfizer, a major pharmaceutical company, had withdrawn \$250,000 worth of advertising because an [article](#) appearing in JAMA had cast one of their drugs in an unfavorable light.

Preventing And Reversing Osteoporosis By Alan R Gaby MD, page 249

Another area in which pharmaceutical companies wield enormous influence is medical "education." Most doctors in this country are visited on a regular basis by "representatives," salesmen from large pharmaceutical companies. In surveys, doctors list pharmaceutical salesmen as one of their most important sources of information about new drugs. Salesmen and drug company "literature" are where doctors first learn about things like "[serotonin](#) imbalances" and serotonin "selectivity."

Lavish advertisements in medical journals carry similar messages.

Prozac Backlash by Joseph Glenmullen MD, page 226

Doctors have access to many other sources of medical information. Some invite pharmaceutical representatives into their offices and conferences, and some attend industry-sponsored conferences. Some avidly read free pamphlets and journals sent to them by pharmaceutical companies. By contrast, some read only the journals that come as part of membership in a professional society, and pay their own money to subscribe to sources that are not dependent on pharmaceutical company support, contain no advertising, and are funded entirely by subscription fees.

On The Take by Jerome P Kassirer M.D., page 84

Dr. Richard Smith, editor of the British Medical Journal, has raised the concern that lucrative advertising and reprint sales can be a corrupting influence. One experience at the Annals of Internal Medicine in 1992 sent a chill down the spines of editors and publishers alike. When the (then) editors, Drs. Suzanne and Robert Fletcher, published a study sharply critical of the pharmaceutical industry, pharmaceutical advertising in the journal declined substantially, and remained lower than usual for months thereafter. For editors of many journals whose profit margins are not robust, that experience might [lead](#) them to be chary about criticizing the advertisers who support their

publications.

On The Take by Jerome P Kassirer M.D., page 91

Drug companies often claim that they are just helping the public by providing physicians the best information possible. They admit that they might make friends and generate goodwill for their companies in the process, but their primary goal, they claim, is education, not marketing. One provider of [medical education](#), Joe Torre, the chief executive of an advertising agency that owns its own clinical research company, said, "Very often doctors are more influenced by what other doctors say than what pharmaceutical companies have to say. So companies work through medical education companies to have doctors who support their products talk about their products in a favorable way. That's called medical education."

On The Take by Jerome P Kassirer M.D., page 93

In effect, the publication is more a paid advertisement for industry than a publication of a learned medical society. In fact, the misleading headings are only part of the deception. The title, Symposia Excerpts, misleads the reader to thinking that he is reading selected summaries of key talks on the formal schedule of the [conference](#). In fact, they are summaries of after-hours conferences sponsored by pharmaceutical companies. Despite the assertion on the cover that the Symposia Excerpts is a publication of the ATS, the ATS carefully disavows responsibility with a disclaimer that reads: "The opinions expressed in this publication are those of the speakers and do not necessarily reflect the opinions or recommendations of their affiliated institutions, the publisher, the American Thoracic Society, or any other persons."

On The Take by Jerome P Kassirer M.D., page 121

The PDR, free meetings and gifts, and direct contact by drug-company representatives constitute three major ways that drug companies influence physicians' choices of medications. A fourth way is advertising. Most of this advertising is done in medical journals, which also serve as an important source of information for physicians.

Overdose by Jay S Cohen, page 56

In fact, pharmaceutical companies spend more than 21 billion dollars a year on promoting and marketing their products, of which about 88 percent is directed at physicians. With approximately 600,000 physicians in active practice this amounts to more than \$30,000 spent on each physician. Although industry market research data are unavailable, studies of physicians show what common sense predicts, namely that physicians are influenced by all kinds of marketing tactics.

On The Take by Jerome P Kassirer M.D., page 78

Beyond these direct influences, drug companies exert broad influence over the drug information received by doctors and consumers. The vast majority of everything physicians and consumers read and know about medications comes from the drug companies. Medication package inserts, drug advertising toward physicians and consumers, and the information in the ubiquitous Physicians' Desk Reference come directly from the drug companies. Where do most doctors turn for medication and dosage information? To the PDR, to drug company representatives who make the rounds of doctors' offices, and to advertising in medical journals. Yet, the medication information offered by these drug-company-supported sources is often biased, incomplete, and sometimes inaccurate.

Overdose by Jay S Cohen, page 16

A cursory look at almost any medical journal will reveal dozens of advertisements by the drug companies. Glossy ads promote the efficacy or ease of usage of drugs. Some ads boast that physicians don't have to bother reducing the drugs' dosages for older people, not even for those with other disorders or taking other medication. The content of these ads is based on the information in package inserts, with the same limitations or omissions of important side effects and/or lower, safer doses.

Overdose by Jay S Cohen, page 56

A historical perspective of pharmaceutical advertising

One may guess that papers taking advertising dollars from poppers' pharmaceutical source were in no hurry to dig up the unflattering history of animal experiments that did see immune damage stemming from use of the drug.

Aids A Second Opinion by Gary Null PhD with James Feast, page 200

Back in the World War II era, it was the same for tobacco. Page through a few magazines of the day to look at the advertisements for Pall Mall or Lucky Strike and you will find that smoking is not only proclaimed to be safe but even said to promote health! Moreover, everybody was lighting up, just as in a certain strata, everybody was inhaling. Poppers and cigarettes were sexy, for god's sake. What is being asserted, then, is that certain practices that now seem unconscionably risky were once seen as innocent, as innocent as, in days gone by, puffing on a Lucky.

Aids A Second Opinion by Gary Null PhD with James Feast, page 265

Fishbein was the most powerful man in American medicine in his day. The [AMA](#) (and Fishbein) consolidated their hold over American medicine. Subscriptions to the Journal had increased from 13,078 in 1900 to over 80,000 by 1924. Income from pharmaceutical advertising was already in the hundreds of thousands of dollars. Yet AMA leaders were conscious of the threat posed by irregular practitioners. Ironically, the long-time General Manager of the Association, George H. Simmons, MD, had himself been a homoeopathic practitioner in Lincoln, Nebraska, "and one of a rather partisan hue."

Herbs Against Cancer by Ralph W Moss PhD, page 75

FDA control (or lack of control) of pharmaceutical advertising

Another connection between the FDA and the pharmaceutical industry is through the pharmaceutical Advertising Council (PAC). In 1985, the PAC teamed up with the FDA to solicit funds from the pharmaceutical industry for the purpose of combating medical [quackery](#). "The pharmaceutical Advertising Council and the FDA also issued a joint statement addressed to the presidents of advertising and PR agencies nationwide asking them to cooperate with a joint venture anti-fraud and quackery campaign," according to Mark Blumenthal, Executive Director of the American Botanical Council.

Alternative Medicine by Burton Goldberg, page 48

The primary culprit in promoting the misprescribing and overprescribing of drugs is the pharmaceutical industry, which now sells about \$80 billion worth of drugs in the United States alone. By intimidating the [Food and Drug Administration](#) (FDA) into approving record numbers of me-too drugs (drugs that offer no significant benefit over drugs already on the market) that often have dangerous adverse effects and by spending well in excess of \$12 billion a year to promote drugs, using advertising and promotional tricks that push at or through the envelope of being false and misleading, this industry has been extremely successful in distorting, in a profitable but dangerous way, the rational processes for approving and prescribing drugs. Two studies of the accuracy of ads for prescription drugs widely circulated to doctors both concluded that a substantial proportion of these ads contained information that was false or misleading and violated FDA laws and [regulations](#) concerning advertising.

Worst Pills Best Pills by Sidney M Wolfe MD and Larry D Sasich PharmD MPH, page 10

The division at FDA responsible for policing prescription drug advertising has not been given adequate resources to keep up with the torrent of newly approved drugs. As a result, the drug industry correctly believes it can get away with more violative advertising than in the past. The role of the U.S. Congress in pushing the FDA into approving more drugs, and passing, with the FDA's reluctant approval, legislation to further weaken the FDA's ability to protect the public, cannot be overlooked.

Worst Pills Best Pills by Sidney M Wolfe MD and Larry D Sasich PharmD MPH, page 10

Though broadcast advertising of prescription drugs has been legal for years, guidelines released by the FDA in 1997 clarified the rules for advertising directly to consumers. According to these

guidelines, drug companies can fulfill their obligations for informing consumers about prescription drugs by referring in advertisements to four sources of additional information: their doctor, a toll-free number, a magazine or newspaper ad and a website.

Ephedra Fact And Fiction by Mike Fillon, page 77

Health care advocates were shocked by the decision of the Food and Drug Administration (FDA) to allow drug makers to advertise prescription drugs on television giving only minimal information about the risks involved.

Under The Influence Modern Medicine by Terry A Rondberg DC, page 70

And for the first time in decades, pharmaceutical companies are advertising heavily direct to the public. The 1962 Harris-Kefauver Amendment to the Federal Food and Drug Act imposed strict regulations on pharmaceutical company advertising. The requirements brought to a halt the aggressive marketing of notorious drugs like amphetamine antidepressants and barbiturates. But in the mid-1990s, the FDA liberalized the requirements pharmaceutical companies have to meet. The result has been a surge of advertising drugs direct to consumers.

Prozac Backlash by Joseph Glenmullen MD, page 231

Wilkes and a group of colleagues had earlier conducted a study of prescription drug advertisements which showed "many claims prove to be inaccurate or misleading." The study was published in the June 1, 1992 issue of the Annals of Internal Medicine. For the study, Wilkes' group asked medical experts to [review](#) 109 advertisements from the country's ten leading medical journals. Using the FDA's guidelines for pharmaceutical company advertising, the reviewers "indicated that 92% of advertisements were not in compliance in at least one area" of the FDA's guidelines. Wilkes' group speculated "that the FDA is unable or unwilling to enforce adequately its rules relating to drug advertising.

Prozac Backlash by Joseph Glenmullen MD, page 232

For years the pharmaceutical industry was allowed to market its drugs only to doctors. It did this through medical journals, continuing medical education, sponsored events, sales calls, and junk mail. Then, in 1981, the drug industry proposed that the FDA allow advertising directly to consumers, arguing that the public should not be denied access to the "knowledge" that would be provided by such marketing. Four years later, the pharmaceutical industry got its foot in the door when the FDA agreed to allow "direct-to-consumer" (DTC) advertising. But the rules were strict, and the content of the ads was, therefore, limited: Drugs could be mentioned by name, but advertisements that discussed the treatment of specific conditions were required to include a lengthy list of side effects and contraindications (situations in which the drug should not be used). As a result, the ads were vague and unfocused, primarily brand-awareness campaigns designed to smooth the way at the doctor's office.

Overdosed America by John Abramson MD, page 151

In the fall of 1971, the FDA also made a serious attempt to halt the growth of the increasingly popular field of alternative medicine. By defining all unorthodox medical treatments as "quackery," which they interpreted as "misinformation about health," the FDA attempted to prevent physicians, manufacturers, and consumers from practicing alternative therapies. The federal government's war against quackery was supported by the pharmaceutical companies and the AMA. In 1985 the pharmaceutical Advertising Council and the FDA solicited funds from the pharmaceutical industry to combat medical quackery; they also issued a joint statement addressed to the presidents of advertising and PR agencies nationwide, asking them to cooperate with the anti-quackery campaign.

Innocent Casualties by Elaine Feuer, page 11

Although it is entirely legal for a doctor to use a drug off-label, it is illegal for a drug company to advertise a drug for any purpose other than the one or ones approved by the FDA. By recruiting physicians to discuss off-label uses, therefore, the drug companies, in essence, bypass official channels and create a potent marketing force of physicians. One flagrant example of physicians

aiding in marketing came to light when a whistleblower charged that Warner-Lambert had engaged in unlawful off-label marketing of the anti-epilepsy drug, Neurontin. In May 2004, Pfizer pled guilty to Medicaid fraud and agreed to pay fines of approximately \$430 million.

On The Take by Jerome P Kassirer M.D., page 28

Government intervention is also warranted on industry-initiated and industry-sponsored "front organizations." These groups, often led by financially conflicted physicians, sponsor ventures such as pamphlets, brochures, pocket books, Web sites, and registries, and they have gotten out of hand, often subtly recommending off-label drugs and promoting expensive drugs. Although federal agencies have control over drug advertising, these ventures apparently have escaped detection and oversight. Nonetheless, they may have even more impact on the use and misuse of drugs than pharmaceutical advertising in medical journals and in the lay media. These publications masquerade as educational materials, but many are largely marketing efforts that deserve as much scrutiny as drug advertisements.

On The Take by Jerome P Kassirer M.D., page 207

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The following is a Street Spirit interview with Robert Whitaker, author of *Mad In America: Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill*. It is reprinted here with permission from [the Street Spirit](#) in Oakland, California. The interview is conducted by Terry Messman, editor of Street Spirit.

Investigative reporter Robert Whitaker, author of the groundbreaking book *Mad In America*, is now pursuing a fascinating line of [research](#) into how the mammoth [psychiatric drug](#) industry is endangering the American public by covering up the untold cases of suffering, anguish and [disease](#) caused by the most widely prescribed [antidepressants](#) and antipsychotic [medications](#).

