PROHIBITING GRAY MARKET PRESCRIPTION DRUGS: THE ETHICAL DIMENSIONS

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I. INTRODUCTION

This paper deals with the ethical implications of the gray market for prescription drugs in the United States. It focuses on attempts by people and states to reduce the high cost of domestic prescription drugs by importing or re-importing drugs from countries such as Canada, Mexico, and China, and attempts by the government and drug companies to limit or prohibit such practices.

On average, brand-name drug prices are approximately seventy-percent higher in the United States than elsewhere. U.S. consumers would have saved an estimated $59.7 billion during 2004 had they purchased all brand-name drugs at Canadian prices. For instance, in Beebe Plains, Vermont, there is a street, 'appropriately named Canusa Avenue,' that runs along the U.S.-Canada border. The difference in what residents of opposite sides of the street pay for the same prescription drugs is considerable. Residents of the northern side of the avenue can purchase a ninety-day supply of Lipitor (atorvastatin) for $170, for example, while residents of the southern side of the street must pay $330 to fill the same prescription. [1]

This situation is complex, emotional, and multi-faceted, and it affects and is effected by numerous parties and principles. It has been in a long period of stasis, where politics trumps law, making this an ideal opportunity to apply the filter of ethical reasoning and analysis. Additionally, it is the kind of visceral real world issue that can be used as an ideal exercise to teach

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[1] Kristen E. Schleiter, *Court Support for FDA Regulation of Drug Importation*, 11 AMA J. ETHICS 521 (July 2009).

the various types of potential ethical approaches and how they can result in contradictory conclusions.

II. THE GRAY MARKET DEBATE

Gray marketing, also known as parallel importation, occurs when genuine and legitimately manufactured trademarked products intended for a particular country market are diverted to a different country market through unauthorized distribution channels.[2] The predominant reason for gray markets to exist is price differentials across international markets.[3] Distributors in lower-priced markets often divert products to middlemen in higher-priced markets, who subsequently offer these products to their customers at substantial discounts compared to authorized intermediaries in these markets.[4] Gray markets have existed in a number of product markets, including automobiles, textbooks, and drugs. The Food and Drug Administration (FDA) has been active in combatting the re-importation of prescription drugs. Recently, the State of Maine has defied the FDA and has been defeated in the trial court over its practice of re-importation of drugs to reduce its health care obligations.[5]

Gray markets employ "irregular but not illegal methods . . .: a market that legally circumvents authorized channels of distribution to sell goods at prices lower than those intended by the manufacturer."[6] The practice of re-importing to the United States prescription drugs that were manufactured in the United States and then exported for sale in another country is referred to as *drug re-importation*.[7] In 1988, Congress enacted a special restriction on importation of "American goods returned."[8] That restriction prohibits any person other than the original manufacturer to import into the United States

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[2] Dale F. Duhan & Mary Jane Sheffet, *Gray Markets and the Legal Status of Parallel Importation*, 52 J. MARKETING., 75 (July 1988).
[3] Barry Berman, *Strategies to Combat the Sale of Gray Market Goods*, 47 BUS. HORIZONS 51 (July 2004).
[4] Soumava Bandyopadhyay, *The Internet of Gray Marketing*, 9 INT'L BUS. & ECON. RES. J. 95, 95 (June 2010).
[5] Ouellette v. Mills, 91 F.Supp.3d 1 (D. Me. 2013); An Act to Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies, 2013 Me. Legis. Serv. Ch. 373 (S.P. 60) (West) (2013) (codified as 32 M.R.S.A. §§ 13731(1) & 13799).
[6] Gray Market, MERRIAM-WEBSTER, (type in "gray market" in the search bar) http://www.merriam-webster.com/dictionary/gray%20market).
[7] Monali J. Bhosle & Rajesh Balkrishnan, *Drug reimportation practices in the United States*, THERAPEUTICS AND CLINICAL RISK MANAGEMENT (2007), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1936287/.
[8] *See* Prescription Drug Marketing Act of 1987 Pub. L. No. 100–293, 102 Stat 95 (codified in part at 21 U.S.C. § 381(d) (1988)).

a prescription drug that was originally manufactured in the United States and sent abroad.[9] Congress specifically found that this restriction was necessary to protect the health and safety of the American public because "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become sub-potent or adulterated during foreign handling and shipping."[10]

A. *The Price Problem*

"For people without insurance, prescription drugs often are less expensive outside the U.S. The reason is simple: the U.S. is the only country where there are no price controls over prescription drugs." [11] Americans spend close to $1,000 per person, which is almost forty-percent more than the next highest country's average.[12] A 2012 comparative price report from the International Federation of Health Plans found that a month's supply of Cymbalta, which is used to treat depression or chronic pain, costs $149 on average in the United States, compared with $113 in Canada. The allergy drug Nasonex cost Americans $105 but Canadians only $29 for a month's supply.[13] According to the IMS Institute for Healthcare Informatics, in 2012 the average U.S. resident spent $892 on prescription drugs, while the average Canadian spent only $420, and residents of the European Union spend, on average, $375.[14] These price differences are due to the unique way that the United States handles its pharmaceutical marketplace. In most other countries, governments either set pricing caps or negotiate lower prices directly with drug makers. In the United States, pricing is determined by

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[9] *See id.* at § 381(d)(1).
[10] *Id.* at § 381(d)(4).
[11] *When Crossing the Border for Prescriptions, It's Buyer Beware*, WEBMD HEALTH NEWS (March 17, 2000), http://www.webmd.com/news/20000317/when-crossing-border-for-prescriptions-its-buyer-beware.
[12] Samantha Lachman, *McCain, Klobuchar Team Up On Bill Allowing Prescription Drug Imports From Canada*, HUFFINGTON POST, (July 9, 2014) http://www.klobuchar.senate.gov/public/2014/7/mccain-klobuchar-team-up-on-bill-allowing-prescription-drug-imports-from-canada.
[13] International Federation of Health Plans, *International Federation of health Plans 2012 Comparative Price Report: Variation in Medical and Hospital Prices by Country*, (2012), http://hushp.harvard.edu/sites/default/files/downloadable_files/IFHP%202012%20Comparative%20Price%20Report.pdf, at slide 26-27.
[14] IMS Institute for Healthcare Informatics, *The Global Use of Medicines: Outlook Through 2016*, (2012), https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Global%20Use%20of%20Medicines%20Outlook%20Through%202016/Medicines_Outlook_Through_2016_Report.pdf.

market competition among pharmaceutical companies, which have little incentive to keep prices down. The U.S. system enables American drug companies to support pharmaceutical research, which is virtually nonexistent in Mexico and Canada.

