# Public Health and the Placebo: The Legacy of the 1906 Pure Food and Drugs Act

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The current literature regarding Food and Drug Administration (FDA) regulation of drugs generally focuses on measuring the costs and benefits of the rather long drug approval process that was created by the Kefauver-Harris Amendments of 1962.[1] Peltzman (1973), for example, concludes that the high compliance cost of the amendments reduces R&D productivity and thus reduces new drug innovation. He also finds that the opportunity cost of forgone new drugs that are not approved (or the lost value of the benefits in the years they are undergoing approval) exceeds the benefit of the ineffective drugs that are avoided as a result of the law by a wide margin.[2] Over the past 30 years, the average approval time of new drugs by the FDA has risen by more than 10 years.[3] Gieringer (1985) estimates that a one-year delay in new drug benefits costs between 37,000 and 76,000 lives per decade in the U.S. population. Relative to the number of lives saved by the avoidance of unsafe drugs, he finds that the cost of the policy outweighs the benefit by a margin of at least 4 to 1. Gieringer concludes that the FDA's approval system *itself* is neither safe nor effective. As Klein (2000) discusses, the body of economic research on the FDA points unanimously toward relaxing FDA restrictions on the introduction of new drugs. Perhaps most economists' opinion on this

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[1]See, for examples and further references, Peltzman (1973), Dranove (1991), Dranove and Meltzer (1994).

[2]This tradeoff between Type I and Type II errors and some numerical estimates on the deaths caused can be found in Klein (2000).

[3]However, there is some evidence that important drugs do get more rapidly approved (Dranove and Meltzer 1991, and Dranove 1991).

issue is summarized in Milton Friedman's statement that the "FDA has done enormous harm to the health of theAmerican public."[4]

Perhaps more directly related to the issues raised here are previous papers that explore whether there is a market failure to begin with, and whether there are possible free market alternatives to the current bureaucratic FDA regulatory system for pharmaceuticals. To make a legitimate economic case for government intervention in the market requires demonstrating some type of market failure in the industry.[5] One commonly cited potential failure is that drug makers might not internalize or account for the full cost to society from the introduction of a dangerous drug. This issue has been addressed by Jarrell and Peltzman (1985), who find that drug manufacturers suffer major reductions in market value in the event of a drug recall, giving them a strong incentive to internalize the costs of manufacturing dangerous or ineffective drugs.

A second potential failure in the market might be an asymmetric information problem if consumers do not have the appropriate information to evaluate the potential benefits, effectiveness, or risk associated with a drug. Within this context it may be important to require that product labels be truthful (which was the main thrust of the original 1906 legislation), but it does not necessarily imply that the government should intervene in the market to the current extent of deciding which levels of effectiveness, and what tradeoffs with risk, well-informed consumers should be permitted to have available (as it does today). This issue is directly addressed in Gieringer (1985:198), who proposes a type of consumer drug warning system and concludes that "the risk of new drug accidents could be controlled as well by informational warnings as by strict premarket approval standards." The widespread use of off-label drug prescribing by medical doctors discussed by Tabarrok (2000) is evidence that doctors have and employ information about drug effectiveness for treatments not yet approved by the FDA.

The extent of any information problem will depend on how frequently consumers purchase the product and on how well product reputation (through brand names, for example) can be passed among consumers and relied upon as signals of product quality. The markets for repeat purchase items such as cold or cough medications, which consumers purchase repeatedly, are much less prone to informational

[4]This quote is from Klein (2000), who takes it originally from Pearson and Shaw (1993).