Whitaker exposes the massive lies and cover-ups that have corrupted the Food and Drug Administration's drug [review](#) process, and co-opted research trials in order to spin the [results](#) of drug tests and conceal the serious hazards and even deadly side-effects of brand-name drugs like [Prozac](#), [Zoloft](#), [Paxil](#) and [Zyprexa](#).

The story becomes even more frightening when we look at the aggressive tactics these giant [drug companies](#) have used to silence prominent critics by defaming them in the press, and by using their [money](#) and power to have widely respected scientists and eminent [medical researchers](#) fired for

daring to point out the hazards and risks of suicide and [premature death](#) caused by these [drugs](#).

Whitaker starts by debunking the effectiveness of these massively hyped wonder drugs -- antidepressants like Prozac, [Zoloft](#) and Paxil, and the new atypical [antipsychotic drugs](#) like Zyprexa. His research shows how they often are barely more effective than placebos in treating [mental disorder](#) and depression, despite the glowing adulation they have received in the mainstream media.

But he goes on to make the startling claim that these new [psychiatric drugs](#) have directly contributed to an alarming new epidemic of drug-induced [mental illness](#). The very drugs prescribed by physicians to stabilize [mental disorders](#) in fact are inducing pathological changes in [brain chemistry](#) and triggering suicide, manic and psychotic episodes, [convulsions](#), violence, diabetes, pancreatic [failure](#), metabolic diseases, and premature [death](#).

Whitaker originally was a highly regarded medical reporter at the Albany Times Union and also wrote off and on for the [Boston Globe](#). A series he co-wrote for the Boston Globe on harmful psychiatric research was a finalist for the Pulitzer Prize in 1998. When he began his investigative research into psychiatric issues, Whitaker was still a believer in the story of progress that [psychiatry](#) has been telling the public for decades.

He said, "I absolutely believed the common wisdom that these antipsychotic drugs actually had improved things and that they had totally revolutionized how we treated [schizophrenia](#). People used to be locked away forever, and now maybe things weren't great, but they were a lot better. It was a story of progress."

That story of progress was fraudulent, as Whitaker soon found out when he gained new insight from his research into torturous psychiatric practices such as electroshock, lobotomy, [insulin](#) coma, and neuroleptic drugs. Psychiatrists told the public that these techniques "cured" psychosis or balanced the chemistry of [the brain](#).

But, in reality, the common thread in all these different treatments was the attempt to suppress "mental [illness](#)" by deliberately damaging the higher functions of the [brain](#). The stunning truth is that, behind closed doors, the psychiatric establishment itself labeled these treatments as "brain-damaging therapeutics."

The first [generation](#) of antipsychotic drugs created a drug-induced brain [pathology](#) by blocking the neurotransmitter dopamine and essentially shutting down many higher brain functions. In fact, when [antipsychotics](#) such as Thorazine and Haldol were first introduced, [psychiatrists](#) themselves said that these neuroleptic drugs were virtually indistinguishable from a "chemical lobotomy."

In recent years, the media have heralded the arrival of so-called designer drugs like Prozac, [Paxil](#) and Zyprexa that are supposed to be superior and have fewer [side effects](#) than the old tricyclic antidepressants and the first antipsychotics. Millions of Americans have believed this story and have enriched drug companies like [Eli Lilly](#) by spending billions of dollars annually to purchase these new medications.

Whitaker's research into the tragic cases of disease, suffering and early deaths caused by these drugs shows that millions of consumers have been misled by a massive campaign of lies, distortions, and bought-and-paid-for [drug trials](#). Eminent medical researchers who have tried to warn us of the perils of these drugs have been silenced, intimidated and defamed. In the process, the [Food and Drug Administration](#) has become the lapdog of the giant [pharmaceutical industry](#), not its watchdog.

Street Spirit interviewed Robert Whitaker about this new "epidemic" of mental [disorders](#), and how the giant drug [companies](#) have profited from selling drugs that make us sicker.

Street Spirit: Your new line of research indicates that there has been an enormous rise in the incidence of mental illness in the [United States](#), despite the seeming advances in a new generation of psychiatric drugs. Why do you refer to this increase as an [epidemic](#)?

Robert Whitaker: Even people like the psychiatrist E. Fuller Torrey wrote a book recently in which he said it looks like we're having an epidemic of mental illness. When the National Institute of Mental Health publishes its figures on the incidence of mental illness, you see these rising numbers of [mentally ill](#) people. Some recent reports even say that 20 percent of Americans now are mentally ill.

So what I wanted to do was two-fold. I wanted to look into exactly how dramatic is this increase in mental illness, and particularly severe mental illness. Part of this rise in the number of people said to be mentally ill is just definitional. We draw a big wide boundary today and we throw all sorts of people into that category of mentally ill. So [children](#) who are not sitting neatly enough in their school rooms are said to have [attention deficit hyperactivity disorder](#) (ADHD), and we created a new [disorder](#) called social anxiety disorder.

SS: So what used to be called simply shyness or [anxiety](#) in relating to people is now labeled a mental disorder and you supposedly need an antidepressant like Paxil for social anxiety disorder.

RW: Exactly. And you need a stimulant like Ritalin for ADHD.

SS: This increases psychiatry's clients, but doesn't it also increase the number of people that giant [pharmaceutical companies](#) can sell their psychiatric drugs to?

RW: Absolutely. So part of what we're seeing is nothing more than the creation of a larger market for drugs. If you think about it, as long as we draw as big a circle as possible, and expand the boundaries of mental illness, psychiatry can have more clients and sell more drugs. So there's a built-in economic incentive to define mental illness in as broad terms as possible, and to find ordinary, distressing [emotions](#) or behaviors that some people may not like and label them as mental illness.

SS: Your research also shows that there is a real increase in people who have a severe mental disorder. Now, this seems counterintuitive, but is it true that you believe much of this increase is caused by the overuse of some of the new generations of psychiatric drugs?

RW: Yes, exactly. I looked at the number of the so-called severely disabled mentally ill -- people who aren't working or who are somehow dysfunctional because of mental illness. So I wanted to chart through history the percentage of the population who are considered the disabled mentally ill.

Now, by 1903, we see that roughly 1 out of every 500 people in the United States is hospitalized for mental illness. By 1955, at the start of the modern era of psychiatric drugs, roughly one out of every 300 people was disabled by mental illness. Now, let's go to 1987, the end of the first generation of antipsychotic drugs; and from 1987 forward we get the modern psychiatric drugs. From 1955 to 1987, during this first era of psychiatric drugs -- the antipsychotic drugs Thorazine and Haldol and the tricyclic antidepressants (such as Elavil and Anafranil) -- we saw the number of disabled mentally ill increase four-fold, to the point where roughly one out of every 75 persons are deemed disabled mentally ill.

Now, there was a shift in how we cared for the disabled mentally ill between 1955 and 1987. In 1955, we were hospitalizing them. Then, by 1987, we had gone through social change, and we were now placing people in shelters, nursing homes, and some sort of community care, and gave them either SSI or SSDI payments for mental disability. In 1987, we started getting these supposedly better, second-generation psychiatric drugs like Prozac and the other selective [serotonin](#) re-uptake inhibitor ([SSRI](#)) antidepressants. Shortly after that, we get the new, atypical antipsychotic drugs like Zyprexa (olanzapine), Clozaril and Risperdal.

What's happened since 1987? Well, the disability rate has continued to increase until it's now one in every 50 Americans. Think about that: One in every 50 Americans disabled by mental illness today. And it's still increasing. The number of mentally disabled people in the United States has been increasing at the rate of 150,000 people per year since 1987. That's an increase every day over the last 17 years of 410 people per day newly disabled by mental illness.

SS: So that leads to the obvious question. If psychiatry has introduced these so-called wonder drugs like Prozac and Zoloft and Zyprexa, why is the incidence of mental illness going up dramatically?

RW: That's exactly it. This is a scientific question. We have a form of care where we're using these drugs in an ever more expansive manner, and supposedly we have better drugs and they're the cornerstone of our care, so we should see decreasing disability rates. That's what your expectation would be.

Instead, from 1987 until the present, we saw an increase in the number of mentally disabled people from 3.3 million people to 5.7 million people in the United States. In that time, our spending on psychiatric drugs increased to an amazing degree. Combined spending on antipsychotic drugs and antidepressants jumped from around \$500 million in 1986 to nearly \$20 billion in 2004. So we raise the question: Is the use of these drugs somehow actually fueling this increase in the number of the disabled mentally ill?

When you look at the research literature, you find a clear pattern of outcomes with all these drugs -- you see it with the antipsychotics, the antidepressants, the anti-anxiety drugs and the stimulants like Ritalin used to treat ADHD. All these drugs may curb a target symptom slightly more effectively than a [placebo](#) does for a short period of time, say six weeks. An antidepressant may ameliorate the symptoms of [depression](#) better than a placebo over the short term.

What you find with every class of these psychiatric drugs is a worsening of the target symptom of depression or psychosis or anxiety over the long term, compared to placebo-treated [patients](#). So even on the target [symptoms](#), there's greater chronicity and greater severity of symptoms. And you see a fairly significant percentage of patients where new and more severe psychiatric symptoms are triggered by the [drug](#) itself.

SS: New psychiatric symptoms created by the very drugs people are told will help them recover?

RW: Absolutely. The most obvious case is with the antidepressants. A certain percentage of people placed on the [SSRIs](#) because they have some form of depression will suffer either a manic or psychotic attack -- drug-induced. This is well recognized. So now, instead of just dealing with depression, they're dealing with mania or psychotic symptoms. And once they have a drug-induced manic episode, what happens? They go to an emergency room, and at that point they're newly diagnosed. They're now said to be bipolar and they're given an antipsychotic to go along with the antidepressant; and, at that point, they're moving down the path to chronic disability.

SS: Modern psychiatry claims that these psychiatric drugs correct pathological brain chemistry. Is there any [evidence](#) to back up their claim that abnormal brain chemistry is the culprit in schizophrenia and depression?

RW: This is the key thing everyone needs to understand. It really is the answer that unlocks this mystery of why the drugs would have this long-term problematic effect. Start with schizophrenia. They hypothesize that these drugs work by correcting an imbalance of the neurotransmitter dopamine in the brain.

The theory was that people with schizophrenia had overactive dopamine systems; and these drugs, by blocking dopamine in the brain, fixed that chemical imbalance. Therefore, you get the metaphor that they're like insulin is for [diabetes](#); they're fixing an abnormality. With the antidepressants, the theory was that people with depression had too low levels of serotonin; the drugs upped the levels of serotonin in the brain and therefore they're balancing the brain chemistry.

First of all, those theories never arose from investigations into what was actually happening to people. Rather, they would find out that antipsychotics blocked dopamine and so they theorized that people had overactive dopamine systems. Same with the antidepressants. They found that antidepressants upped the levels of serotonin; therefore, they theorized that people with depression must have low levels of serotonin.

But here is the thing that one wishes all of [America](#) would know and wishes psychiatry would come

clean on: They've never been able to find that people with schizophrenia have overactive dopamine systems. They've never been able to find that people with depression have underactive serotonin systems. They've never found consistently that any of these disorders are associated with any chemical imbalance in the brain. The story that people with mental disorders have known chemical imbalances -- that's a lie. We don't know that at all. It's just something that they say to help sell the drugs and help sell the biological model of mental disorders.

But the kicker is this. We do know, in fact, that these drugs perturb how these chemical messengers work in the brain. The real paradigm is: People diagnosed with mental disorders have no known problem with their neurotransmitter systems; and these drugs perturb the normal function of neurotransmitters.

SS: So rather than fixing a chemical imbalance, these widely prescribed drugs distort the brain chemistry and make it pathological.

RW: Absolutely. Stephen Hyman, a well-known neuroscientist and the former director of the National Institute of Mental Health, wrote a paper in 1996 that looked at how psychiatric drugs affect the brain. He wrote that all these drugs create perturbations in neurotransmitter functions. And he notes that the brain, in response to this drug from the outside, alters its normal functions and goes through a series of compensatory adaptations.

In other words, it tries to adapt to the fact that an antipsychotic drug is blocking normal dopamine functions. Or in the case of antidepressants, it tries to compensate for the fact that you're blocking a normal reuptake of serotonin. The way it does this is to adapt in the opposite way. So, if you're blocking dopamine in the brain, the brain tries to put out more dopamine and it actually increases the number of dopamine receptors. So a person placed on antipsychotic drugs will end up with an abnormally high number of dopamine receptors in the brain.

If you give someone an antidepressant, and that tries to keep serotonin levels too high in the brain, it does exactly the opposite. It stops producing as much serotonin as it normally does and it reduces the number of serotonin receptors in the brain. So someone who is on an antidepressant, after a time ends up with an abnormally low level of serotonin receptors in the brain. And here's what Hyman concluded about this: After these [changes](#) happened, the patient's brain is functioning in a way that is "qualitatively as well as quantitatively different from the normal state." So what Stephen Hyman, former head of the NIMH, has done is present a paradigm for how these drugs affect the brain that shows that they're inducing a pathological state.

