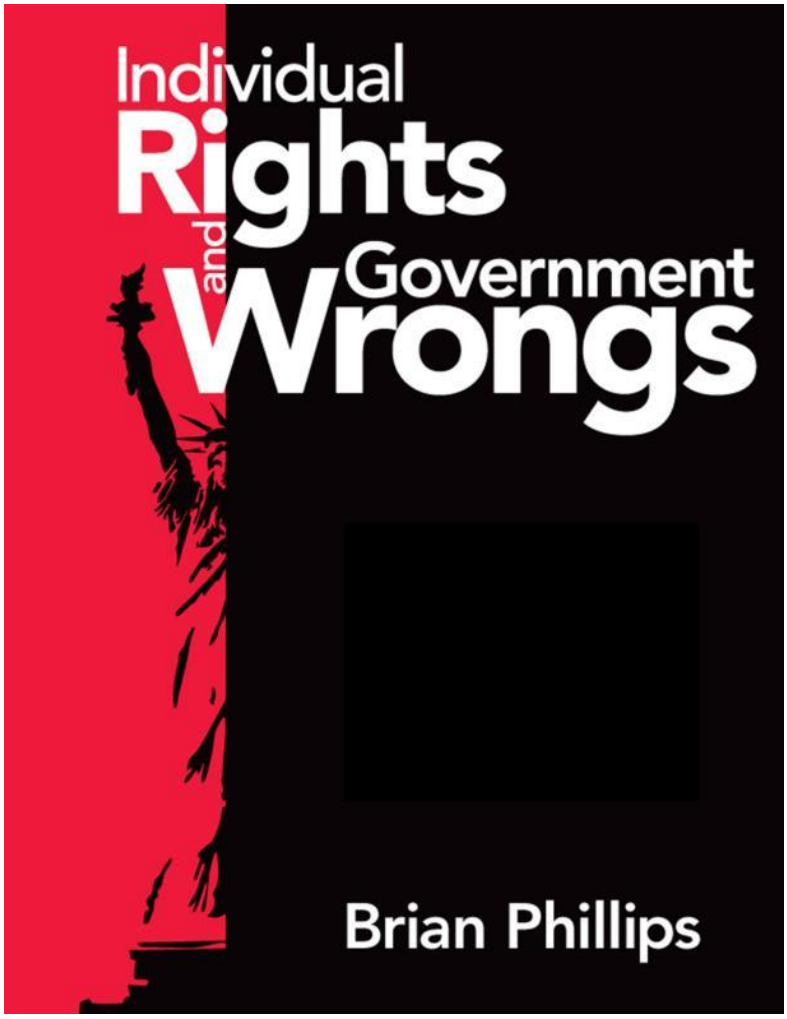

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It's Your Life

One morning in April 2011, armed members of three federal agencies raided the Pennsylvania farm of Dan Allgyer, culminating a yearlong sting operation. The Amish farmer was not dealing in stolen buggies. He was not manufacturing counterfeit designer handbags. He was shipping milk across state lines. But this was no ordinary milk. It was raw, unpasteurized milk—milk as it comes out of a cow. And the federal government did not like that fact. "It is the FDA's position that raw milk should never be consumed," said a spokesman for the Food and Drug Administration (FDA).[1] The raid prompted an outcry from across the nation. Progressives and conservatives alike denounced the raid, declaring that individuals should be allowed to eat and drink whatever they choose. The FDA disagrees, and when it comes to what you may legally ingest, the FDA has the final word.

Few would dispute the fact that contaminated food and toxic drugs are harmful to human life. But what would happen if government did not set standards for food and drug safety? Wouldn't an absence of government regulations lead to the marketing of unsafe products? If individuals were free to purchase the food and medicines of their choice, wouldn't some jeopardize their well-being by purchasing dangerous products? Don't we need agencies such as the FDA to protect consumers and ensure a safe food supply?

Such questions imply that, without government intervention, private companies would abandon all standards. They imply that, without regulations, private businesses would be willing to jeopardize the safety and health of their customers, and in the process, ruin their business. Or, to ask what is really meant by the above questions: without government regulations, why wouldn't private companies intentionally poison their customers to increase profits? It should be clear that no rational business would do such a thing—providing safe products is in the self-interest of every business. In truth, it is government regulations, and particularly those imposed by the FDA, that threaten consumer safety and health. To understand this, let us look at what the FDA does.

