

MEDICAL ECONOMICS END FOOD AND DRUG ADMINISTRATION (FDA) AND THEIR IMPACTS ON PUBLIC HEALTH

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ABSTRACT

The aim of this research was to know what FDA was done to get pure food and drug. Was it to put all the eggs in one basket and entrust the objective to a monopolistic agency which suffered no financial losses when it errors or would the writer be better off relying on a private, competitive certification industry, the firms of which can earn profits for accurate assessments and losses for erroneous ones? Ensuring the quality of pharmaceuticals was concerned, the best and most efficient means toward that end was reliance on free enterprise. The method used was the literature review by applying what the authors knew about the difference between competition and monopoly to an arena where all too seldom was it applied. It finds that the FDA cannot eliminate risk; only deny people from taking the calculated risk in the hope of curing disease. Legislation such as the Compassionate Freedom of Choice Act has been introduced with the intention of empowering patients to make informed decisions and allow them to take drugs not approved by the FDA.

Keywords: *medical economics, food and drug administration, pharmaceuticals, free enterprise*

INTRODUCTION

The Food and Drug Administration first took on its role as a regulator for interstate commerce regarding food and drugs with the passing of the 1906 Pure Food and Drugs Act (FDA, 2015). This law is passed to prohibit the misbranding and mislabeling of food and drugs sold across state lines. Since then, the FDA has become increasingly more involved in the regulation of food and drugs in the United States. The U.S. Food, Drug, and Cosmetics Act of 1938 granted the power to FDA to premarket evaluations for the first time (FDA, 2015). The law allows the FDA to block drugs from entering the market if it does not pass certain tests. This enormous power entrusted to the FDA has had serious negative repercussions, such as bureaucratic incentives to not approve drugs and increasing the time it takes to introduce them to the market. The FDA's banning of helpful products and the delayed process of approving them is responsible for the deaths of thousands of Americans each year. The legislation allows terminally ill patients to have access to remedies that are not certified by the FDA has been introduced in the House of Representatives. The purpose of this section is to explore the shortcomings of the FDA, evaluate whether this organization creates any benefit to Americans, and offer a libertarian perspective for alternative food regulation (Becker, 2002; Goodman, 2011; Gottlieb, 2010; Henninger, 1990; Higgs, 1994; Hoppe, 1993; Kaitin *et al.*, 1987; Klein and Tabarrok, (n.d.); Peltzman, 1973, 1974; 1987a, 1987b, 2005; Sardi, 2007; Spiro, 2012; Steinreich, 2005).

The writer can explain the incentives of FDA bureaucrats by distinguishing between two the types of errors they could commit. A type 1 error is passing a drug that ultimately ends up having negative effects and harms the public (the false positive). The type 2 error is refusing to approve a drug that is safe (the false negative). In either case, the public is worse off. The bureaucrats' self-interest is more likely to lead them to commit the type 2 error, rather than type 1. By committing the latter, the negative repercussions will be worse than committing the former. For example, if a drug is accepted by the FDA that kills people, the public will be much more aware of the direct decision making made by the bureaucrat, and it will likely lose his job. In comparison, by not approving of a helpful drug that could save lives, fewer people will be aware of this failure on their part, and those most affected by the decision will probably never miss it. The FDA is more likely not to approve a drug than approving it because it is less risky. Friedman (2012) explains, as a bureaucrat, the self-interest lies in taking all kinds of chances of failing to approve a good drug to reduce the chance that will approve of a bad drug. Those who approve the fewest number of drugs are likely to stay in power longest. This leads to an FDA mostly filled with bureaucrats who commit type 2 errors. The result is the deaths of thousands of Americans each year.

In the authors' point of view, it is unwise in the extreme to place any great reliance on a governmental monopoly institution such as the FDA to ensure the quality of these goods. It is far better to rely on the competitive institutions of the free enterprise system. In the former case, there is no automatic penalty for errors, as there is in the latter. Also, the profit system awards those firms in the private food and drug certification industry for accurate evaluations. Thus, they can expand their base of operation, replacing those prone to error. The burden of part II is to defend the proposition that the private profit and loss institutions of *laissez-faire* capitalism. The authors' best guarantee of the quality of medicines that is claimed by the Food and Drug Authority. The government's attempt to attain this goal, not only has been a dismal failure but that this is a necessary condition.

METHODS

The research applied qualitative method with the literature review style. For the references, the writer cited and clarified the cases in the American setting by showing the differences between competition and monopoly concerning FDA roles and the administration of food and drug to support public health.