SS: So the paradox is there's no evidence for modern psychiatry's claim that there is any pathological biochemical imbalance in the brain that [causes](#) mental illness, but if you treat people with these new wonder drugs, that is what creates a pathological imbalance?

RW: Yes, these drugs disrupt normal brain chemistry. That's the real paradox here. And the real tragedy is, that even as we peddle these drugs as chemical balancers, chemical fixers, in truth we're doing precisely the opposite. We're taking a brain that has no known abnormal brain chemistry, and by placing people on the drugs, we're perturbing that normal chemistry. Here's how Barry Jacobs, a Princeton neuroscientist, describes what happens to a person given an SSRI antidepressant. "These drugs," he said, "alter the level of synaptic transmission beyond the physiologic range achieved under normal environmental biological [conditions](#). Thus, any behavioral or physiologic change produced under these conditions might more appropriately be considered pathologic rather than reflective of the normal biological role of serotonin."

SS: One of the SSRI antidepressants that's widely believed to be a wonder drug is Prozac. Yet your research found that the Food and Drug Administration ([FDA](#)) received more adverse reports about Prozac than any other drug. What sort of ill effects were people reporting?

RW: First of all, with Prozac and the SSRIs that followed, their level of efficacy was always of a very minor sort. In all the clinical trials of the antidepressants, roughly 41 percent of the patients got

better in the short term versus 31 percent of the patients on placebo. Now just one other caveat on that. If you use an active placebo in these trials -- an active placebo causes a physiologic change with no benefit, like a dry mouth -- any difference in outcome between the antidepressant and placebo virtually disappears.

SS: Weren't the early drug [tests](#) of Prozac so unpromising that they had to manipulate test results to get FDA approval at all?

RW: What happened with Prozac is a fascinating story. Right from the beginning, they noticed only very marginal efficacy over placebo; and they noticed that they had some problems with [suicide](#). There were increased suicidal responses compared to placebo. In other words, the drug was agitating people and making people suicidal who hadn't been suicidal before. They were getting manic responses in people who hadn't been manic before. They were getting psychotic episodes in people who hadn't been psychotic before. So you were seeing these very problematic side effects even at the same time that you were seeing very modest efficacy, if any, over placebo in ameliorating depression.

Basically, what Eli Lilly (Prozac's manufacturer) had to do was cover up the psychosis, cover up the mania; and, in that manner, it was able to get these drugs approved. One FDA reviewer even warned that Prozac appeared to be a dangerous drug, but it was approved anyway. We're seemingly finding all this out only now: "Oh, Prozac can cause suicidal impulses and all these SSRIs may increase the [risk of suicide](#)." The point is, that wasn't anything new. That data was there from the very first trial. You had people in Germany saying, "I think this is a dangerous drug."

SS: Even back in the late 1980s, they already knew?

RW: Before the late 1980s -- in the early '80s, before Prozac gets approved. Basically what Eli Lilly had to do was cover up that [risk](#) of mania and psychosis, cover up that some people were becoming suicidal because they were getting this nervous agitation from Prozac. That's the only way it got approved.

There were various ways they did the cover-up. One was just to simply remove reports of psychosis from some of the data. They also went back and recoded some of the trial results. Let's say someone had a manic episode or a psychotic episode; instead of putting that down, they would just put down a return of depression, and that sort of thing. So there was a basic need to hide these [risks](#) right from the beginning, and that's what was done.

So Prozac gets approved in 1987, and it's launched in this amazing PR campaign. The pill itself is featured on the cover of several magazines! It's like the Pill of the Year [laughs]. And it's said to be so much safer: a wonder drug. We have [doctors](#) saying, "Oh, the real problem with this drug is that we can now create whatever personality we want. We're just so skilled with these drugs that if you want to be happy all the time, take your pill!"

That was complete nonsense. The drugs were barely better than placebo at alleviating depressive symptoms over the short term. You had all these problems; yet we were touting these drugs, saying, "Oh, the powers of psychiatry are such that we can give you the mind you want -- a designer personality!" It was absolutely obscene. Meanwhile, which drug, after being launched, quickly became the most complained about drug in America? Prozac!

SS: What were the level of complaints when Prozac hit the market?

RW: In this county, we have Medwatch, a reporting system in which we report [adverse events](#) about psychiatric drugs to [the FDA](#). By the way, the FDA tries to keep these adverse reports from the public. So, instead of the FDA making these easily available to the public, so you can know about the dangers of the drugs, it's very hard to get these reports.

Within one decade, there were 39,000 adverse reports about Prozac that were sent to Medwatch. The number of adverse events sent to Medwatch is thought to represent only one percent of the actual number of such events. So, if we get 39,000 adverse [event](#) reports about Prozac, the number

of people who have actually suffered such problems is estimated to be 100 times as many, or roughly four million people. This makes Prozac the most complained about drug in America, by far. There were more adverse event reports received about Prozac in its first two years on the market than had been reported on the leading tricyclic antidepressant in 20 years.

Remember, Prozac is pitched to the American public as this wonderfully safe drug, and yet what are people complaining about? Mania, psychotic depression, nervousness, anxiety, agitation, [hostility](#), hallucinations, [memory](#) loss, tremors, impotence, convulsions, insomnia, nausea, suicidal impulses. It's a wide range of serious symptoms.

And here's the kicker. It wasn't just Prozac. Once we got the other SSRIs on the market, like Zoloft and Paxil, by 1994, four SSRI antidepressants were among the top 20 most complained about drugs on the FDA's Medwatch list. In other words, every one of these drugs brought to market started triggering this range of adverse events. And these were not minor things. When you talk about mania, hallucinations, psychotic depression, these are serious adverse events.

Prozac was pitched to the American public as a wonder drug. It was featured on the covers of magazines as so safe, and as a sign of our wonderful ability to effect the brain just as we want it. In truth, the reports were showing it could trigger a lot of dangerous events, including suicide and psychosis.

The FDA was being warned about this. They were getting a flood of adverse event reports, and the public was never told about this for the longest period of time. It took a decade for the FDA to begin to acknowledge the increased suicides and the [violence](#) it can trigger in some people. It just shows how the FDA betrayed the [American people](#). This is a classic example. They betrayed their responsibility to act as a watchdog for the American people. Instead they acted as an agency that covered up harm and risk with these drugs.

SS: In light of the FDA's failure to warn us about Prozac, what about their recent negligence on the issue of the risk of suicide in children given antidepressants like Paxil? Weren't England's [mental health](#) officials far better than their American counterparts in the FDA in warning about the dangers of suicidal attempts when antidepressants are given to [youth](#)?

RW: Yes. The children's story is unbelievably tragic. It's also a really sordid story. Let's go back a little to see what happened to children and antidepressants. Prozac comes to market in 1987. By the early 1990s, the pharmaceutical companies making these drugs are saying, "How do we expand the market for antidepressants?" Because that's what drug companies do -- they want to get to an ever-larger number of people. They saw they had an untapped market in [kids](#). So let's start peddling the drugs to kids. And they were successful. Since 1990, the use of antidepressants in kids went up something like seven-fold. They began prescribing them willy-nilly.

Now, whenever they did pediatric trials of antidepressants, they found that the drugs were no more effective on the target symptom of depression than placebo. This happened again and again in the pediatric drug trials of antidepressants. So, what that tells you is there is no real therapeutic rationale for the drugs because in this population of kids, the drugs don't even curb the target symptoms over the short term any better than placebo; and yet they were causing all sorts of adverse events.

For example, in one trial, 75 percent of youth treated with antidepressants suffered an adverse event of some kind. In one study by the University of Pittsburgh, 23 percent of children treated with an SSRI developed mania or manic-like symptoms; an additional 19 percent developed drug-induced hostility. The clinical results were telling you that you didn't get any benefit on depression; and you could cause all sorts of real problems in kids -- mania, hostility, psychosis, and you may even stir suicide. In other words, don't use these drugs, right? It was absolutely covered up.

SS: How was it covered up?

RW: We had psychiatrists -- some of those obviously getting money from the drug companies --

saying the kids are under-treated and they're at risk of suicide and how could we possibly treat kids without these pills and what a tragedy it would be if we couldn't use these antidepressants.

Finally, a prominent researcher in England, David Healy, started doing his own research on the ability of these drugs to stir suicide. He also managed to get access to some of the trial results and he blew the whistle. He first blew the whistle in England and he presented this data to the review authorities there. And they saw that it looks like these drugs are increasing the risk of suicide and there are really no signs of [benefits](#) on the target symptoms of depression. So they began to move there to warn doctors not to prescribe these drugs to youth.

What happens in the United States? Well, it's only after there's a lot of pressure put on the FDA that they even hold a hearing. The FDA sort of downplays the risk of these drugs. They're slow to even put black box warnings on them. Why? Aren't kids lives worth protecting? If we know that we have a scientifically shown risk that these drugs increase suicide, shouldn't you at least warn about it? But the FDA was even digging in its heels about putting that [black box warning](#) on the drugs.

SS: If Prozac is the nation's most complained about drug, if Paxil is shown to be a suicide risk for youth, how do these antidepressants continue to have a reputation as near-magic cures for depression? And why did the FDA failed to warn us about Paxil and Prozac for such a long time?

RW: There's a couple reasons for that. The FDA's funding changed in the 1990s. An act was passed in which a lot of the FDA's funding came from the [drug industry](#): the PDUFA Act, or Prescription Drug User Fee Act. Basically, when drug companies applied for FDA approval they had to pay a fee. Those fees became what is funding a large portion of the FDA's review of drug applications.

So all of a sudden, the funding is coming from the drug [industry](#); it's no longer coming from the people. As that act comes up for renewal, basically the drug lobbyists are telling the FDA that their job is no longer to be critically analyzing drugs, but to approve drugs quickly. And that was part of Newt Gingrich's thing: Your job is to get these drugs to market. Start partnering with the drug industry and facilitating drug development. We lost this idea that the FDA had a watchdog role.

Also, in a human way, a lot of people who work for the FDA leave there and end up going to work for the drug companies. The old joke is that the FDA is sort of like a showcase for a future job in the drug industry. You go there, you work awhile, then you go off into the drug industry. Well, if that's the progression that people make, in essence they're making good old boy network connections, so they're not going to be so harsh on the drug companies. So, that's what really happened in the 1990s. The FDA was given new marching orders. The orders were: "Facilitate getting drugs to market. Don't be too critical. And, in fact, if you want to keep your funding, which was coming now from the drug industry, make sure you take these lessons to heart."

SS: So the giant pharmaceutical companies have a vast amount of [power](#) to cook the results of drug tests and make researchers and even the FDA itself bow to their will?

RW: The FDA, in essence, was kneecapped in the early 1990s, and we really saw it with the psychiatric drugs. The FDA became a lapdog for the pharmaceutical industry, not a watchdog. It's only now that this has become common knowledge. We have Marcia Angell, the former editor of the New England Journal of Medicine, write a book in which she says that the FDA became a lapdog. It's basically now well recognized that you had this decline and fall. As the editor of the New England Journal of Medicine, the most prestigious medical journal we have, Marcia Angell is someone who was at the very heart of American [medicine](#), and she concluded that the FDA let down the American people. And she lost her job at the New England Journal of Medicine for starting to criticize pharmaceutical companies.

She was the editor of the journal in the late 1990s and there was a corresponding [doctor](#) named Thomas Bodenheimer who decided to write an article about how you couldn't even trust what was published in the medical journals anymore because of all the spinning of results. So they did an [investigation](#) about how the pharmaceutical companies are funding all the research and spinning the

trial results, so you can no longer really trust what you read in scientific journals. They pointed out that when they tried to get an expert to review the scientific literature related to antidepressants, they basically couldn't find someone who hadn't taken money from the drug companies.

Now, the New England Journal of Medicine is published by the Massachusetts Medical Society which publishes a lot of other journals, and they get a lot of pharmaceutical [advertising](#). So what happens after that article appears by Thomas Bodenheimer and an accompanying editorial by Marcia Angell about the sorry state of American medicine because of this? They both lose their jobs! She's gone and so is Thomas Bodenheimer. Think about this. We have the leading medical journal firing people, letting them go, because they dared to criticize the dishonest [science](#) and the dishonest process that was poisoning the scientific literature.

So we have the FDA that's acting as lapdogs. You can't trust the scientific literature. All this shows how the American public was betrayed and didn't know about all the problems with these drugs and why it was kept from them. It has to do with money, prestige and old boy networks.

SS: It also has to do with the silencing of critics. Eli Lilly uses the media to trumpet Prozac's benefits and gives perks to doctors to attend conferences to hear about its benefits, and buys off researchers. But don't they also use their power and money to silence their critics?

RW: An example is Dr. Joseph Glenmullen, a psychiatrist who also works for Harvard University Health Services, and who wrote a book called Prozac Backlash to warn about the dangers of Prozac. He's finding that the drugs are being overused and cause severe side effects. He even raises questions about long-term memory problems with the drugs and cognitive dysfunction. Well, Eli Lilly then mounted a public relations campaign to try to discredit him. They sent out notices to the media questioning his affiliation with Harvard Medical School, etc. It was all about silencing the critics.

