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REGULATING OFF-LABEL DRUG PROMOTION: A NEW PERSPECTIVE

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Abstract

For almost two decades, the FDA's attempts to regulate off-label drug promotion have been a source of controversy among the agency, drug companies, and First Amendment advocates. Critics of the FDA say that regulation is both a First Amendment violation as well as an obstacle to patients receiving the best possible drug treatments. Advocates for regulation, however, warn that the consequences of allowing drug companies to freely promote off-label uses could be fatal. This paper analyzes the conflict from all angles and then proposes a recommendation that not only seeks to satisfy all parties involved but also allows for patients to receive the best possible drug therapies.

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I. Introduction

A. Background

One of the biggest challenges currently facing pharmaceutical manufacturers is how to legally market and promote their products to doctors and patients. Perhaps the issue that presents the biggest challenge is that of off-label marketing. Off-label drug use is the practice of using a drug for a purpose other than the one specified and approved by the FDA (Salbu 187). A physician engages in off-label prescription when he or she approves a product "1) for some use other than its indicated use, 2) in a population that is not included in the approved labeling, or 3) in dosages different from that on the label" (Hall 6). The practice is legal and common. In fact, a recent study showed that 21% of drugs listed in a data set were being prescribed for off-label uses (Henney 306). Another found that 50% of all prescriptions given to cancer patients were off-label (O'Reilly 298).The reason for this practice is that it is the drug manufacturer's burden to get a drug approved for new uses, and often times these companies "are reluctant to invest the resources necessary to develop the evidence required for FDA review" (Henney 395). This reluctance does not mean that the off-label uses of a particular drug are not completely safe and appropriate in certain cases. Therefore, physicians can and will prescribe drugs for off-label purposes. The question then becomes if pharmaceutical companies become aware of a new use for a drug already on the market, should they be able to promote that new use despite it not being approved by the FDA?

The FDA believes they should not, as off-label uses are untested and sometimes dangerous. Since 1972, the FDA has made several attempts to limit and restrict off-label promotion (Tabarrok 41). In the 1990's, the FDA successfully implemented a series of

regulations that increased restrictions on off-label marketing practices. In 1994, the FDA published Guidance Documents that restricted drug companies from "disseminating to physicians peer-reviewed journal articles, textbooks, compendiums, and other information supporting off-label usage of drugs" (Tabarrok 41). Then, in 1997 Congress passed the Food and Drug Administration Modernization Act (FDAMA), which attempted compromise on the issue by giving drug companies the ability to promote off-label uses of their products via the aforementioned outlets (O'Reilly 302). However, in order to do so, the law required that companies meet several burdensome conditions. Two of the major restrictions were that the company needed to provide all materials to the FDA 60 days before publication and that the manufacturer must verify its plans to seek approval for the new uses (Field 220). As a result, The Washington Legal Foundation, a non-profit legal organization that champions free market principles, challenged the FDA's policies in what would prove to be two pivotal court decisions. In 1994, the WLF challenged the constitutionality of the Guidance Documents in *WLF v. Friedman,* claiming that documents infringed on drug companies' First Amendment rights. While that case was pending, Congress passed the FDAMA in 1997 and the WLF again decided to challenge, this time in *WLF v. Henney*. In both cases (which are discussed in detail throughout the remainder of this paper) the court agreed that requiring companies to comply with these restrictions did in fact violate the First Amendment, and in doing so granted even more freedom to the drug companies (Reed Smith LLP).

Despite the WLF rulings, the issue remains far from resolved. After years of debate both in and out of the courts, there are still several rulings, laws, and policies that conflict each other. For example, the FDA "maintains that to protect public health, it must closely monitor and control a manufacturer's information disclosures to healthcare providers, particularly before