[5]Holcombe (1995: chap. 8) addresses the issue of whether there is a market failure, and whether the market could provide a more efficient medical system than it does now if government regulation were lowered.

failures than markets for one-time, or infrequent, purchase items. This paper will focus on FDA policy mostly toward over-the-counter (OTC) medications, almost all of which are repeat purchase items about which consumers could easily acquire information from other consumers or from brand-name reputation. The question here is whether patients should be allowed to make these choices and tradeoffs regarding safety and effectiveness themselves (and with the advice of their doctors if they decide) or whether the FDA will make a centralized choice for every consumer. Of course, the choices made by the FDA for consumers regarding these tradeoffs are not made in a vacuum, as a recent *USA Today* investigation revealed that at 92 percent of FDA advisory committee meetings at least one member had a financial conflict of interest, and at 55 percent of the meetings, half or more than half of the members had a direct financial interest in the drug or topic that they were evaluating.[6]

The purpose of this paper is to show that the current FDA definition of effectiveness as "effective *beyond* a placebo" is an improper policy that is detrimental to public health. My claim is that these effectiveness standards deny consumers the benefit of a *proven* placebo treatment that would improve their condition even when this may be the only, or at least is the safest, treatment available. This is an argument that is entirely new to the economics literature on drug regulation and has fairly broad implications for government policy toward consumer products more generally. The social cost of the FDA's effectiveness policy that prohibits placebo therapy has the potential to greatly outweigh the social cost involved in the delay times for new drug approval.

## The Evolution of Current FDA Standards

The history of the pharmaceutical industry and its regulation by the U.S. federal government is important in the process of evaluating the current FDA standards for two reasons. First, it is important to understand how the industry worked before any regulations, as this has implications for how a less regulated system might work today. Second, to properly assess the current policy requires some background on how the current policy evolved and why regulation began. An overview of the evolution of U.S. food and drug law is presented in Table 1.

[6]Story in September 25, 2000, edition of *USA Today* (www.usatoday.com/news/washdc/ncsun06.htm).

TABLE 1

Major Events in Food and Drug Regulatory History

| | |
|---|---|
| 1905 | A series of articles by Samuel Hopkins Adams titled "The Great American Fraud" in *Collier's, The National Weekly* began that severely attacked the industry, The series greatly swayed public support for federal legislation. |
| 1906 | Original 1906 Food and Drugs Act is passed prohibiting misbranded and adulterated foods, drinks, and drugs. |
| 1911 | Supreme Court rules in *U.S. v. Johnson* that the 1906 act did not prohibit false therapeutic claims but only false and misleading statements about ingredients. To reverse the effect of the ruling, Congress enacts the Sherley Amendment prohibiting labeling medicines with false therapeutic claims intended to defraud the purchaser. |
| 1924 | Supreme Court rules in *U.S. v. 95 Barrels Alleged Apple Cider Vinegar* that the act makes illegal every statement, design, or device which may mislead or deceive, even if technically true. |
| 1927 | A separate law enforcement agency, the Food, Drug, and Insecticide Administration is created. It is renamed the Food and Drug Administration (FDA) in 1930. |
| 1938 | After a heated 5-year legislative battle, the Federal Food, Drug, and Cosmetic Act is passed. It greatly expands powers of FDA including extending control to cosmetics and therapeutic devices, requiring new drugs be shown safe before marketing, authorizing factory inspections, and eliminating the Sherley Amendment requirement that the FDA prove intent to defraud in drug misbranding cases. |

| | |
|---|---|
| 1938 | Federal Trade Commission's powers expanded by Wheeler-Lea Act, which makes unlawful the dissemination or the causing of the dissemination of false advertisements of food, drugs, devices, or cosmetics. |
| 1950 | U.S. Court of Appeals rules in *Alberty Food Products v. U.S.* that the directions for use on a drug label must state the purpose for which the drug is offered. Because of this, "a worthless remedy cannot escape the law by not stating the condition it is supposed to treat." |
| 1950 | Durham-Humphrey Amendment defines some drugs unsafe for self-medication and restricts their sale to by-prescription-only by a licensed practitioner. |
| 1962 | Kefauver-Harris Drug Amendment passed requiring drug manufacturers to prove effectiveness to FDA *before* marketing drugs. Law is retroactively applied to 1938 (pre-1938 drugs "grandfathered" in). |
| 1966 | FDA begins evaluating the effectiveness of more than 4,000 drugs approved on the basis of safety alone between 1938 and 1962. |
| 1970 | U.S. Court of Appeals rules in *Upjohn v. Finch* that commercial success alone does not constitute substantial evidence of drug efficacy or safety. |

SOURCES: U.S. Food and Drug Administration (www.fda.gov/fdac/special/newdrug/benlaw.html and www.fda.gov/opacom/backgrounders/miles.html).