If you sing the tune that the drug companies want, at the very top levels, you get paid a lot of money to fly around and give presentations about the wonders of the drugs. And those who come, and don't ask any embarrassing questions, get the lobster dinners and maybe they get a little honorarium for attending this educational meeting. So if you want to be part of this gravy train, you can. You sing the wonders of the drug, and you don't talk about their nasty side effects, and you can get a nice payment as one of their guest speakers, as one of their experts.

But if you're one of the ones saying, "What about the mania, what about the psychosis?" -- they do silence you. Look at what happened to David Healy. Healy is even the best example. David Healy has this sterling reputation in England. He's written several books on the history of psychopharmacology. He's like the former Secretary of the Psychopharmacology Association over there. He gets offered a job at the University of Toronto to head up their psychiatry department. So while he's waiting to assume that position at the University of Toronto, he goes to Toronto and delivers a talk on the elevated risk of suicide with Prozac and some of the other SSRIs. By the time he's back [home](#), the job offer has been rescinded.

Now does Eli Lilly donate some money to the University of Toronto? Absolutely. So, to answer your question, yes, Eli Lilly silences dissenters as well.

SS: What is the story behind the secret settlement between Eli Lilly and the survivors who sued the company after Joseph Wesbecker shot 20 coworkers after being put on Prozac?

RW: During this trial in which Eli Lilly was being sued, the judge was going to allow some very damaging evidence showing wrongdoing by Eli Lilly in a previous instance. The judge said, "Go ahead and introduce this at the trial." But next thing you know, they don't introduce this; and in fact, all of a sudden, the plaintiffs no longer are presenting very damaging evidence to make their case. So the judge wonders why they are not presenting their best case anymore. He smells a rat. He suspects Eli Lilly has settled with the plaintiffs secretly and the deal is that, as part of this settlement, the plaintiffs will go ahead with a sham trial so that Eli Lilly will win the trial. Then Eli

Lilly can claim, "See our drug doesn't cause people to become violent."

And, indeed, that's what happened. Eli Lilly felt it was going to lose this trial. They went to the plaintiffs and said they would give them a lot of money. They agreed to go ahead and settle the case, but had the plaintiffs go ahead with the trial. That way Eli Lilly can publicly claim that they won the trial and Prozac doesn't cause harm.

SS: How did this even come out into the light of day?

RW: We would never have known about this except for two things. One, believe it or not, the judge, in essence, appealed the decision in his own court. He said, "I smell a rat." And through that, he found out that there was this secret settlement and that it was a sham proceeding that continued on. He said it was one of the worst violations of the integrity of the legal process that he'd ever seen. And second, an English journalist named John Cornwell wrote a book called *Power to Harm: Mind, Medicine, and Murder on Trial*. He wrote about this case, and yet in the United States, we got almost no news about this secret settlement and this whole perversion of the legal process. It was an English journalist who was exposing this story.

My point here is this: They silence people like Marcia Angell. They pervert the scientific process. They pervert the legal process. They pervert the FDA drug review process. It's everywhere! And that's how we as a society end up believing in these psychiatric drugs. You asked the question a while back, "Why do we still believe in Prozac?" One of the reasons is that the story about Prozac is, in effect, maintained. It's publicly maintained because we do all this silencing along all these lines.

The other thing to remember is that some people on Prozac do feel better. That's true. That shows up, just in the same way that some people on placebos feel better. And those are the stories that get repeated: "Oh, I took Prozac and I'm feeling better." It's that select group that does better that becomes the story that is told out there, and the story that the public hears. So that's why we continued to believe in the story of these wonder drugs that are very safe in spite of all this messy stuff that gets covered up.

SS: Let's now move from the antidepressants like Prozac to consider another new group of supposed wonder drugs -- the new antipsychotic drugs. You write that long-term use of antipsychotic drugs -- both the original neuroleptic drugs like Thorazine and Haldol and the newer atypicals like Zyprexa and Risperdal -- cause pathological changes in the brain that can [lead](#) to a worsening of the symptoms of mental illness. What changes in brain chemistry result from the antipsychotics, and how can that lead to the most frightening prospect you describe -- chronic mental illness that is locked in by these drugs?

RW: This is a line of research that goes across 40 years. This problem of chronic illness shows up time and time again in the research literature. This biological mechanism is somewhat well understood now. The antipsychotics profoundly block dopamine receptors. They block 70-90 percent of the dopamine receptors in the brain. In return, the brain sprouts about 50 percent extra dopamine receptors. It tries to become extra sensitive.

So in essence you've created an imbalance in the dopamine system in the brain. It's almost like, on one hand, you've got the accelerator down -- that's the extra dopamine receptors. And the drug is the brake trying to block this. But if you release that brake, if you abruptly go off the drugs, you now do have a dopamine system that's overactive. You have too many dopamine receptors. And what happens? People that go abruptly off of the drug, do tend to have severe relapses.

SS: So people that have been treated with these antipsychotic drugs have a far greater tendency to relapse, and have new episodes of mental illness, as opposed to people who have had other kinds of non-drug therapies?

RW: Absolutely, and that was understood by 1979, that you were actually increasing the underlying biological vulnerability to the psychosis. And by the way, we sort of understood that if you muck

with the dopamine system, that you could cause some symptoms of psychosis with [amphetamines](#). So if you give someone amphetamines enough, they're at increased risk of psychosis. This is well known. And what do amphetamines do? They release dopamine. So there is a biological reason why, if you're mucking up the dopamine system, you're increasing the risk of psychosis. That's in essence what these antipsychotic drugs do, they muck up the dopamine system.

Here's just one real powerful study on this: Researchers with the University of Pittsburgh in the 1990s took people newly diagnosed with schizophrenia, and they started taking MRI pictures of the [brains](#) of these people. So we get a picture of their brains at the moment of diagnosis, and then we prepare pictures over the next 18 months to see how those brains change. Now during this 18 months, they are being prescribed antipsychotic medications, and what did the researchers report? They reported that, over this 18-month period, the drugs caused an enlargement of the basal ganglia, an area of the brain that uses dopamine. In other words, it creates a visible change in morphology, a change in the size of an area of the brain, and that's abnormal. That's number one. So we have an antipsychotic drug causing an abnormality in the brain.

Now here's the kicker. They found that as that enlargement occurred, it was associated with a worsening of the psychotic symptoms, a worsening of negative symptoms. So here you actually have, with modern technology, a very powerful study. By imaging the brain, we see how an outside agent comes in, disrupts normal chemistry, causes an abnormal enlargement of the basal ganglia, and that enlargement causes a worsening of the very symptoms it's supposed to treat. Now that's actually, in essence, a story of a disease process -- an outside agent causes abnormality, causes symptoms...

SS: But in this case, the outside agent that triggers the disease process is the supposed [cure](#) for the disease! The psychiatric drug is the disease-causing agent.

RW: That's exactly right. It's a stunning, damning finding. It's the sort of finding you would say, "Oh Christ, we should be doing something different." Do you know what those researchers got new grants for, after they reported that?

SS: No, what? You'd guess they got funding to carry out these same [studies](#) on other classes of psychiatric drugs.

RW: They got a grant to develop an implant, a brain implant, that would deliver drugs like Haldol on a continual basis! A grant to develop a drug delivery implant so you could implant this in the brains of people with schizophrenia and then they wouldn't even have a chance not to take the drugs!

SS: Unbelievable. Designing an implant to provide a constant dose of a drug that they had just discovered causes pathology in the brain chemistry.

RW: Right, they had just found that they're causing a worsening of symptoms! So why would you go on to a design a permanent implant? Because that's where the money was. And no one wanted to deal with this horrible finding of an enlargement of the basal ganglia caused by the drugs, and that is associated with the worsening of symptoms. No one wanted to deal with the fact that when you look at people medicated on antipsychotics, you start to see a shrinking of the frontal lobes. No one wants to talk about that either. They stopped that research.

SS: What other side effects are caused by prolonged use of these antipsychotic drugs?

RW: Oh, you get tardive dyskinesia, a permanent brain dysfunction; and akathisia, which is this incredible nervous agitation. You're just never comfortable. You want to sit but you can't sit. It's like you're crawling out of your own [skin](#). And it's associated with violence, suicide and all sorts of horrible things.

SS: Those kinds of side-effects were notorious with the first generation of antipsychotic drugs, like Thorazine, Haldol and Stelazine. But, just as with Prozac, so many people are still touting the new generation of atypical antipsychotics -- Zyprexa, Clozaril and Risperdal -- as wonder drugs that

control mental illness with far fewer side effects. Is that true? What have you found?

RW: No, it's just complete nonsense. In fact, I think the newer drugs will eventually be seen as more dangerous than the old drugs, if that's possible. As you know, the standard neuroleptics like Thorazine and Haldol have had quite a litany of harm with the tardive dyskinesia and all. So when we got the new atypical drugs, they were touted as so much safer. But with these new atypicals, you get all sorts of metabolic dysfunctions.

Let's talk about Zyprexa. It has a different profile. So it may not cause as much tardive dyskinesia. It may not cause as many Parkinsonian symptoms. But it causes a whole range of new symptoms. So, for example, it's more likely to cause diabetes. It's more likely to cause pancreatic disorders. It's more likely to cause obesity and appetite-disregulation disorders.

In fact, researchers in Ireland reported in 2003 that since the introduction of the atypical antipsychotics, the [death rate](#) among people with schizophrenia has doubled. They have done death rates of people treated with standard neuroleptics and then they compare that with death rates of people treated with atypical antipsychotics, and it doubles. It doubles! It didn't reduce harm. In fact, in their seven-year study, 25 of the 72 patients died.

SS: What were the causes of death?

RW: All sorts of physical illnesses, and that's part of the point. You're getting respiratory problems, you're getting people dying of incredibly high cholesterol counts, heart problems, diabetes. With olanzapine (Zyprexa), one of the problems is that you're really screwing up the core metabolic system. That's why you get these huge weight gains, and you get the diabetes. Zyprexa basically disrupts the machine that we are that processes [food](#) and extracts energy from that food. So this very fundamental thing that we humans do is disrupted, and at some point you just see all these pancreatic problems, faulty glucose regulation, diabetes, etc. That's really a sign that you're mucking with something very fundamental to [life](#).

SS: There's supposedly an alarming increase in mental illness being diagnosed in children. Millions are diagnosed with depression, bipolar and psychotic symptoms, attention deficit hyperactivity disorder, and social anxiety disorder. Is this explosive new prevalence of mental illness among children a real increase, or is it a [marketing](#) campaign that enriches the psychiatric drug industry, a bonanza for the pharmaceutical corporations? **RW:** You're touching on something now that is a tragic scandal of monumental proportions. I talk sometimes to [college](#) classes, psychology classes. You cannot believe the percentage of youth who have been told they were mentally ill as kids, that something was wrong with them. It's absolutely phenomenal. It's absolutely cruel to be telling kids that they have these broken brains and mental illnesses.

There's two things that are happening here. One, of course, is that it's complete nonsense. As you remember as a kid, you have too much energy or you behave sometimes in not altogether appropriate ways, and you do have these extremes of emotions, especially during your teenage years. Both children and teenagers can be very emotional. So one thing that's going on is that they take [childhood](#) behaviors and start defining behaviors they don't like as pathological. They start defining emotions that are uncomfortable as pathological. So part of what we're doing is pathologizing childhood with straight-out definition stuff. We're pathologizing poverty among kids.

For example, if you're a foster kid, and maybe you drew a bad straw in the lottery of life and are born into a dysfunctional [family](#) and you get put into foster care, do you know what happens today? You pretty likely are going to get diagnosed with a mental disorder, and you're going to be placed on a psychiatric drug. In Massachusetts, it's something like 60 to 70 percent of kids in foster care are now on psychiatric drugs. These kids aren't mentally ill! They got a raw deal in life. They ended up in a foster home, which means they were in a bad family situation, and what does our society do? They say: "You have a defective brain." It's not that society was bad and you didn't get a fair deal. No, the kid has a defective brain and has to be put on this drug. It's absolutely criminal.

Let's talk about bipolar disorder among kids. As one doctor said, that used to be so rare as to be almost nonexistent. Now we're seeing it all over. Bipolar is exploding among kids. Well, partly you could say that we're just slapping that label on kids more often; but in fact, there is something real going on. Here's what's happening. You take kids and put them on an antidepressant -- which we never used to do -- or you put them on a stimulant like Ritalin. Stimulants can cause mania; stimulants can cause psychosis.

SS: And antidepressants can also cause mania, as you pointed out.

RW: Exactly, so the kid ends up with a drug-induced manic or psychotic episode. Once they have that, the doctor at the emergency room doesn't say, "Oh, he's suffering from a drug-induced episode." He says he's bipolar.

SS: Then they give him a whole new drug for the mental disorder caused by the first drug.

RW: Yeah, they give him an antipsychotic drug; and now he's on a cocktail of drugs, and he's on a path to becoming disabled for life. That's an example of how we're absolutely making kids sick.

SS: It's like society or their [schools](#) are trying to make them manageable and they end up putting them on a chemical roller coaster against their will.

RW: Absolutely.

SS: There's an astonishing number of kids being given Ritalin to cure hyperactivity. But what 10-year-old boy in a confined school setting isn't hyperactive? You write that the effect of Ritalin on the dopamine system is very similar to [cocaine](#) and amphetamines.