FDA approves a drug's use (Hall 2). But, even within the government's policies, inconsistencies can be found. Because of the 2002 Best Pharmaceuticals for Children Act, the FDA is required to publicize the results of clinical trials of drugs for pediatric purposes, regardless of whether the drug was approved for such use (Best Pharmaceuticals Act). Additionally, in some cases drug companies have been pressured by the government to be more forthcoming with off-label research. In 2004, New York State Attorney General brought a fraud charge against GlaxoSmithKline for *failing* to disclose clinical trial results relating to off-label uses of the drug Paxil. Paxil was initially approved to treat general anxiety disorder in adults, not children. Glaxo was accused of fraud for "not publishing a number of studies which concluded that [Paxil] was ineffective against depression for under-18s, and which, in aggregate, suggested the drug might increase suicidal thoughts" (Foley). As part of the settlement, Glaxo "agreed to disclose *all* clinical trial information from all its current and future drug studies, including off-label uses" (Hall 3). On the other hand, in 2005, the FDA filesd lawsuit against Serono Inc., claiming the company had encouraged doctors to prescribe the HIV/AIDS drug Serostim for off-label uses that were not medically necessary (Hagens Berman Sobol Shapiro LLP). The suit ended up costing the company over $700 million (Hall 10). The current standards to which drug companies are held pose serious conflictions and opportunities for confusion.

B. Motivation and Question to be Addressed

In order to solve this conflict, lawmakers must create clear, unambiguous legislation outlining the standards to which drug manufacturers must be held. This paper will first outline the current challenges and conflicts surrounding the issue. It will explain the constitutional and public health concerns that must be addressed. To be successful, new legislation will have to protect drug maker's First Amendment rights while at the same time keep public health and

safety in mind. This paper will provide suggestions for finding that balance and in doing so should serve as a guide for future legislation.

II. Constitutional Issues

A. Defining Off-Label Speech

In order to determine the constitutionality of restricting off-label promotion, it is necessary to first define such speech as either commercial or non-commercial, as the two are seen very differently in the eyes of the law. Although the First Amendment was not originally intended to protect commercial speech, in the 1976 case *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.* the Supreme Court struck down a law that prevented the promotion of drug prices (Kesselheim 1727). In finding that the "free flow of commercial information" can allow consumers to make "intelligent and well-informed" decisions, the Supreme Court created a First Amendment protection for commercial speech (Kesselheim 1727). But, the question of how much consumers can actually understand about the effects of pharmaceuticals still remains.

Regardless, commercial speech is given far less protection than fully protected personal speech, so it is imperative to define the type of speech being analyzed. The most definitive guidelines for doing so are provided by *Bolger v. Youngs Drug Products Corp.* (Petty 172). In the case, a pharmaceutical company attempted to disseminate, via unsolicited mailings, a pamphlet on venereal disease and use of condoms as a preventative measure (*Bolger v. Youngs Products Corp*.). The Court ruled that, although the pamphlets were not just an attempt to create a commercial transaction, they still constituted commercial speech because they "(1) were produced as traditional advertisements (not public service announcements), (2) referred to specific products, and (3) were prepared with a profit motive" (Petty 172). The Supreme Court

has consistently used this model, known as the *Bolger Test*, as a precedent for defining speech. It is important to remember that, under the *Bolger* ruling, speech can serve the public interest yet still be defined as commercial. This idea is echoed in the case of *Nike, Inc. v Marc Kasky*. The Court ruled that just because the speech concerns public issues it "is not sufficient to take it out of the realm of commercial speech for to do so would enable a company to immunize false or misleading product information from government regulation simply by including references to public issues" (*Nike Inc. v. Kasky*).

Using the *Bolger* test, courts have consistently found pharmaceutical promotion to be commercial speech (Kesselheim 1727). As a result, it is not entitled to the same protection as personal speech. In *Central Hudson Gas & Electric Corp. v. Public Service Comission of New York*, the Supreme Court established a four-pronged test for determining when restrictions commercial speech do or do not violate the First Amendment (Linder). The *Central Hudson* test is the foremost standard for determining the constitutionality of commercial speech regulation. Because the Courts have almost universally defined off-label speech as commercial speech, the remainder of this paper will also accept it as commercial speech. Therefore, it must be analyzed using the *Central Hudson* test.