In the late 1800s, prior to any federal legislation, products were being sold over-the-counter to consumers, claiming to cure everything from asthma to cancer.[7] Brand name reputations were very important and some brands had been household names for over 50 years. Product advertisements relied heavily on testimonials from well-known people. There were, however, no laws regulating the content, labeling, or advertising of these products. These "patent medicines," as they were called, were very popular and included many brands that would still be recognized in modern times including Campho-Phenique, Ex-Lax, Grape-Nuts, Listerine, Pond's Extract, Sominex, and Vaseline.[8] Some patent medicines had alcohol contents approaching 30 percent and some contained more potent substances such as opium, heroin, and cocaine, which were all still legal at that time.[9] It is, however, important to note that in some cases, alcoholic drinks were being sold as medicines solely to evade federal liquor taxes, and they were not specifically attempting to make false claims about their effectiveness.

Interest groups with strong economic gains to be had from the enactment of federal legislation (such as the AMA and the American Pharmaceutical Association) became very active in lobbying for the introduction of new laws regulating this industry. Instrumental in the eventual passage of the first federal legislation were not consumer groups, but rather groups of competing health care producers and manufacturers.[10] At the federal level, the patent medicine lobby had successfully blocked several previous attempts at federal legislation, including the Paddock bill in 1892.[11] In 1904 the bill that eventually

[7]According to Young (1961), there were approximately 50,000 patent medicines being made and sold in the United States just prior to the adoption of the 1906 legislation, with an estimated market value equivalent to $1.4 billion in 1998 dollars.

[8]Interestingly, Pond's Extract was one of the products specifically targeted in a later *Collier's* article by Samuel Hopkins Adams. Most of the historical accounts here are from Young (1961) and Holbrook (1959).

[9]The sale of cocaine and heroin was prohibited by the federal government in 1914. Federal prohibition of alcohol began in 1920 and was repealed in 1933. In 1937 the sale of marijuana was prohibited.

[10]This is plainly clear in a statement from the American Pharmaceutical Association in 1893: "Do we not recognize, that this [patent medicine] industry is one of our greatest enemies, and that there are millions of dollars' worth sold all over the country, thus diverting money which rightly belongs to the retail drug trade, in the way of prescriptions and regular drugs?" (Young 1961).

[11]The Paddock bill passed the Senate in March of 1892. It would have meant that the label could not say ingredients were present if they were not, or list only certain substances and leave others off the list. Because of lobbying pressure, the bill did not come up for vote in the House.

became the 1906 Pure Food and Drugs Act, was presented in the Senate by Porter McCumber and Weldon Heyburn, but lobbying pressures from the patent medicine industry prevented the Senate from taking up the bill. After a several-year public relations campaign against the industry in popular periodicals, the bill was reintroduced in the Senate and passed February 21, 1906.[12]

The 1906 Pure Food and Drugs Act required some ingredients like alcohol, opium, chloral hydrate, and acetanilide to be listed on the label or package. In addition, the Act stated that "any statement, design, or device" regarding the medicine or its ingredients which was "false or misleading in any particular" was illegal.[13] Very different from the situation present today, this act required the FDA to pursue and prove fraudulent claims before a product could be taken off the market.[14] There were no requirements for the manufacturer to prove statements or ingredients before using them. In essence, the burden of proof was on the government to prove the claim was false or misleading after the product was already on the market being sold. The impact of the 1906 act on the industry was devastating, as Figure 1 shows.