RW: Ritalin is methylphenidate. Now methylphenidate affects the brain in exactly the same way as cocaine. They both block a molecule that is involved in the reuptake of dopamine.

SS: So they both increase the dopamine levels in the brain?

RW: Exactly. And they do it with a similar degree of potency. So methylphenidate is very similar to cocaine. Now, one difference is whether you're snorting it or if it's in a pill. That partly changes how quickly it's metabolized. But still, it basically affects the brain in the same way. Now, methylphenidate was used in research studies to deliberately stir psychosis in schizophrenics. Because they knew that you could take a person with a tendency towards psychosis, give them methylphenidate, and cause psychosis. We also knew that amphetamines, like methylphenidate, could cause psychosis in people who had never been psychotic before.

So think about this. We're giving a drug to kids that is known to have the possibility of stirring psychosis. Now, the odd thing about methylphenidate and amphetamines is that, in kids, they sort of have a counterintuitive effect. What does speed do in adults? It makes them more jittery and hyperactive. For whatever reasons, in kids amphetamines will actually still their movements; it will actually keep them in their chairs and make them more focused. So you've got kids in boring schools. The boys are not paying attention and they're diagnosed with ADHD and put on a drug that is known to stir psychosis. The next thing you know, a fair number of them are not doing well by the time they're 15, 16, 17. Some of those kids talk about how when you're on these drugs for the long term, you start feeling like a zombie; you don't feel like yourself.

SS: Hollowed-out, blunted emotions. And this is being done to millions of kids.

RW: Millions of kids! Think about what we're doing. We're robbing kids of their right to be kids, their right to grow, their right to experience their full range of emotions, and their right to experience the world in its full hue of colors. That's what growing up is, that's what being alive is! And we're robbing kids of their right to be. It's so criminal. And we're talking about millions of kids who have been affected this way. There are some colleges where something like 40 to 50 percent of the kids arrive with a psychiatric prescription.

SS: It looks like a huge social-control mechanism. Society gives kids Ritalin and antidepressants to

subdue them and make them conform. On the one hand, it's all about social control and conformity. But it also has a huge marketing payoff.

RW: You're right, it creates customers for the drugs, and hopefully lifelong customers. That's what they're told, aren't they? They're told they are going to be on these drugs for life. And next thing they know, they're on two or three or four drugs. It's brilliant from the capitalist point of view. It does serve some social-control function. But you take a kid, and you turn them into a customer, and hopefully a lifelong customer. It's brilliant.

We now spend more on antidepressants in this country than the Gross National Product of mid-sized countries like Jordan. It's just amazing amounts of money. The amount of money we spend on psychiatric drugs in this country is more than the Gross National Product of two-thirds of the world's countries. It's just this incredibly lucrative paradigm of the mind that you can fix chemical imbalances in the brain with these drugs. It works so well from a capitalistic point of view for Eli Lilly. When Prozac came to market, Eli Lilly's value on Wall Street, its capitalization, was around 2 billion dollars. By the year 2000, the time when Prozac was its number-one drug, its capitalization reached 80 billion dollars -- a forty-fold increase.

So that's what you really have to look at if you want to see why drug companies have pursued this vision with such determination. It brings billions of dollars in wealth in terms of increased stock prices to the owners and managers of those companies. It also benefits the psychiatric establishment that gets behind the drugs; they do well by this. There's a lot of money flowing in the direction of those that will embrace this form of care. There's advertisements that enrich the media. It's all a big gravy train.

Unfortunately, the cost is dishonesty in our scientific literature, the corruption of the FDA, and the absolute harm done to children in this country drawn into this system, and an increase of 150,000 newly disabled people every year in the United States for the last 17 years. That's an incredible record of harm done.

SS: Everyone gets rich -- the drug companies, the psychiatrists, the researchers, the advertising agencies -- and the clients get drugged out of their minds and damaged for life.

RW: And you know what's interesting? No one says that the mental [health](#) of the American people is getting better. Instead, everyone says we have this increasing problem. They blame it on the stresses of modern life or something like that, and they don't want to look at the fact that we're creating mental illness.

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28 Senators vote to maintain Big Pharma monopoly over U.S. consumers; Republicans oppose free trade for medicine



Monday, May 07, 2007

by Mike Adams, the Health Ranger

Editor of NaturalNews.com ([See all articles...](#))

On May 3rd, 2007, U.S. Senators voted on an amendment to the 2007 Prescription Drug User Fee bill that aims to reform the FDA and enhance drug safety. This amendment, known as the "Dorgan Amendment No. 990," threatened to break Big Pharma's monopoly over pharmaceutical sales and allow U.S. consumers, cities, states and businesses to purchase their pharmaceuticals from safety-certified pharmacies located in Canada, Japan, the U.K. and other nations.

Americans currently pay the highest prices in the world for [prescription drugs](#). Canadians, Europeans, and even citizens of Mexico pay only about one-half to as little as one-tenth the price paid by Americans for the very same [chemicals](#). Drug companies actually import many of the raw materials used in [pharmaceuticals](#) from other countries, meaning that some U.S. [medicines](#) are already sourced from countries like the U.K. and Germany.

Drug [companies](#) mark up their prescription [drugs](#) as much as 569,000% over the price of the raw materials. (A typical markup is more in the 30,000% - 50,000% range.) Retailing pharmaceuticals is hugely profitable. There is no [business](#) in the world with more profit built in to the retail price of the product. The purpose of restricting Americans from buying drugs from other countries is to enforce a [medical monopoly](#) in the United States, forcing [consumers](#) to purchase drugs at the highest [prices](#) in the world, further padding the [profits](#) of powerful and influential pharmaceutical corporations who exert strong influence over the Bush Administration and Republican lawmakers.

The [FDA](#) has, over the past several years, colluded with [drug](#) companies to maintain a monopoly market in the [United States](#) in order to protect those profits. It has taken actions such as raiding a bus load of senior citizens returning to the U.S. from [Canada](#), searching the elderly for **legal** drugs. The FDA has gone to great lengths to pressure U.S. customs to seize pharmaceutical shipments being imported for sale to individual consumers in the United States, and it has even invoked the

fantasy-based fear tactic of suggesting that [terrorists](#) might adulterate pharmaceuticals coming to the U.S. from Canada (and therefore we should all buy our drugs only from U.S. monopoly-controlled [pharmacies](#) because of "terrorists").

Dorgan amendment proposes [free trade](#) for medicine

The Dorgan amendment, entitled, "Pharmaceutical Market Access and Drug Safety Act of 2007," proposes what is essentially a free trade policy on prescription [medications](#). It would allow Americans to buy their drugs from certain certified organizations registered as valid importers or exporters. The bill states, "...a [prescription drug](#) is neither safe nor effective to an individual who cannot afford it," and goes on to describe rigorous [safety](#) requirements that would be required by the amendment, including safety [inspections](#) and registrations as well as funding efforts to locate and shut down fraudulent [internet](#) sales of counterfeit prescription drugs.

If passed into the law, this amendment would save U.S. citizens, businesses, and [government](#) entities (local, state and federal) billions of dollars each year by allowing them to source medications in a price competitive environment. Many [cities](#) and states are right now facing the very real possibility of bankruptcy due to [health care](#) costs (providing benefits to current and former government [employees](#)). A large percentage of those [costs](#) are spent on monopoly-priced pharmaceuticals. This Dorgan amendment would set city and state governments free to finally engage in fundamental [free market](#) price comparisons and save substantial sums of [money](#) in sourcing the very same chemical medications for their employees and retirees.

28 [Republicans](#) voted against the Dorgan amendment, voting to enforce the pharmaceutical monopoly and keep [Big Pharma](#) in control of virtually the entire U.S. [medication](#) market.

There were no Democrats that voted against the amendment. But why would 28 Republican Senators vote against breaking a marketplace [monopoly](#) and encouraging the use of free market economics to save American consumers billions of dollars? The answer isn't complicated: Because nearly all of them have taken money from pharmaceutical companies!

The Big Pharma 28

Here's the list of the 28 Senators who voted to protect Big Pharma's monopoly:

Alexander (R-TN)
Allard (R-CO)
Bennett (R-UT)
Bond (R-MO)
Bunning (R-KY)
Burr (R-NC)
Chambliss (R-GA)
Cochran (R-MS)
Cornyn (R-TX)
Crapo (R-ID)
Dole (R-NC)
Domenici (R-NM)
Ensign (R-NV)
Enzi (R-WY)

Gregg (R-NH)
Hagel (R-NE)
Hutchison (R-TX)
Inhofe (R-OK)
Isakson (R-GA)
Kyl (R-AZ)
Lugar (R-IN)
McConnell (R-KY)
Murkowski (R-AK)
Roberts (R-KS)
Stevens (R-AK)
Sununu (R-NH)
Thomas (R-WY)
Voinovich (R-OH)

These Senators cite "safety concerns" as a reason for enforcing a U.S. monopoly on prescription drugs and allowing Big Pharma to bilk Americans out of billions of dollars by operating an obvious profiteering scheme. But the truth is that **the price you pay for a drug does not affect its safety**. And those concerned that adulterated medications from other countries might harm patients conveniently forget that **FDA-approved drugs sold in the United States already kill 100,000 Americans each year**. It would be difficult to find any source more dangerous than the pharmacies operating in the U.S. right now.

Medications are universally dangerous because they are made from synthetic chemicals that simply do not belong in the human [body](#). **Every drug has unintended side effects** which include nutritional deficiencies, biochemical imbalances, liver damage, heart damage and even death. Vioxx alone -- which was approved by [the FDA](#) and heavily pushed by drug company advertising -- reportedly killed well over 50,000 Americans according to the FDA's own senior [drug safety](#) scientist Dr. David Graham. **The idea that prescription drugs are safe is ludicrous**, and trying to "ensure drug safety" by forcing Americans to pay the highest prices in the world for dangerous synthetic chemicals is a logical fallacy and nothing more than a thinly veiled attempt to protect the profiteering drug racket while claiming to be protecting the public.

President Bush has promised to veto the bill if the Dorgan amendment stands. Free trade for [medicine](#) simply will not be tolerated in the United States. There's too much money at stake.

62 Senators supported the amendment

Here's the list of the 63 Senators who voted in favor of the Dorgan amendment and, hence, free trade for medicines:

Akaka (D-HI)
Baucus (D-MT)
Bayh (D-IN)
Boxer (D-CA)
Brown (D-OH)
Byrd (D-WV)
Cantwell (D-WA)
Cardin (D-MD)
Carper (D-DE)
Casey (D-PA)
Clinton (D-NY)

Coburn (R-OK)
Coleman (R-MN)
Collins (R-ME)
Conrad (D-ND)
Corker (R-TN)
Craig (R-ID)
DeMint (R-SC)
Dorgan (D-ND)
Durbin (D-IL)
Feingold (D-WI)
Feinstein (D-CA)
Grassley (R-IA)
Harkin (D-IA)
Inouye (D-HI)
Kennedy (D-MA)
Kerry (D-MA)
Klobuchar (D-MN)
Kohl (D-WI)
Landrieu (D-LA)
Lautenberg (D-NJ)
Leahy (D-VT)
Levin (D-MI)
Lieberman (ID-CT)
Lincoln (D-AR)
Lott (R-MS)
Martinez (R-FL)
McCaskill (D-MO)
Menendez (D-NJ)
Mikulski (D-MD)
Murray (D-WA)
Nelson (D-FL)
Nelson (D-NE)
Obama (D-IL)
Pryor (D-AR)
Reed (D-RI)
Reid (D-NV)
Rockefeller (D-WV)
Salazar (D-CO)
Sanders (I-VT)
Schumer (D-NY)
Sessions (R-AL)
Shelby (R-AL)
Smith (R-OR)
Snowe (R-ME)
Specter (R-PA)
Stabenow (D-MI)
Tester (D-MT)
Thune (R-SD)
Vitter (R-LA)
Webb (D-VA)
Whitehouse (D-RI)
Wyden (D-OR)

Nine Senators did not vote

Biden (D-DE)
Bingaman (D-NM)
Brownback (R-KS)
Dodd (D-CT)
Graham (R-SC)
Hatch (R-UT)
Johnson (D-SD)
McCain (R-AZ)
Warner (R-VA)

Text of the Dorgan amendment

What follows is the partial text of the Dorgan amendment as printed in the Congressional Record for the Senate. The remainder of the text can be found [by clicking here](#).

SA 990. Mr. DORGAN (for himself, Ms. Snowe, Mr. Grassley, Mr. McCain, Ms. Stabenow, Mr. Nelson of Florida, Mr. Pryor, Mr. Sanders, Mr. Whitehouse, and Mrs. McCaskill) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the appropriate place, insert the following:

TITLE __--IMPORTATION OF PRESCRIPTION DRUGS

SEC. X01. SHORT TITLE.

This title may be cited as the Pharmaceutical Market Access and Drug Safety Act of 2007".

SEC. X02. FINDINGS.