When accused of price gouging in the U.S. market, the companies claim that the high costs are required to pay off sunken research and development costs — averaging over $1 billion per drug,[15] according to Pharmaceutical Research and Manufacturers of America, PhRMA. The claim has been debated, with some studies estimating the cost to be much lower, more like $50 million to $75 million.[16] Regardless, because other countries force pharmaceutical companies to sell drugs cheaply abroad, U.S. residents are stuck with the bill, essentially subsidizing the affordable prescription drugs in other countries.

According to *Nation on the Take: How Big Money Corrupts Our Democracy and What We Can Do About It,*[17] lobbying, campaign contributions, and other types of legalized or soft corruption among government policy makers and politicians is why Americans pay more for exactly the same prescription drug than citizens of other countries. According to the authors, the Pharmaceutical Research and Manufacturers of America (PhRMA) has been a key player in undermining efforts to control drug prices.[18]

B. *The Safe and Affordable Drugs from Canada Act*

Senators John McCain and Amy Klobuchar, a Republican and a Democrat, revived a congressional effort to allow individuals to import cheaper prescription drugs for their personal use by introducing the Safe and Affordable Drugs from Canada Act,[19] which could rein in drug costs and

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[15] Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES, (Feb. 10, 2012, 67:41 AM), http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/#5559922e4477.

[16] Donald W. Light & Rebecca Warburton, *Demythologizing the high costs of pharmaceutical research,* 6 BIOSOCIETIES 34 (2011).

[17] WENDELL POTTER & NICK PENNIMAN, NATION ON THE TAKE: HOW BIG MONEY CORRUPTS OUR DEMOCRACY AND WHAT WE CAN DO ABOUT IT (2016).

[18] *Id.*

[19] U.S. Senate Bill 122 "[a]mends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require the Department of Health and Human Services (HHS) to promulgate regulations within 180 days permitting individuals to import a prescription drug purchased from an approved Canadian pharmacy that:

- is dispensed by a pharmacist licensed in Canada;
- is purchased for personal use in quantities not greater than a 90-day supply;
- is filled using a valid prescription issued by a physician licensed to practice in the United States; and

stimulate greater competition within the pharmaceutical industry. The legislation would mandate that imported prescription drugs have to be purchased from an approved Canadian pharmacy and dispensed by a licensed pharmacist. The Senators have pledged to get the bill passed before the 2016 elections.[20] Whether this is likely is debatable.

Members of Congress from both parties have been pursuing legislation to allow prescription drug imports since the Clinton administration without success. In 2004, a bill was introduced in Congress that would allow the reimportation of American-made drugs from Canadian pharmacies; it was never enacted because of Republican opposition. In 2007, a bill proposed by Democrats to allow Medicare to negotiate lower drug prices was quashed in the Senate, creating a prohibition against any future negotiation.[21]

Advocates of drug importation policies last saw an opening in 2009 as lawmakers helped shape an enormous package of health bills under Obamacare. During his campaign in 2008, President Obama voiced strong support for a change in drug policy saying all Americans should be able to import medicines "if the drugs are safe and prices are lower outside the U.S."[22] When he was drafting what would eventually become the Affordable Care Act, President Barack Obama considered adding a section that would enable Medicare to negotiate drug prices. However, he gave that away as a bargaining chip to gain the overall support of the pharmaceutical industry for the Obamacare legislation.[23] The measure to legalize the importation of prescription drugs from Canada and other countries failed in the Senate as part of the pending health care reform bill.[24] The proposal would have saved

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- has the same active ingredient or ingredients, route of administration, dosage form, and strength as a prescription drug approved under the FFDCA."

The bill sets forth exceptions, including for controlled substances and biological products, establishes a certification process for approving Canadian pharmacies, and requires HHS to publish a list of approved Canadian pharmacies. S.122, 114th Cong. (2015).

[20] *Id.*

[21] Allan Rubins & Harold Rubins, *Crossing the Border to Obtain Cheaper Prescription Drugs-Part V of a VII Part Article*, WWW.RUBINS.COM, (Oct. 11, 2013), http://www.therubins.com/medicare/drugcost4.htm.

[22] *Id.*

[23] The agreement between the president and the drug industry involved the pharmaceutical industry foregoing about $80 billion in profits that it would have earned if Medicare Part D cardholders would have to pay for drugs that they purchased in the "doughnut" hole at only half the usual price for the drug. *Id.*

[24] Ramin Oskoui, *High Prescription Prices Won't Drop Soon. One reason: lobbying. A second: corruption. No wonder we're sick*, HEALTHZETTE HEALTH. EXPLAINED., (March 24, 2016, 1:02 AM), http://www.lifezette.com/healthzette/high-prescription-prices-wont-drop-soon/.

Senators voted 51-48 in favor of the amendment, but it required 60 votes in order to be adopted. A different amendment, supported by the drug industry that would have allowed the

the federal government $10.4 billion over the next 10 years according to the Congressional Budget Office.

