

# How the FDA Went Bad:

## Health Serfdom and the Rise of Tyranny

By Jonathan W. Emord

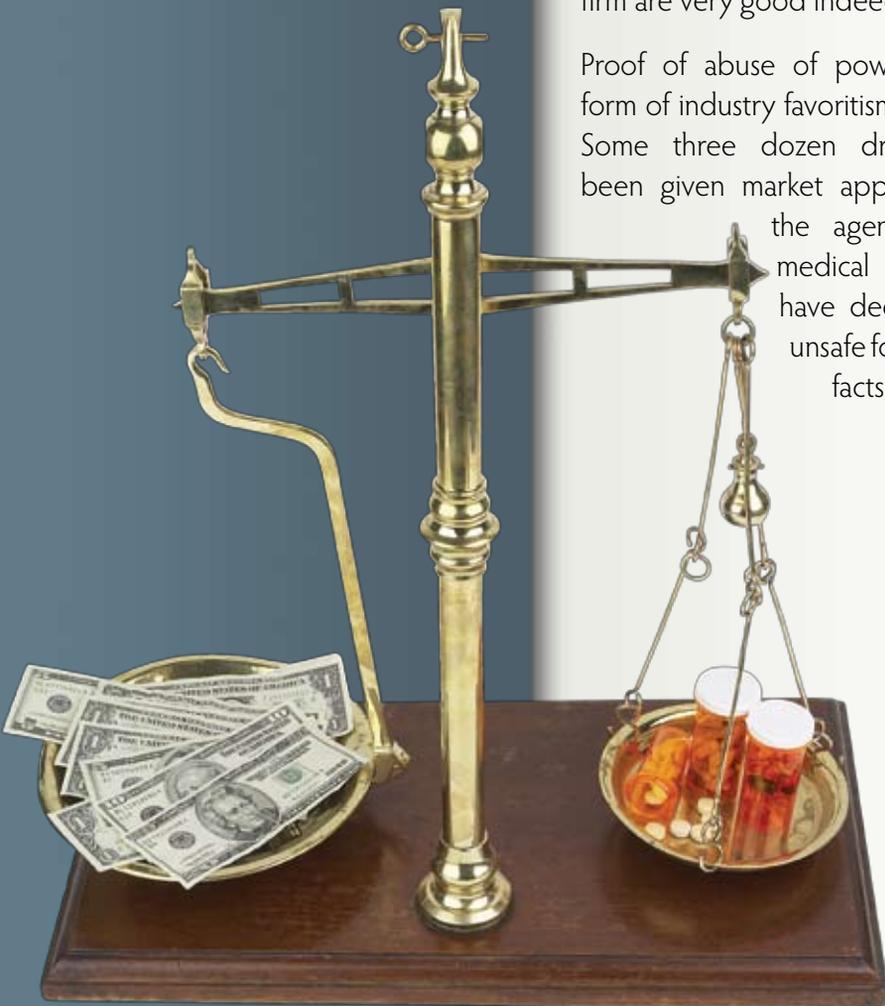
### The prevailing view on Capitol Hill is that money will solve most of the FDA's problems.

However, the FDA's costliest failings have nothing to do with the agency's budget and everything to do with the efforts of political appointees at the agency to pave the way for lucrative post-government employment by doing the bidding of the agency's most powerful regulatees, the world's largest drug companies. For those agency heads and political managers who play their cards right and keep the pressure on for approval of drugs, even unsafe drugs, prospects for obtaining high paying jobs in a drug company or drug company lobbying firm are very good indeed.

Proof of abuse of power in the form of industry favoritism is legion. Some three dozen drugs have been given market approval that the agency's own medical reviewers have deemed too unsafe for use. The facts revealing

widespread corruption and abuse of power are known to members of Congress, including those who chair the committees with FDA oversight responsibilities. To be sure, members, like House Energy and Commerce Subcommittee on Oversight and Investigations chair Bart Stupak, verbally flog the FDA Commissioner and the Center for Drug Evaluation and Research Director but never pass any meaningful reform legislation to reign in their abuses. You see the single largest lobbying institution, the one that paid members of Congress from both major political parties \$1 billion over the past decade, the pharmaceutical lobby, largely gets its way. To quote Congressman Dan Burton from Indiana, the pharmaceutical lobby has "unlimited resources" and "when they push real hard to get something accomplished in Congress . . . they can get it."