Congress finds that--

- (1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;
- (2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;
- (3) a prescription drug is neither safe nor effective to an individual who cannot afford it;
- (4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the [Food and Drug Administration](#) will provide a level of safety to American consumers that they do not currently enjoy;
- (5) American spend more than \$200,000,000,000 on prescription drugs every year;
- (6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to

55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to [health](#) care savings and allow greater access to therapy, improving health and saving lives.

SEC. X03. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

SEC. X04. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) In General.--Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section X03, is further amended by inserting after section 803 the following:

SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

(a) Importation of Prescription Drugs.--

(1) IN GENERAL.--In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers--

(A) the limitation on importation that is established in section 801(d)(1) is waived; and

(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

(2) IMPORTERS.--A qualifying drug may not be imported under paragraph (1) unless--

(A) the drug is imported by a [pharmacy](#), group of pharmacies, or a wholesaler that is a registered importer; or

(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

(3) RULE OF CONSTRUCTION.--This section shall apply only with respect to a drug that is imported or offered for import into the United States--

(A) by a registered importer; or

(B) from a registered exporter to an individual.

(4) DEFINITIONS.--

(A) REGISTERED EXPORTER; REGISTERED IMPORTER.--For purposes of this section:

(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

(B) QUALIFYING DRUG.--For purposes of this section, the term 'qualifying drug' means a drug for which there is a corresponding U.S. label drug.

(C) U.S. LABEL DRUG.--For purposes of this section, the term 'U.S. label drug' means a prescription drug that--

(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and [strength](#) as the qualifying drug;

(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

(iii) is approved under section 505(c); and

(iv) is not--

(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including--

(aa) a therapeutic [DNA](#) plasmid product;

(bb) a therapeutic synthetic peptide product;

(cc) a monoclonal antibody product for in vivo use; and

(dd) a therapeutic recombinant DNA-derived product;

(III) an infused drug, including a peritoneal dialysis solution;

(IV) an injected drug;

(V) a drug that is inhaled during surgery;

(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

(VII) a sterile ophthalmic drug intended for topical use on or in the eye.

(D) OTHER DEFINITIONS.--For purposes of this section:

(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary under

subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that--

(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to--

(AA) the training of [pharmacists](#);

(BB) the practice of pharmacy; and

(CC) the protection of the [privacy](#) of personal medical [information](#); and

(bb) the importation of drugs to individuals in the United States from the country will not adversely affect [public health](#).

(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(iv) The term 'pharmacy' means a person that--

(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

(II) employs 1 or more pharmacists.

(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

(vi) The term 'wholesaler'--

(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

(II) does not include a person authorized to import drugs under section 801(d)(1).

(E) PERMITTED COUNTRY.--The term 'permitted country' means--

(i) Australia;

(ii) Canada;

(iii) a member country of the European Union, but does not include a member country with respect to which--

(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical [products](#) that has not expired; or

(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutical products expires;

(iv) [Japan](#);

(v) New Zealand;

(vi) Switzerland; and

(vii) a country in which the Secretary determines the following requirements are met:

(I) The country has statutory or regulatory requirements--

(aa) that require the [review](#) of drugs for safety and effectiveness by an entity of the government of the country;

(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by [experts](#) employed by or acting on behalf of such entity and qualified by scientific [training](#) and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

(III) The importation of drugs to the United States from the country will not adversely affect public health.

(b) Registration of Importers and Exporters.--

(1) REGISTRATION OF IMPORTERS AND EXPORTERS.--A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

(ii) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation

(which shall not exceed 3 places of business except by permission of the Secretary).

(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration [conditions](#) under--

(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a [pharmacist](#); conditions for individual importation; and maintenance of records and samples).

(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

(D) An agreement by the registrant to--

(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

(ii) provide for the return to the registrant of such drug; and

(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B) against a party in the chain of custody of a qualifying drug with respect to the [authority](#) of the Secretary under clauses (ii) and (iii) of that subsection.

(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of--

(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

(I) In the case of an exporter--

(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to

any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of--

(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

(II) \$1,000,000;

(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

(iv) An agreement by the exporter to report to the Secretary--

(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the previous fiscal year.

(J) In the case of an importer, an agreement by the importer to report to the Secretary--

(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting--

(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

(ii) importation by individuals of qualifying drugs under subsection (a).

(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.--

(A) IN GENERAL.--Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the

Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

(B) CHANGES IN REGISTRATION INFORMATION.--Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.-- Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone

number accordingly.

(4) SUSPENSION AND TERMINATION.--

(A) SUSPENSION.--With respect to the effectiveness of a registration submitted under paragraph (1):

(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i)(2)(F), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice,

and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

(B) TERMINATION.--The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1

year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(5) DEFAULT OF BOND.--A bond required to be posted by an exporter under paragraph (1)(I)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter has--

(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance

with subsection (g)(2)(A), (g)(4), or (i); or

(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

(c) Sources of Qualifying Drugs.--A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

(1) The drug was manufactured in an establishment--

(A) required to register under subsection (h) or (i) of section 510; and

(B)(i) inspected by the Secretary; or

(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured for distribution in a foreign country that is not a permitted country).

(3) The exporter or importer obtained the drug--

(A) directly from the establishment; or

(B) directly from an entity that, by contract with the exporter or importer--

(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

(6) The exporter or importer retains a sample of each lot of the drug for testing by the Secretary.

(d) Inspection of Facilities; Marking of Shipments.--

(1) INSPECTION OF FACILITIES.--A registration condition is that, for the purpose of assisting the Secretary in determining whether the exporter involved is in compliance with all other registration conditions--

(A) the exporter agrees to permit the Secretary--

(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

(ii) to have access, including on a day-to-day basis, to--

(I) records of the exporter that relate to the export of such drugs, including financial records; and

(II) samples of such drugs;

(iii) to carry out the duties described in paragraph (3); and

(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

(2) MARKING OF COMPLIANT SHIPMENTS.--A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall--

(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

(3) CERTAIN DUTIES RELATING TO EXPORTERS.--Duties of the Secretary with respect to an exporter include the following:

(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter at which qualifying drugs are stored and from which qualifying drugs are shipped.

(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically

significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

(D) Monitoring the affixing of markings under paragraph (2).

(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

(F) Determining whether the exporter is in compliance with all other registration conditions.

(4) PRIOR NOTICE OF SHIPMENTS.--A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include--

(A) the name and complete contact information of the person submitting the notice;

(B) the name and complete contact information of the importer involved;

(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

(E) the country from which the drug is shipped;

(F) the name and complete contact information for the shipper of the drug;

(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

(J) such other information as the Secretary may require by regulation.

(5) MARKING OF COMPLIANT SHIPMENTS.--A registration condition is that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug

that has been imported under subsection (a), to affix to each container of such drug such markings or other [technology](#) as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required

on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall--

(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

(6) CERTAIN DUTIES RELATING TO IMPORTERS.--Duties of the Secretary with respect to an importer include the following:

(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the importer at which a qualifying drug is initially received after importation.

(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not

for that reason be excluded from importation by an importer.

(C) Reviewing notices under paragraph (4).

(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

(E) Determining whether the importer is in compliance with all other registration conditions.

(e) Importer Fees.--

(1) REGISTRATION FEE.--A registration condition is that the importer involved pays to the Secretary a fee of \$10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

(2) INSPECTION FEE.--A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than [October 1](#) and April 1 of each fiscal year in the amount provided for under paragraph (3).

(3) AMOUNT OF INSPECTION FEE.--

(A) AGGREGATE TOTAL OF FEES.--Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated

with--

(i) inspecting the facilities of registered importers, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

(B) LIMITATION.--Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

(C) TOTAL PRICE OF DRUGS.--

(i) ESTIMATE.--For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1

through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

(ii) CALCULATION.--Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

(iii) ADJUSTMENT.--If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

(D) INDIVIDUAL IMPORTER FEE.--Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

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About the author: Mike Adams is a natural health researcher, author and award-winning journalist with a passion for sharing empowering information to help improve personal and planetary health. He is a prolific writer and has published thousands of articles, interviews, reports and consumer guides, impacting the lives of millions of readers around the world who are experiencing phenomenal health benefits from reading his articles. Adams is a trusted, independent journalist who receives no money or promotional fees whatsoever to write about other companies' products. In 2010, Adams launched NaturalNews.TV, a [natural health video site](#) featuring videos on holistic health and green living. He also launched an [online retailer of environmentally-friendly products](#) (BetterLifeGoods.com) and uses a portion of its profits to help fund non-profit endeavors. He's also a veteran of the software technology industry, having founded a [personalized mass email software product](#) used to deliver email newsletters to subscribers. Adams is currently the executive director of the [Consumer Wellness Center](#), a 501(c)3 non-profit, and enjoys outdoor activities, nature photography, Pilates and martial arts training. He's also author a large number of health books offered by [Truth Publishing](#) and is the creator of numerous reference website including [NaturalPedia.com](#) and the free downloadable [Honest Food Guide](#). His websites also include the free reference sites [HerbReference.com](#) and [HealingFoodReference.com](#). Adams believes in free speech, free access to nutritional supplements and the innate healing ability of the human body. Known by his callsign, the 'Health Ranger,' Adams posts his missions statements, health statistics and health photos at [www.HealthRanger.org](#)

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FDA accused of suppressing drug safety information (commentary)



Friday, October 14, 2005

by Mike Adams, the Health Ranger

Editor of NaturalNews.com ([See all articles...](#))

Here's a report on the FDA that could only come from outside the United States. I'm reading to you from *The Independent*, a British newspaper, that says, "Vital data on prescription medication found in millions of British homes has been suppressed by the powerful U.S. drug regulators, even though the information could potentially save lives." An investigation by *The Independent* states that, under pressure from the pharmaceutical industry, the American Food and Drug Administration routinely conceals [information](#) it considers commercially sensitive, leaving medical specialists unable to assess the true [risks](#).

This no surprise to those who are regular readers of this site, but to a lot of consumers in the [United States](#), it is a big surprise. They can't believe that the [Food and Drug Administration](#) would censor and suppress [drug safety](#) information. They think [the FDA](#) is looking out to protect them. The heroic [FDA](#), protecting American consumers from greedy [drug companies](#) selling dangerous drugs, putting [public safety](#) first and corporate [profits](#) last. Of course, that's all a myth.

The real FDA: Profits first, [safety](#) last

Here's the real FDA, in my view: Colluding with drug [companies](#), suppressing clinical trial data, covering up the truth about dangerous [prescription drugs](#), refusing to pull [drugs](#) off the market even though they are literally killing hundreds of thousands of Americans. The FDA: Censoring its own [drug](#) safety scientists to make sure they don't go public with their information about how dangerous these drugs are. The FDA: Under the table deals with drug companies? Maybe. Lots of political influence with the leaders of drug companies? Probably. Covering up facts about the dangers of prescription drugs? Most definitely. Absolutely. Without question.

This is the FDA that we have here in the United States, running the [drug industry](#). Running it! The FDA that tries to create a monopoly drug market in this country by banning the import of generic prescription drugs from elsewhere around the world. This is an agency that has attempted again and again to discredit Chinese [medicine](#), nutritional supplements, herbal medicine and anything that

would compete with prescription drugs. It has sought to outlaw these [natural](#) substances and herbs that have been proven healers for literally 2,000 years in the [history](#) of medicine. This is the FDA that has put drug profits first, and public safety last, time and time again.

This is the agency that rigs its own safety panels. "Oh, is there a dangerous drug out there? Let's have a panel and a hearing. Let's rig the hearing with decision makers who are paid by pharmaceutical companies. They're the ones who will get to vote." Wow, what a big surprise. They all voted to make the drug legal again. That's what happened with Vioxx. Oh, it only killed 50,000 or 60,000 people. "Ahh, that's just a side effect," they said, and the panel voted to put it back on the market. "It's safe enough for us. We're the FDA." Apparently, a drug has to kill more than 60,000 people to be considered dangerous.

Does it have to kill half a million people to be pulled by the FDA? How many Americans have to die before the FDA says, "This is a dangerous drug. Maybe it shouldn't be on the market?" How many [children](#) have to be doped up on [antidepressants](#), committing suicide and shooting each other in public [schools](#) before the FDA says, "Well, maybe children shouldn't be on these dangerous drugs that alter [brain chemistry](#)?" Think about this.

How many senior citizens have to die of gastrointestinal bleeding from the [consumption](#) of nonsteroidal anti-inflammatory drugs (NSAIDs) before the FDA will say, "Gee, maybe they should have a warning on them?" How many people have to die in this country before the FDA will stand up and do its job? When will the [American people](#) start listening?

You know, everywhere else around the world, the FDA is a complete joke. Here's *The Independent* in the U.K., doing a report on the FDA that you probably would never see in the United States. Why not? Because the mass media apologizes for the drug [industry](#), and most of the media outlets in this country are funded by drug [money](#). Look at any magazine, newspaper, or cable news program, and what do you see? Drug ads. Those ads are paying the salaries of the very people who decide what's news and what isn't.

Drugs, drugs everywhere

Have you picked up a magazine lately? Have you picked up any of those news magazines on the newsstands? Have you picked up a medical journal? Did you notice that they're 50 percent drug ads? There's hardly any news in the news magazines at all. The news that you find is highly censored and edited. Much of the bad news about drugs is suppressed.

