POLICY ANALYSIS

Texas Institute for Property Rights

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Free Market Alternatives:
Life without the FDA

When I make a statement that some government program or agency should be abolished, I am often asked how certain values will be provided by the private sector. Recently, one of the most common topics of such conversations is the Food and Drug Administration (FDA). How, I am asked, would we ensure that our food and pharmaceuticals are safe without the FDA?

Those asking the question typically want a detailed explanation. They want to know who will inspect food, who will test drugs, who will protect the public from tainted food and dangerous drugs. As much as I would like to provide such details, I can't. I am neither omniscient nor prescient. But I can provide a compelling answer to those who are willing to listen.

My answer is not about details, but rather, about principles. And the guiding principle is: Free individuals, and only free individuals, create the values that humans want and need to sustain our lives. If we want to learn the details of what life would be like without the FDA, then we must free the innovators who will create those values.

The telephone industry provides an enlightening example.

From Monopoly to Innovation

When Alexander Graham Bell's telephone patents expired in 1884, thousand of companies began offering telephone service and the price of telephone service dropped. As telephone service became more affordable the number of telephone calls per one thousand people increased from thirty seven in 1895 to three hundred and ninety one in 1910.[1] In Michigan alone, about two hundred companies were offering telephone service by 1900.

American Telephone and Telegraph (AT&T), which was the main company of Bell's business, began buying out rivals in response to the increased competition. As AT&T's dominance of the industry grew, federal authorities started an antitrust investigation against the company. In 1913, company officials proposed a compromise.

Theodore Vail, AT&T's president at the time, argued that telephone service could be provided more efficiently by one company. His motto, "One Policy, One System, Universal Service," was soon embraced by government officials.

During this time, the electric industry was establishing the precedent of a government protected monopoly. The similarities between the electric and telephone industries gave Vail's position credibility in the eyes of government officials, who soon began to decry competition in telephone service. For example, a report in 1921 by the Michigan Public Service Commission stated,

1. Diane S. Katz and Dr. Theodore Bolema, "Crossed Lines: Regulatory Missteps in Telecom Policy," December 3, 2003, accessed August 23, 2019, http://www.mackinac.org/6033.

"Competition resulted in duplication of investment," and that state governments were justified to prohibit competition in phone service.[2] That same year, a report from the United States House of Representatives similarly concluded, "There is nothing to be gained by local competition in the telephone business."[3] Establishing a telephone monopoly had broad political support, because politicians could promise universal service to their constituents. It seemed to benefit everyone—AT&T, politicians, and many American voters.

As with the electric utilities, AT&T's motivation was the elimination of competition. And the company was successful. Until the early-1980s, AT&T controlled more than 80 percent of the telephone business. Competition in the telephone industry was illegal.

During the decades of the AT&T monopoly, innovation was virtually non-existent. Consumers could not own their phone and could only rent equipment from the telephone company. It was illegal to modify telephone equipment, which even included a prohibition on putting a protective cover on the phone book! Telephones had few features, and consumers had virtually no choice in regard to service plans. The government protected monopoly did what it wanted, and consumers had no choice in the matter. There was nobody else to call, both literally and figuratively.

With competition prohibited, AT&T had little incentive to innovate. There were no competitors offering less expensive service plans. There were no competitors offering telephones with added features. And with no incentive to innovate, phone service and equipment remained nearly stagnant for decades. For seventy years—nearly three generations—telephone service remained virtually the same because the social and political conditions—freedom and a respect for property rights—necessary for innovation did not exist. That began to change in the mid-1980s.

In the mid-1970s, the government filed antitrust charges against AT&T. Which means, the federal government prosecuted the company for engaging in practices that the government itself had previously encouraged and made possible—the government had protected the company's monopoly status by prohibiting competition. Ending the government protected monopoly was proper, but not through antitrust prosecution. AT&T should have never enjoyed government protection from competition in the first place. The government should have simply repealed the legal prohibitions on competition and set the innovators free.

Ten years later, the AT&T monopoly was ended. The break-up of the telephone monopoly had almost immediate effects.

The first innovations in telephone service came in long-distance service. Within a few years of the breakup of AT&T's monopoly, companies such as MCI and Sprint, along with hundreds of others, were offering long-distance service with a variety of plans. The new companies were charging 25 percent to 30 percent less than AT&T.[4] The success of the new phone companies is testimony to the fact that innovators were quick to respond to their freedom to offer new services and consumers were eager to exercise their freedom to choose.

During the decades of the telephone monopoly, innovators were a coiled spring kept harnessed by the prohibition on competition. But when that prohibition was lifted, the spring was released and entrepreneurs burst forth with creative energy.

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2. Ibid.

3. Ibid.

4. William R. Greer, "Long Distance Lines: Making Right Choice," *New York Times*, December 14, 1985, accessed August 23, 2019, http://www.nytimes.com/1985/12/14/style/long-distance-lines-making-right-choice.html.