As FDA medical reviewers have repeatedly stated in congressional testimony, FDA views the drug industry as its "client" and does its client's bidding when it approves unsafe drugs. Many of those reviewers have said that they and their colleagues have been silenced by FDA management, have been coerced into altering their reports to remove findings of harm, have been kept from testifying of harms before drug review panels, have had their reports suppressed to prevent them from reaching drug review panels, or have been ostracized and reassigned, replaced with those who will conform to the



political managers' desires. The FDA Commissioner has operated an Office of Internal Affairs that has repeatedly forced agency scientists who identify risks of drugs to be the subject of investigations and threats of prosecution. Some have also been the victims of character assassination in the academic publishing community and on Capitol Hill.

The consequences of FDA's industry favoritism have been profoundly horrific: well over 100,000 Americans lives lost and many more injured, some permanently. More money will not eliminate those abuses. Most in Congress well know that increased appropriations to FDA will give those responsible for the abuses more authority with which to do mischief. Hence, we can expect that abuses will continue largely unabated.

Four years ago, FDA Associate Director of the Office of Drug Safety David J. Graham, M.D., publicly sounded the alarm. Despite threats and cajolery to force him either to change his position on the lack of safety of Vioxx or intimidate him into not testifying before Congress, he defied them, did testify, and still has his FDA day job. "We are virtually defenseless," he told Congress and America and then listed over a half dozen unsafe drugs approved by the FDA despite the presence of convincing evidence that the drugs in question would produce the very harms that in fact occurred after the drugs entered the market. Graham

explained that the FDA's Center for Drug Evaluation and Research "views the pharmaceutical industry it is supposed to regulate as its client."

Graham and his colleagues have explained that numerous drugs never should have been approved given the evidence of the threats posed to public health: **Vioxx**, a pain killer, linked to an estimated 140,000 heart attacks and 60,000 deaths from heart attack; **Redux**, an appetite suppressant, linked to potentially lethal pulmonary hypertension; **Rezulin**, a type-2 diabetes drug, linked to liver and heart toxicity; **Avandia**, a type-2 diabetes drug, linked to heart toxicity; **Ketek**, an antibiotic, linked to liver toxicity; **Paxil**, **Zoloft**, and **Effexor**, antidepressants, linked to increased suicidal thoughts in children; **Omniflox**, an antibiotic, linked to hemolytic anemia; **Trovan**, an antibiotic, linked to liver toxicity; **Lotronex**, a treatment for irritable bowel syndrome, linked to ischemic colitis; **Baycol**, a cholesterol lowering drug, linked to muscle injury and kidney toxicity; **Bextra**, a non-steroidal anti-inflammatory drug for arthritis and painful menstruation, linked to heart attacks and strokes; **Seldane**, an antihistamine, linked to heart arrhythmias; **Propulsid**, a drug for night-time heartburn relief, linked to heart arrhythmias; **Accutane** and **Arava**, rheumatoid arthritis drugs, linked to liver toxicity; **Crestor**, a cholesterol lowering drug, linked to myopathy and rhabdomyolysis; **Meridia**, a weight loss drug, linked to heart

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arrhythmias; and **Serevent**, an asthma drug, linked to an increased risk of death from asthma.

The FDA's approval of unsafe drugs has come under criticism not only from those outside of the government but also from institutions and individuals within the government, including the Government Accounting Office, the National Academy of Sciences of the Institute of Medicine, the FDA Commissioner's own Science Board, and FDA's medical reviewers. Former FDA medical reviewer David B. Ross, M.D. testified before the House Subcommittee on Oversight and Investigations that "FDA managers were so bent on approving Ketek that they suppressed evidence of fraud and pressured reviewers—including myself—to change their reviews." In a more politic but no less alarming report, the National Academy of Sciences Institute of Medicine concluded that "FDA and the pharmaceutical industry do not consistently demonstrate accountability and transparency to the public by communicating safety concerns in a timely and effective fashion." The FDA's own Science Board issued a report in December of 2007 that concluded that FDA was "at risk" of failing to fulfill its mission, a gross understatement given the facts.

