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2015

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Recommended Citation

29 Notre Dame J.L. Ethics & Pub. Pol'y 375 (2015)

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Cover Page Footnote

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APPLYING LESSONS FROM THE OPIOID ABUSE EPIDEMIC TO PROTECT CONSUMERS FROM GRAY MARKET BIOLOGICS

MICHAEL C. BARNES* & STACEY L. WORTHY**

I. INTRODUCTION

Almost 17,000 people die per year of overdoses involving prescription opioids,¹ controlled substances prescribed to treat pain and addiction. As such, the Centers for Disease Control and Prevention (“CDC”) has deemed prescription drug abuse² a national epidemic.³ In addition to opioids, several other classes of prescription medications have become prone to abuse, including stimulants and benzodiazepines.⁴ As many as twenty percent of college students have used stimulants at some point in their studies for nonmedical use,⁵ and the number of admissions to substance abuse treatment programs for benzodiazepine use nearly tripled between 1998 and 2008.⁶ And in 2011,

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1. Press Release, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, Opioids Drive Continued Increase in Drug Overdose Deaths (Feb. 20, 2013), http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html.

2. “Prescription drug abuse,” as used herein, is “the intentional self-administration of a medication for a nonmedical purpose such as ‘getting high.’” This “includes all degrees of medication use with the intention of experiencing a high, from teens swallowing pills from medicine cabinets to inveterate addicts ‘shooting’ morphine. Abuse and nonmedical use are synonymous for the purpose of this [A]rticle.” CENT. FOR LAWFUL ACCESS & ABUSE DETERRENCE, NATIONAL PRESCRIPTION DRUG ABUSE PREVENTION STRATEGY 7 (2010) [hereinafter NATIONAL STRATEGY].

3. *Policy Impact: Prescription Painkiller Overdoses*, CDC, <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/> (last updated July 2, 2013). The CDC defines “epidemic” as “[t]he occurrence of disease within a specific geographical area or population that is in excess of what is normally expected.” *Glossary*, CDC, <http://www.cdc.gov/vaccines/about/terms/glossary.htm#e> (last updated July 8, 2013).

4. Ryan Jaslow, *New U.S. Drug Survey: Marijuana and Heroin Increasing*, CBS NEWS (Sept. 4, 2013, 4:28 PM), <http://www.cbsnews.com/news/new-us-drug-survey-marijuana-and-heroin-increasing/>.

5. Charles Corra, *Abusing Prescription Adderall Hurts Those with ADHD*, THE DAILY ATHENAEUM (Mar. 24, 2010, 12:00 AM), http://www.thedaonline.com/article_5a527a21-9605-5538-86b8-654b3c047a29.html.

6. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., THE TEDS REPORT: SUBSTANCE ABUSE TREATMENT ADMISSIONS FOR ABUSE OF BENZODIAZEPINES 5 (2011), available at <http://store.samhsa.gov/product/Substance-Abuse-Treatment-Admissions-for-Abuse-of-Benzodiazepines/TEDS11-0602>.

benzodiazepines caused the most prescription drug overdose deaths in Georgia.⁷

To prevent prescription drug abuse, the White House and various US agencies have developed policies,⁸ states have enacted legislation, and both federal and state governments have begun to vigorously enforce controlled substance regulations.⁹ These efforts are beginning to yield results.¹⁰

One approach to reducing controlled substance abuse has been to encourage the development of alternative medications that cannot be abused as easily, including biologics.¹¹ Biologics are pharmaceutical products made through a biological process rather than being chemically synthesized.¹² Although relatively new in comparison to traditional small molecule, chemical drugs, the market for biologics is

7. Press Release, Georgia Bureau of Investigation, Deaths Related to Prescription Drug Overdoses Decline in 2011 (Aug. 14, 2012), <http://gbi.georgia.gov/press-releases/2012-08-14/deaths-related-prescription-drug-overdoses-decline-2011>.

8. Agencies advocating for opioid abuse prevention and treatment include the Office of National Drug Control Policy, the National Institute on Drug Abuse, the U.S. Food and Drug Administration, and the Substance Abuse and Mental Health Services Administration, to name a few. See OFFICE OF NAT'L DRUG CONTROL POLICY, NATIONAL DRUG CONTROL STRATEGY (2013), http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs_2013.pdf; NAT'L INST. ON DRUG ABUSE, PRINCIPLES OF DRUG ADDICTION TREATMENT: A RESEARCH-BASED GUIDE (THIRD EDITION), available at <http://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/principles-effective-treatment>; Press Release, U.S. FOOD & DRUG ADMIN., FDA Approves Abuse-Deterrent Labeling for Reformulated OxyContin (Apr. 16, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm>; *Prevent Prescription Drug Abuse*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., available at <http://www.samhsa.gov/rx/safety> (last updated Sept. 11, 2009).

9. Twenty-two states have statutes and regulations that address prescriber education, and about 73% of those states require education. TRUST FOR AMERICA'S HEALTH, PRESCRIPTION DRUG ABUSE: STRATEGIES TO STOP THE EPIDEMIC (Oct. 2013), available at <http://tfah.org/reports/drugabuse2013/> [hereinafter STRATEGIES TO STOP THE EPIDEMIC].

10. States such as Florida, Kentucky, and Utah have seen a reduction in prescription drug-related overdose deaths. In 2013, Maine pharmacy robberies fell by nearly 80 percent. Moreover, prescription drug abuse has declined among adults ages 18 to 25. Press Release, Fla. Dep't of Law Enforcement, Prescription Drug Deaths Falling Across Florida (Sept. 24, 2013), <http://www.fdle.state.fl.us/Content/News/2013/September/Prescription-drug-deaths-falling-across-Florida.aspx>; *Kentucky Sees Slight Decline in Drug Overdose Deaths, Including Prescription drug Overdose*, NAT'L ASS'N OF BDS. OF PHARMACY (Aug. 7, 2013), <http://www.nabp.net/news/kentucky-sees-slight-decline-in-drug-overdose-deaths-including-prescription-drug-overdose>; UTAH PHARM. DRUG CRIME PROJECT, UTAH PHARMACEUTICAL DRUG ABUSE BRIEF (Feb. 2012), <http://www.useonlyasdirected.org/wp-content/uploads/2014/07/upd.pdf>; *Maine Pharmacy Robberies Fall Nearly 80 Percent*, WCSH6, June 10, 2013, available at <http://host-38.242.54.159.gannett.com/news/article/246527/2/Maine-pharmacy-robberies-fall-nearly-80-percent>; Donna Leinwand Leger, Prescription Drug Abuse Drops Among Young People, USA TODAY (Sept. 25, 2012), available at <http://usatoday30.usatoday.com/news/nation/story/2012-09-25/prescription-drug-use/57838922/1>.

11. CENT. FOR LAWFUL ACCESS & ABUSE DETERRENCE, NATIONAL PRESCRIPTION DRUG ABUSE PREVENTION STRATEGY 2011-2012 UPDATE 16 (2012), http://claad.org/wp-content/uploads/2013/10/CLAAD_Strategy2011_v3.pdf [hereinafter NATIONAL STRATEGY UPDATE].

12. Biologics are pharmaceutical products made with viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, blood components or derivatives, allergenic products,

growing at twice the rate of the market for chemical drugs.¹³ Biologics have been responsible for breakthroughs in treating cancer, multiple sclerosis, rheumatoid arthritis, HIV/AIDS, and many other illnesses and conditions.¹⁴

Biologics are highly sensitive medications that require strict temperature and storage controls, the lack of which could make them ineffective. They must be transported, stored, and handled with care from the point of manufacture until the point of patient administration.¹⁵ And yet, much like opioids, biologics are also commonly diverted from their intended destination and uses, which means these drugs risk being compromised before the patient receives them. For instance, state investigators in Florida found a biologic used to treat cancer in an unimaginable place: an oversized cooler in the back room of a strip club.¹⁶ Although the medication strayed from the closed system of pharmaceutical distribution, undoubtedly, this medication was still intended for resale.

Similarly, between 2004 and 2008 alone, 31 health care practitioners were arrested for knowingly injecting an unapproved substitute of the biologic, botulinum toxin type A—a pharmaceutical approved to treat patients with certain neuromuscular conditions and chronic migraines and also used cosmetically to reduce wrinkles—into nearly 1,000 unknowing patients. The botulinum biologic was purchased from illicit sources and caused paralysis in a least four people.¹⁷ Most of the health care professionals involved misrepresented the product to their patients, causing them to believe they were receiving the US Food and Drug Administration (“FDA”)-approved botulinum toxin type A.¹⁸

In 2012, the FDA found that a total of 76 physicians in 22 states had purchased cancer-treating biologics from unapproved sources

protein, or analogous products that are applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(i) (2012).

13. Tanaz Petigara & Gerard Anderson, *Strategies to Reduce the High Cost of Biologics*, HEALTH POL’Y MONITOR (2008), <http://www.hpm.org/us/b12/3.pdf>. For instance, the FDA’s Center for Drug Evaluation and Research approved 39 new molecular entities in 2012—the largest number in 15 years. See *New Molecular Entity Approvals for 2012*, FDA, www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm336115.htm (last visited Aug. 10, 2013).