The inception of the FDA can be traced to the Pure Food and Drug Act of 1906, which stated that the act's intention was to prevent "the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes."[2] (Ironically, Dan Allgyer was busted for selling unadulterated milk.) As one commentator put it at the time, "The ultimate value of the national food law depends upon the wisdom of the Bureau of Chemistry [a precursor of the FDA], which body must arbitrarily become food-gods, determining what is

1. Stephen Dinan, "Feds Sting Amish Farmer Selling Raw Milk Locally," *The Washington Times*, April 28, 2011, accessed May 30, 2011, http://www.washingtontimes
.com/news/2011/apr/28/feds-sting-amish-farmer-selling-raw-milk-locally/.

2. The Pure Food and Drug Act of 1906, 34 U.S. Stats. 768 (1906).

good and what is bad."[3] Today, the FDA is much more than an arbitrary "food-god." The powers of the FDA go far beyond merely keeping "poisonous or deleterious" foods and drugs off the market—it controls and regulates not only food and drugs, but veterinary products, cosmetics, tobacco, and medical devices. Its determination of what is good and what is bad is forced upon producers and consumers alike, and sometimes with life or death implications. With such sweeping regulatory powers, the FDA is one of the most powerful agencies of the federal government. Such restrictions imply that your body and your life are not yours, but the government's.

What are the existential consequences of such an abhorrent premise? Do these restrictions and controls provide any practical benefits? While the FDA has likely kept some potentially unsafe products off the market—even a chronic liar occasionally speaks the truth—it has also done incomputable harm. Until 1962, the FDA was a relatively benign (though still immoral) government agency whose primary purpose was to test new drugs for safety. However, with the passage of the Kefauver Harris Amendment to the Federal Food, Drug, and Cosmetic Act (in 1962), the FDA was charged with the task of ensuring that new medicines are effective, as well as safe. One harmful result of this new government mandate has been an increase in the time for approval of a new drug. Prior to 1962, the approval time was seven months; by the late 1970s, it took more than ten years to get a new drug approved.[4] By the mid-2000s, the time had grown to an average of fifteen years.[5] At the same time, foreign nations are approving drugs much faster. Economist Daniel B. Klein writes: "A 1987 study catalogued 192 generic and 1,535 brand-name tested drugs available abroad but not approved in the United States. Of the drugs approved by the FDA between 1987 and 1993, fully 73 percent had already been approved abroad."[6] In other words, while patients in other countries have access to these life-saving drugs, Americans are forced—by their own government—to endure needless suffering, and many wind up dying before the drug is eventually approved. Unless the FDA grants permission, Americans are prohibited from buying medicines which, in their judgment, will be beneficial.

While it is impossible to calculate the precise number of deaths resulting from the delays imposed by the FDA, some have estimated that more than 200,000 Americans died between 1967 and 1997 because they were denied access to drugs used elsewhere in the world.[7] As one example, Dr. Louis Lasagna, director of Tufts University's Center for the Study of Drug Development, estimated that 119,000 Americans died because of the FDA's seven year delay in approving beta blocker heart medicines. A four year delay in approving a clot-busting

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3. Dr. Edward A. Ayers, "What the Food Law Saves us From," in *The World's Work, Vol. 14* (New York: Doubleday Page and Co., 1907), p. 9322, accessed January 22, 2011, http://books.google.com/books?id=sojNAAAAMAAJ&pg=RA1-PA9316#v=onepage &q&f=false.

4. "Theory, Evidence and Examples of FDA Harm," FDAReview.org, accessed December 29, 2010, http://www.fdareview.org/harm.shtml.

5. "Food and Drug Administration," in Cato Handbook on Policy*, 6th ed. (Cato Institute, 2005), p. 394, accessed December 29, 2010, http://www.cato.org/pubs /handbook/hb109/hb_109-40.pdf.*

6. Daniel B. Klein, "Economists Against the FDA," The Independent Institute, accessed December 29, 2010, http://www.independent.org/publications/article.asp ?id=279.

7. "Food and Drug Administration," in *Cato Handbook for Congress: Policy Recommendations for the 105th Congress*, (Cato Institute, 1997), p. 340, accessed December 29, 2010, http://www.cato.org/pubs/handbook/hb105/105-32.pdf.

drug called tissue plasminogen activator cost an estimated 30,000 lives.[8] How do these delays protect patients? What good is promoted by denying patients access to drugs and leaving them to die?