B. Analysis under Central Hudson Test

The test sets forth four requirements that must be satisfied in order to legally restrict commercial speech. The test asks:

> 1) Whether the speech at issue concerns lawful activity and is not misleading and (2) whether the asserted governmental interest is substantial; and, if so, (3) whether the regulation directly advances the governmental interest asserted and (4) whether it is not

more extensive than is necessary to serve that interest. (*Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*)

If the Court finds that the government has not satisfied the four prongs of the test, then the restriction of the speech is constitutionally prohibited. The problem, however, is that the answer to these questions is often quite ambiguous, especially when it comes to off-label promotion.

1. Prong One

This question simply asks if the conduct that the speech is promoting is illegal or misleading. If so, then the speech can obviously be restricted. Here, the Supreme Court is referring to the legality of the activity the speech is promoting, not the legality of the speech itself. The practice of off-label medicine is widely accepted as a perfectly legal activity, even by the FDA. "The United States Supreme Court has emphasized that off-label use is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine" (*Davenport v. Meditronic, Inc.).* Therefore, issues of contention with prong one generally focus on the idea that, if given the opportunity to promote off-label uses, drug companies might be misleading or untruthful in their promotional activities. However, the First Amendment does not protect such speech. "The FDA retains its full armamentarium of enforcement options against factually false and misleading speech even under a Central Hudson analysis" (Hall 17). Therefore, even if off-label promotion was freely allowed, the FDA would still be able to prosecute unscrupulous companies who propagated misleading speech. As a result, when talking about *truthful* off-label promotion, the speech typically survives prong one.

2. Prong Two

This condition requires that the government prove they have a substantial interest in restricting the speech in question. In their attempts to regulate off-label promotion, the FDA

typically cites two substantial interests: Protecting public health and convincing drug companies to submit their new uses for FDA approval. "This prong of the Central Hudson test is not typically dispositive, particularly in the food and drug field where the government clear[ly] has a substantial interest in ensuring the public availability of safe, effective and properly labeled medicines" (Bachrach 227). However, while the government generally satisfies prong two, it still warrants closer examination in the specific case of off-label speech.

Although the government's interest in protecting public health is indisputable, there are questions as to whether limiting off-label speech is actually in the government's best interest. The FDA's policy is paternalistic; it assumes that if consumers and physicians are given full disclosure, they will make poor decisions. The Courts have rejected this view. In *Western States*, the Court said:

> This concern amounts to a fear that people would make bad decisions if given truthful information about compounded drugs …We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. (*Thompson v. Western States*)

Regardless of the means in which an off-label use is being promoted, according to prong one the government could shut down any piece of off-label speech that is misleading or untruthful. Therefore, any off-label speech that has reached prong two consideration would have to be truthful. This idea, combined with the *Western States* ruling, leads to the conclusion that it would be extremely difficult for the government to satisfy prong two in the case of off-label marketing.

Prong Three

In order to satisfy prong three, the government must prove its regulations directly advance the interest purported in prong two. In the case of off-label promotion, the FDA would have to show that limiting off-label speech would directly protect public health and/or encourage drug companies to seek approval. In *Edenfield,* the Court established that "a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." The claims cannot rely on "mere speculation or conjecture" (*Edenfield v. Fane*). As a result, satisfying prong three can be challenging. However, in *WLF v. Friedman,* the Court found that FDA regulation did, in the case of off-label promotion, satisfy prong three. They wrote, "One of the few mechanisms available to FDA to compel manufacturer behavior is to constrain their marketing options; i.e. control the labeling, advertising and marketing." It continues "if a manufacturer is proscribed from distributing enduring materials and/or sponsoring CME seminars that address that manufacturer's product absent FDA approval of that use, that proscription provides a strong incentive to get the use on-label" (*WLF v. Friedman*).

The problem, of course, is that the process to get a use on-label is expensive and, more importantly, time-consuming. In order to get the FDA to approve a new use for an already approved drug, the manufacturer must satisfy the same amount of clinical trials as they do when the drug is initially approved. Then, the manufacturer must submit a Supplemental New Drug Application seeking approval for the new indication (Hall 5). The process for seeking approval of a new use is essentially equally burdensome as that of seeking approval for an entire new drug.

If a manufacturer discovers a new use for an existing drug that could potentially save lives, is it in the public interest for that company to be able to disseminate such information?