Have you looked around your local community lately? Did you notice how many [pharmacies](#) are being constructed? There's a drug [store](#) on every corner, it seems. Even grocery stores are building pharmacies like mad. Everyone wants to get in the drug business all of a sudden. It's like we have a country of drug pushers, drug runners, drug retailers, drug manufacturers and drug apologizers. And who's the Al Capone [running](#) the drug racket? The FDA, of course.

And then we have this "War on drugs," which does really important things like outlawing [hemp](#). Oh yes, hemp is so dangerous. My God, you can make [paper](#) with it! It's so dangerous, this hemp. You can make a pair of jeans out of hemp. You can make sails for ships out of hemp, as some history buffs know. You can make [car](#) bumpers out of hemp and recyclable car parts. You can make [biodiesel](#) out of hemp. Oh, you can make a lot of things out of hemp, including highly nutritious hemp seeds, loaded with omega-3 [fatty acids](#), outstanding for health and human [nutrition](#). The one thing you can't do with hemp is get high from [smoking](#) it. The THC content is so low in industrial hemp that you'd have to smoke a hundred pounds of hemp just to feel anything resembling a buzz. And yet we have to outlaw hemp in this country because we're fighting "the [war on drugs](#)!" Meanwhile, the real drug threat is prescription drugs. They're the 4th leading cause of death in this country. And they remain perfectly legal. Hmmm... are the politicians smoking crack?

America is a drug nation

The FDA: The Fraud and Drug Administration. Making sure everyone in America has the right to keep on buying, selling and consuming drugs. I remember we used to have a society in which Nancy Regan would teach children to say, "Just say no to drugs." We used to have signs in front of our schools that said, "This is a drug-free zone." In fact, we still have some of these signs, but if you walk past these signs and walk into the school, you find out that **as many as 30 to 40 percent of these children are on drugs**. They're on powerful narcotics that have been prescribed to them by [doctors](#), psychiatrists and school counselors, and pushed onto them by school administrators and [parents](#) who are cowering in fear over what might happen if their little Johnny doesn't stop being so hyper. We've got to put them on drugs! It's a drug nation; a pharmaceutical factory. We have so many [kids](#) on drugs that they've actually made it [illegal](#) *not* to put your kids on drugs!

There's a [family](#) that fought child protective services authorities because they didn't want to put their daughter on chemotherapy drugs. They wanted to treat their daughter naturally, with their own method of healing. But the state said, "No, you can't do that. We're going to force your [child](#) to be poisoned with chemotherapeutic agents that generate profits for [prescription drug](#) companies... chemical agents that don't have any sort of documented benefit for enhancing the lifespan of kids or adult [patients](#), and yet are used by every oncologist in the country. We're going to force these drugs into the [body](#) and bloodstream of your daughter. We're going to take your daughter away from you." And they did. That's how drugged up we are in this nation. We've made drugs mandatory.

We're drugging each other, and when we refuse to be drugged, we invoke the law and steal children from parents and put people in jail; yet, you still can't grow hemp. Oh no, hemp's dangerous. Oh boy, what would happen if everyone grew hemp? Gee, let's see, you'd have a huge multi-billion dollar industry for American [farmers](#). Wouldn't that be terrible? Let's see, you'd have a renewable energy source, you'd have a crop that's good for the environment, a crop that doesn't need to be grown with pesticides or herbicides. Wouldn't that be terrible? To re-invigorate the whole farming industry in this country? Gotta outlaw hemp, but keep those drugs pumping.

Keep that drug economy pumping!

Keep that drug industry legal. Keep on poisoning the hearts, minds, bodies and nervous systems of all the people in this country. You've got to keep them on drugs. Why? Well, drugs are profitable. We're all invested in the drug companies. Gee, if the drug companies weren't making money, people wouldn't have their retirement portfolios, so you sure don't want to do anything that would harm the drug companies. You gotta keep everything moving along. That's what the Fraud and Drug Administration helps do: Keep it all pumping right along and keep those drugs coursing through the veins of our people.

How many drugs? So many that you can now find traces of these drugs in the public water supplies. If you put a little drug sensor at the end of the Mississippi river where it empties into the [Gulf of Mexico](#), you can find drugs – prescription drugs – just coming right on down the river. Here they come! We could bottle these up and sell them back to the same people who took them once already. These drugs are, of course, killing the oceans, the coral reefs and the ocean life in the Gulf of [Mexico](#). The Gulf of Mexico is half dead now, which is better than the American population, which is half [brain](#) dead. We're all on statin and antidepressant drugs and other kinds of prescription drugs that basically sap our cognitive ability, sap our lucidity and take away our ability to think clearly about issues like [health](#).

Information suppression and other tricks of the FDA's trade

Now, getting back to the report by The Independent, one team of investigators found that 28 pages of data had been removed from the FDA files on a new family of painkillers because of what? Confidentiality. It's a trade secret. That's how the FDA covers up negative information. "Gee, did the study show that 10 percent of the people died from heart attacks? Don't worry. We can just call it a trade secret. Then we'll take it out of the official report. No one will know."

Information about cox-2 inhibitors has been suppressed. One of the Swiss investigators, Dr. Peter Juni, who helped expose the risks of these drugs, claims the FDA obstructed his efforts. We all know about the suppression of Dr. David Graham's testimony by the FDA, and how he had been threatened in a variety of ways to make sure that he wouldn't go public with his information. Finally, he was able to testify before Congress, something the FDA certainly did not like. And this is a guy who works there.

There is another guy, Dr. Andrew Mosholder, an expert at the FDA's Office of Drug Safety, who presented an analysis of 22 different studies on more than 4,000 children, covering nine antidepressants. He found that the risk of suicide-related events was twice that of children given a placebo. For those who can't do the math, that's a 200 percent increase, or twice the chance. That's a tremendous increase in the risk of suicide-related events for taking these drugs.

The FDA is committing crimes against humanity

Keep on dosing these children. That's right, call it a brain chemistry imbalance and put those kids on drugs. It's not like children need to do things like play outdoors. It's not like they need physical exercise and sunshine. It's not like they need healthy school lunches or good nutrition. It's not like they need any of that. What they need is drugs. Clearly. The evidence shows it; this is medical science here, and this is clinically proven stuff. This is rational medicine; this is scientifically based.

Oh yeah, we have a bunch of people with a bunch of initials after their names (also known as "psychiatrists"), and they say, "Give the kids more drugs." That's what's happening in the country today. There doesn't seem to be any end in sight. Now, all of this just confirms what I've been saying about the FDA all along. While some people are out there talking about, "Let's reform the FDA," my view continues to be, "Let's *arrest* the FDA." Let's make some arrests. Let's get some criminal convictions of these people, because in my view **they are committing crimes against humanity**.

That's what's really going on here. Crimes against humanity. These are not small violations of local law. This is not some guy at WorldCom fixing the numbers to move a couple of billion dollars into his private bank account. These are bureaucrats, decision makers, even politicians, who have been given the responsibility of protecting the public and who have sold out that responsibility. They have sold their souls in exchange for whatever money or power they're receiving from the drug industry. They have sold out.

The drugging of our children is a chemical holocaust

Do you know who's paying the price? Our children -- the health and the minds of our children. And

the rest of the population too, you name it: Adults, senior citizens, [expectant mothers](#) – forty percent of our nation is now on prescription drugs. It is unprecedented in the history of the world. The level of corruption and the number of [criminals](#) now running our health care system is unprecedented in the history of the world. These are criminals who need to be arrested. Someone in a position of authority – someone like the Attorney General – needs to run in there and make some arrests.

Set an example that says, "Hey, you know what? You cannot conduct this kind of chemical [holocaust](#) on the children of our nation and get away with it. You can't do this in America." America is the land of the free, the [home](#) of the brave and a country where we're supposed to understand what justice is all about and where we fought for [freedom](#), they say. Freedom of what? Freedom to keep dosing our children on prescription drugs? No! I say **we have the freedom to know the truth about the drug companies.**

The only [freedoms](#) we're really fighting for are freedoms like the one I'm exercising here, freedom of speech. This is the one freedom that is the most powerful of all, because it is the freedom that can protect all the other freedoms, and, ultimately, our children. It can protect us from the criminals running our nation. Criminals like those at the FDA.

Legalize hemp and make long-term prescription drug use illegal

Now, if we had honest leaders in this country, prescription drugs would be illegal, at least for long-term use, and hemp would be legal. We could grow hemp for industrial use. Create new revenue streams for farmers. Grow our own biodiesel and reduce our need to import foreign oil.

At the same time, we need to outlaw many prescription drugs, especially for long-term use. We need to outlaw, for one thing, the use of these drugs in children. Instead of doing the responsible thing of addressing children's nutritional habits, of taking [junk foods](#) out of schools, banning the advertising of soft drinks, junk [foods](#) and sugar cereals to children, instead of giving them some recess time, what do we do? We drug them. We say, "Oh, well, they just have some brain chemistry imbalance," and we dose them full of drugs.

That is not an answer to the problems of our nation. We need to [ban](#) these drugs; we need to outlaw them. And we need to arrest these criminals at the FDA and the criminals at the top of these drug companies who are allowing this to happen; in fact, they're pushing for it. They're devising new ways to drug more and more people with more and more prescription drugs as the years go by. They're actually fabricating new diseases and finding ways to convince people they are "afflicted" with completely fictitious disorders like "Social Anxiety Disorder" or "Premenstrual Dysphoric Disorder."

Drug companies can't wait for the coming wave of Alzheimer's patients. They just drool over the [diabetes](#) numbers, because more and more American citizens are going to be diabetic in the years ahead. That has them patting themselves on the back, rubbing their hands in greed, "Oh, can't wait for those diabetes people. They're going to need a lot of drugs for that."

The medical destruction of the USA

Something has got to change around here. And it may be too late. It really may be, because our nation is destroying itself. It's drugging itself into oblivion, and, all the while, spending more money than it has available. We're spending ourselves into medical [bankruptcy](#) – all the while hiding behind this illusion of so-called science-based medicine.

We are missing out on a huge opportunity to do something productive; something like teaching

expectant mothers how to have healthy babies through nutrition or teaching superlearning strategies all children that involve new [learning](#) technologies. We are missing the opportunity to combine that with outstanding nutrition and the mass consumption of essential fatty acids that are absolutely crucial for healthy brain development development.

Our medical system had a great opportunity, a golden opportunity to do something really helpful for humanity, and they flushed it away out of a quest for profits. The Fraud and Drug Administration stands at the top of this pyramid of control, pulling the strings and making sure the Drug Empire continues to tighten its [iron](#) grip. And it has happened. More people are taking drugs. Drugs are more and more profitable, dangerous drugs are not removed from the market and Americans have few alternative choices. That's what's happening today, and if you aren't outraged by it, then you are not aware of what's going on.

America has been conned by the FDA

If you think all these drugs are medically justified, you've been conned. If you think doctors have been trained on how to help people be healthy, then you've been fooled. These drugs haven't been proven safe, and the FDA is not looking out for the public safety. Just like every other American out there, you've been conned. And the whole world is laughing at us; that is, when we're not bombing them.

So, I just have one question from all of this: for how long will the American people allow this to continue? I'm really curious because I want to know. Will the people continue to allow their children and their senior citizens to be drugged? Will they continue to allow drug companies to extract more and more dollars from their pockets and leave them in financial ruin? Is this what people are going to allow to continue happening in this country?

Because maybe the answer is they'll allow it forever. Maybe they'll never be the wiser. Keep on eating those processed foods, those junk foods, those restaurant foods, all those unhealthy, toxic, disease-causing ingredients. Keep on buying those personal care products, coating your hair in cancer-causing ingredients, coloring your hair with cancer-causing solvents. That's right. Keep on drinking all that alcohol, smoking all those cigarettes, watching that prime-time television sitcom to distract yourself from the crumbling of our nation that's happening all around you this very minute. We've got to keep people distracted. Maybe they won't notice.

Keep them drugged up. They'll just keep on working, because somebody's got to pay for all this, right? Somebody's got to foot the bill. And the person footing the bill is, of course, Joe Public. Nearly every American consumer out there is writing a check to the drug companies right now, and saying, "Keep on drugging me, my children and my parents in the nursing home. I'm going to keep writing you checks until I have no more money left. I'm going to keep on writing them anyway after that, and put myself in medical bankruptcy, just to stay addicted to these prescription and over-the-counter drugs." That's what Americans are saying right now.

And the FDA must be standing back watching, laughing its head off, [thinking](#), "Wow, it worked." It's what they must be thinking right now. "I can't believe we pulled this off! They bought it. Can you believe it? These people are suckers, they bought it!"

And by the way, there's another new [disease](#) out there that's very dangerous to your health. It's called "Conventional Medicine Belief Disorder" (CMBD) and its primary symptom is an irrational belief in a system of medicine that has nothing to do with promoting health. The cure for CMBD isn't a drug, it's an ANTI-drug. What is the ANTI-drug? That will be revealed in a later article. But here's a hint: you don't need a prescription to get it. Thanks for tuning in to this commentary.