C. *The Supreme Court Permits Gray Market Importation of Textbooks*

In 2013, the U.S. Supreme Court, in a 6-3 decision, in *Kirtsaeng, DBA Bluechristine99 v. John Wiley & Sons, Inc.*[25] ruled that U.S. companies that make and sell products abroad cannot prevent those items from being resold in the United States. This case involves a part of the copyright law that was aimed at so-called gray market goods—U.S. copyrighted products that are manufactured in other countries for sale there, then purchased and imported to the United States for discounted resale. The defendant got as many textbooks from Asia as he could and resold them on eBay, making a profit of about $100,000. The publisher sued for copyright infringement and won in the lower court. The defendant appealed to the Supreme Court, contending that he was protected by a rule called the first sale doctrine, which says that once a person buys a product, it is his or hers to do with as s/he pleases. The Supreme Court reversed the lower court's decision and held that to impose geographic limits on the first sale doctrine made no sense. Justice Stephen Breyer, writing for the majority, said goods, once sold lawfully, whether within the U.S. or elsewhere, can now be resold in the United States without the copyright holder's permission. An unlikely trio of dissenters, Ginsburg, Scalia, and Kennedy, alleged that the court's ruling ignored an explicit goal of the copyright laws—"to protect copyright owners against the unauthorized importation of low-priced, foreign-made copies of their copyrighted works."[26] Concurring with the majority, Kagan and Alito suggested that Congress can change the law if it thinks copyright holders need more protection against such import-and-resale schemes.[27]

Of course, textbooks do not constitute the same risk to health as adulterated prescription drugs. But drugs represent a significant safety issue that textbooks do not. The FDA's comprehensive, closed regulatory scheme for protecting patient safety prohibits importation of any new drug that has not been approved by the FDA, any medication that has not been labeled in

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imports only with a safety clearance from the FDA, also failed by a 56-43 vote, with 60 votes being needed.
See Rubins, *supra* note 21.
[25] 133 S. Ct. 1351 (2013).
[26] *Id*. *See also* Nina Totenberg, *Supreme Court OKs Discounted Resale Of 'Gray Market' Goods*, NPR (March 19, 2013, 3:28 PM), http://www.npr.org/blogs/thetwo-way/2013/03/19/174757355/supreme-court-oks-discounted-resale-of-gray-market-goods.
[27] *Id.*

accordance with federal law, and any prescription medicine dispensed without a valid prescription issued by a licensed practitioner.[28]

D. *Skirting the Rules*

Legal importation of prescription drugs into the United States remains a gray area. Since all attempts to legalize the importation of prescription drugs to the United States have been unsuccessful so far, many Americans devise schemes to surreptitiously order drugs from foreign countries. For example, some people have their doctors prescribe twice the needed dose, while others split pills, and some people obtain their medications from family members or friends who have more comprehensive insurance coverage. Some groups have suggested that it should be legal to buy prescription drugs, made by large U.S. manufacturers in other countries, such as Canada, to be shipped here. After all, U.S. citizens paid for them with tax-breaks, university grants, and so much more. So why should U.S. consumers have to pay 5, 10, 100 times what people in any other country pay? Estimates indicate that buying medicines from a certified Canadian pharmacy can save Americans 20%–80% on brand name drugs.[29]

In 2003, Congress enacted the Medicaid Prescription Drug, Improvement, and Modernization Act, which authorizes the Secretary of Health and Human Services to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States and to grant to individuals a waiver of the prohibition of importation of a prescription drug.[30] To date, however, the Secretary has not certified to Congress that importation will be safe and cost-effective, as required to permit such imports. The FDA has repeatedly stated, "virtually all prescription drugs imported for personal use into the United States from Canada" or other countries "violate the Food, Drug, and Cosmetic Act (FDCA) because they are either unapproved new drugs, labeled incorrectly, or dispensed without a valid prescription."[31] At least one federal district court has already concluded that a state plan for importing drugs from Canada violated the FDCA.[32]

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[28] 21 U.S.C. §§ 352-355 (2016); *see* Vermont v. Leavitt*,* 405 F. Supp.2d 466, 473 (D. Vt. 2005).
[29] Jesse C. Vivian, *Canadian Drug Imports*, 28 U.S. PHARMACIST 7 (2003).
[30] 21 U.S.C. §§ 384(b) & (j)(2)(A) (2003).
[31] Randall D. Lutter, *Nevada: Gov. Kenny Guinn*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (May 20, 2005), http://www.fda.gov/Drugs/DrugSafety/ucm179414.htm.
[32] *See Leavitt,* 405 F. Supp. *2*d at 474.

The FDA's position on purchasing prescription drugs online is stated clearly on its website and in letter opinions to multiple states. On the FDA's BeSafeRx FAQ Page[33], it states that the

> FDA does not have jurisdiction over prescription medication from other countries; therefore, FDA cannot guarantee the safety or effectiveness of those medications. Medicines approved in other countries may have slight variations, or different ingredients, that could cause you to develop a resistance to your medicine or result in a misdiagnosis by your doctor. If you take more than one medicine, these differences could also cancel out the effects of your medicines or cause harmful interactions. Additionally, many of these illegal pharmacies use fake 'storefronts' to make consumers think they come from countries with high safety standards, but the medicines could have been made anywhere.[34]

The FDA also believes that "[o]nly 3 percent of online pharmacies reviewed by the National Association of Boards of Pharmacy are in compliance with U.S. pharmacy laws and practice standards."[35]

The FDA fights re-importation of prescription drugs one state at a time informing state officials in at least 15 states that local laws purporting to authorize the importation of prescription drugs from Canada or other foreign countries—including state laws limiting such importation to private individuals for their personal use—run afoul of the FDCA and are preempted.[36] The FDA's main concern is patient safety.

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[33] *BeSafeRx: Know Your Online Pharmacy, For the Media*, U.S. FOOD & DRUG ADMINISTRATION http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/ucm294170.htm#FAQs, (last updated Sept. 24, 2013).