14. NAT’L PHYSICIANS BIOLOGICS WORKING GROUP, ALLIANCE FOR PATIENT ACCESS, BIOLOGICS: A DIFFERENT CLASS OF MEDICATIONS THAT MAKE A DIFFERENCE FOR OUR PATIENTS 2 (2011), <http://allianceforpatientaccess.org/120117%20NPBWGWhitePaper.pdf> [hereinafter ALLIANCE FOR PATIENT ACCESS]

15. See *What Are “Biologics” Questions and Answers*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> (last visited Feb. 27, 2014).

16. Thomas T. Kubic, *Beer Cooler Biologics: The Dangers of Counterfeit Drugs*, THE POLICE CHIEF, http://www.policechiefmagazine.org/magazine/index.cfm?fuseaction=display_arch&article_id=1575&issue_id=82008 (last visited Feb. 27, 2014).

17. *FDA Law Enforcers Crack Down on Illegal Botox Scammers*, U.S. FOOD & DRUG ADMIN. (Oct. 2009), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143721.pdf> [hereinafter *FDA Law Enforcers Crack Down*]; Antigone Barton et al., *Some Suspect Faux Botox Paralyzed 4 Patients*, THE PALM BEACH POST, Dec. 1, 2004, at 1A.

18. *Id.*

throughout an illicit distribution chain.¹⁹ According to one oncologist, patients who received the illegally obtained cancer medication instead of the legitimate medication “could have lost several months of their lives.”²⁰

Unfortunately, improper channels of distribution are not uncommon due to the sophistication of the gray market for pharmaceuticals, and for biologics in particular. In contrast to the black market, which deals in medications that start off as counterfeit, the gray market supplies legitimate, legally compliant goods that are made by licensed manufacturers but are distributed by unauthorized dealers or to unauthorized purchasers.²¹ The gray market involves “diversion” of prescription drugs, which is “defined as the transfer of a prescription medication from a lawful to an unlawful channel of distribution or use.”²² Drugs may be diverted to unauthorized distributors or corrupt physicians²³ operating “pill mills”²⁴ or to individuals seeking drugs to sell or abuse.²⁵ In fact, those who traffic controlled substances, such as opioids, often traffic biologics as well in order to increase profits at patients’ expense.²⁶

19. Christopher Weaver & Jeanne Whalen, *How Fake Cancer Drugs Entered U.S.*, Wall St. J. (July 20, 2012, 3:02 PM), <http://online.wsj.com/news/articles/SB10001424052702303879604577410430607090226>.

20. *Id.*

21. William Richardson, *Limiting Counterfeit Goods and Parallel Imports: An Effective Approach*, 2 IN-HOUSE PERSP. 5, 6 (2006).

22. NATIONAL STRATEGY UPDATE, *supra* note 11.

23. As used in this article, the term “physician” includes all licensed prescribers.

24. “A ‘pill mill’ is a [physician’s] office, clinic, or health care facility that routinely colludes in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates [state or federal laws] regarding the prescribing or dispensing of controlled prescription drugs.” *Office of Drug Control’s Definition of a ‘Pill Mill,’* FLA. PDMP FOUND., INC., <http://www.flpmpfoundation.com/documents/Office%20of%20Drug%20Control%20Definition%20of%20a%20Pill%20Mill.pdf>.

25. *United States v. Cabrera*, 284 F. App’x. 674, 685 (11th Cir. 2008); *United States v. Costanzo*, 4 F.3d 658, 660 (8th Cir. 1993). In 2012, a survey showed that most of the opioids used by individuals for nonmedical purposes (80.3%) were diverted from the originally intended recipient.

Among persons aged 12 or older in 2011-2012 who used pain relievers nonmedically in the past year, 54.0 percent got the pain relievers they most recently used from a friend or relative for free Another 10.9 percent bought them from a friend or relative. In addition, 4.0 percent of these nonmedical users in 2011-2012 took pain relievers from a friend or relative without asking. An annual average of 4.3 percent got pain relievers from a drug dealer or other stranger; 1.8 percent got pain relievers from more than one doctor; 0.8 percent stole pain relievers from a doctor’s office, clinic, hospital, or pharmacy (which was higher than the 0.2 percent in 2009-2010); and 0.2 percent bought the pain relievers on the Internet.

Only one in five (19.7 percent) received the medications through a prescription from one doctor. See SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., RESULTS FROM THE 2012 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS Ch. 2 (2013), <http://store.samhsa.gov/product/Results-from-the-2012-National-Survey-on-Drug-Use-and-Health-NSDUH-H-47-Mental-Health-Findings/SMA13-4805> [hereinafter 2012 SURVEY].

26. See Press Release, U.S. Attorney’s Office, Eastern District of Missouri, Local Doctor Pleads Guilty to Making False Statement to Agent (Nov. 6, 2013), http://www.justice.gov/usao/moe/news/2013/november/falconer_erick.html.

Quality is uncertain for gray market products that leave the legitimate supply chain.²⁷ Gray market medications may be expired, diluted, contaminated, tainted due to improper storage conditions, or relabeled with the wrong information.²⁸ And yet, much like the public's misperception that controlled substances are inherently less risky than illicit substances, most health care professionals are misinformed about the safety of gray market biologics. One key distinction between the illicit markets for controlled substances and biologics is that the end users of biologics are typically unwitting participants in the gray market, and, therefore, are unaware of the risks to their health.²⁹

The regulation of pharmaceuticals, including biologics, is fractionated. State law governs distribution, repackaging, dispensing, and returns of pharmaceuticals, often without coordination between states.³⁰ "Drug approval and manufacturing is governed by federal law, often with limited coordination with state activities and underfunding for enforcement,"³¹ leading the FDA to prosecute only the most egregious cases.

Gray market activity exists throughout the entire system of distribution, and involves brokers, wholesalers, importers, repackagers, sales representatives, physicians, and pharmacists. However, health care practitioners and pharmacists are the gatekeepers of both controlled substances and biologics—the last link in the chain of distribution before the medication reaches the patient. They have an obligation to ensure patients are dispensed or administered legitimate medications that are distributed through closed systems designed to ensure patient safety. In doing so, they also protect themselves from civil and criminal liability. Yet, according to a recent survey of purchasing agents and pharmacists at 549 hospitals, 52 percent of all respondents reported purchasing one or more pharmaceutical products from gray market vendors over a two year period,³² many mistakenly believing that such activity is legal.

27. *FDA Conducts Preliminary Review of Agency's Diversion and Counterfeit Criminal Case Information*, U.S. FOOD & DRUG ADMIN., Sept. 2011, <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM272150.pdf> [hereinafter *FDA Conducts Preliminary Review*].

28. *Id.*

29. *Prescription Drug Abuse*, OFFICE OF NAT'L DRUG CONTROL POLICY, <http://www.whitehouse.gov/ondcp/prescription-drug-abuse> (last visited Aug. 14, 2012) ("Some individuals who [abuse] prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist.")

30. Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. 279, 288 (2006).

31. *Id.* See NAT'L ASS'N OF BDS. OF PHARMACY, WHOLESALE DRUG DISTRIBUTION: PROTECTING THE INTEGRITY OF THE NATION'S PRESCRIPTION DRUG SUPPLY 1, 8–9 (AUG. 2013), http://www.nabp.net/system/rich/rich_files/rich_files/000/000/064/original/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf.

32. *Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis*, INST. FOR SAFE MEDICATION PRACTICES (Aug. 25, 2011), <http://www.ismp.org/newsletters/acutecare/showarticle.asp?ID=3> [hereinafter *Gray Market, Black Heart*].

When regulating the dispensing, administering, and reselling of biologics, much like regulating opioids, states are in the best position to deal with potential drug-related health and safety threats, as exemplified by statutes and regulations promulgated to prevent diversion and overprescribing of controlled substances and enforcement thereof.³³ In order to ensure pharmacists and health care practitioners, first, understand legal requirements and harmful repercussions for dispensing and administering gray market biologics and, second, are punished severely enough to deter others from participation in such activities, state lawmakers should look to the education and enforcement systems used in the opioid abuse epidemic as a framework within which to direct their actions. This includes requiring proper prescriber and pharmacist education, investigating suspicious activity, referring intentional wrongdoing to prosecutors, and directing cases of negligence or ignorance to licensing boards. Health care institutes and professionals must ensure compliance by following best practices in risk management. Increasing consumer awareness is also an essential component of reducing the threats associated with gray market biologics.

This Article examines the gray market for biologics, provides a comprehensive analysis of the various federal and state criminal laws that health care practitioners and pharmacists may violate,³⁴ identifies problems with the current legal landscape, and proposes solutions that can be incorporated into the education and enforcement systems used to curb the prescription drug abuse epidemic. This Article may be used as a resource for physicians, pharmacists, and their legal counsel to educate themselves on the criminal liability health care providers may face. It may serve as a valuable source for state policymakers to use in assessing laws and regulations. It may also be useful to prosecutors and law enforcement in investigations.