RESULTS AND DISCUSSIONS

The drug *Bristol-Myers Squibbs' Yervoy (ipilimumab)* is an example of the case that is handled by FDA. This medication is used to treat Melanoma, the deadliest form of skin cancer, which claims 8,700 lives per year according to the National Cancer Institute. The FDA takes a year and a half to approve it. Goodman (2011) explains that 46% of the subjects taking the drug were alive one year later, and 20% were alive two years later. In the control group, only 25% survived one year, and 14% two years. The difference between 46% and 25% is 21%. 21% of 8,700 is 1,827 lives. Similarly, the difference between 20% and 14% is 6% or 522 of 1827 lives.

This shows how a type 2 error made by the FDA cost 1,827 of Americans to lose one year of their life and 522 people to lose the second year. No one should underestimate how extreme the consequences can be from just a year and a half of postponing the use of a single medicine. A similar example of a type 2 error responsible for the death of thousands of Americans is the four-year delay of the approval of *pirfenidone*, a product used to cure idiopathic pulmonary fibrosis. This lung disease is

responsible for the death of more than 150,000 Americans according to Dr. Henry I. Miller, the founding director of the FDA's Office of Biotechnology (as cited in Harris, 2014). This drug treatment has already been approved in Europe, Japan, Canada, and China. It is impossible to calculate all the lives that have been lost to type 2 errors because potentially life-saving drugs will never make it to the market. Lives are not only lost due to delays from regulation, but also by the elevated cost.

Speaking of which, yet another way in which the FDA harms the public is by increasing the price of drugs. The FDA does this by requiring research and developers to meet increasingly higher and higher standards for approval. As a result, companies must spend more time and money to receive the imprimatur of this regulatory busy body. The Kefauver Harris Amendment of 1962 is an example of this kind of regulation.

This enactment comes about as a response to the worldwide Thalidomide crisis. This is a medicine that is used to treat morning sickness in pregnant women. The drug, however, leads to birth defects in over 10,000 children in 46 countries (Bren, 2001). As a response, the Kefauver Harris Amendment is passed, which required pharmaceutical companies to prove the efficacy of their offering, or the ability to produce a desired or intended result. This new rule has caused the process of approval to become much longer and costlier. Before the amendment, the average time from the filing of an Investigational New Drug application (IND) to approval was seven months. By 1998, it took an average of 7.3 years from the date of filing to the final decision (Peltzman, 1973). It is impossible to quantify the amount lives that could have been saved if this regulation did not exist. It does not only require more time on average for drugs to be approved but also costs the industry more money.

Becker (2002) states that the typical drug undergoes about 30 clinical trials that involve some 3000 patients. Now, it must go through more than 60 clinical trials with almost 6,000 patients. Studies indicate that the need to conduct these various stages of clinical trials adds almost 40% to the cost of R&D for a new drug. Such a dramatic increase in the cost to supply drugs will undoubtedly raise the price paid by consumers. Some drugs may take less time and money than others. The point is the FDA makes all of them more expensive than they otherwise would be.

The FDA is regarded by many as an agency that keeps safe because its intentions may be good, but these regulations are the reason why many do not receive helpful drugs in time and cost-efficient manner. It is because the drugs must receive the FDA approval to be administered to patients. If the latter is given a choice to take a risky but potentially life-saving drug that is not approved by the FDA, would they take it? Does the FDA make consumers better or worse-off by banning drugs?

Higgs (1994) answers these questions by asserting that risk is inevitable in a market. He states that just banishing risk, whether by regulation or otherwise, is not a feasible option. This means that no matter how much the regulation a government attempts to impose, the individual will still have to bear some risk. Suppose an individual does not know about a risk associated with a product. The consumer may well be better off knowing about the risks than not knowing them. Perhaps the individual may have chosen not to consume the product if he/she is aware of the risks. Higgs asserts that banning the product is quite different from giving the new information. By simply denying the option to consume, FDA has made the patients worse off, because FDA has removed the patient's most preferred object of choice from the set of alternatives open to the patients. This distinction has direct implications to FDA outlawing drugs. The risk of taking an unapproved drug could still leave a patient better off than not doing so. By enforcing regulations, the FDA limits the ability of patients to assume risk in the hope of treating illness. This paternalistic behavior on the part of the FDA ultimately renders consumers of drugs worse off by limiting their ability to take on risk. Higgs (1994) concludes that nothing in economic theory is correctly understood, supports the imposition of product bans such as those enforced by the FDA through its testing requirements. The bans help no consumer; they hurt some consumers. Political changes may be underway to help reduce the damage caused by the FDA. The point is if the FDA is

limited to recommend, rather than prohibiting, the harm it causes would be greatly attenuated. Even better, of course, would be to end it entirely.