One of the most important subsequent changes to the 1906 act was the addition of the Sherley Amendment in response to the ruling of the U.S. Supreme Court in the case of *U.S. v. Johnson* in 1911.[15] The

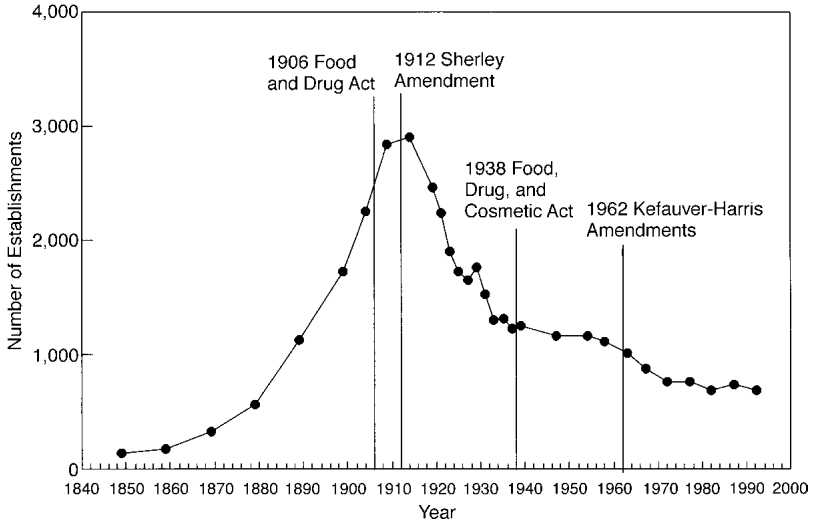
[12]Essential in the passage of this act was a series of articles by Samuel Hopkins Adams titled "The Great American Fraud" in *Collier's*. Many cartoons and editorials building up to the series began in April of 1905 and continued until the series began on October 7, 1905. The first series of articles ran through February 17, 1906 (note that the original act passed the Senate on February 21). A second series of his articles ran from July 14, 1906, until September 22, 1906. According to Holbrook (1959), in these articles, Adams attacked 264 concerns and individuals by name. Adams's articles were even reprinted by the American Medical Association and sold over 500,000 copies. In 1904, the editor of the *Ladies' Home Journal*, Edward Bok, also began attacking the industry in editorials which listed the ingredients of the medicines. Doctor Pierce's Favorite Prescription sued the editor for libel and won a $16,000 award because the medicine no longer contained the ingredients listed by Bok.

[13]To protect the secrecy of the patent formula, not all ingredients were required to be listed; however if something was listed, it was legally required to be present in the quantity stated. Manufacturers were also, for example, prohibited from making false statements about the geographic origin of the product or where it was manufactured.

[14]Enforcement was with the Bureau of Chemistry USDA from 1907–27, when it went to the Food and Drug Insecticide Administration (USDA), which was changed to the Food and Drug Administration in 1930.

[15]This was a misbranding case made against O.A. Johnson, doing business in Kansas City as the Dr. Johnson Remedy Company. The charge was that the product was misbranded because it was a worthless treatment for cancer in contrast to the claim of the seller. The Supreme Court essentially stated that the law related only to claims about the identity of the ingredients, not to claims about the therapeutic or medicinal effects of the medicine.

FIGURE 1
NUMBER OF PATENT AND PROPRIETARY MEDICINE ESTABLISHMENTS, 1840–2000




Supreme Court ruled that the 1906 act did not prohibit false therapeutic claims but only false and misleading statements about the ingredients or identity of a drug. In specific response to this ruling, Congress enacted the Sherley Amendment, which expressly prohibited labeling medicines with false therapeutic claims intended to defraud the purchaser. The burden to pursue and prove false claims, however, still remained with the government. In addition, the government had to prove legally that the claim was made with *intent* to defraud.