Part I of this article provides a summary of the prescription drug abuse epidemic, the nature of biologics, and why the gray market for biologics exists. Part II provides an analysis of the most common criminal causes of action brought under federal and state law when physicians and pharmacists divert pharmaceuticals to the gray market. Finally, based on the prescription drug abuse model, Part III will suggest steps that can be taken to hold gray market participants accountable and improve the safety and welfare of patients who may otherwise unknowingly be dispensed or administered harmful or ineffective diverted biologic medications.³⁵

33. Jason Kane, *Drug Prices Soar as Hospital Suppliers Are Forced into 'Gray Market'*, PBS NEWSHOUR (Aug. 29, 2011, 5:18 PM), <http://www.pbs.org/newshour/rundown/2011/08/drug-prices-soar-as-pharmacists-are-forced-into-gray-market.html> (noting that the FDA's Office of Criminal Investigations looks into complaints about blatant safety concerns in the gray market but the agency defers to the states to do the bulk of regulation).

34. Although manufacturers and distributors may also be bad actors within the gray market distribution chain, this article does not focus on them.

35. See *infra* Part III.

II. OVERVIEW OF OPIOID ABUSE AND THE GRAY MARKET FOR BIOLOGICS

This section describes the prescription drug abuse epidemic and biologics, and provides an overview of biologics. It explains how the gray market for biologics operates, including the various ways in which biologics commonly travel through illicit channels and reasons for the existence of the gray market for biologics.

A. *The Prescription Opioid Epidemic*

Opioids can be useful in treating both pain and addiction when used as prescribed.³⁶ When opioids and other medications are used in ways that are not as prescribed, abuse occurs.³⁷ Recent data indicates that over 1.9 million people begin abusing opioids every year.³⁸ Public perception sees prescription medications as inherently safer than illicit substances,³⁹ and yet, in 2009, nearly 4.6 million emergency room visits were drug related, approximately 2.1 million of which involved misuse or abuse of pharmaceuticals.⁴⁰ In 2010, 16,651 overdose deaths involved opioid medications.⁴¹ Opioid “diversion occurs at every point in the drug supply chain,” including at the distribution and retail levels through theft, illicit online pharmacies, and pill mills.⁴² Some drug abusers acquire prescription medications through illicit channels, while others obtain prescriptions directly from prescribers.⁴³ Although at the fringe, some physicians operate pill mills, acting as little more than drug dealers.⁴⁴ The rapid increase in opioid deaths directly correlates to the increase in opioid pain medication sales, and it is clear that the

36. NAT'L SAFETY COUNCIL, *PRESCRIPTION NATION: ADDRESSING AMERICA'S PRESCRIPTION DRUG ABUSE EPIDEMIC* (2013), http://www.nsc.org/safety_home/PrescriptionDrugOverdoses/Documents/Prescription%20Nation%20Report.pdf [hereinafter *PRESCRIPTION NATION*].

37. Misuse is distinguishable from abuse. Abuse, as defined above, is “the intentional self-administration of a medication for a nonmedical purpose such as ‘getting high.’” In contrast, misuse is “the use of medication for a medical purpose other than as directed or indicated, whether willful or unintentional, and whether harm results or not. Misusing medications includes behaviors such as self-medicating without a prescription, using the medication for another indication than that for which it was prescribed, and increasing the dose of a prescribed medication.” In this Article, “abuse” includes “misuse.” See also *NATIONAL STRATEGY*, *supra* note 2.

38. 2012 SURVEY, *supra* note 25.

39. *Prescription Drug Abuse*, *supra* note 29 (“Some individuals who [abuse] prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist.”).

40. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *THE DAWN REPORT: HIGHLIGHTS OF THE 2009 DRUG ABUSE WARNING NETWORK (DAWN) FINDINGS ON DRUG-RELATED EMERGENCY DEPARTMENT VISITS* (2010), <http://www.oas.samhsa.gov/2k10/DAWN034/EDHighlights.htm>.

41. Press Release, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 1.

42. Laura A. Stokowski, *Drug Diversion in the United States*, *MEDSCAPE NEUROLOGY*, Mar. 31, 2008, <http://www.medscape.com/viewarticle/572103>.

43. Michael C. Barnes & Stacey L. Sklaver, *Active Verification and Vigilance: A Method to Avoid Civil and Criminal Liability When Prescribing Controlled Substances*, 15 *DEPAUL J. HEALTH CARE L.* 93, 95 (2013).

44. *Id.*

increase in the availability of opioids parallels an increase in addiction and overdose deaths.⁴⁵

To prevent diversion and resultant overdose deaths, the federal Controlled Substances Act (“CSA”) was promulgated in 1970,⁴⁶ and states have promulgated their own state controlled substances acts.⁴⁷ Authority to regulate the flow of medicine through interstate commerce falls under the federal purview while the authority to regulate intrastate commerce and the practice of medicine falls under state purview.⁴⁸ The CSA imposes duties on the entities along the closed system of controlled substance distribution related to the products’ manufacture, labeling and packaging, transportation, prescribing, sale, and disposal, and allows the US Drug Enforcement Administration (“DEA”) and state law enforcement to investigate and criminally prosecute those who improperly prescribe.⁴⁹ At the same time, states have broad authority under their police powers to regulate professional practice, and have traditionally regulated both the practices of medicine and pharmacy.⁵⁰ While differences between state laws and regulations may contribute to the national epidemic,⁵¹ state leadership and action have also resulted in signs of improvement over the past few years.⁵² In fact, a government report showed that prescription drug abuse decreased in ten states from 2010 to 2011 and did not increase in any state that year.⁵³ Strategies employed to reduce prescription opioid diversion may also be used to reduce diversion of biologics, as described herein.

B. Overview of Biologics

Biologics are made up of large, complex cells and living organisms, in contrast to traditional, small molecule chemical drugs, which have

45. PRESCRIPTION NATION, *supra* note 36, at 5.

46. 21 U.S.C. §§ 801–971 (2011).

47. Barnes & Sklaver, *supra* note 43 at 96.

48. Michael C. Barnes & Gretchen Arndt, *The Best of Both Worlds: Applying Federal Commerce and State Policy Powers to Reduce Prescription Drug Abuse*, 16 J. HEALTH CARE L. & POL’Y 271, 280 (2013).

49. 21 C.F.R. § 1301.71(a); *Practitioner’s Manual, An Informational Outline of the Controlled Substances Act*, U.S. DRUG ENFORCEMENT ADMIN., OFFICE OF DIVERSION CONTROL (2006) <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html> (last visited Feb. 17, 2014).

50. *See, e.g.*, Barnes & Arndt, *supra* note 48, at 273 (noting that both the federal government and the states regulate prescription drugs concurrently). For example, courts have recognized that federal law does not restrict the ability of a physician to prescribe a legal drug for any purpose, regardless of whether the FDA has approved the drug for that specific use. *See* Wash. Legal Found. v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000) (approving of “off-label” prescriptions).

51. PRESCRIPTION NATION, *supra* note 36.

52. *Prescription Drug Abuse Decreasing in Some States*, DRUGFREE.ORG (Jan. 9, 2013), <http://www.drugfree.org/join-together/prescription-drugs/prescription-drug-abuse-decreasing-in-some-states>.

53. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., THE NATIONAL SURVEY ON DRUG USE & HEALTH REPORT: STATE ESTIMATES OF NONMEDICAL USE OF PRESCRIPTION PAIN RELIEVERS (2013), <http://www.samhsa.gov/data/2k12/NSDUH115/sr115-nonmedical-use-pain-relievers.htm>.

well-defined chemical structures.⁵⁴ Biologics are manufactured using a complex process,⁵⁵ making it almost impossible to reproduce identical copies.⁵⁶ The process of creating biologics is important to the medication's efficacy, and therefore, any minor change to the manufacturing process can significantly alter the biologic and its effectiveness in the body.⁵⁷ After biologics leave the manufacturer, they must remain in their approved containers, be maintained according to precise handling processes, be stored within a specific temperature range, and be used before the expiration date.⁵⁸ Otherwise, the drug product may lose efficacy or potency, "which can lead to interruptions in treatment protocol, adverse events, or failure to relieve patient symptoms."⁵⁹ Such problems not only impact the individual's health but can become a widespread public health issue, particularly when vaccines are involved.⁶⁰

C. Overview of The Gray Market

In the proper closed system of distribution, biologics manufacturers typically sell their products to wholesale distributors, and wholesale distributors then sell to pharmacies, hospitals, or authorized practitioners pursuant to the Food, Drug and Cosmetics Act ("FDCA").⁶¹ The

54. *How do Drugs and Biologics Differ?*, BIOTECHNOLOGY INDUS. ORG. (NOV. 10, 2010), <http://www.bio.org/articles/how-do-drugs-and-biologics-differ>; ALLIANCE FOR PATIENT ACCESS, *supra* note 14. Biologics may be composed of sugars, proteins, nucleic acids, or other living entities, although many of the most commonly used biologics are proteins. *What Are "Biologics" Questions and Answers*, *supra* note 15; AM. SOC'Y FOR CANCER ACTION NETWORK, UNDERSTANDING BIOLOGIC MEDICINES FROM THE CANCER PATIENT PERSPECTIVE 17 (2013) [hereinafter UNDERSTANDING BIOLOGIC MEDICINES].