It wasn't long before consumers had other choices. Freed from arbitrary government restrictions, a multitude of manufacturers began offering phones with added features, such as call waiting, re-dialing, and answering machines. In the ten years after the break-up of the telephone monopoly, consumers saw more innovations in telephone equipment and service than AT&T had introduced in seventy years. But the innovations were only beginning.

Mobile telecommunications were first introduced in the 1940s. However, the mobile equipment was large, expensive, and had to be installed in an automobile or other vehicle. The available service area was very limited. In 1973, Motorola introduced the first handheld mobile phone, but it wasn't until the 1980s that a widely deployed cellular system was available in the United States.

During the 1990s, innovations in cellular technology began to accelerate. Second generation (2G) mobile phone systems were developed, which allowed for expanded features, such as texting and accessing media content. These new features gave mobile phones added popularity, with cell phone subscriptions increasing from about 5.2 million in 1990 to nearly 110 million in 2000.[5] Today, nearly every American household has a cell phone, and more than 40 percent of American households no longer have a land line.[6]

For nearly seventy years, the government effectively prohibited innovation in the telephone industry. We were limited to a land line telephone that did little more than make and receive phone calls. Today's smart phones offer features far beyond making and receiving phone calls. We can take photographs, send and receive email, listen to music, surf the World Wide Web, and so much more. And we can do it from almost anywhere. Smart phone manufacturers have introduced more innovations in less than ten years than the AT&T monopoly introduced in seventy years.

For decades, the AT&T monopoly was defended on the grounds that a government protected telephone service more efficient, provide lower cost service, and was beneficial to consumers. But the history of the telephone industry belies this myth.

For seventy years, the government restricted the innovators and denied consumers a choice in the name of protecting those very same consumers. When the government freed the innovators, the options available to consumers grew rapidly. The stagnation of the government protected monopoly gave way to the innovation of a competitive marketplace.

Today, we are told that the FDA and similar government agencies are necessary to protect the public. Today, innovators in health care are prohibited from offering anything that is not sanctioned and controlled by the government. It is the AT&T monopoly all over again, only applied to health care. Is it any wonder that consumers are fed up with the country's health care system?

Once they were freed of government control, innovators created a revolution in the telephone industry. They will do the same in food, pharmaceuticals, health care. But first, they must be free of government control.

Admittedly, food, pharmaceutical, sand health care have greater life and death implications than telephones. We might suffer without our smart phone, but we can die if we consume tainted food or toxic medicines. So, why should we abolish the FDA? Isn't it better to retain the FDA and remain safe, rather than abolish the agency and later rue that decision?

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5. "Cell Phone Subscribers in the U.S., 1985–2010," InfoPlease.com, accessed August 23, 2019, http://www.infoplease.com/ipa/A0933563.html.

6. "Drew Desilver, "CDC: Two of every five U.S. households have only wireless phones," July 8, 2014, Pew Research, August 23, 2019, http://www.pewresearch.org/fact-tank/2014/07/08/two-of-every-five-u-s-households-have-only-wireless-phones/.

The FDA is Hazardous to Your Health

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).[7] 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? 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."[8] (Ironically, Dan Allgyer was arrested 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 good and what is bad."[9] Originally charged with the task of ensuring that foods weren't adulterated, the FDA now arrests individuals for selling foods that aren't adulterated. The FDa has truly become an arbitrary "food-god."

Today, 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

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7. Stephen Dinan, "Feds Sting Amish Farmer Selling Raw Milk Locally," *The Washington Times*, April 28, 2011, accessed August 23, 2019, http://www.washingtontimes .com/news/2011/apr/28/feds-sting-amish-farmer-selling-raw-milk-locally/.

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

9. 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 August 23, 2019, http://books.google.com/books?id=sojNAAAAMAAJ&pg=RA1-PA9316#v=onepage&q&f=false.

government. Such restrictions imply that your body and your life are not yours, but the government's. Such restrictions make it illegal to consume foods or medicines that have not been approved by the government.

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 (compared to today) 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.[10] By the mid-2000s, the time had grown to an average of fifteen years.[11] 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."[12] 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, may 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.[13] 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 drug called tissue plasminogen activator cost an estimated 30,000 lives.[14] 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.[15] 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 nearly fifteenyears later,[16] it is little wonder that the cost of drugs and medicines is soaring. Pharmaceutical companies

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

11. "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.*

12. Daniel B. Klein, "Economists Against the FDA," The Independent Institute, accessed August 23, 2019, http://www.independent.org/publications/article.asp?id=279.

13. "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.