The next major event in the evolution of U.S. food and drug law is the passage of the Federal Food, Drug, and Cosmetic Act of 1938.[16] Several major changes in the law resulted from the passage of this act. First, it did away with the legal requirement for the government to prove an intent to defraud. It also extended the powers of the agency to cosmetics and therapeutic devices. But most importantly, it

[16]Note that the 1938 Federal Food, Drug, and Cosmetic Act did not apply to false advertising in publications, on billboards, or over the radio. False advertising of claims was the responsibility of the Federal Trade Commission under the 1938 Wheeler-Lea Act. The Wheeler-Lea Act even had specific provisions for false advertisement of drugs and medicines. The Federal Trade Commission had long been pursuing the industry, and even had a Special Board of Investigation reviewing drugs ads from 1929 to 1938.

required manufacturers to show through testing that new drugs were safe *before* they were sold on the market.

After the 1938 legislation, the law continued to evolve through court decisions. In 1950, for example, the court of appeals ruled in *Alberty Food Products Co. v. U.S.* that labels must include a statement of the purpose or condition which the medicine is offered to treat. Up until this point, several medicines had dropped all curative claims on the bottle, but still had a popular public reputation for treating an illness and thus still sold well despite the lack of a curative claim on the label. This decision forced those companies to either begin to state on the label the condition their drugs were intended to treat (and have this claim subject to legal scrutiny) or pull their drugs from the market. In 1950, the Durham-Humphrey Amendment defined several classes of drugs unsafe for self-medication and restricted their sale to prescription only. Throughout this period, the FDA was active in pursuing and seizing drugs that it claimed were making false or misleading therapeutic claims. In 1960, for example, a total of 187 products were seized for making unfounded claims to cure or ward off disease. This was typical of the FDA's annual activities in this pre-1962 amendment era, as 140 products had been seized in 1959, and 153 in 1958.

The next major change to the food and drug legislation was the 1962 Kefauver-Harris Drug Amendments. The major change provided by this legislation was the requirement that drug makers prove to the FDA the effectiveness of new products *before* selling them on the market. Prior to this legislation a manufacturer had only to prove a product safe. The product could be then be marketed making whatever claims it wanted, and it was then up to the FDA to find false claims in the marketplace, litigate against them, and prove they were false. Even more costly to the industry was that this new proof of effectiveness and safety was retroactively applied to all drugs approved on the basis of safety alone since 1938. Each and every one of the more than 4,000 drugs approved over this period would now have to prove its effectiveness to continue selling. It is interesting, however, that "pre-1938 drugs were grandfathered in, allowed to be sold because they were generally recognized as safe and effective, provided no evidence to the contrary developed."[17] This is particularly interesting in light of the ruling of the U.S. Court of Appeals in 1970 that commercial success alone does not constitute substantial evidence of drug effectiveness or safety. Because of the magnitude of the

[17]U.S. Food and Drug Administration, www.fda.gov/fdac/special/newdrug/benlaw.html.

requirement to revisit all drugs approved, the FDA decided to simply group medicines by active ingredients and test those ingredients. In November of 1990, the FDA banned more than 200 ingredients, and several hundred more were banned in May of 1993. Essentially the modern policy is that the FDA now requires for each drug that documented research can provide substantial evidence that the drug is effective, in a well-controlled study, beyond a *placebo effect* or the drug cannot be approved for sale in the marketplace.