[34] *Id.*

[35] *Id.*

[36] *See generally Randall* D. Lutter, *Hawaii: Governor. Linda Lingle*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Aug. 14, 2008), http://www.fda.gov/Drugs/DrugSafety/ucm179204.htm;
Randall D. Lutter, *Washington Dept. of Health: Dir. Steven Saxe*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (March 17, 2006), http://www.fda.gov/Drugs/DrugSafety/ucm179358.htm;
Randall D. Lutter, *Texas: Attorney General Greg Abbott*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (July 27, 2005), http://www.fda.gov/Drugs/DrugSafety/ucm179382.htm;
Randall D. Lutter, *Texas: Governor. Rick Perry*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (June 17, 2005), http://www.fda.gov/Drugs/DrugSafety/ucm179411.htm;
William K. Hubbard, *California: Deputy Attorney General Gregory Gonot*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Aug. 25, 2003), http://www.fda.gov/Drugs/DrugSafety/ucm179893.htm;

E. *FDA Exceptions Make Things More Gray*

Under certain defined circumstances, as a matter of enforcement discretion, the FDA allows consumers to import otherwise illegal drugs. Under this policy, the FDA permits individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the United States. A patient seeking to import such a product must also provide the name of the licensed physician in the United States responsible for his or her treatment with the unapproved drug product.[37] However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the United States, particularly when the foreign versions of such drugs are being commercialized to U.S. citizens. In its discretion, the FDA does not always enforce regulations for importing prescription drugs and has issued guidelines entitled Coverage of Personal Importations. This policy is not a law or a regulation, but serves as a guide for FDA personnel and, at their discretion, U.S. Customs agents at U.S. borders. Under these guidelines, the FDA may allow an individual entering the U.S. to import a 90-day supply of an unapproved drug if all of the following conditions are met:

a. The intended use of the medication is for a serious condition for which effective treatment may not be available in the U.S.
b. The medication will not be sold by the person bringing the medication into the U.S.
c. The medication is considered not to represent an unreasonable risk.
d. The individual seeking to bring the medication into the U.S. affirms in writing that the drug is for the his or her own use and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the medication; or, the individual provides

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William K. Hubbard, *Rhode Island: Attorney General Patrick C. Lynch*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Jan. 28, 2005), http://www.fda.gov/Drugs/DrugSafety/ucm179416.htm;
Randall D. Lutter, *Minnesota: Mayor Don Ness*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Feb. 6, 2008), http://www.fda.gov/Drugs/DrugSafety/ucm179322.htm.

[37] *See* FDA REGULATORY PROCEDURES MANUAL, http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-2.html (last visited Nov. 15, 2016).

> evidence that the medication is for the continuation of a treatment begun in a foreign country.[38]

According to media, there is a common misconception that anyone can import a 90-day supply of any prescription drug from Mexico or Canada.[39]

The guidelines still make it illegal to buy medications online from Canadian pharmacies and did not address prescription drugs bought by mail from Canada. It is difficult to understand the logic behind distinguishing between drugs that are bought at a Canadian pharmacy and brought into the U.S. by the purchaser and the same drug bought online from the same pharmacy.[40]

F. *Maine's Importation Law*

In 2013, the state of Maine passed a law authorizing any "licensed retail pharmacy located in Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia or New Zealand that meets its country's statutory or regulatory requirements…to export prescription drugs by mail or carrier to a resident of [Maine] for that resident's personal use."[41] The law also exempts from the Maine Pharmacy Act's licensing requirements any "entity that contracts to provide or facilitate the exportation of prescription drugs from "a foreign mail-order pharmacy, and directs that any such entity "may provide or facilitate the provision of prescription drugs

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[38] Michael Bihari, *Foreign Pharmacies – Buying Drugs from Canada and Mexico*, VERYWELL, (April 21, 2016), http://healthinsurance.about.com/od/prescriptiondrugs/a/foreign_pharmacies.htm.

[39] Eamom McNiff, *ABC News Investigation Into Counterfeit Prescription Drug Operations in the US*, ABC NEWS (May 15, 2015, 7:08 PM), http://abcnews.go.com/Health/abc-news-investigation-counterfeit-prescription-drug-operations-us/story?id=31077758 ("at another Canadian storefront in a town 15 minutes away, there, the owner is waiting and tells us 'Americans are allowed under federal law to order up to a 90 day supply of non-controlled medications.' The FDA said that statement is untrue, they only allow the importation for a very rare exception when someone has a serious health condition for which there is no treatment. Not the case in any of our drugs ordered.");
See also Imported Drugs Raise Safety Concerns, U.S. FOOD & DRUG ADMINISTRATION (May 4, 2016), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm ("That means if you buy your high blood pressure or other medication from a foreign country because it's cheaper--even though a drug with the same name is approved for sale in the United States--generally the drug will be considered unapproved and the FDA's personal use guidance will not apply. The Drug Enforcement Administration has additional requirements for controlled drugs.").

[40] Rubins, *supra* note 21.

[41] An Act to Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies, 2013 Me. Legis. Serv. Ch. 373 (S.P. 60) (West) (effective Oct. 9, 2013) (codified as 32 M.R.S.A. §§ 13731(1) & 13799).

from that pharmacy by mail or carrier to a resident of this State for that resident's personal use."[42] The Maine statute thus authorizes unlicensed foreign pharmacies and brokers to import prescription drugs into Maine, even though they are not subject to the patient-health safeguards of federal and state laws—and, in fact, may not be regulated at all.

A lawsuit was filed on September 10, 2013, by licensed Maine pharmacists, a group of Pharmacist Associations, and PhRMA claiming that the Importation Law exposes Maine patients to the substantial health risks posed by unapproved, misbranded, mislabeled, adulterated, improperly handled, or counterfeit prescription drugs, and by inaccurate or incomplete information, that Congress sought to eliminate when it enacted the comprehensive, closed system for distribution of prescription drugs in the United States.[43]

III. AN ETHICS MORASS

As the foregoing discussion indicates, the legal wrangling over the importation and re-importation of prescription drugs is fraught with complicated and knotty public policy issues. Perhaps the best way to cut through this Gordian Knot is not with logic, but ethics. There are ethical issues surrounding the roles and motives of three main players: the federal government, drug companies, and customers in search of cheaper drugs. The remainder of this paper will attempt to explain various ethical approaches to address these issues with an eye toward using this very topical issue as a case study in a classroom discussion of business ethics.