55. Often times, the process invokes a recombinant technique, which involves the "insertion of select genes into cell lines grown in cultures to manufacture molecules with specific qualities." Once the molecules are isolated, they are used as the active ingredients in the biological drug. UNDERSTANDING BIOLOGIC MEDICINES, *supra* note 54, at 6–7.

56. Bryan A. Liang, *Regulating Follow-On Biologics*, 44 HARV. J. ON LEGIS. 363, 369–70 (2007) (noting that whereas biologics are composed of "thousands to millions of atoms [that] form[] . . . an interconnected group of hundreds [and even] thousands of amino acids aggregated into chains and subgroups," chemical drugs usually consist of only dozens of atoms that form a single molecule). See also Press Release, U.S. FOOD & DRUG ADMIN., U.S. FDA Considerations: Discussion by National Regulatory Authorities with World Health Organization (WHO) on Possible International Non-proprietary Name (INN) Policies for Biosimilars (Sept. 1, 2006), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm375086.htm> (finding that biologics from different manufacturers may not be interchangeable because "[d]ifferent large protein products, with similar molecular composition may behave differently in people and substitution of one for another may result in serious health outcomes . . .").

57. *How do Drugs and Biologics Differ?*, *supra* note 54.

58. *Majority of Physicians Concerned about Risks to Patients from Heat Damaged Products*, BUSINESS WIRE (June 22, 2010), <http://www.businesswire.com/news/home/20100622005537/en/Majority-Physicians-Concerned-Risks-Patients-Heat-Damaged#.Uw9XwldW4J>.

59. *Id.*

60. *Id.*

61. See 21 U.S.C. § 353(e)(3)(B) (2012) (defining the term wholesale distribution). Approximately 90% of pharmaceutical sales involve direct transactions from large wholesale distributors to pharmacies or practitioners. Liang, *supra* note 30, at 287. It should be noted that smaller hospitals or pharmacies tend to use secondary distributors because

pharmacy, hospital, or practitioner will then dispense or administer the biologic to the patient. In some cases, the manufacturer delivers the biologic directly to licensed health care professionals without using a distributor.⁶² The limited number of transactions in the traditional supply chain ensures that biologics pass through as few hands as possible in order to maintain the products' safety and integrity.

In contrast, biologics in a gray market chain deviate from the closed system of distribution and enter a longer process, in which they are often sold multiple times between middlemen before they are ultimately dispensed to a patient.⁶³ The complexity of this drug supply chain presents an array of opportunities for the drugs to be contaminated, expire, spoil, or lose their efficacy.⁶⁴ Moreover, the gray market creates greater opportunity for counterfeit biologics to enter the marketplace.⁶⁵ Given that the same dishonest parties who operate on the gray market also operate on the black market, counterfeit medications and legitimate gray market medications are often combined and sold together in the same lot.

There is no certainty that a biologic from the gray market is safe or is what it is purported to be, especially because biologics are particularly easy to mimic or dilute.⁶⁶ Many injectable biologics come in the form of clear fluids in traditional vials.⁶⁷ A counterfeit biologic can be a diluted version of the drug or even mere saline with no active ingredient.⁶⁸ In some cases, active ingredients have been replaced with potentially harmful ones, including powdered cement, toxic yellow road paint, floor wax, boric acid, or antifreeze, in hopes of making counterfeit chemical drugs appear more realistic.⁶⁹ Yet, unlike buying an imitation Rolex watch at a street kiosk, consumers who purchase pharmaceutical drugs rarely have any indication that their medications

they lack the purchasing power to buy directly from major distributors. Kane, *supra* note 33.

62. See *Allergan's Botox – Botulinum Toxin Type A – Not the Cause of Botulism in Florida Patients*, BUSINESS WIRE (Dec. 13, 2004, 9:01 AM), <http://www.businesswire.com/news/home/20041213005370/en/Allergans-BOTOX—Botulinum-Toxin-Type—#VEGrefnF9dM> (stating that “Allergan only ships BOTOX(R) and BOTOX(R) Cosmetic on dry ice directly to the licensed health care professional . . .”).

63. *Id.*

64. *Securing Our Nation's Prescription Drug Supply Chain: Hearing Before the House Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. 12 (2013) (statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration).

65. Liang, *supra* note 30, at 287.

66. See, e.g., Wyatt Yankus, *Counterfeit Drugs: Coming to a Pharmacy Near You*, THE AM. COUNCIL ON SCI. & HEALTH 8 (Aug. 2006), http://www.acsh.org/wp-content/uploads/2012/04/200608171_counterfeitdrugw.pdf (discussing the FDA's inability to verify the safety of re-imported drugs because they lie outside of the regulated supply chain); *Internet Drug Outlet Identification Program Updated Progress Report: April 2012 – Re-issued May 14, 2012*, NAT'L ASS'N OF BDS. OF PHARMACY 6 (May 14, 2012), <http://www.nabp.net/news/assets/IDOIRreportApril11.pdf>; Liang, *supra* note 56, at 379.

67. Liang, *supra* note 56, at 379.

68. *Bad Medicine*, 25 NATURE BIOTECHNOLOGY 707, 708 (2007); see Liang, *supra* note 56, at 379 (discussing opportunities for diversion).

69. Liang, *supra* note 30, at 284.

are imitations because such drugs are dispensed in legitimate pharmacies and medical settings.

When the stability of active ingredients in a biologic is threatened, the patient taking such a drug may incur an adverse immune response.⁷⁰ However, rather than worry about harm to the end consumer, participants in the gray market are typically more focused on profits.⁷¹ On average, gray market medications cost 650% more than the initial price by the time the medication reaches the end user.⁷² Bad actors exploit shortages for complex, life-saving biologics, such as those used for oncology, cardiology, and critical care, by hoarding such medications and selling them on the gray market.⁷³ Purchasing agents are then placed in difficult ethical situations where they must choose between going without vital medications or purchasing medications at high prices with no guarantee of their safety and efficacy.⁷⁴ Another reason that the gray market for biologics exists is the high costs of such pharmaceuticals that can stem from complex manufacturing

70. In a phenomenon known as immunogenicity, the immune system may begin to create its own anti-bodies that fight off the biologic that it deems as foreign, similarly to how it fights a virus like the flu. This response is typically absent in traditional, chemical drugs because their small molecule size typically goes undetected by the immune system. As a result of the “foreign” biologic, subsequent administrations of the drug become ineffective and in severe instances cause anaphylactic shock and death. The timing of the immune response may vary and multiple administrations of the biologic may occur prior to the presence of physical evidence, making it difficult to establish whether the reaction is due to the biologic, human variation, or the progression of the individual’s disease. UNDERSTANDING BIOLOGIC MEDICINES, *supra* note 54, at 15.

71. KATHERINE EBAN, DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA’S DRUG SUPPLY 2 (2005); *see also* PEW HEALTH GROUP, AFTER HEPARIN: PROTECTING CONSUMERS FROM THE RISKS OF SUBSTANDARD AND COUNTERFEIT DRUGS, 15 (Jul. 12, 2011), <http://www.pewtrusts.org/en/research-and-analysis/reports/2011/07/12/after-heparin-protecting-consumers-from-the-risks-of-substandard-and-counterfeit-drugs> (noting that “the return on counterfeit prescription drugs may be 10 times greater than that of the sale of illegal narcotics”).

72. SEN. COMM. ON COMMERCE, SCIENCE, & TRANSPOR., SHINING LIGHT ON THE “GRAY MARKET” AN EXAMINATION OF WHY HOSPITALS ARE FORCED TO PAY EXORBITANT PRICES FOR PRESCRIPTION DRUGS FACING CRITICAL SHORTAGES 5 (July 25, 2012) [hereinafter SHINING LIGHT ON THE “GRAY MARKET”].

73. *Mitigating Risks To The Supply Chain After A Drug Shortage Occurs*, RX-360 SUPPLY CHAIN SECURITY DRUG SHORTAGE WORKING GROUP 3 (May 3, 2013), <http://www.rx-360.org/LinkClick.aspx?fileticket=wHdILXf0DXA%3d&tabid=246>; Justin Schuster, *America’s Drug Problem*, THE POLITIC: THE YALE UNDERGRADUATE J. (Feb. 11, 2013). Causes of shortages include increased demand, corporate delays in manufacturing or shipping, quality issues that mandate a recall or stop in production, distribution disruptions, production changes, unavailability of component materials, new indications, decisions to discontinue the product, or natural disasters. *CBER-Regulated Products: Possible Causes of Shortage*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/Safety-Availability/Shortages/ucm351909.htm> (last updated Aug. 9, 2013).