The costs imposed by the FDA are not limited to the lives lost. It is estimated that *85 percent* of the cost of developing a new drug is a result of the mandates imposed by the FDA.[9] With the cost of developing a new drug averaging more than $800 million in 2003, and the cost of a new drug discovered in 2003 reaching nearly $2 billion by the time it gets to the market twelve years later,[10] it is little wonder that the cost of drugs and medicines is soaring. Pharmaceutical companies must recover their investments and the additional costs imposed by FDA mandates, or they will have no motivation to continue such risky ventures. If government regulations add 85 percent to the cost of developing a new drug, it makes sense that those costs are then added to the price of the medicines you buy. Remember this the next time you hear someone complain about the high price of drugs. And because of the arbitrary powers held by the FDA, developing new drugs is extremely risky.

The uncertainty associated with the approval process imposes a huge financial risk on drug companies, as jumping through the FDA's hoops is no guarantee that a drug will be approved. A businessman can invest hundreds of millions of dollars and years of research and testing, only to be told by the FDA that his judgment is irrelevant. Drug companies cannot act by right, but only with the permission of government bureaucrats. With such uncertainty looming, the drug companies' incentive for developing new drugs is greatly diminished. Nor does the uncertainty end with a drug's approval. As Daniel B. Klein writes, the FDA also decides what a company can say about its products.[11]

This control over what may or may not be said can reach absurdity. For example, for years it was known that aspirin is beneficial for heart-attack victims. But the FDA prohibited aspirin manufacturers from advertising that fact.[12] Similarly, in 1992, the Centers for Disease Control and Prevention (CDC)—another federal agency—recommended folic acid supplements for women of child-bearing age to help prevent some debilitating and deadly birth defects, such as anencephaly and spina bifida. The FDA promptly announced that it would prosecute any food or vitamin manufacturer who advertised this fact. And then, in 1998 (only six years later), it demanded that manufacturers begin fortifying certain products with folic acid![13] Even the most minor issues do not escape FDA mandates; the FDA ordered one company to destroy cookbooks that contained information on stevia, an herb used as a sweetener.[14] Eager to flex its dictatorial muscles, the FDA steadfastly refuses to allow either manufacturers or consumers to act on their own judgment. Whether it is issuing prohibitions or mandates, the FDA has the final word, and acting contrary to their dictates can lead to fines, prison, or both. And the results of actually following their edicts can be even worse.

The perversity of the FDA's policies reaches its pinnacle when it comes to the terminally ill. Often, experimental (and unapproved) drugs are the only hope for terminally ill patients.

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8. Ibid., pp. 340-41.

9. Ibid., p. 341.

10. "Food and Drug Administration," in *Cato Handbook on Policy, 6th ed.* (2005), p. 394.

11. Klein, "Economists Against the FDA."

12. "Theory, Evidence and Examples of FDA Harm."

13. Ibid.

14. Dr. Mary J. Ruwart, "Death by Regulation," International Society for Individual Liberty, accessed January 22, 2011http://www.isil.org/resources/lit/death-regulation
.html.

Yet, the FDA routinely refuses to allow patients to use these experimental drugs. Abigail Burroughs is one example. Shortly after the nineteen-year-old was diagnosed with squamous cell carcinoma, her

> family learned of an investigational cancer drug that showed good response in early trials. Abigail's prominent oncologist at Johns Hopkins Hospital believed the drug had a significant chance of saving her life. But every effort on the part of her family, physician, and supporters to procure the drug for Abigail failed. She was ineligible for a clinical trial and the drug company couldn't provide it for her for compassionate use. The FDA was unmoved by her life-and-death situation.[15]

After a futile seven month battle with the FDA, Abigail died. Less than five years later, the drug was approved by the FDA for Abigail's type of cancer. The FDA arbitrarily played God, and Abigail lost her life. Why? Who benefited from this? Sadly, Abigail's story is not unique.

Contracting a deadly disease is tragic. When government bureaucrats deny an individual access to potentially life-saving drugs, they amplify the tragedy. What would your attitude be if you were diagnosed with a terminal disease but were denied access to an experimental treatment? How would you feel if the FDA essentially issued you a death sentence? If, in consultation with your doctor, you conclude that a particular medicine is worth trying, why should the FDA stop you from doing so? You have a moral right to take any drug you choose—it is your life. If your judgment is wrong, you will bear the consequences. When the FDA is wrong, you must also bear the consequences, regardless of your own judgment.