Currently, doctors have to learn such information from less efficient avenues. For example, a physician might have to make requests to their medical affairs departments or get information from peer-reviewed journals(Sorrell). Essentially, physicians must seek the information on their own and are still liable for prescribing something for the wrong use" (Sorell). Consequently, they are much less likely to find, let alone use, a potentially beneficial off-label therapy. It therefore seems that the public is best served by the freest flow of information possible. So, even if FDA regulation encourages companies to seek FDA approval, there are contentions that such encouragement actually counteracts the more over-arching government interest of protecting public health.

Prong Four

Prong four requires that the restrictions on speech be "(1) not necessarily perfect, but reasonable, (2) represent not necessarily the single best disposition, but one whose scope is in proportion to the interests served, and (3) employs not necessarily the least restrictive means, but a means narrowly tailored to achieve the desired objective" (*Board v. Fox*). The government, therefore, must explore alternative means to achieve the purported interest in prong two. If the Court finds that such options exist, then the government must exercise them rather than imposing speech restrictions. In *WLF*, this is where the Court found the FDA regulations to be in violation of the First Amendment. The Court based this determination "in large part upon the fact that there exists less-burdensome alternatives to this restriction on commercial speech – most obviously, 'full, complete, and unambiguous disclosure by the manufacturer" (Rogers 1439). The Court's ruling signifies more than merely the failure to satisfy prong four. It shows that there are more effective means of achieving the goals of the regulation, and these need to be explored

by lawmakers. Before exploring those more effective means, it is first necessary to understand the public health implications of off-label marketing.

III. Impact on Public Health

A. Potential Benefits

There are several instances in which the promotion of off-label uses has been beneficial to public health. Proponents of off-label marketing claim that the more information physicians have, the more effective they will be in treating patients. The FDA's authority with regards to off-label marketing extends only to drug manufacturers, not physicians (Salbu 191). In fact, the FDA does not even discourage physicians from prescribing off-label, stating "[I]t is not the agency's [FDA's] policy, intent, or bias to indicate that off-label uses are wrong, improper or even investigational (Beck 78). Therefore, since the FDA cannot and does not try to stop physicians from prescribing off-label, proponents say it makes sense to at least give physicians as much information as possible in the hopes that their off-label prescriptions will be based on adequate knowledge.

Moreover, the beneficial effects of common off-label drugs cannot be overlooked. Even Michael R. Taylor, the FDA's former Deputy Commissioner for Policy, conceded that off-label uses are "often essential to good medical practice and in some areas…off-label use constitute a significant portion of standard therapy" (Polubinski 998). Some doctors, such as former AMA Vice President Dr. Roy Schwarz, even say that in some cases a physician who did not prescribe a drug for a particular off-label use could be guilty of malpractice (Polubinski 998). Off-label uses have, in many cases, proven to be the best treatment available.

Nowhere is this clearer than in the prescribing of aspirin to prevent heart attacks. As of 1999, experts suggested that "tens of thousands of heart attacks would have been averted had it

been lawful to advertise the benefits of aspirin for this purpose" (Salbu 195). Although promotion of over-the-counter drugs is regulated not by the FDA but by the Federal Trade Commission, the idea is clear: It is undeniable that in many cases limiting the free flow of information can cost lives. Another prime example is the case of HIV/AIDS therapies. Currently, more than 80% of AIDS patients are receiving at least one off-label treatment (Herrmann). Salbu perfectly explains how beneficial such off-label uses have been to thousands of AIDS patients:

> Suppose we denied HIV and AIDS patients access to combination therapy until the combinations were tested and approved under the procedures the FDA uses for new drugs. Thousands of patients who have thrived using the unapproved cocktails would have met the same fate as patients before the advent of protease inhibitors- they would have deteriorated quickly, suffered terrible illnesses, and died. (225)

Off-label uses, because of their nature, are discovered at a much quicker rate than the FDA can keep up with. According to the agency's own mission statement it is, "responsible for advancing the public health by helping to speed innovations that make medicines…more effective… and helping the public get the accurate, science-based information they need to use medicines…to improve their health" (FDA). Based on this part of the mission statement, it seems the FDA's goals and the goals of those who favor off-label promotion are quite similar. Both believe in expediting medical innovation and spreading accurate information. However, while their intentions might be similar, disagreement remains concerning whether off-label promotion would achieve such goals.