## The Placebo and Public Health

Current federal law requires a drug be shown both safe and effective prior to its introduction on the market. As amended, the Federal Food, Drug, and Cosmetic Act, chapter 5, subchapter A, section 501 states:

> As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Thus, federal legislation requires proof of effectiveness in the general form of "adequate and well-controlled investigations." The implementation of this requirement, however, is at the discretion of the FDA. By its own regulation, the FDA currently specifies proof of effectiveness to be shown (at a 5 percent critical value) in either a placebo controlled study or a study against another "active" control (a medicine already proven effective against a placebo).[18] A placebo is defined as "an inert or innocuous substance used especially in controlled experiments testing the efficacy of another substance (as a drug)."[19] In practice, some patients will be given the actual drug while others are given a pill made from some inactive substance such as salt or sugar. The result of the treatment on the two groups is then

[18]The regulation requires either placebo controls, dose-comparison studies, no treatment concurrent controls, active treatment concurrent controls, or historical controls. However, there is a strong impression within the pharmaceutical industry that the FDA is really insisting on the first of these, under almost all circumstances (www.fda.gov/cder/foi/special/99/case-trans-42199.txt).

[19]Merriam-Webster dictionary (www.m-w.com/dictionary.htm).

compared to decide whether the drug is indeed effective by FDA standards.

> The U.S. FDA has seen many analgesic studies including both active and placebo controls in which patient response was similar in the placebo control, active control, and investigational drug groups. Had the placebo not been included, it would not have been apparent that these were "failed" studies [Finkel 1985: 421].

The FDA definition of effectiveness as effective *beyond* a placebo is an improper policy that is detrimental to public health. In essence, the effectiveness standards deny consumers the benefit of a *proven* placebo treatment that would improve their condition even when this may be the only, or at least the safest, treatment available. The placebo effect is a real, documented increase in the welfare of patients and a permanent improvement their condition. Patients who have been given a placebo and told it will improve their condition often can improve simply because of the immense power the mind has over controlling some physical body functions (release of chemicals, etc.). The statistical evidence is now overwhelming that many conditions can be successfully treated by placebo alone.[20] This point is admitted, almost by default, with the FDA requiring drugs to be tested against a placebo in the first place.

The following quote essentially admits the point that because the FDA subtracts the placebo improvement away, the FDA evaluation procedure does not really measure the true effectiveness of a drug at all:

> Placebos set a minimum standard of effectiveness that legitimate treatments must surpass. The standard methodology in the evaluation of new drugs is to compare the drug against a placebo. The drug must result in more improvement than the placebo in order for the drug to be considered an effective treatment for a particular problem [Bootzin 1985: 196–97].

Because of the necessity for almost every medical study to include the results for the groups given placebo treatments, the amount of statistical evidence on the effectiveness of the placebo itself (relative

[20]A study by Hrobjartsson and Gotzsche (2001) has been widely cited in the popular press recently. They claim that placebos are not as effective as is generally thought. In a review of 114 studies they find that in the 32 studies where patient responses to questions were on a yes-or-no basis, that smaller studies were more likely to show a positive placebo effect than larger studies. Thus they conclude that these placebo effects are possibly due to statistical bias in these small sample studies. However, they also concede that in the 82 studies where patient conditions were measured on a continuous scale, the placebo did appear to be modestly effective, particularly for the relief of pain.

TABLE 2

CONDITIONS PROVEN TO RESPOND SIGNIFICANTLY TO PLACEBO TREATMENT

| | |
|---|---|
| Adrenal gland secretion | Headache |
| Allergies | Hypoglycemia and other glucose deficits |
| Anxiety | Impotence |
| Arthritis (both rheumatoid and degenerative) | Insomnia |
| Asthma | Multiple sclerosis |
| Blood pressure | Nausea |
| Cancer | Pain |
| Common cold | Parkinsonism |
| Cough | Phobia |
| Depression | Pupil dilation and constriction |
| Diabetes | Respiration rates |
| Fever | Seasickness |
| Gastric acid secretion | Ulcers (including bleeding ulcers) |
| Hay fever | Warts |

SOURCES: Rawlinson (185), Wickramasekera (1985), Evans (1985).

to no treatment at all) is now overwhelming. To summarize this, Rawlinson (1985: 409) states that "placebos appear to be therapeutically beneficial in approximately 35 percent of patients," while Brody (1980: 46) states that "a placebo has a 30-40% probability of being effective for almost any disorder." Table 2 gives a listing of selected medical conditions that have been shown through clinical testing to respond significantly to placebo treatment.