A. *An Ethics Primer*

What is meant by ethics? Dictionaries give several different, but related meanings to ethics, such as moral principles, rules of conduct, or more technically, a branch of philosophy dealing with the study of what a culture values. Business and Society type of textbooks generally just equate ethics with morality, the study of right and wrong, good and evil, fair and unfair, or just and unjust. A more scholarly approach talks about two broad categories of ethical thought, namely the teleological approach and the deontological approach. In teleology one considers "acts are morally right or acceptable if they produce some desired result."[44] There are two teleological approaches – egoism and utilitarianism. In egoism, actions are considered right or

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[42] *Id.*
[43] Ouellette v. Mills*,* 91 F.Supp.3d 1 (D. Me. 2013).
[44] O. C. FERRELL, JOHN FRAEDRICH & LINDA FERRELL, BUSINESS ETHICS ETHICAL DECISION MAKING AND CASES, 157 (10th ed. 2015) [hereinafter FERRELL ET AL.].

acceptable if they "maximize a particular person's self-interest as defined by the individual."[45] In utilitarianism, actions are defined as right or acceptable if they "maximize total utility, or the greatest good for the greatest number of people"[46] Deontology, on the other hand "focuses on the preservation of individual rights and on the intentions associated with a particular behavior rather than on its consequences"[47] This rights focus has usually been associated with so-called ethical/religious principles.

B. *Egoism*

Associated with writers and philosophers such as Epicurus, Nietzsche, and Ayn Rand, egoism is generally considered a lower form of ethics, generally equated with selfishness,[48] or, in the case of Epicurus, the belief that pleasure is the highest form of good. It would be extremely difficult to find a company that claims to espouse that brand of ethics. Drug companies claim that higher prices in the United States offset their research and development and research expenses, which result in saved lives down the road (and to increased profits and stock prices in the highly competitive prescription drug market). Are the drug companies free of the charge of egoism/selfishness? Customers and elected officials, however, have no problem painting the prescription drug companies as greedy and immoral.[49] The recent controversy surrounding Martin Shkreli's purchase of the rights to a relatively old drug, Daraprim, has been a validation to many of the drug-companies-are-greedy meme.[50]

From the standpoint of the consumer of imported/re-imported drugs, each person who purchases prescription drugs on the Gray Market has determined what is best for himself or herself who wants the right to get his or her prescription drugs at more affordable prices. If s/he financially is unable or merely unwilling to purchase it in the United States, then why not

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[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] Ayn Rand was the author of The VIRTUE OF SELFISHNESS (1953).
[49] Robert Pearoct, *Drug Industry, Having Long Smiled on G.O.P., Now Splits Donations Equally,* N.Y. TIMES (Oct. 10, 2008), http://www.nytimes.com/2008/10/14/us/politics/14money.html (John McCain criticized drug companies at a presidential debate in January 2008 with Mitt Romney, who told him, "Don't turn the pharmaceutical companies into the big bad guys." Mr. McCain replied, "Well, they are.")
[50] Tom Howell Jr., *Coalition proposes ways to cut rising drug costs,* THE WASHINGTON TIMES (April 25, 2016), http://www.washingtontimes.com/news/2016/apr/25/campaign-sustainable-rx-pricing-proposes-ways-cut-/?utm_source=RSS_Feed&utm_medium=RSS ("Congress is also delving into the issue, chastising "pharma bro" Martin Shkreli earlier this year for acquiring a decades-old drug and jacking up its price more than 50-fold.").

go across the border or over the internet to purchase it for a more reasonable price?[51] Is this just putting self first or selfishness? Or do American citizens have a natural right to do what they think is necessary to preserve their lives or their wealth from the intrusive hand of government? The drug companies would argue that they are "free-riders" who are not paying for the research and development costs that other Americans absorb. Additionally, are not those countries such as Canada and Mexico free-riders, riding for free on the backs of the Americans who pay outsized drug costs?

How clean are the hands of the federal government on this issue? The pharmaceutical companies are prodigious lobbyists, and the laws in this country have certainly been more favorable to them than in many others. Many articles have been written about the many millions of dollars spent annually by pharmaceutical companies for purposes of lobbying the federal government.[52]

C. *Utilitarianism*

Utilitarianism is considered by many to be the de facto brand of ethics for business firms (at least for those amoral firms that do not spend much time worrying about ethics). It resembles the standard business decision-

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[51] RXASSIST (last visited Nov. 15, 2016), http://www.rxassist.org/ (Drug companies offer low-cost or free prescription drugs to the truly poor. According to the RxAssist Web site: "Patient assistance programs are run by pharmaceutical companies to provide free medications to people who cannot afford to buy their medicine. RxAssist offers a comprehensive database of these patient assistance programs, as well as practical tools, news, and articles so that health care professionals and patients can find the information they need. All in one place.").

[52] *See generally* Ken Cooper, *Drug Companies Give Million-Dollar Boost to Lobbying (Corrected),* ROLL CALL (Apr. 22, 2014, 11:52 AM), http://www.rollcall.com/news/drug-companies-give-million-dollar-boost-to-lobbying#sthash.Q3MzzibU.dpuf. Here are the top pharmaceutical spenders in the first quarter of 2014:

Pfizer Inc. $3,190,000 - up from $2,090,000.
Novartis $2,580,000 - up from $920,000.
Amgen USA Inc. $2,560,000 - up from $2,330,000.
Eli Lilly & Co. $2,086,000 - down from $2,430,000.
Johnson & Johnson Services $2,110,000 - up from $860,000.
Bayer - $2,040,000, up from $1,000,000.
Merck & Co. $2,000,000 - up from $820,000.
Glaxosmithkline $1,630,000 - up from $421,000. (Corrected.)
Sanofi US Services Inc. $1,570,000 - up from $790,000.
AbbVie $1,450,000 - up from $600,000.
Genentech Inc. $1,152,000 - down from 1,220,700.
Teva Pharmaceuticals USA Inc. $1,160,000 - up from $800,000.
AstraZeneca* $1,030,000 - up from $560,000.
Novo Nordisk Inc. $710,000 - down from 820,000.
Bristol-Myers Squibb Co. $520,000 - down from 740,000.
Abbott Laboratories $410,000 - down from $700,000.

making technique known as cost-benefit analysis. It is most closely associated with philosophers Jeremy Bentham and John Stuart Mill. It is often summarized by the expression, "The greatest good for the greatest number." It is not considered a particularly edifying form of ethics, though it is probably more esteemed than egoism.