The legislation has been proposed to give terminally ill patients the freedom to take the drugs that are not certified by the FDA. The Compassionate Freedom of Choice Act of 2015 attempts to give terminally ill patients this long-denied precious freedom. The bill states FDA shall not implement or enforce any provision of law preventing or restricting, the manufacture, importation, distribution, or sale of an investigational drug or device intended for use by a terminally ill patient in accordance with subsection (b) that describe as criteria for the terminally ill patient. This law is still in its introductory state and has not yet been passed in neither the House of Representatives nor the Senate. This bill has serious implications for terminally ill patients because it allows patients to choose to take drugs that are not approved by the FDA. This type of legislation can help fight the paternalistic behavior of the FDA and grant terminally ill patients more freedom in their consumption decision-making. Consumers would be better off under a system in which they have the liberty to take whichever drugs they please and had better information about the safety of drugs. All people should enjoy the freedom of choice. Although, we readily concede that it is particularly grievous not to all those with only a few weeks to live to throw the dice in one last attempt to save their lives. Only a government bureaucracy could impose such a harsh rule on the helpless. Such freedoms could be achieved under a libertarian system of third-party food and drug safety agencies.

Many people may wonder how food and drugs could be regulated without the government. They might also wonder who could be trusted to ensure the safety of food and drugs other than the state apparatus. Fortunately for consumers, there are some libertarian alternatives to the FDA that already exist. These could be applied to drugs as well if the laws were to change.

Different private agencies already regulate the food industry in their unique ways. Whole Foods, for example, have privately developed a system for rating the welfare of farm animals. The 5-Step Animal Welfare Rating Standards (2016) gives information about the conditions the animal lived in before being butchered and brought to the store. Animals with a low rating meet minimal standards, such as cages big enough for animals to walk around. The higher the rating, the better the conditions in which the animals raised. The conditions include no crates, enriched environments, outdoor access, space to roam, physical alterations, and entire life on the same farm (Animal Welfare Standards, 2016). Cuts of meat with the highest ratings will come from animals that lived their entire lives on the same farm. Whole Foods introduced this system as a response to the market, rather than out of legal obligation. Shoppers at Whole Foods are conscious about the source and quality of their meat products. Nor can the authors ignore such institutions as Yelp, Consumers' Reports and Good Housekeeping Seals of Approval. Other private food rating agencies would also come into being under a libertarian system. The point is there is a general acceptance of the adage that competition brings about a better-quality product at a lower price. This great insight should not be applied in rating the quality of pharmaceutical products. If the Acme Certification Agency makes a type 1 or 2 error, it will lose money and soon go bankrupt, if it keeps up with the error of its ways. This is all to the good, since, its departure would leave more room for more effective market participants. But when the FDA acts erroneously, does it lose money? Is it in any danger of going bankrupt? The reason the authors have pretty good quality and reasonably low prices for shoes, ships, and sealing wax is this self-same market process. Why do not apply it to drugs, where it is needed even the more?

Private food rating agencies could inspect and rank food based on the criteria consumers demand. If consumers want food that is locally grown and organic, then the private certification firms could respond by including these criteria in their ratings. On the contrary, if consumers do not care about the conditions in which their food produced, they can purchase groceries and drugs that are not organic or grown locally. These private companies would compete against each other. The private companies would incentivize them to respond the consumer preferences to achieve good ratings, to earn profits, and thus stay in business. These agencies would also be encouraged not to lie or deceive because if they

caught their reputations will be ruined and neither food sellers nor food buyers will want the ratings of the deceptive agencies. This same system of private third-party rating agencies can also apply to drug safety. There is a danger they could be bought off by unscrupulous drug companies, and paid to give good ratings. But the identical risk occurs in the so-called public sector. The only difference is that under capitalism, any company that besmirched itself in this way would risk losing all its capital. This vulnerability exists only in a greatly attenuated manner in government bureaus, if at all.

A libertarian society would allow for many different private drug safety agencies, rather than depending on a single-government-run agency. Good investment advice always includes diversification. This investment would apply in the present context in spades.

CONCLUSIONS

The FDA is weighing down the American economy; at least a significant part of it. The incentive of FDA bureaucrats is to commit type 2 errors, which is to not pass helpful drugs in the fear that they may have some negative side effects. These type 2 errors are responsible for the deaths of thousands of Americans each year. By banning risky drugs, the FDA does not make patients better off; it simply limits their ability to make their own informed decisions. The FDA cannot eliminate risk; only deny people from taking the calculated risk in the hope of curing disease. Legislation such as the Compassionate Freedom of Choice Act has been introduced with the intention of empowering patients to make informed decisions and allow them to take drugs not approved by the FDA. The libertarian system under which many different food and drug rating agencies compete against each other would benefit consumers by providing more information, reducing time and money needed to approve drugs, and allowing consumers to take on risk on their accounts, with professional help from the private sector.

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