Looking at the list of conditions in Table 2, one is struck by the similarity between that list and lists of the claims made on the patent medicines removed from the market by the FDA. In fact, the history of the FDA has been that of removing treatments from the market that were commercially successful because they created placebo improvements in the conditions of consumers. Many of these treatments had been around for decades and had well-defined reputations. They were, in fact, resulting in improvements in the conditions of the consumers who were taking these medicines. By any standard, a policy that results in the withholding of beneficial treatments is and must be welfare reducing. Medical industry representatives have always argued that the placebo treatments are actually bad for consumers because they keep patients from pursuing professional help or from taking more effective, "real" treatments that might have been available. We should note, however, that even in a case where a "real" treatment (with an active ingredient) is more effective, it is almost

universally the case that the placebo treatment is both safer and less prone to side effects. With no active ingredient necessary, the placebo will be safer and less risky than a similar medicine with active ingredients present.

There are several possibilities with regard to the relation between the availability of an "active" treatment and the welfare enhancement made possible by the availability of a placebo treatment. The most important case is when there are no active-ingredient medicines approved by the FDA to treat a condition that is placebo treatable. Perhaps the best example is male impotence, a dysfunction that affects millions of men in the United States. The first drug approved to treat impotence, Viagra (sildenafil), was approved by the FDA on March 27, 1998. Prior to that time it was illegal for anyone to advertise or state that medications were effective in the treatment of male impotence, despite the fact that the vast majority of cases of impotence respond significantly to placebo treatment. In addition, many drugs and devices have been removed or withdrawn from the market since the passage of the 1906 act that had claimed to be treatments for this dysfunction. In essence, there have been millions and millions of men in the United States who have suffered from impotence between 1906 and 1998 *because* of FDA policy. Had the FDA allowed medications to be available on the market, even vitamin tablets or sugar pills, which *truthfully* claimed to be shown through clinical testing to improve the condition relative to no treatment, these men could have taken these treatments and improved or completely cured their conditions. Even now with the availability of Viagra it is not clear that the availability of a placebo alternative would not be beneficial because placebos create fewer side effects and are simply safer. As a case in point, in November 1998, Viagra had to change its label and advise doctors about new, postmarketing reports of serious adverse effects from the medication, particularly with the concurrent use of Viagra and nitrates. For a given patient whose impotence could be cured by either a placebo treatment or a Viagra treatment, the placebo would be equally effective, but safer, less risky, and certainly much cheaper.

When no FDA approved treatment exists, the FDA's withholding and forbidding of products from the marketplace that create placebo improvements is clearly welfare reducing to patients who could have improved their conditions. But even in cases where an FDA approved, more effective treatment is available, it is not necessarily the case that the placebo is a less attractive treatment. Medical research shows, for example, that placebos are 56 percent as effective as a standard injection of morphine in reducing severe clinical pain, with-

out any of the potentially serious or fatal side effects of morphine (Evans 1985). Indeed, even though the active ingredient is more effective, the placebo would be both safer and less expensive in such cases. Perhaps these tradeoffs between effectiveness, price, and risk are simply something that consumers should be allowed to evaluate for themselves based solely on good information.

## Truthful Advertising and Medical Use of Placebo Therapy

There are several ethical and legal issues involved in the marketing of medicines that create placebo improvements in patients. First, it is worthwhile to note that medical research shows that the strength of the improvement in a patient's condition will depend upon the strength of their belief in the medical claim. In other words, despite the casual word-of-mouth reputation vitamin C has for improving the common cold, the amount of improvement in the common cold experienced by actually *taking* vitamin C would be greater if the product itself made a strong and clear claim on the label. This is precisely the claim FDA policy has banned on vitamin C.