In practical terms, what is the worse thing that can happen to a terminally ill patient who takes an experimental drug that proves ineffective? He is already facing near certain death. Further, what is the best way to test experimental drugs, if not on willing patients?

As we have seen, the FDA imposes tremendous, and often deadly, costs on Americans. Scientists, doctors, businessmen, and patients are forced to subjugate their judgment to politicians and bureaucrats. Patients are forced to pay substantially higher costs, endure needless suffering, and even die because of prohibitions and delays. Suffering and death are the ultimate consequences of the FDA's coercive power to deny our freedom to purchase and use life-saving medicines.

Making matters worse, many Americans have placed unreasonable demands on the pharmaceutical industry. Many expect drug companies to be omniscient and infallible, to produce drugs that are safe for all individuals under all circumstances. (As evidence, consider the lawsuits that result whenever an adverse side effect to a drug is discovered.[16]) Meeting such expectations is simply impossible. As Richard E. Ralston, Executive Director of Americans for Free Choice in Medicine, writes:

> When a new drug comes to market, no one can know all of its side effects, nor the impact on all other medical conditions that a patient might have, nor how it might interact with any dosage of any combination of an infinite number of other drugs—nor the cumulative effect

15. William Faloon, "The Abigail Alliance: A Relentless Campaign to Reform the FDA," *Life Extension Magazine*, November 2010, accessed January 29, 2011, http://www.lef.org/magazine/mag2010/nov2010_FDA-Delay-of-One-Drug-Causes-Lost-Life-Years_01.htm.

16. As one example, Merck paid $4.85 billion to settle lawsuits arising from its painkiller Vioxx.

> of ten, twenty, or thirty years of use. If omniscience is required, no new drug will come to market.[17]

For a drug company to test a product under every possible condition before releasing it to the public would mean that drug production would come to a grinding halt, which is essentially what happens because of the exorbitant costs imposed by the FDA's regulations. Drug companies must spend enormous sums of money to satisfy the FDA, rather than investing that money in research and development. And these costs aren't the only threat to drug companies.

By the FDA's standards, if a particular drug poses a potential threat to *some* individuals under *some* conditions, approval should be denied. If this standard were applied consistently and literally, there is no drug that could pass such an absurd and arbitrary standard. Economist Walter E. Williams writes:

> There's little or no cost to the FDA for not approving a drug that might be safe, effective and clinically superior to other drugs for some patients but pose a risk for others. My question to FDA officials is: Should a drug be disapproved whenever it poses a health risk to some people but a benefit to others? To do so would eliminate most drugs, including aspirin, because all drugs pose a health risk to some people.[18]

Indeed, virtually everything—including water—can be harmful. As an example, in 2007 a California woman died from water intoxication after participating in a water drinking contest.[19] Would the FDA ban water because it poses a risk to some individuals under certain circumstances?

The fact that every drug can pose a risk to someone does not mean that drug companies should introduce new products without adequate research and testing. It does mean that if they follow established scientific protocol, then objective law would not consider the companies negligent or legally culpable for adverse reactions to their products. In other words, drug companies should not be held to an impossible standard. Doing so will simply mean that they will be litigated out of existence. Who would benefit from killing the companies that produce life-saving drugs? At the same time, patients must understand that every drug carries some risk with its use. They must weigh those risks versus not treating their disease or condition. And they should not blame the drug companies every time they experience an adverse reaction.

What of companies that negligently release dangerous drugs? Don't regulations prevent rogue companies from endangering patients? While it is certainly possible for companies to disregard the health and safety of their customers, this is not a very rational business practice. Killing one's customers is not good for business. But when negligence does occur, there are legitimate laws already on the books that protect the rights of patients. Rather than treat businessmen as enemies, the government should protect the freedom of drug companies to develop and market their life-saving products.

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17. Richard E. Ralston, "Finding Alternatives to the Food and Drug Administration," Freedom from FDA, accessed January 29, 2011, http://www.freedomfromfda.org /fdaalternatives.html.

18. Walter E. Williams, "FDA: Friend or Foe?," *The Washington Examiner*, May 31, 2007, accessed January 29, 2011, http://washingtonexaminer.com/node/258656.

19. "Woman Dies After Water-drinking Contest," MSNBC.com, accessed January 29, 2011, http://www.msnbc.msn.com/id/16614865/ns/us_news-life/.