Business people have been known to become quite hostile when it is suggested that utilitarianism is the general standard of business ethics. Both utilitarianism and cost benefit analysis entail making guesses (hopefully, educated) or estimates of the plusses and minuses involved in the decision. That calls to mind the phrase *gigo*, which stands for *garbage in, garbage out*. Utilitarianism was given a serious blow in the aftermath of the Ford Pinto debacle when it turned out that Ford refused to follow an engineer's suggestion that a safer gasoline filler pipe should be used because of a tendency of the cheaper version to shear off and spill gasoline after an accident. Memos uncovered during the discovery process in wrongful death suits against Ford showed that the company officials felt it was cheaper to save the few extra dollars per car that the safer pipe would cost and just pay for a few extra lawsuit settlements. The company was almost destroyed economically by these lawsuits and its reputation was dealt a very serious blow.

A cost-benefit/utilitarian analysis can be applied to each of the three main player-groups in this debate, namely consumers, the pharmaceutical industry, and the government. The government's stance as set out in a letter issued by the FDA to the State of Hawaii[53] sets out some of the minuses involved in the importation/re-importation debate:

> Illinois Auditor General found that 40% of inspection forms for pharmacies inspected for the I-Save Rx program were incomplete, and that the State did not monitor whether prescriptions were being filled only by approved pharmacies. Moreover, it found that the State had not adequately monitored the pharmacy benefits manager of the program regarding compliance with provisions of the contract . . . . While FDA works to protect Americans from such potentially unsafe unapproved drugs, we do not have the ability and resources to assure the safety of unapproved imported drugs that claim to be "just as good" as FDA-approved drugs. Consequently, FDA cannot condone any program that encourages Americans to use unapproved and potentially unsafe drugs.[54]

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[53] *See supra* note 36. (The various letters listed there contain virtually identical language.)
[54] Randall D. Lutter, *Hawaii: Governor. Linda Lingle*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Aug. 14, 2008), http://www.fda.gov/Drugs/DrugSafety/ucm179204.htm.

From the government's standpoint, then, the most serious cost associated with an importation program is a decrease in the safety to the consumer.[55] Absent from the government's stated reasoning is the mountain of cash spent on lobbying by the pharmaceutical companies, which might be considered a benefit to elected officials benefiting from such largesse.

For the consumer, the plus, of course, would be a putative decrease in cost, but how beneficial is a fractional savings from the price of a valid drug when the saving is achieved from the purchase of a bogus one? The analysis for the consumer would involve weighing the cost savings against the risk of being defrauded and possibly killed or injured by a fake drug. One might argue that if statistics showed a one-in-four chance of death, one result would be dictated, whereas a one-in-a-million chance might, for many people, dictate another. Are there such statistics? Most of the information is anecdotal, but a consensus seems to be developing that the problem is real and growing.[56] This is an issue that is drawing increasing attention by the media. According to a 2015 story titled, *The Fake Drug Industry Is*

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[55] *Imported Drugs Raise Safety Concerns, supra* note 39 (According to the FDA's report, "Potential Health Risks With Imported Drugs"

Quality assurance concerns. Medications that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product.

Counterfeit potential. Some imported medications--even those that bear the name of a U.S.-approved product--may, in fact, be counterfeit versions that are unsafe or even completely ineffective.

Presence of untested substances. Imported medications and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or contain other dangerous substances.

Risks of unsupervised use. Some medications, whether imported or not, are unsafe when taken without adequate medical supervision. You may need a medical evaluation to ensure that the medication is appropriate for you and your condition. Or, you may require medical checkups to make sure that you are taking the drug properly, it is working for you, and that you are not having unexpected or life-threatening side effects.

Labeling and language issues. The medication's label, including instructions for use and possible side effects, may be in a language you do not understand or may make medical claims and suggest specific uses that have not been adequately evaluated for safety and effectiveness.

Lack of information. An imported medication may lack information that would permit you to be promptly and correctly treated for a dangerous side effect caused by the drug.".

[56] Barbara Moran, *Cracking Down on Counterfeit Drugs*, PBS (Aug. 20, 2013), http://www.pbs.org/wgbh/nova/next/body/uncovering-counterfeit-medicines/ ("Fueled by easy internet sales, global supply routes, and minimal punishments, counterfeit prescription drugs have become an exploding industry, with an estimated market worth $75 billion a year worldwide.").

Exploding, and We Can't Do Anything About It[57]: "Even in wealthier countries like the U.S. and the United Kingdom, where drugs are tested frequently, fakes can slip through, often when patients or clinicians buy them over the Internet. Studies show that about 90 percent of drugs purchased online come from a different country than what the website claims, and Internet pharmacies often buy drugs from countries with lax regulatory systems."[58] The risks associated with imported/reimported drugs are largely unknown,[59] but the severity of the risk can be lethal. Additionally, difficult to quantify is the cost associated with breaking the law. If one is caught there are penalties.[60]

From the standpoint of the pharmaceutical industry there would not seem to be any benefits, only costs, associated with allowing the importation or re-importation of drugs. The only true cost to preventing the practice might be the increased cost associated with lobbying efforts. The benefits would revolve around selling their drugs in a closed system (the U.S.) at higher prices than they can charge elsewhere.

As will be seen in the discussion of principles-based deontology, a person of principle is one who is consistent. If s/he does not believe in stealing, it will not matter if the tempting amount is large or small or if the prospect of getting caught is high or low. Utilitarianism can result in different decisions based on such factors. If one tells someone in a restaurant that he dropped a ten-dollar bill on the floor, s/he did an honest thing, but is s/he honest? Maybe s/he is. If s/he goes into the parking lot and sees a Brinks truck drive away leaving behind a bag of money and s/he throws it in the back of his or her car because no one is around to catch him or her, is s/he an honest person? Utilitarianism can allow for rationalization of bad choices.