In 2006, the Union of Concerned Scientists, a non-profit group dedicated to protecting the professional independence of government scientists, conducted a

survey of FDA scientists. One-fifth of those surveyed indicated that they had been "asked for non-scientific reasons to inappropriately exclude or alter technical information or their conclusions in a FDA scientific document."

Those FDA abuses and others, including the agency's relentless censorship of truthful nutrient-disease information, I have documented in *The Rise of Tyranny*. As stated there, the solution to the FDA's chronic history of unsafe drug approvals lies in removing from the FDA the drug approval power. Need there be any more proof, any more lives lost, to establish that the FDA cannot be trusted to approve only safe drugs? The solution also lies in prohibiting the FDA employees from taking positions in or receiving benefits from the drug industry. The solution lies in prohibiting members of Congress from taking positions in or receiving benefits from the drug industry. Ultimately, the solution lies in restoring constitutional governance by preventing the unelected heads of the FDA (and the other independent regulatory agencies) from creating law through regulation unless those elected by the people, the Congress of the United States, enact the regulations in question through majorities in both Houses and with the signature of the President, the way the Constitution specifies for laws to be enacted.

Indeed, we may remark with considerable awe at the fact that the



founding fathers foresaw this rise of tyranny, corruption, and destruction of the people's liberties over two hundred years ago as they crafted and achieved ratification of the Constitution and the Bill of Rights. In a letter dated October 17, 1788, to Thomas Jefferson, James Madison wrote: "... a succession of artful and ambitious rulers may by gradual and well-timed advances finally erect an independent Government on the subversion of liberty." They knew that if ever any two of the legislative, executive, and judicial powers of governance were combined in single hands rather than kept separate, balanced, and checked as prescribed by the Constitution, liberty would be at an end and tyranny would rise in its place.

Since 1935, the Congress of the United States has ceded governing control over this nation to some 182 independent regulatory commissions whose unelected heads have the power to make law through regulations, prosecute the violators of those regulations, and adjudge those they charge with the violations. They are thus the law-makers, the law-enforcers, and the judges of law violations. Indeed, fully three quarters of all federal law comes in the form of regulations adopted by the unelected heads of the all-powerful bureaucratic agencies and not in the form of statutes adopted by our elected representatives. The combination of governing powers in single hands James Madison considered "the very definition of tyranny." In his

*Thoughts on Government* (1776), John Adams, likewise, presciently observed:

I think a people cannot be long free, nor ever happy, whose government is in one assembly... [b]ecause a single assembly possessed of all powers of government would make arbitrarily laws for their own interest, execute all laws arbitrarily for their own interest, and adjudge all controversies in their own favor.

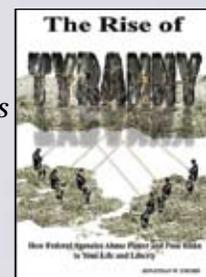
Congress has seen fit to invest in the FDA supreme power to regulate all foods, dietary supplements, drugs, biologics, and medical devices, giving that agency authority not only to create the regulations that govern but to prosecute violations of those regulations. As the founding fathers predicted, investing that extraordinary power in single hands has given rise to tyranny. Having no power to vote out of office the FDA Commissioner or the political managers who run the agency, the people are not sovereign over health issues. Instead, we are victims of a bureaucratic oligarchy that has replaced the limited federal republic entrusted to us by the founding generation. Like serfs to a King, we are ruled by one not answerable to us. Unless we reverse course and take back the governing power Congress wrongfully delegated to the FDA, we will not see an end to the tyranny that now sacrifices Americans lives, and we will see even greater abuses of power and corruption. **HK**



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Washington, D.C. He has defeated the FDA in federal court a remarkable six times. He is the author of three critically-acclaimed books, *Freedom, Technology, and the First Amendment* (1991); *The Ultimate Price* (2008); and *The Rise of Tyranny* (2009). His books are available for purchase from Sentinel Press (888-783-7331). He is the host of Health, Law and Politics on the Talk Star Radio Network. He is the 2008 recipient of the Cancer Control Society's Humanitarian of the Year award.

***The Rise of Tyranny: How Federal Agencies Abuse Power and Pose Risks to Your Life and Liberty***



by Jonathan W. Emord

Emord exposes: Drug industry control of FDA; approval of drugs over FDA medical reviewers' objections; congressional complicity in FDA corruption; drug industry control of Congress; and precise reforms to restore constitutional governance.