14. Ibid. pp. 340-41.

15. Ibid. p. 341.

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

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 and his drug will not be approved. 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.[17]

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.[18] 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, as another example of the FDA's arbitrary policies, in 1998 (only six years later), it demanded that manufacturers begin fortifying certain products with folic acid![19] 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.[20] 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. 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

17. Klein, "Economists Against the FDA."
18. "Theory, Evidence and Examples of FDA Harm."
19. Ibid.
20. Dr. Mary J. Ruwart, "Death by Regulation," International Society for Individual Liberty, accessed January 22, 2011, http://www.isil.org/resources/lit/death-regulation.html.

> 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.[21]

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?

With the passage of the Right to Try Law in 2018, terminally ill patients now have the freedom to take experimental drugs that had not been approved by the FDA. But for decades, the FDA denied patients the freedom to take such drugs. And even with this modicum of freedom, the FDA retains great control over the nations food and pharmaceuticals.

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 and arbitrary 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.[22]) 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 of ten, twenty, or thirty years of use. If omniscience is required, no new drug will come to market.[23]

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21. 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.

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

23. Richard E. Ralston, "Finding Alternatives to the Food and Drug Administration," Freedom from FDA, accessed August 23, 2019, http://www.freedomfromfda.org/fdaalternatives.html.

For a drug company to test a product under every possible condition before releasing it to the public would mean that the development of new drugs would come to a grinding halt. As it is, the exorbitant costs imposed by the FDA's regulations stifle and impede the development and introduction of new drugs. 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.[24]

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

25. "Woman Dies After Water-drinking Contest," NBCNews.com, accessed August 23, 2019, http://www.nbcnews.com/id/16614865/ns/us_news-life/t/woman-dies-after-water-drinking-contest/.

Free Market Alternatives to the FDA

Without the FD's arbitrary dictates, information about adverse reactions, new uses, and other drug related issues would flow freely. Doctors, drug companies, and other interested parties would be free to issue reports, discuss test results, and make recommendations without fear of legal prosecution. Not only would this speed the discovery of adverse reactions and unexpected consequences of drugs, it would 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."[26]

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.[27]

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."[28] 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

26. "About Consumerlab.com," Consumerlab.com, accessed August 23, 2019, http://www.consumerlab.com/aboutcl.asp.

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

28. "Council on Pharmacy and Chemistry, American Medical Association," *The Boston Medical and Surgical Journal*, March 19, 1905, p. 288, accessed August 23, 2019, http://www.nejm.org/doi/pdf/10.1056/NEJM190503091521009.

select such 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.[29]

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.

The Lesson to be Learned

For seventy years, Americans were told that government control of the phone industry was beneficial to consumers. For seventy years, it was impossible and illegal for anyone to demonstrate that those claims were wrong. But when that control was lifted—when competition became legal—innovation sprung forth. The myth that had been forced upon Americans was exposed and exploded.

For more than a century, Americans have been told that the FDA is necessary to ensure safe food and medicines. For more than a century, it has been virtually impossible to demonstrate that those claims are wrong. But why should we believe those claims? Similar claims about telephone service proved to be grossly wrong.

In principle, there is no difference between government control of telephone service and government control of food and medicines. In both instances, government control prohibits individuals—both producers and consumers—from acting on their own judgment. In both instances, individuals are prohibited from creating, trading, and using the material values that they believe will sustain or enhance their lives. In both instances, consumers have fewer choices and pay higher costs. In both instances, the myth that government is protecting us is a fraud.

29. Klein, "Economists Against the FDA."

It is impossible to know what alternatives to the FDA will be created. We briefly examined a few possibilities, but nobody can predict the values that innovators will create. As an example, at the time the telephone innovators were unshackled, nobody could predict the innovations that would soon flood the market. Nobody saw the smart phone coming. While we cannot predict what values will be created, we can predict that free individuals will create the values humans need to survive and flourish. While we cannot predict what innovations will occur when the FDA is abolished, we can predict that innovations—amazing innovations—will occur.

Throughout this paper, we have focused primarily on existential issues. We examined the cause and consequences of the AT&T monopoly, as well as what occurred when that monopoly was ended. We have examined the history and consequences of the FDA's monopoly.

But the fundamental issue isn't existential; the fundamental issue is moral. Should individuals be free to produce, trade, and use material values that they believe will sustain and enhance our lives? Or, should politicians and bureaucrats decide what individuals may produce, trade, and use? There is no other alternative.

Some may say that we need the FDA, but its powers have grown too immense. Retain the FDA, they might say, but scale down its powers. But regardless of the scope of those powers, the FDA would still retain the power to determine what individuals may ingest. Individuals would not be free to act on their own judgment.

The history of the telephone industry clearly demonstrates that free individuals—and only free individuals—produce the material values that make our lives immensely better. Steve Jobs amazed us with the iPhone. There are countless people who could amaze us in food and medicine, but they can only do so if they are free. It is time for us to free the innovators in food and medicine and let *them* amaze us.