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[57] Alexandra Ossola, *The Fake Drug Industry Is Exploding, and We Can't Do Anything About It*, (Sept. 17, 2015, 6:55 AM) http://www.newsweek.com/2015/09/25/fake-drug-industry-exploding-and-we-cant-do-anything-about-it-373088.html.

[58] *Id.* ("The closest protocol now is the Medicrime convention: Since 2011, countries can sign the informal treaty to criminalize pharmaceutical fraud within their borders. But countries aren't under much pressure to pass more formal legislation or to enforce the statutes of the convention. And in fact, they often have incentives not to. Some countries, like India and Brazil, are dragging their feet on international enforcement regulations because poor-quality pharmaceuticals make up such a large part of their economy . . . .").

[59] *Id.* ("Task forces are finding more fake drugs every year. Interpol's flagship pharmaceutical investigation, Operation Pangea, for example, says it seized 2.4 million fake and illicit pills in 2011; in 2015, the total number of pills and other medications that officials seized jumped to 20.7 million.").

[60] *Imported Drugs Raise Safety Concerns, supra* note 39 ("Even though your bag may not be checked, it is against the law not to properly declare imported medications to customs. Failure to declare products could result in penalties.").

D. *Deontological Approaches and the Importance of Intention*

Deontological ethics are based on principles, which can be defined as an accepted or professed rule of conduct. As Sylvester Stallone and other movie heroes have stated: a man has to have a code. If one professes to follow certain accepted principles, but it turns out that s/he does not, s/he opens up himself or herself to charges of hypocrisy. All religions are based on principles. A few people throughout history have been willing to die for their deeply held principles.

Under the various deontological approaches to ethics, intentions matter more than they do in egoism and utilitarianism. Egoists tend to do the right thing for self-serving reasons. Utilitarians tend to do the right thing because the bottom line tells them that the result is a net positive.[61] Under the various deontological approaches, intent to do the right thing because it is the right thing to do is the dominant consideration. Are the intentions of the drug manufacturers, lobbyists, and legislators really focused on preserving individual rights -- the health of the consumers, -- or are: 1) the prescription drug manufacturers concerned about their profits, 2) the lobbyists worried about the profits of their employers, and 3) the legislators more focused on the campaign contributions and perks they receive from the lobbyists and drug manufacturers? Is the Golden Rule at the base of their decision making – protecting consumers as they would want to be protected? Or if the categorical imperative were applied, are they acting in a "manner [that] is suitable to become a universal principle guiding behavior"[62]? The answer to that question would depend on whether they were again doing it to protect the public or for more selfish reasons. What follows are discussions of how several of the major deontological approaches to ethics might address the drug importation/reimportation issue.

E. *The Categorical Imperative and the Golden Rule*

As stated above, the distinction between duty-based and consequences-based ethics is intent. For Immanuel Kant, the basis for a Theory of the Good lies in the intention or the will. Those acts are morally praiseworthy that are done out of a sense of duty rather than for the consequences that are expected (utilitarianism), particularly the consequences to self (egoism). The only

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[61] This is often referred to as the "bottom-line mentality" which is defined as one-dimensional thinking that revolves around securing bottom-line outcomes to the neglect of competing priorities. Rebecca L. Greenbaum, Mary Bardes, & Gabi Eissa, *Bottom-Line Mentality as an Antecedent of Social Undermining and the Moderating Roles of Core Self-Evaluations and Conscientiousness*, 97 J. APPLIED PSYCHOL. 343 (March 2012).

[62] FERRELL ET AL, *supra* note 44, at 161.

thing good about the act is the will, the good will. That will is to do one's duty, which is to act in such a manner that a person would want everyone else to act in a similar manner in similar circumstances towards all other people. Kant expressed this as the Categorical Imperative.[63] Kant differs sharply from the utilitarians in stressing that the essence of morality is to be found in the motive from which an act is done. All such motives are reduced to one: a person is moral when s/he acts from a sense of duty.[64]

The Categorical Imperative is universal and impartial -- universal because all people, in virtue of being rational, would act in precisely the same way, and impartial because their actions are not guided by their own biases, but because they respect the dignity and autonomy of every human being and do not put their own personal ambitions above the respect that others deserve.[65] Applying the categorical imperative to the drug manufacturers would require them to act the same in every country—either spreading out the high cost of research and development over all consumers in all countries or absorbing the costs by reducing their profits. It would not support the reality that many U.S. citizens are not able to afford prescription drugs and go without. Addressing this fact by establishing a drug task force in the House of Representatives, U.S. Representative Lloyd Doggett has urged the National Institute of Health (NIH) and the Health and Human Services Department to issue official guidance on the "march-in" rights of a 1980 law that would allow the breaking of patents on high-priced pharmaceuticals developed with tax payer assistance.[66] Under this law, if the NIH determines that a pharmaceutical developed with federally funded research is not sufficiently available, it could essentially ignore a patent and grant additional licenses for that drug. This effort illustrates the categorical imperative's approach of respecting the rights of every individual to access prescription drugs in the same manner and attempts to neutralize "major pharmaceutical companies . . . giant marketing operations", who, according to Doggett, "have become expert at avoiding taxes and wielding political influence.[67] He is also pressing the NIH, which was created by the

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[63] PHILIP A. PECORINO, MEDICAL ETHICS Ch. 2, Sec. 11 (2002).
[64] RICHARD H. POPKIN & AVRUM STROLL, PHILOSOPHY MADE SIMPLE: A COMPLEE GUIDE TO THE WORLD'S MOST IMPORTANT THINKERS AND THEORIES 37 (Three Rivers Press 2d ed.1993).
[65] Garth Kemerling, *Kant: The Moral Order*, PHILOSOPHY PAGES http://www.philosophypages.com/hy/5i.htm (last modified Nov. 12, 2011).
[66] Bill Lambrecht, *Texas' Doggett leads fight on Soaring Drug Costs*, SAN ANTONIO EXPRESS-NEWS, May 15, 2016, at page #?; 35 U.S.C. § 200-212 (2016) (The Bayh–Dole Act or Patent and Trademark Law Amendments Act, Public Law 96-517, December 12, 1980 is United States legislation dealing with intellectual property that results from federal government-funded research. The Act was sponsored by Senators Birch Bayh and Bob Dole and was adopted in 1980. It is codified at 94 Stat. 3015, and in 35 U.S.C. § 200-212, and is implemented by 37 C.F.R. 401.)
[67] Lambrecht, *supra* note 66.