74. *See Gray Market, Black Heart*, *supra* note 32 (noting that many prescription drug purchasers feel pressured by physicians and hospital administrators to purchase gray market drugs, despite costs and safety concerns). Biologics that are essential to treating critically ill patients are often marked up even higher than other types of pharmaceuticals in the gray market. Extreme examples include a 4,533% mark-up on the cardiology drug Labetalol and a 3,980% mark-up on the oncology drug Cytarabine. COLEEN CHERICI ET AL., BUYER BEWARE: DRUG SHORTAGES AND THE GRAY MARKET 2 (2011), <http://www.chcablog.com/wp-content/uploads/2011/08/Gray-Market-Analysis-David-Edit.pdf>.

processes⁷⁵ and extensive research and development.⁷⁶ In fact, biologics may cost up to twenty two times more than traditional chemical drugs.⁷⁷

Some entities throughout the system of distribution lack the knowledge to realize that their actions are illegal or could result in danger to the patients. They may act with altruistic intentions, such as trying to save patients money or obtain life-saving medications in short supply. Others participate in willful wrongdoing. These criminals exploit ignorance about the law and harmful effects of gray market biologics, furthering their unlawful aim. Furthermore, as is the case with opioids, criminals use many methods to obtain legitimate biologics and divert them to illicit uses. This section discusses some of those methods.

1. Resale of Biologics Intended for Nonprofits and Foreign Markets

Pursuant to the Robinson-Patman Act, both biologic and chemical pharmaceutical manufacturers may maintain a bifurcated pricing structure.⁷⁸ Manufacturers may offer a standard market price to wholesale distributors who resell the drugs to the majority of buyers in the United States.⁷⁹ They may also offer a second, deeply discounted price to distributors who resell to nonprofit organizations, such as charitable hospitals and pharmacies, and to US exporters who obtain drugs manufactured in the United States and resell them abroad.⁸⁰ Drugs intended for foreign markets may be sold at lower rates than their US market versions, especially those foreign markets subject to government-imposed price controls.

To comply with the Robinson-Patman Act, nonprofits may only buy deeply discounted drugs if such drugs are exclusively for the nonprofits' internal use.⁸¹ Similarly, US exporters may only accept the discounted rate if they export the drug out of the United States to sell to

75. See Jeanne Yang, *A Pathway to Follow-On Biologics*, 3 HASTINGS SCI. & TECH. L.J. 217, 223 (2011) (noting that compared with chemical medications, which require forty to fifty laboratory tests during manufacturing, scientists creating biologics must undertake 250 or more tests).

76. See PHARM. RESEARCHERS & MFRS. OF AM., 2013 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE 32 (July 2013), <http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf> (confirming that the average cost of creating a new biologic is \$1.2 billion and typically takes ten to fifteen years from the initial discovery).

77. See Hilary Kramer, *Why Biologics Remain Expensive*, FORBES (Dec. 4, 2009), <http://www.forbes.com/2009/12/03/kramer-health-care-intelligent-investing-pharmaceuticals.html> (noting the lack of generic alternatives to biologics as one of the reasons for its high cost for consumers). For example, the chemical drug to treat rheumatoid arthritis costs approximately \$300 per year, but the biologic, which treats the same condition, costs approximately \$26,000 per year. Julie D. Polovina, *Mutant Biologics: The 2010 Health-Reform Legislation's Potential Impact on Reducing Biologic Research and Development Costs*, 100 GEO. L.J. 2291, 2296 (2012).

78. Robinson-Patman Act, 15 U.S.C. §§ 13–13(c) (2012); *United States v. Weinstein*, 762 F.2d 1522, 1527 (11th Cir. 1985).

79. *Weinstein*, 762 F.2d at 1527.

80. *Id.*

81. 15 U.S.C. § 13c (2012).

the intended country abroad.⁸² Such drugs may not be reimported back into the United States for domestic sale.⁸³ The same is true for distributors who purchase drugs intended for foreign markets from manufacturers located abroad.⁸⁴

Yet, incentivized by the prospect of profit and sometimes under the guise of greater fairness by lowering costs to consumers, gray market distributors often seek to purchase biologics in short supply back from willing nonprofit organizations, exporters, and foreign distributors at discounted rates to then resell them in the US market at a higher cost.⁸⁵ This arrangement allows gray market participants to purchase prescription drugs at relatively low cost and then divert them to third-party purchasers to which credible, initial wholesalers may not normally sell.⁸⁶

2. Pharmacies

A 2012 congressional report studying 300 drug distribution chains found that more than two-thirds of gray market pharmaceuticals were diverted from pharmacies.⁸⁷ Instead of dispensing the drugs according to professional duties, state laws, and the expectations of their trading partners, these pharmacies resold the drugs to gray market wholesalers.⁸⁸ In fact, some pharmacies sold their entire inventories into the gray market, operating for the sole purpose of acquiring and selling short-supply drugs.⁸⁹

Internet pharmacies are particularly problematic. A recent study showed that nearly 97% of online pharmacies are not in compliance with US pharmacy laws and practice standards,⁹⁰ and in June 2013, the FDA took action against 9,600 illegal internet pharmacy websites, including seizing offending websites and over forty million dollars worth of illegal medications worldwide.⁹¹ Many online pharmacies obtain both counterfeit and gray market medications from distributors and resell the drugs below the US market value for legitimate medica-

82. 21 U.S.C. § 381(e) (2012).

83. See *infra* Part III.

84. See 21 U.S.C. §§ 352–353, 355 (2012). Any drug that is not approved for use in the United States by the FDA may not be imported into the United States; therefore, drugs intended for other countries violate these provisions. See also *infra* Part II.A.

85. *Weinstein*, 762 F.2d at 1527; SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 72, at 18–20.

86. Schuster, *supra* note 73. Courts have held that this type of action is fraud. See *infra* Part II.B for further discussion.

87. SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 72, at 16.

88. *Id.*

89. *Id.* at 17.

90. *For the Media*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/ucm294170.htm> (last updated Sept. 24, 2013).

91. Press Release, FDA Takes Action to Protect Consumers from Dangerous Medicines Sold by Illegal Online Pharmacies (June 27, 2013), <http://www.fda.gov/news-events/newsroom/pressannouncements/ucm358794.htm>.

tions emanating from the proper closed system of distribution.⁹² Many of the drugs sold on these sites are counterfeit, expired, stolen, diluted, improperly stored, or impure, or they contain the wrong concentration.⁹³

3. Samples, Theft, and Buy-Backs

Manufacturers are permitted to distribute sample biologics to pharmacists and physicians as long as the drugs contain labels stating that they are not intended for sale.⁹⁴ However, in some instances, manufacturers or distributors provide samples to pharmacists or physicians, who will then sell the samples to gray market participants at market price.⁹⁵ Additionally, criminal entities sometimes steal biologics from manufacturers, distributors, or pharmacies and sell them to willing gray market purchasers.⁹⁶ Others may purchase medications from consumers who bought the medications for personal use or physicians who have an extra supply.

4. Practitioners Who “Have No Other Choice”

Practitioners who treat their patients with medications in short supply are sometimes placed in an ethical conundrum in which they must choose between having no supply of a drug or purchasing the drug at an exorbitant price from the gray market.⁹⁷ According to a recent survey, forty-two acute care hospitals reported receiving a total of 1,745 gray market solicitations from eighteen recorded gray market vendors in just two weeks alone, and all of the solicitations involved drugs that were back-ordered or unavailable through traditional distribution channels.⁹⁸ While some hospitals and practitioners maintain policies that require them to buy drugs only through their regularly trusted networks, others have decided to buy drugs from gray market participants because they feel they have no other choice.⁹⁹

III. FEDERAL LAW GOVERNING THE GRAY MARKET

Despite a common misperception in the health care industry that gray market activity is legal, pharmacists and physicians may be prosecuted under various federal laws for their participation in the gray mar-

92. See *Internet Drug Sales: Hearing Before the H.R. Comm. on Gov't Reform*, 108th Cong. (Mar. 18, 2004) (statement of William K. Hubbard, Assoc. Comm'r for Policy and Planning and Legis., FDA).

93. *Deceptive Practices by Illegal Online Drug Sellers Give Consumers a False Sense of Legitimacy and Safety*, Reports NABP, NAT'L ASS'N OF BDS. OF PHARMACY (July 26, 2013), <http://www.nabp.net/news/deceptive-practices-by-illegal-online-drug-sellers-give-consumers-a-false-sense-of-legitimacy-and-safety-reports-nabp> [hereinafter *Deceptive Practices*].

94. 21 U.S.C. § 353(c)(1) (2012).

95. *FDA Conducts Preliminary Review*, *supra* note 27.

96. Schuster, *supra* note 73.

97. SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 72, at 5.

98. CHERICI, *supra* note 74, at 2.

99. *Id.*

ket.¹⁰⁰ This section discusses some of the criminal causes of action that may be brought against a gray market participant and also evaluates their effectiveness. While some of the cases discussed herein deal with distributors rather than pharmacists or physicians, and discuss chemical drugs rather than biologics, the same legal doctrines apply to pharmacists and physicians who dispense or administer biologics.