In addition to enabling doctors to prescribe more effective treatments, proponents of off-label marketing also cite cost-containment opportunities to support their argument. Approval for new off-label uses can cost many millions of dollars (Polubinski 1006). Eventually, this cost will

be redirected onto society in the form of higher drug prices or less research and development. Also, as Alan Slobodin, former House Commerce Committee counsel, explains, "The FDA expends resources unnecessarily on relatively unimportant side issues such as the monitoring of off-label uses" (Salbu 195). According to Slobodin, if the FDA focused simply on its "core mission- the expedient assessment of new drugs and devices," significant tax dollars would be saved (195). No evidence could be found regarding the estimated amount that could be saved by allowing free promotion of off-label drugs. However, in an era in which legislators are exploring health reform that will cost about $1 trillon (Andrews), such significant opportunities to save the system money must be given credence.

Finally, it should be noted in this section that during the course of this study there seemed to be very little information available pertaining to how off-label uses are discovered or disseminated outside of medical literature or company promotional materials. While there was ample information concerning the legal issues of off-label uses, it was difficult to find any description of how these uses come about in the first place. The lack of such information certainly makes it more difficult to determine the potential benefits of free promotion of off-label drugs. Therefore, future research aimed at providing such data would prove to be beneficial.

B. Potential Consequences

Returning back to the FDA's mission statement, the agency also makes itself responsible for "protecting the public health by assuring the safety, efficacy, and security of…drugs" (FDA). Regarding off-label promotion, it appears that the FDA places more weight on this part of its job. And, there is no denying that significant evidence exists to support the claim that off-label promotion could put "safety, efficacy, and security" of certain drugs at risk. After all, off-label uses, while not experimental, do not go through the rigors of an FDA-approved use.

The off-label combination of the drugs phentermine and fenfluramine is a classic example of a dangerous off-label concoction. Both drugs were approved as appetite-suppressant weight-loss drugs and had been approved by the FDA in 1959 and 1973, respectively. Fenfluramine, when used by itself, was known to cause fatigue. But, in the 1990's researchers found that, if combined with phentermine, patients no longer felt the fatigue side effect (Tabarrok 38). Immediately, prescriptions for the drugs spiked, and by 1996 doctors had prescribed 18 million prescriptions for the two drugs (Salbu 203). The cocktail, known as fen-phen, was off-label, as the FDA never approved the drugs to be used in combination. In 1997, however, doctors at the Mayo Clinic began noticing unusual heat-valve disease in twenty-four female patients taking fen-phen, and further research confirmed that heart-valve disease was "shockingly common" in women taking fen-phen (Tabarrok 38). Fenfluramine was withdrawn from the market in September 1997, but not before an estimated 285,000 users suffered damage to heart valves in a very brief period (Salbu 203). During this time, off-label promotion was completely illegal in any sense of the word. According to Salbu, "Doctors began prescribing [fen-phen] not because manufacturers pressured them with an advertising blitz, but simply because the doctors read the primary scientific evidence…or heard about the scientific evidence by word of mouth" (203). This, Salbu says, can be interpreted in one of two ways. First, the fact that doctors can prescribe off-label is itself dangerous enough to threaten public health, regardless of whether or not manufacturers try to promote it. Or, one could argue that had manufacturer's been allowed to freely promote the cocktail, the amount of patients harmed by the drug would have skyrocketed. Perhaps the truth lies somewhere between the two theories. Nevertheless, the case of fen-phen should as a cautionary tale to those who claim off-label promotion is a benefit to public health.

Equally troubling as the fen-phen disaster is the evidence that shows children could be harmed by flawed off-label prescriptions. Often times, a physician will prescribe a drug approved for adults to a child at a much lower dosage. Because a deviation from the FDA-approved dosage recommendation is considered an off-label use, one of the most common specialties in which off-label prescriptions occur is pediatrics. In fact, a study conducted by the Children's Hospital of Philadelphia showed that nearly 80% of hospitalized children in the US receive some sort of off-label treatment. The study also found that only a small number of those drugs had ever been tested on children (Ascenzi).