Affordable Care Act to spend more of its money on studying which drugs work best and then notify consumers of its findings.[68]

Another, and equally famous, formulation of the categorical imperative is the following: "So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as a means only".[69] It is another way of stating such maxims as "Do unto others as you would have them do unto you."[70] It is an injunction to us to respect other people because they are rational human beings like ourselves.[71] Accordingly, in any sort of conflict between people, each person must be counted as being of equal value in the conflict; regardless of that person's history, his/her present social status, or his/her present economic worth, he/she is not to be discriminated against. All must be treated equally with others in the eyes of the law. The government allowing some citizens to access prescription drugs from across the border but not allowing online sales from foreign pharmacies and re-importation of prescription drugs, fails both Kantian ethics and the Golden Rule. The drug companies charging US citizens up to three times more than consumers in other countries also violates these maxims. According to a study from the Kaiser Institute in April 2016, roughly 25% of Americans who take prescription drugs have difficulty paying for them.[72]

What is the function of reason in this issue? The Kantian theory is an interesting and plausible one because it attempts to do justice considering both moral motivation and the search for something objective. To behave morally one must behave consistently, that is, to universalize his or her

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[68] *Id.* ("Doggett is seeking action from the Patient-Centered Outcomes Research Institute, a little-know entity established in the 2010 Affordable Care Act. The nonprofit, funds research projects aimed at producing wise decisions about health care treatments. It receives $500 million yearly from a $2 tax on every health insurance policy on top of $150 million annually from the Treasury.").

[69] IMMANUEL KANT, GROUNDWORK OF THE METAPHYSICS OF MORALS (Yale University Press 2002).

[70] Also known as the Golden Rule, this maxim is the foundation of many religions and has been stated in many ways: (1) "Do to no one what you yourself dislike." *Tobit 4:15; (2)* "Recognize that your neighbor feels as you do, and keep in mind your own dislikes." *Sirach 31:15. (3)* Hillel, an elder contemporary of Jesus of Nazareth, summed up the Torah concisely: "That which is hateful to you, do not do to your fellow. That is the whole Torah; the rest is the explanation; go and learn." *Talmud, Shabbat 31a. (4)* Two New Testament passages quote Jesus: "Do to others what you would want them to do to you." *Matthew* 7:12; *Luke* 6:31. (5) It is also found in the Quran and the sayings of Muhammad: *"Aheb li akheek ma tuhibu li nafsik,"* which is translated as "Wish for your brother, what you wish for yourself" *Suran* 24 or "Love your brother as you love yourself." *Suran* 83.

[71] KANT, *supra* note 69 (According to Kant, the categorical imperative is not equal to the Golden Rule. The Golden Rule's focus is on the self only. It is all about how one person would want other people to act towards him. Kant's Categorical Imperative, in contrast, focuses on all mankind. It is about how all people would wish for all people to act towards everyone, and not just to himself.)

[72] Lambrecht, *supra* note 66.

behavior. The government's discretionary and inconsistent implementation of its ban on gray market prescription drugs through the FDA's "Coverage of Personal Importations" guidelines[73] fails the rationality test of Kant's theory. The inconsistent enforcement/nonenforcement of the law is an illustration of the injustice Kant seeks to avoid. According to Kant, the search for universal laws is central to human morality.

Human reason is principally constituted by the search for universality and necessity. When a patient in Texas travels to Mexico once a year to fill a year's worth of prescription drugs under the FDA's 90-day rule, and a similar patient in Ohio goes without because he lacks proximity to a border, this is immoral. The Categorical Imperative is devised by Kant to provide a formulation by which human reason can be applied to determine the right, or the rational thing to do, which is each person's our duty.

F. *Virtue Ethics*

Virtue Ethics argues that ethical behavior involves not only adhering to conventional moral standards but also considering what a mature person with a 'good' moral character would deem appropriate in a given situation."[74] How would one view the consumer who bends the rules by crossing the border to purchase gray market drugs? Is it appropriate for the law to restrict citizens from purchasing gray market drugs? Is it appropriate that the consumers close to the Canadian border can get those drugs more cheaply when there are people in the heart of the country who cannot access those drugs? Is it appropriate that domestic companies can charge more in the United States than in other countries for their drugs? Is it appropriate that certain people simply cannot afford their medications and do not fill their prescriptions?

G. *Aristotle's Doctrine of the Mean*

Perhaps the U.S. government's approach is best summarized by Aristotle's Doctrine of the Mean: "all things in moderation." The government has attempted to compromise the needs of people to acquire limited amounts of affordable drugs with the needs of those same people, the health care system, and society in general to be safe when consuming prescription drugs.

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[73] *See* FDA REGULATORY PROCEDURES MANUAL, *supra* note 37.
[74] FERRELL ET AL, *supra* note 44, at 164.

H. *The Justice Approach*

Finally, there is the philosophical approach called justice, which "evaluates ethicalness on the basis of fairness.'[75] Under distributive justice[76], are all consumers receiving the same benefits? Is it fair for the law to restrict citizens from purchasing gray market drugs? Is it fair that the consumers close to the Canadian border can get those drugs more cheaply when there are people in the heart of the country who cannot access those drugs? Is it fair that domestic companies can charge more in the United States than in other countries for their drugs, thus burdening U.S. citizens with more of the research and development costs than people in other countries?

IV. CONCLUSION

The current state of affairs in the drug importation/reimportation debate can be viewed as a case of paralysis by analysis. Arguments abound on all sides of the issue. There are virtues associated with all of the parties involved as well as vices. If nothing else this paper should form the basis for an interesting discussion of ethics in the real world.

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[75] *Id.* at 157.

[76] JOHN BOUVIER, A LAW DICTIONARY, (6th ed.1856) ("That virtue, whose object it is to distribute rewards and punishments to every one according to his merits or demerits.").