In a capitalist society, information about adverse reactions, new uses, and other drug related issues flows freely. Doctors, drug companies, and other interested parties are free to issue reports, discuss test results, and make recommendations without fear of legal prosecution. Not only does this speed the discovery of adverse reactions and unexpected consequences of drugs, it also allows doctors and patients to discover new uses for a drug. As in other areas of consumer "protection," third parties can play a crucial role in educating the public. Numerous organizations—such as Underwriters Laboratories, Good Housekeeping, Angie's List, and Consumers Union—test products, provide recommendations, and offer other information to consumers. Independent third parties have long been an effective means for consumers to learn about products and services.

There is no reason that these organizations, or others like them, cannot or will not do the same in regard to drugs, medical devices, and food. Indeed, this is the case even in today's heavily regulated medical marketplace. For example, ConsumerLab.com provides "independent test results and information to help consumers and healthcare professionals identify the best quality health and nutrition products."[20]

The United States Pharmacopeia (USP) is a more compelling example of a non-government agency providing information and setting industry standards. Founded in 1820, the USP is

> a non-governmental, official public standards–setting authority for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. USP also sets widely recognized standards for food ingredients and dietary supplements. USP sets standards for the quality, purity, strength, and consistency of these products—critical to the public health.[21]

This private, non-profit organization uses volunteers from academia, healthcare professions, the pharmaceutical industry, food industries, and consumer organizations to oversee its operations and avoid conflict-of-interest. Its strict scientific standards have made it a recognized leader around the world. And, as often happens when men are free, alternatives to the USP have also been developed.

In 1905, a group of physicians met in Pittsburgh to found the Council on Pharmacy and Chemistry of the American Medical Association (AMA). A newspaper article at the time stated that "the immediate object of the council is to examine…the composition and status of medicinal preparations offered to physicians which are not included in the United States Pharmacopeia or in other standard books."[22] Together, the USP and the AMA provided physicians and consumers with independent information on drugs and medicines, without the involvement of the government. (The AMA discontinued the Council in 1972.) However, unlike the FDA, neither the USP nor the AMA have the legal authority to prohibit doctors from prescribing drugs that are not approved by their respective organization. In the absence of the FDA, doctors would be free to act on their own judgment and prescribe remedies that they deem appropriate, and patients would be equally free to select such

20. "About Consumerlab.com," Consumerlab.com, accessed July 21, 2011, http://www.consumerlab.com/aboutcl.asp.

21. "About USP," United States Pharmacopeia, accessed December 29, 2010, http://www.usp.org/aboutUSP/.

22. "Council on Pharmacy and Chemistry, American Medical Association," *The Boston Medical and Surgical Journal*, March 19, 1905, p. 288, accessed December 29, 2010, http://www.nejm.org/doi/pdf/10.1056/NEJM190503091521009.

treatments. And this is precisely the type of activity that has led to countless discoveries in medicine.

When the FDA approves a particular drug, that approval is for a specific use or disease—this is called the "on-label" use. However, doctors often find other uses for a drug—these are "off-label" uses. While not officially sanctioned by the FDA, these off-label uses are not prohibited either. Daniel Klein writes:

> Doctors learn of off-label uses from extensive medical research, testing, newsletters, conferences, seminars, Internet sources, and trusted colleagues. Scientists and doctors, working through professional associations and organizations, make official determinations of "best practice" and certify off-label uses in standard reference compendia such as AMA Drug Evaluations, American Hospital Formulary Service Drug Information, and US Pharmacopoeia Drug Information—all without FDA meddling or restriction.[23]

Klein goes on to point out that off-label uses that later get FDA approval appear in the USP on average two and one-half years before FDA approval. In other words, a private organization following rigorous scientific standards, rather than political whim, recognizes the life-saving benefits of drugs thirty months before the bureaucrats at the FDA. How many lives are saved and how much suffering is reduced during those thirty months?

These off-label uses demonstrate that doctors and their patients can make rational health care decisions without government meddling, dictates, or controls. Indeed, they demonstrate that patients benefit tremendously when they are free to act on their own judgment, in consultation with their doctors. In contrast, the FDA believes that you should not be free to eat, drink, or ingest what you choose. According to the FDA, your body and your life belong to the government. And that can have deadly consequences.

Freedom to contract in medicine is moral. And, as we have seen in other areas of life, it is also practical, that is, if what one wishes to practice is the relief of human suffering and saving lives.

Having examined the practical and moral reasons for getting the government out of our pantry and out of our medicine chest, let us now examine the reasons for getting the government out of our economic lives.

23. Klein, "Economists Against the FDA."