A. *Unapproved New and Misbranded Drugs Under the FDCA*

Under the FDCA, the FDA regulates the integrity of pharmaceuticals intended for the US market throughout the supply chain, including approval, production, distribution, and advertising of prescription drugs.¹⁰¹ The FDA aims to prevent “unsafe, ineffective, subpotent, superpotent, or adulterated drugs from reaching pharmacies and patients in the United States—whether introduced on purpose or inadvertently.”¹⁰² Virtually all gray market drugs violate the FDCA because they are either unapproved new drugs or misbranded.¹⁰³ Biologics may be classified as “drugs,” based on their mode of action¹⁰⁴ and intended use, and as such, the FDCA drug provisions apply to these biologics.¹⁰⁵

1. Unapproved New Drugs

Pursuant to section 355 of the FDCA, “No person shall introduce or deliver for introduction into interstate commerce *any new drug*, unless” the FDA has approved the drug.¹⁰⁶ This includes pharmacists and physicians.¹⁰⁷ A “new drug” is defined as follows:

- (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ;
or
- (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effective-

100. Brokers, manufacturers, wholesalers, importers, repackagers, sales representatives, pharmacists, physicians, other practitioners, consumers, and any other individuals or entities who participate in gray market activity may be prosecuted under various federal and state laws; however, this article will focus solely on pharmacists and physicians.

101. SUSAN THAUL, CONG. RESEARCH SERV., R43106, PHARM. SUPPLY CHAIN SEC. 3 (June 12, 2013), *available at* http://www.rx-360.org/LinkClick.aspx?fileticket=2MO1dO9_xU0%3D&tabid=355.

102. *Id.*

103. 21 U.S.C. §§ 352–353, 355 (2012); *see* 42 U.S.C. § 262(j) (2006).

104. “Mode of Action” is defined as the means by which a product achieves its intended therapeutic effect or action. Definition of Primary Mode of Action of a Combination Product, 70 Fed. Reg. 29848, 49850 (Aug. 25, 2005).

105. *United States v. Gallant Pharma Int’l, Inc.*, Indictment, Criminal No. 1:13CR130, at *2 (E.D. Va. Mar. 27, 2013).

106. 21 U.S.C. §§ 355(a), 331(d) (2012) (emphasis added); *United States v. 1500 90-Tablet Bottles*, 384 F. Supp. 2d 1205, 1214 (N.D. Ill. 2005).

107. *United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981).

ness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.¹⁰⁸

Before a new biologic drug may be introduced into interstate commerce in the United States, a drug manufacturer must obtain FDA approval of that drug by submitting a Biologic License Application (“BLA”) or other relevant application.¹⁰⁹ The BLA must contain certain information, including:

- (A) [F]ull reports of investigations which have been made to show whether or not such drug is safe . . . ;
- (B) [A] full list of the articles used as components of such drug;
- (C) [A] full statement of the composition of such drug;
- (D) [A] full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug;
- (E) [S]amples of such drug . . . ; [and]
- (F) [S]pecimens of the labeling proposed to be used for such drug.¹¹⁰

The FDA also requires BLAs to include detailed information regarding the specific facilities that manufacture and process the new drug.¹¹¹ Upon receipt of a BLA, the FDA reviews the application and decides whether or not to approve it.¹¹² If a drug deviates from any of the characteristics in the approved BLA, it is considered an unapproved new drug and may not be offered for sale in the United States.¹¹³ This is because the FDA does not have the opportunity to review the unapproved new drug product before it is marketed to ensure the combination of ingredients is safe and effective, that the labeling contains adequate dosing information and appropriate warnings and precautions, and that it was produced, packaged, and handled in safe and proper conditions.¹¹⁴ The new drug approval process reflects “a Congressional view that the way in which drugs are mixed and packaged is

108. 21 U.S.C. § 321(p) (2012).

109. 21 U.S.C. § 355 (2012); 42 U.S.C. § 262(a) (2006); *United States v. Genendo Pharm.*, 485 F.3d 958, 960 (7th Cir. 2007). Drug manufacturers may also submit a new drug application (“NDA”) for new small molecule drugs, an abbreviated new drug application (“ANDA”) for generic small molecule drugs, or a 505(b)(2) application for generic small molecule medications or follow-on biologics. *Id.*; 21 U.S.C. § 355(j) (2012).

110. 21 U.S.C. § 355(b)(1) (2012).

111. 21 C.F.R. § 314.50(d) (2013).

112. 21 U.S.C. § 355(b)(1); *United States v. 1500 90-Tablet Bottles*, 384 F. Supp. 2d 1205, 1214 (N.D. Ill. 2005).

113. 21 U.S.C. § 321(p)(1); *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1208.

114. Unapproved and Misbranded Oral and Injectable Drugs Labeled for Prescription Use Containing Codeine Sulfate, Codeine Phosphate, or Dihydrocodeine Bitartrate, 79 Fed. Reg. 1879 (Jan. 10, 2014) (notice).

no less important than the chemical makeup of the drugs.’”¹¹⁵ Therefore, it is not enough that a medication intended for use abroad and the US-approved version share the same chemical makeup.¹¹⁶ To be introduced into interstate commerce under the cover of an FDA-approved BLA, the drugs must comply with all requirements of that BLA.¹¹⁷

In many cases, biologics that are manufactured and packaged for sale outside of the United States are not manufactured or packaged in a facility that is FDA-approved.¹¹⁸ Moreover, even if a manufacturer produces the FDA-approved biologic and an identical biologic intended for foreign markets, the version produced for foreign markets usually does not meet all of the FDA requirements in the approved BLA.¹¹⁹

In *United States v. Genendo Pharmaceutical*, a pharmaceutical distributor located in Curacao, Netherlands Antilles, attempted to import into the United States a version of a prescription drug, atorvastatin, that was intended for sale in other countries.¹²⁰ It was undisputed that the seized atorvastatin had the same chemical composition, as well as other similarities to FDA-approved atorvastatin.¹²¹ However, the FDA-approved new drug application (“NDA”)¹²² for atorvastatin required that the medication: (1) be manufactured at a specific facility in Ireland; (2) be packaged at specific facilities in Germany or Puerto Rico; (3) be packed in 100-tablet boxes containing ten blister cards of ten tablets each; (4) be labeled in English; and (5) have a two-year expiration period.¹²³ Yet, although the medication was produced by the same manufacturer in Ireland, it was packaged at a facility in Brazil rather than an FDA-approved facility in Germany or Puerto Rico.¹²⁴ Moreover, it was packaged in boxes containing thirty tablets each and labeled in Portuguese rather than English.¹²⁵ Finally, the drug had a three-year expiration period rather than the approved two-year expiration period.¹²⁶

115. *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1215 (quoting *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1411 (7th Cir. 1990)).

116. *Id.*

117. *Id.*

118. Often, even if a manufacturer makes a drug intended for a foreign market that is identical to the FDA-approved drug intended for the U.S. market, the manufacturer will still produce and package that drug in a separate facility from the one used for the identical U.S. drug to ensure that it meets best practices as established by the FDA and to distinguish the FDA-approved drug from the non-FDA-approved drug.

119. See 21 U.S.C. § 355 (2012); Liang, *supra* note 30, at 308–10.

120. *United States v. Genendo Pharm.*, 485 F.3d 958, 960 (7th Cir. 2007).

121. *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1207. This case was an action by the government for the seizure and condemnation of the drugs that Genendo attempted to import. It took place prior to the criminal case against Genendo but involves the same lot of prescription drugs.

122. A “new drug application” is the application used to obtain FDA approval for new, small molecule drugs.

123. *Genendo Pharm.*, 485 F.3d at 961.

124. *Id.*

125. *Id.*

126. *Id.*

Genendo argued that the deviations from the NDA-approved requirements were permissible under an FDCA exemption because the drugs were being shipped to an FDA-authorized repackager. The FDCA exemption allows deviations from the FDA-approved labeling and packaging requirements while they are in transit to a repackager if, among other things, the repackager and the distributor have a written agreement that ensures the ultimate drugs will not be adulterated or misbranded.¹²⁷ Genendo had a written agreement with the repackager to this effect.¹²⁸ However, the exception applies to drugs that can be brought into compliance, such as drugs that lack a label that the repackager needs to add. However, the deviations from the approved NDA could never be rectified at repackaging because this lot of atorvastatin was packaged at an unapproved facility in Brazil.¹²⁹ The court ruled that the drugs were new drugs under the FDCA and could not be introduced into US interstate commerce.

Similarly, a pharmacist or a physician who introduces a gray market biologic containing any deviation from the biologic's BLA into the gray market, either by reselling it or through any other means, violates the FDCA.

2. Misbranded Drugs

Under the FDCA, a biologic is misbranded if, among other things, information on the label is false or misleading, the label lacks information required by the FDA-approved BLA or otherwise required under the FDCA, or certain information is not prominently placed on the label.¹³⁰ Required information includes facts regarding the manufacturer, packer, distributor, proprietary name, directions for use, warning, packaging, and precautions about deterioration.¹³¹ The biologic is also misbranded if it is placed in a misleading container or packaging, or is offered for sale under a misleading name or the name of another drug.¹³²

The FDCA prohibits introducing into, delivering into, and receiving in interstate commerce a misbranded biologic or causing the misbranding of a biologic.¹³³ It also prohibits the misbranding of a biologic while it is held for sale after shipment in interstate commerce.¹³⁴ Given that the flow of commerce begins with the manufacturer of the biologic and ends with the patient, nearly anyone involved in the distribution of biologics, including a pharmacist or physician who holds the drug for use in his practice, may be held liable for deal-

127. *Id.*

128. *Id.*

129. *Id.* at 964.