Unfortunately, data also shows that children do not always respond positively to off-label treatments. The study could not determine an exact percentage of patients who experienced adverse outcomes, however it did conclude that, "Using drugs that have been insufficiently studied in children has contributed to adverse outcomes, which have been documented in the medical literature" (Ascenzi). The most convincing of this medical literature actually comes from outside of the United States. A study published by the British Journal of Clinical Psychology found a strong correlation between off-label drug use and adverse reactions in pediatric patients. Adverse drug reactions were found in 6% of patients using off-label treatments compared to only 3.9% of patients for approved prescriptions (Turner 967). While the study was conducted abroad, the fact remains that off-label drugs are used just as commonly in the United States and should therefore be given equal concern.

While there is proof that some off-label treatments have proved disastrous, no evidence is available as to whether the *promotion* of these treatments would make the outcomes any worse. Thus far, most of the adverse outcomes from off-label prescriptions have come about without the

manufacturers pressing the issue. It is certainly possible that promotion would only perpetuate such outcomes. However, that leap cannot be made as of yet.

IV. Recommendation

In searching for a resolution to this conflict, two major factors must be balanced. First, from a health care perspective, the safety and best interest of the American public must be protected. But from a legal perspective, any new policy must not infringe upon the First Amendment rights of drug companies or doctors. In the past, it seems that the assumption has been that these two forces are at odds. But, after evaluating the legal and public health issues, this paper proposes that the two conditions can be satisfied in a mutually beneficial relationship.

In order to put forth a proposal that satisfies the First Amendment concerns, one must look no further than *WLF v. Friedman* and *WLF v. Henney*, the most pertinent cases relating to this issue. In both cases, the Washington Legal Foundation successfully challenged the constitutionality of the FDA's off-label marketing restrictions. The rulings set a clear precedent that explicitly established that off-label speech must be protected. Interestingly, however, using the Central Hudson test, the courts determined that the FDA did in fact satisfy prongs two and three. Regarding prong two, the court actually identified two substantial government interests of making sure physicians receive accurate and reliable information as well as encouraging drug manufacturers to seek supplemental approvals for the new uses (Kamp 561). The court also agreed that the FDA restrictions satisfied the prong 3 requirement of ensuring that the restrictions directly advance the substantial government interest. The courts concluded that in both the guidance documents and FDAMA the FDA "provides an incentive for drug manufacturers to seek FDA approval for off-label treatments" (561). That brings the discussion back to prong four. As previously mentioned, this is where the FDA failed in both cases. Ultimately, the courts

found that the restrictions were more extensive than necessary, mostly because less restrictive solutions existed (Rogers 1441).

This idea is the basis for this paper's proposal. Essentially, the court provided its own recommendation for how the FDA could achieve its goals without violating the First Amendment. This proposal accepts that recommendation and incorporates it with the author's own idea. In *Friedman,* the judge offered a four-point recommendation for the FDA. Those four recommendations were that the FDA could:

> 1) Require conspicuous notifications that the uses discussed were not approved by the agency; 2) require that the articles and textbook reprints come from peer reviewed journals and bona fide independent publishers; 3) require that the sponsor of CME seminars be "independent program providers"; and 4) require authors and manufacturers to disclose their financial interests. (Kamp 562)

The major difference between the judge's suggestions and the guidelines in the FDAMA is that, under the new suggestion, drug manufacturers would no longer have to submit materials to the FDA prior to publication and also would no longer have to verify plans to get the new use approved.