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- [The great direct-to-consumer prescription drug advertising con: how patients and doctors alike are easily influenced to demand dangerous drugs](#)
- [Psychiatric Drugs: Chemical Warfare on Humans - interview with Robert Whitaker](#)
- [28 Senators vote to maintain Big Pharma monopoly over U.S. consumers; Republicans oppose free trade for medicine](#)
- [The raw \(and ugly\) truth about the war on drugs](#)
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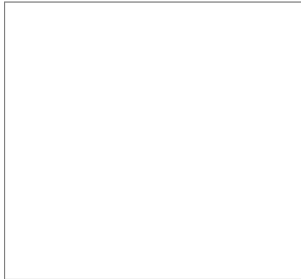
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The raw (and ugly) truth about the war on drugs



Monday, August 15, 2005

by Mike Adams, the Health Ranger

Editor of NaturalNews.com ([See all articles...](#))

Drugs are bad. Drugs destroy peoples' lives. Didn't you know that marijuana turns regular everyday people into zombie pot smokers? That's why we have a war on drugs in America: to protect our children from potheads.

Drugs are bad. Especially marijuana. I learned this the other day when I visited an elementary school as a guest speaker. The schoolchildren were well trained in describing the dangers of drugs. On command, they would spout out any number of statements describing them.

But then a funny thing happened. I started asking how many of them were on [drugs](#). You know, drugs their [doctor](#) prescribed. Drugs that alter [brain chemistry](#) to keep them docile, or free of [pain](#), or to dilate their [lungs](#) so they could breathe easier.

It turned out that 60% of these schoolchildren were either on drugs at that very moment, or had been on such drugs within the last twelve months. Two-thirds of the teachers were on drugs, too. And it's not at all a stretch to believe that 40% or more of all [parents](#) are on drugs. Mild-altering drugs like [antidepressants](#), no less.

A nation of [drug addicts](#)

Fact is, we are a nation of [drug](#) addicts. We drug ourselves, our elderly and our [children](#) on a daily basis. We do it with prescription [medications](#), over-the-counter pills, alcohol, [caffeine](#), nicotine... and we say it's all fine because those drugs are legal.

But wait a minute, you say. Those [legal drugs](#) are different from marijuana. They're FDA-approved drugs, prescribed by a doctor. They have a medical purpose.

Oh really? Ritalin has a medical purpose? What medical symptoms does Ritalin treat, then? What measurable physiological state is addressed with Ritalin? There are none, of course. **Ritalin is an authority drug. It keeps children in line. It makes teachers feel less stress and parents feel less**

guilt. Ritalin is a mind-altering narcotic, and yet millions of children are on it today. Its purpose is not to help children, but to make [life](#) more convenient for those who manage children.

You think [statin drugs](#) have a medical purpose? Think again. In reality, they only have a profit purpose. These drugs were invented to sell pills that **manage disease states in people**, not that solve any real [health](#) problem. Don't believe me? Just stop taking your statin drugs, if you dare, and watch your cholesterol skyrocket. You'll find out you're a slave to the drug, and no healthier than before.

What's the difference between legal and [illegal drugs](#)?

So what's the real difference between legal drugs and [illegal](#) drugs? Some people think that only illegal drugs are habit-forming. Yet legal drugs can be just as addictive as illegal drugs. Just ask anyone who has tried to quit [smoking](#), go off caffeine, or kick to Oxycontin habit.

So is there some other difference between illegal drugs and legal drugs? People argue that legal drugs are safe. They're FDA-approved! And yet they fail to recognize that **[prescription drugs](#) kill more Americans each year than all the crack, meth, and [heroin](#) deaths combined.**

Okay, then, what about the argument that illegal drugs have no [medicinal](#) purpose, and legal drugs do have a medicinal purpose. What about that? Wrong again. Medical marijuana is a medically proven treatment for a variety of conditions, yet marijuana still remains illegal. Even MDMA (now called "Ecstasy" on the street) was long considered an effective "experiential drug" that helped severely traumatized adult [patients](#) overcome past pains through improved clarity. At the same time, [tobacco](#) smoke has no medical purpose whatsoever, yet [cigarettes](#) remain perfectly legal.

No, the real difference between these two classes of drugs is not their medical merit, nor their safety. The real difference is something far more sinister. It gets right down to answering the question of why DEA agents will raid [medical marijuana](#) clinics, yet stand by doing nothing while Americans smoke themselves to [death](#) on tobacco.

Want to know the real answer? I very much doubt you do. Because, like most Americans, you won't believe it. You've been blinded to the obvious truth for your whole life, manipulated by the media, and brainwashed by [advertising](#) that has turned you into a statistically-validated consumer. You'll think, no, this couldn't possibly be true. The world isn't that unjust, you think. But you're wrong. (Take the free [Gullibility Factor test](#) to find out if you're really a mind slave or not...)

Here's the raw, blunt truth about the [war on drugs](#). **Drugs are declared legal or illegal based primarily on who benefits from their manufacture, distribution and sale.**

Corporate and [government](#) profits determine the legality

Let me put this another way. You know why cigarettes are still legal? Consider this: here's a product that admittedly kills people. It has no health benefit whatsoever. It is a threat to the public health. Yet why does it remain legal? **Because states get a cut of cigarette sales** thanks to the Big Tobacco settlement a few years back. Keeping cigarettes legal results in desperately-needed revenues for states... revenues that are almost never spent on anti-smoking campaigns, by the way.

It's a classic racket: **tobacco is allowed to remain legal because powerful institutions get a cut of the action.** While people die from lung cancer, states get financial resuscitation by taking a cut of every sale. States are trading your health for their revenues.

Think I'm being overly cynical? Let's take a look at [gambling](#) laws. Organized gambling is illegal at both the state and federal levels in this country. Except, of course, when government gets a cut. Casino-friendly states didn't just make casinos legal for the good of the public: they legalized gambling in exchange for a cut of the action. It's a classic, mob-style "protection fee."

If you want to test this theory, launch your own online gambling website. You'll be shut down almost immediately and charged with serious crimes. Gambling and organized betting is illegal, didn't you know? That is, unless the state runs the show, as in **state lotteries**.

It's right in your face, folks: **gambling is legal when powerful corporations or institutions get a piece of the action**. It's illegal when they don't. It has nothing at all to do with morality, or protecting people, or doing what's right. It's all about [money](#), pure and simple. Just ask all the corrupt politicians in Missouri who legalized riverboat gambling a few years back.

Getting back to drugs, why do you think [alcohol](#) remains a legal drug? Because states and [cities](#) tax it. **State governments are addicted to alcoholics** as a source of revenue to fund their voter entitlement programs that get politicians reelected. Alcohol is a [cash](#) machine for cities and states.

Sometimes the exact same chemical is both legal and illegal, depending on who [profits](#) from it. The FDA, for example, banned the Chinese [herb ma huang](#) because it contains ephedra. Yet the exact same chemical compound remains perfectly legal in over-the-counter drugs like [Sudafed](#) and a variety of cold medicines. Sudafed even gets its name from ephedra: "pseudo-ephedrine." So why is ephedrine illegal in herbs, yet legal in [pharmacy](#) drugs manufactured by [drug companies](#)? You already know the answer.

With all that in mind, why do you think prescription drugs that kill people remain legal? Think carefully now...

If you guessed, "Because powerful corporations generate billions in profits selling drugs, and governments get a cut of that via state sales [taxes](#) and corporate income taxes" then BINGO! You win a prize: a lifetime of free Prozac to keep you happy!

Legal drugs generate windfall profits for those in [power](#)

Think about it: if prescription drugs were peddled by street dealers instead of [doctors](#), and if all that revenue changed hands in a non-taxable, non-corporate structure (i.e. street cash), then you'd be seeing full-scale [law enforcement](#) action against the makers, distributors and sellers of those drugs. You'd also see endless headlines about how dangerous they were: "Street painkillers kill twelve in South Miami!"

The sad truth of the matter, though, is that those very same painkilling drugs killed at least twelve people in South Miami this very day. But you'll never hear about it in the media. Because the news networks are sponsored by drug [companies](#), of course. (The news is not designed to inform you, it's designed to shape your reality, to turn you into a consumer of whatever products the corporations are peddling this year. Didn't you know?)

Every drug that's legal is legal for one simple reason: **somebody in a position of power is keeping it legal because they're getting a cut.**

Non-patentable drugs are usually outlawed

That's why medical marijuana is illegal: because government doesn't control its distribution, nor does government receive a financial cut. You can bet your life that if Big Pharma owned the [patents](#)

on medical marijuana and could set monopolistic [prices](#) on it, **pot would be perfectly legal to own and smoke**. That is, as long as you got it from a pharmacy where prices and distribution could be controlled.

Control is the key here. You think [the FDA](#) is discrediting drugs from [Canada](#) in order to protect your health? Get real. The [FDA](#) is simply protecting the monopoly drug market in this country. It's controlling distribution points in the U.S. in the same way that a crack dealer assassinates his street corner competition. Eliminate the competition, and you can set whatever price you want. That's why uninformed U.S. consumers pay 30,000% markup prices for drugs that can be acquired in Mexico or Canada for pennies on the dollar.

It's not about your health, it's about their wealth

You see, corporate [America](#) doesn't really care what you put in your mouth, up your nose, through your lungs or into your veins, as long as they get a cut from it. That's the whole [prescription drug](#) racket in a nutshell: it's billions of dollars in annual profits generated from mind-altering (yet legal) drugs that flat-out kill people. Lots of people. Like 100,000 Americans a year (or a lot more if you believe more critical statistics).

So if you've ever wondered why Ritalin -- which has no medical purpose whatsoever -- is perfectly legal, and yet medical marijuana -- which has a well-proven medical purpose -- is outlawed, now you know the answer: **because Ritalin makes powerful people rich**. And marijuana doesn't. Anybody can grow marijuana. Drug companies don't control the patents.

Why I teach people to be 100% drug free

Now, just for the record, I do not personally use any drugs whatsoever (recreational, over-the-counter, prescription or otherwise), and in fact, I teach people to be 100% free of all drugs, including caffeine and alcohol. I bought into the "just say no to drugs" advice of Nancy Reagan, and I actually applied it to ALL drugs, not just selective drugs.

And as far as I can tell, aside from the Mormons and the Amish, there are only a small percentage of truly drug-free people living in this country. Practically everybody I meet is addicted to at least one of the following: coffee, cigarettes, alcohol, pain meds, prescription drugs or sugar (which alters [brain](#) chemistry in drug-like fashion).

At the same time, I'm not at all fooled by this silly "War on Drugs" charade, which is really nothing more than enforcement of corporate drug profits at gunpoint. If we had a genuine war on drugs in this country that really worked to protect the American people **we'd send [DEA](#) agents into drug company offices and confiscate all the legalized but deadly medications being manufactured, distributed and deceptively sold to unwitting Americans today**.

Medical marijuana is a threat to both the profits and power of drug companies, not to mention the credibility of [the DEA](#). Letting grannies smoke pot in California makes DEA agents look silly. If it were allowed, it would also undermine the billions of dollars already spent incarcerating people for "pot crimes." Basically, it would make the whole War on Drugs look stupid. Which it most assuredly is, at least when it comes to marijuana.

I can understand taking a tough stance on hard drugs (crack, [meth](#), heroin, etc.), but arresting cancer patients who smoke joints for pain control sounds a lot more like oppression than law enforcement to me.

So what is the War on Drugs? It's an excuse to control you. It is a system that keeps the population

in a state of constant fear so that heroic politicians can get elected on empty promises to "keep fighting the war on drugs!"

The DEA is AWOL on most drug issues

Where is this War on Drugs when it comes to Grandma in the nursing home, who died of a stroke caused by Cox-2 inhibitor drugs? Where is the War on Drugs when little Johnny schoolboy picks up a rifle and blows away his classmates because he's on antidepressants and can't tell the difference between real life and a first-person-shooter video game? Where is the War on Drugs when 16,500 people each year die, shitting digested blood until they pass out and die because that daily dose of aspirin tore a gaping hole in their stomach?

The War on Drugs, you see, turns a blind eye to the death and suffering caused by these drugs. The DEA pretends prescription drugs don't even exist. No prescription drug death has ever been prevented by the DEA as far as I know. Yet 100,000 Americans are killed each year by FDA-approved drugs. The DEA has no interest whatsoever in protecting Americans from these drugs. Ever wonder why?

The DEA is properly named, by the way. It's the Drug *Enforcement* Agency. It's enforcing drugs. The right drugs. The legal drugs. The drugs that make money for drug companies, drug distributors, drug retailers, cities, states and countries. It's enforcement at gunpoint, and as long as the money keeps flowing, the drugs will stay perfectly legal, regardless of who dies.

The entire distribution system is well in place: the false and misleading television advertising, the outright bribery of drug dealers (doctors), the street corner fulfillment centers (pharmacies), and the coordinating drug lord running the show (the Fraud and Drug Administration). It's a brilliant system for manufacturing, promoting, delivering and selling deadly, addictive drugs to children, adults and seniors while generating corporate profits and [tax](#) revenues for cities, states and nations.

And that's the raw truth about the War on Drugs. You may not like it, but now, at least, you know why it exists.

So I have a common sense question for all the people in this country. If you support the War on Drugs, then why are you taking so many drugs yourself? And why are you allowing your children to be drugged?

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