130. 21 U.S.C. § 352 (2012).

131. 21 U.S.C. § 352(a)-(h).

132. 21 U.S.C. § 352.

133. 21 U.S.C. § 331(a)-(c) (2012).

134. 21 U.S.C. § 331(k).

ing in a misbranded product, even if someone else caused the misbranding in the first place.¹³⁵

The FDA often prosecutes physicians and pharmacists for selling, administering, or dispensing misbranded pharmaceuticals, particularly when patient safety is at issue. Misbranding is a misdemeanor with a sentence of imprisonment of not more than one year, a fine of not more than \$1,000, or both.¹³⁶ However, if the person misbrands with the intent to defraud or mislead, then such act is a felony, carrying a sentence of imprisonment for not more than three years, a fine of not more than \$10,000, or both, and debarment.¹³⁷ A conviction of such act requires “knowledge of the misbranding and proof of specific intent to mislead or defraud connected to the misbranding violation.”¹³⁸ This can be proved, for instance, if forgery or falsification of any part of the packaging material occurs.¹³⁹ Moreover, ramifications for purchasing misbranded drugs with the intent to defraud or mislead extend beyond criminal prosecutions.¹⁴⁰ Purchasing physicians and pharmacists face harm to their professional reputations, possibility of losing their licenses, and potential lawsuits by patients.¹⁴¹ Civil lawsuits can be devastating considering that many, if not most, insurance carriers only provide malpractice coverage for medications bought in the United States, so such physicians cannot rely on insurance to protect them if they purchase an imported or reimported gray market drug.¹⁴²

Moreover, a physician may be found guilty of introducing misbranded drugs with intent to defraud even if he had altruistic intentions. For instance, in 2008, Dr. Vinod Chandrashekm Patwardhan, a

135. *United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981). The FDCA defines the circumstances in which a product is placed in interstate commerce to include “(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.” 21 U.S.C. § 321(b). It is very rare that a pharmaceutical product on the market is not “in interstate commerce” under the law while it travels through the distribution chain. *See Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded*, U.S. FOOD & DRUG ADMIN. (Feb. 9, 2006), <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074248.htm>.

136. 21 U.S.C. § 333(a)(1) (2012).

137. 21 U.S.C. § 333(a)(2). If the FDA “debars” an individual, the individual is prohibited from providing services in any capacity to a person that has an approved or pending drug product application. “Services in any capacity” means any services provided to the drug applicant, regardless of whether related to drug regulations. That means that a debarred individual may not provide non-drug-related services to a drug product applicant (*e.g.*, as a landscaper, accountant, etc.) without violating debarment. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SUBMITTING DEBARMENT CERTIFICATION STATEMENTS 4 (1998).

138. *United States v. Mitcheltree*, 940 F.2d 1329, 1351 (10th Cir. 1991).

139. *See United States v. Milstein*, 401 F.3d 53, 64 (2d Cir. 2005).

140. 21 U.S.C. § 335a(a)(2) (2012); Yvonne M. McKenzie & Colleen C. Kelly, *Misbranded Drugs—A Danger to Physicians and Patients*, LAW360 (Oct. 17, 2013, 4:01 PM), <http://www.law360.com/articles/480500/misbranded-drugs-a-danger-to-physicians-and-patients>.

141. McKenzie & Kelly, *supra* note 140.

142. Robert Aicher, *Off-Shore Injectables Remain Illegal* (May 13, 2013) (unpublished article) (on file with author) (citing *Meza v. S. Cal. Physicians Ins. Exch.*, 62 Cal. Rptr. 2d 91, 92 (Ct. App. 1998)).

California-licensed physician, was convicted of introducing misbranded drugs into interstate commerce with the intent to defraud or mislead, among other things, when he brought pharmaceuticals into the United States from India and Honduras and administered them to his patients.¹⁴³ Dr. Patwardhan frequently treated indigent clients “without much regard for reimbursement.”¹⁴⁴ However, when his practice fell into financial difficulty, he had to change his reimbursement policies.¹⁴⁵ On a trip to India, he learned that cancer medications were far less expensive there, so he began to purchase them at an Indian pharmacy and bring them back to the United States, where he administered them to his patients who could not afford to pay.¹⁴⁶

However, Dr. Patwardhan never informed his patients that the drugs were not FDA-approved. He told his staff not to give patients foreign medications for at-home use after a patient’s mother expressed concern about one label, which was written in Hindi.¹⁴⁷ On appeal, the court found that his actions did not fall under either of the exceptions to the misbranding statute and upheld his conviction.¹⁴⁸

Despite the fact that the judge found it “impossible” to view Dr. Patwardhan’s crime as “one that was motivated by greed” and also found Dr. Patwardhan “extraordinar[ily] unlikely to commit another crime,” Dr. Patwardhan received a sentence of nine months in-home detention followed by five years of probation, a \$10,000 fine, a \$600 assessment, and \$1,313,634 in restitution.¹⁴⁹ In addition, he was prohibited from participating in Medicare, Medicaid, and all federal health care programs for a period of 12 years.¹⁵⁰ However, the state licensing judge did not revoke Dr. Patwardhan’s license to practice based on his “misguided altruism.” This shows a flaw in the system because, even if Dr. Patwardhan acted in good faith, he still placed his patients at risk by providing them with medications that may not be safe or effective. In balancing “misguided altruism” against the risk Dr. Patwardhan’s conduct posed to patients, the scale tips in favor of severely punishing Dr. Patwardhan, including revoking his medical license, so as to deter other physicians from engaging in similar behavior.

Dr. William R. Kincaid, a Tennessee physician and president of a local cancer and blood center, was also charged with receiving misbranded drugs in interstate commerce with intent to defraud or mis-

143. Press Release, U.S. Immigration & Customs Enforcement, Southern California Doctor Charged with Bringing Misbranded Foreign Cancer Drugs into the United States (Aug. 15, 2008), <http://www.ice.gov/news/releases/0808/080815losangeles.htm>.

144. *Patwardhan v. Inspector Gen.*, Docket No. C-11-615, at *4 (HHS Dep’t of Appeals Bd. Dec. 8, 2011).

145. *Id.*

146. *Id.*

147. *United States v. Patwardhan*, 422 F. App’x. 614, 616–17 (9th Cir. 2011).

148. *Id.* at 616.

149. *Patwardhan v. Inspector Gen.*, at *4.

150. Vinod Chandrashekhhar Patwardhan, M.D., Final Decision on Review of Admin. Law Judge Decision, Docket No. A-12-41, Decision No. 2454 (Dept. of HHS Apr. 10, 2012).

lead.¹⁵¹ Dr. Kincaid purchased a misbranded version of bevacizumab, a biologic used to treat cancer, from a Canadian company that obtained the biologics from foreign sources that were not inspected or approved by the FDA.¹⁵² The drugs were improperly labeled, were sold by distributors who were not registered with the FDA, and were intended for distribution in Turkey, India, the European Union, and elsewhere.¹⁵³ The drugs' labels were in foreign languages, did not provide dosage information, and did not express the potency of the drugs in a standard format.¹⁵⁴ After a nurse questioned the medications for bearing labels in foreign languages, Dr. Kincaid had the misbranded drugs shipped to a storage facility where he mingled them with FDA-approved drugs from legitimate sources to avoid further suspicion.¹⁵⁵ The cancer medication requires strict temperature conditions, the lack of which could render it ineffective.¹⁵⁶ However, Dr. Kincaid administered the misbranded biologics to his patients without their knowledge and without any assurance that all storage requirements were met, thereby placing patients' health and safety at risk in order to increase profits. Dr. Kincaid was sentenced to serve 24 months in a federal prison and a \$10,000 fine.¹⁵⁷ As a result of his conviction, he also lost his medical license, his practice, and his reputation.¹⁵⁸

Similarly, Dr. Chad Livdahl and his wife and business partner, Dr. Zahra Karim, were among 29 physicians who were indicted for selling unapproved botulinum toxin type A, which caused paralysis in four patients.¹⁵⁹ The four victims were hospitalized for severe botulism poisoning, a result uncommon with the FDA-approved botulinum toxin type A.¹⁶⁰ Dr. Livdahl and Dr. Karim, owners of Toxin Research International in Tucson, Arizona, sold unapproved botulinum toxin type A to more than 200 physicians throughout the United States who administered the biologic to their patients.¹⁶¹ Karim and Livdahl obtained the drugs from a California laboratory that attempted to mimic the FDA-approved version of the biologic.¹⁶² They promoted the product as a

151. Plea Agreement at 1, *United States v. Kincaid*, 2:12-cr-00116 (E.D. Tenn. Nov. 15, 2012).

152. *Id.* at 4.

153. *Id.*

154. *Id.* (citing 21 C.F.R. §§ 201.56, 610.61(n), (r)).

155. *Id.*

156. *Id.*

157. Press Release, U.S. Att'y's Office E. Dist. of Tenn., Johnson City Physician Sentenced to Serve Two Years in Prison for Violations Related to Unapproved Foreign Drugs (June 11, 2013), <http://www.fbi.gov/knoxville/press-releases/2013/johnson-city-physician-sentenced-to-serve-two-years-in-prison-for-violations-related-to-unapproved-foreign-drugs>.