In the opinion of this author, however, the judge's suggestions only allow the FDA to satisfy one of its two goals. It adequately addresses the issue of making sure physicians get reliable, credible information. However, it does not necessarily provide enough motivation for drug companies to get the new uses approved. As previously mentioned, getting new uses approved by the FDA is both costly and time-consuming. Therefore, companies will not be motivated to go through the approval process unless doing so will not harm their bottom line. Therefore, this paper recommends that the FDA establish a completely separate approval process

for off-label uses. The new process should be expedited and efficient, so drug companies are not weary of subjecting their drugs to the process. In order to fund the new process, the FDA should use the billions of dollars they have collected from drug companies via off-label marketing lawsuits. Additionally, under the new policy, if a company still chooses to keep a use off-label for an extended period of time, they should be subjected to a penalty tax that will also go into funding for the new approval process. This plan will provide proper motivation for drug companies to get approval for new uses while still being able to freely promote those uses in the meantime. Also, since the new uses will now be approved, drug companies will be able to market them directly to consumers as well.

Most important in evaluating this plan is considering how it would have affected the outcomes of actual cases. For example, consider the case of aspirin being able to prevent heart attacks. Under the recommended policy, Bayer, aspirin's maker, would have been able to quickly get the new use approved and then promote that use to both doctors and consumers. Patients would have been able to make more informed decisions regarding their medication, and it is likely that thousands of lives would have been saved.

Similarly, had this policy been in place during the fen-phen disaster, the result might have been quite different as well. Rather than rush the concoction on to the market, drug makers would have submitted it to the FDA for expedited review. The FDA would have realized exactly what the Mayo Clinic doctors did- that the concoction was dangerous and should not be prescribed. However, the FDA would have come to this conclusion before 285,000 women were subjected to heart valve damage.

This policy is designed with both practicality and legality in mind. It will encourage communication among patients and physicians and will ultimately result in better patient

outcomes as well as higher profitability for the drug companies. And, equally as important, the plan fully protects the First Amendment rights of all involved.

V. Conclusion

Despite numerous attempts at legislation, litigation, and compromise, there still remains significant disagreement over how to handle the promotion of off-label drug uses. Regardless, certain fundamental flaws must be fixed before the problem can be successfully solved. The FDA must address the inefficiencies of its approval process for new drugs. Drug companies must change their outlook and become more motivated to get new uses approved. Perhaps most importantly, the lines of communication between the FDA, drug companies, providers, and patients must be reexamined as a means for good, not for deception.

To this end, future research in this area should center on opening those lines of communication. Researchers should explore exactly how physicians become aware of off-label uses and then how they disseminate that information amongst each other. Similarly, further research should focus on how off-label marketing affects patients. For example, researchers should seek to understand whether patients would like to hear more about off-label uses as well as whether or not they are able to fully understand the implications of taking a drug off-label. Finally, many new means of communication have surfaced since the WLF cases. Researchers should explore whether or not information about off-label uses has become more available as a result of the internet and new technologies.

The more information that policymakers have regarding off-label marketing, the better decisions they will make. Therefore, it is imperative that researchers from both the legal and healthcare arenas continue to explore the issue for the sake of all stakeholders involved.

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Vita

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EDUCATION:

The Pennsylvania State University, University Park, PA **Expected Graduation May 2010**

Schreyer Honors Scholar

- Thesis Title, *"Regulating Off-Label Drug Promotion: A New Perspective"*

Bachelor of Science in Health Policy and Administration

• GPA: 3.84/4.00

Dean's List: Summer 2006-Fall 2009

Special Projects:

Penn State College of the Liberal Arts
Summer 2007
Independent Researcher

- Researched and published a rhetorical analysis for Africana Research Center
- Supervised by Dr. Jack Selzer, Associate Dean of the College of the Liberal Arts
- Awarded 2nd place out of 30 entries

Campus Involvement:

Sigma Alpha Epsilon Fraternity **September 2006-May 2010**
Active Brother, THON Chairman

- Coordinated fundraising efforts of over 50 brothers
- Implemented policy that mandated every brother send a minimum of 40 fundraising letters
- Raised $106,126.11 in cooperation with Pi Beta Phi Sorority (25% increase from previous year)

Penn State Dance MaraTHON **October 2008-October 2009**
Family Relations Captain

- Responsible for overseeing Adopt-A-Family Program for approximately 50 organizations
- Reviewed and graded about 150 organization's applications
- Assigned those organizations Four Diamonds Families based on the quality of those applications