In 1975, Congress passed legislation to exempt vitamins and minerals from FDA regulation. However, as Gieringer (1985) notes, "It is illegal for manufacturers to make any reference to possible health benefits of vitamins without becoming subject to new drug application (NDA) approval requirements for proof of efficacy. In prohibiting the advertising of possible anticarcinogenic benefits of vitamins and minerals, present regulations may be having a substantially adverse effect on consumer education and health."[21]

Essentially, I am taking issue with the FDA's legal definition of truthfulness in medical claims on product packaging. Take the case of insomnia, for which medical research shows that placebos result in a mean reduction in sleep latency of 25 percent (Bootzin 1985). Under current law it would be illegal for a product to be marketed with a statement on the package claiming the product is for the treatment of insomnia, even if it truthfully and factually stated that the product is safe and that medical research has shown it effective in 25 percent of insomnia cases relative to no treatment at all. A product such as this

[21]One may also note the similarity to wine labeling because wine makers are also not allowed to make any claims about the health benefits of wine without meeting the FDA's proof of efficacy through a new drug application. The Dietary Supplement Health and Education Act (DSHEA) of 1994, however, makes it allowable for vitamins, herbs, and minerals to make "substantiated" claims without being regulated as a drug.

would be considered ineffective and not approved for sale by the FDA, even if there were no other treatment available.

The medical profession has struggled and has effectively dealt with the issue of placebo treatments for patients. Essentially, doctors know that if they give patients a completely inert pill but tell the patient that it will improve the condition, it indeed will help. Throughout the 1700s and early 1800s, it was common for doctors to give patients bread pills for almost any condition. Brody (1980: 102) states that the "most frequent argument given to support placebo use cites their undeniable efficacy and the advantages of avoiding the side effects of potent drugs," and suggests that the medical norm is to use them for "diseases for which placebos have proved efficacious experimentally" and "diseases for which no pharmacologically active treatment exists" (p. 107). The issue of defining truthfulness, is addressed by Rawinson (1985: 410–11):

> In those cases where placebos may reasonably be expected to be useful, and where pharmacologically active agents are ineffective or contraindicated, a physician could simply report to a patient that the prescribed agent appears to be pharmacologically inert with respect to his or her disorder, but that, *in fact*, it has been shown to be therapeutically effective in other patients suffering from the condition.

As these quotes from medical practitioners show, the FDA's definition of truthfulness in claims of medical effectiveness are far from being simply a test of whether the statement is a factual statement. However, for consumers to make informed decisions they need to be provided with factual information on which to base their choices. If the "market failure" in the case of medicines is indeed an information problem, the FDA's current policy is far from the optimal solution of providing factual information. A free market in over-the-counter medicines, with laws governing the disclosure of ingredients and regarding factual statements about safety and effectiveness would result in an improvement in public health over the current FDA standard.[22]

## Conclusion

The origin of the current FDA practices and policy was the 1906 Pure Food and Drugs Act. That act, far from being pushed

[22]Holcombe (1995, chap. 8) directly discusses how the creation of the FDA lowered the demand for private, market-based information sources for medicines that would have developed had the FDA not been created. He discusses how information flows, through the AMA and private physicians, for example, would enable patients to be well-informed consumers.

through Congress by consumer protection groups, was championed by competing drug sellers and medical service providers. The fast growing patent medicine industry was ravished by the legislation. Within 10 years, approximately one-third of the firms in the industry were gone, and one-half were gone within 20 years. Food and drug law continued to evolve throughout the 20th century with several key court decisions and amendments to the law, including the much studied Kefauver-Harris Amendments of 1962.

This paper has argued that the FDA definition of effectiveness as "effective *beyond* a placebo" is an improper policy that is detrimental to public health. The effectiveness standards deny consumers the benefit of a *proven* placebo treatment that would improve their condition, even when this may be the only, or at least is the safest treatment available. A free market in over-the-counter medicines, with laws regarding only the factual content of statements would result in an improvement in public health.

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