158. Nate Morabito, *Dr. Kincaid Begs Judge for Mercy, Congressman and Sheriff Write Letters on His Behalf*, WSAV (May 31, 2013), <http://www.wsav.com/story/22467984/dr-kincaid-begs-judge-for-mercy-congressman-and-sheriff-write-letters-on-his-behalf>.

159. *FDA Law Enforcers Crack Down*, *supra* note 17; Christopher Weaver, *Illicit Botox Sparks Alert*, THE WALL ST. J. (Dec. 23, 2012), <http://online.wsj.com/news/articles/SB10001424127887324731304578193990868029934>.

160. *FDA Law Enforcers Crack Down*, *supra* note 17.

161. *Id.*

162. *United States v. Livdahl*, 356 F. Supp. 2d 1289, 1292 (S.D. Fla. 2005).

cheap alternative to the brand-name botulinum toxin type A at workshops they conducted, at booths they set up at aesthetic and medical conventions, at training sessions, and in e-mail and fax communications.¹⁶³ The defendants argued that the drug's packaging stated "For Research Purposes Only; Not for Human Use," but the court found that the disclaimer was an attempt to avoid FDA detection and regulation when, in fact, the defendants intended for the product to be used on humans.¹⁶⁴ As a result, they were indicted for misbranding a drug by introducing it into interstate commerce, among other things.¹⁶⁵ Dr. Livdahl was sentenced to nine years in prison, restitution of \$345,567, forfeiture of \$882,565, and surrender of his medical license.¹⁶⁶ Dr. Karim received a similar sentence with shorter prison time.¹⁶⁷

B. *The Prescription Drug Marketing Act of 1987*

In 1987, Congress enacted the Prescription Drug Marketing Act of 1987¹⁶⁸ ("PDMA") as an amendment to the FDCA "to protect American consumers from mislabeled, subpotent, adulterated,¹⁶⁹ expired, or counterfeit pharmaceuticals, which are being dispensed under existing law and practice, and to restore competitive balance in the marketplace."¹⁷⁰ While the PDMA focuses mainly on the actions of wholesale distributors, it is important that pharmacists and physicians understand these requirements for wholesale distributors so they can more easily spot a gray market biologic.¹⁷¹

The PDMA explicitly prohibits exported prescription drugs from being reimported back into the United States for sale.¹⁷² Therefore, physicians and pharmacists should be aware of labels that indicate a

163. *Id.* at 1291–92.

164. *Id.* at 1291.

165. *Id.* at 1290; *FDA Law Enforcers Crack Down*, *supra* note 17.

166. *FDA Law Enforcers Crack Down*, *supra* note 17; *Disciplinary Action: Naturopathic Physicians Medical Board*, STATE OF ARIZ. NATUROPATHIC PHYSICIANS MED. BD. (Mar. 23, 2012), available at <https://nd.az.gov/sites/default/files/documents/files/Disciplinary%20Actions.pdf>.

167. *FDA Law Enforcers Crack Down*, *supra* note 17.

168. Pub. L. No. 100-293, 102 Stat. 95 (1988).

169. An adulterated drug is one that is decomposed; prepared, packed, or held in insanitary conditions where it may have been contaminated; its container is composed of any poisonous substance that may render it hazardous to health; its strength, quality, or purity differs from that which is approved under its BLA; or it is mixed or substituted with another substance to reduce its quality or strength, among other things. 21 U.S.C. § 351 (2012).

170. *RxUSA Wholesale v. Dep't of Health & Human Servs.*, 467 F. Supp. 2d 285, 290 (E.D.N.Y. 2006) (citing H.R. REP. NO. 100-76, at 17 (1987)) (internal quotation mark omitted).

171. See Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t), 333(b), 353(c)–(e), 381(d) (2012); 21 C.F.R. pts. 203 & 205 (2013).

172. 21 U.S.C. § 381(d)(3). The only exception is if the drugs are sent to the initial owner or consignee of the drug for further processing and will then be exported again. Please note that prescription drugs containing insulin that are manufactured in the United States and then exported from being reimported back into the country may not be reimported back into the U.S. even if they are processed and re-exported unless such drugs are necessary for emergency medical care. 21 U.S.C. §§ 381(d)(1)–(2).

biologic is intended for a foreign market. However, the federal government has not strictly enforced this prohibition due to a lack of resources to patrol the millions of drug shipments that enter the United States each year. This is a major problem in gray market enforcement.¹⁷³

Additionally, the PDMA prohibits pharmacists or physicians within charitable organizations, such as hospitals or other “health care entities”¹⁷⁴ from offering, selling, purchasing, or trading any prescription drugs that are obtained at a reduced rate due to their nonprofit status under the Robinson Patman Act, except in limited circumstances.¹⁷⁵ This statute does not prohibit hospitals or health care entities from selling, purchasing, or trading a medication for emergency medical reasons, which is often used as the justification to purchase gray market medications in short supply.¹⁷⁶ Yet, pharmacists and physicians may be held liable under other legal doctrines for purchasing, administering, or dispensing gray market pharmaceuticals, such as the misbranding regulations, so it is unwise to rely on this exception.

The PDMA also prohibits anyone from knowingly selling, purchasing, or trading, or offering to sell, purchase, or trade a prescription drug sample.¹⁷⁷ Although the PDMA allows charitable institutions to receive sample drug donations for dispensing to patients of the charitable institution, the sample medication must be in its original, unopened

173. *Prescription Drug Re-Importation Question and Answer Sheet*, AARP, http://assets.aarp.org/www.aarp.org/_articles/international/ReimportationQA.pdf (last visited Aug. 11, 2013). Agents from Customs and Border Protection (“CBP”), a division of the U.S. Department of Homeland Security, are responsible for inspecting incoming drug packages and notifying the FDA. FDA investigators noted that there are only 16.9 full time FDA employees responsible for covering all packages in international mail facilities in the United States to search for incoming gray market drugs. PEW HEALTH GROUP, *supra* note 71; HHS TASK FORCE ON DRUG IMPORTATION, REPORT ON PRESCRIPTION DRUG IMPORTATION 56 (Dec. 2004), <http://archive.hhs.gov/importtaskforce/Report1220.pdf>.

174. A health care entity is defined as any person that provides diagnostic, medical, surgical, or dental treatment or chronic or rehabilitative care, but does not include any pharmacy or wholesale distributor. 21 C.F.R. § 203.3(q).

175. 21 C.F.R. § 203.20. A charitable organization is defined as a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted nonprofit status under section 501(c)(3) of the Internal Revenue Code. 21 C.F.R. § 203.3(f). This regulation also prohibits solicitations made by gray market distributors to hospitals, health care entities, and nonprofits. 21 C.F.R. § 203.20. The limited circumstances for which the prohibition does not apply can be found in 21 C.F.R. § 203.22 and 21 C.F.R. § 203.23.

176. 21 C.F.R. § 203.22. *See also* 21 C.F.R. § 203.3(m). Emergency medical reasons include, but are not limited to, transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and fire fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage; but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures.

177. 21 U.S.C. § 353(c)(1) (2012).

packaging with its label intact, and inspected by a licensed health care practitioner or state-registered pharmacist to confirm that the drug is not adulterated or misbranded.¹⁷⁸ If the drug does not meet the packaging and labeling requirements, the recipient of the sample must not dispense it to patients and must dispose of the drug by destroying it or returning it to the manufacturer.¹⁷⁹ Violations of this provision are punishable by up to ten years imprisonment.¹⁸⁰ Physicians and pharmacists should be careful to check the label on medications to ensure they are not intended as samples.

The PDMA requires all drug distributors to be licensed by the state from which the drugs are to be shipped, and such state licensing systems must meet federal regulations on minimum requirements for drug storage and security, and for the treatment of returned, damaged, and outdated prescription drugs.¹⁸¹ Many gray market distributors avoid the licensing process altogether to increase the likelihood that they can engage in illegal activities without scrutiny from state authorities. Pharmacists and physicians should only purchase biologics from state-licensed distributors.

C. Drug Quality and Security Act

The federal Drug Quality and Security Act (“DQSA”), enacted on November 27, 2013, established standards to facilitate tracing of drug products through the pharmaceutical supply chain, including requiring that all pharmaceuticals have product identifiers¹⁸² and documentation of the entire transaction history from the manufacturer to the health care practitioner or pharmacist dispensing or administering the medication.¹⁸³ Therefore, when the DQSA goes into effect on January 1, 2015, pharmacists and physicians should not accept biologics lacking product identifiers or without proper documentation.¹⁸⁴ Moreover, the DQSA requires that wholesale distributors operating in states without licensure requirements obtain a license from the Department of Health and Human Services (“HHS”). Consequently, there is no reason to accept a biologic from an unlicensed distributor with these rules in place.

178. 21 C.F.R. §§ 203.39(a), (c) (2012).

179. 21 C.F.R. § 203.39(d).

180. 21 U.S.C. § 333(b)(1)(B) (2012); U.S. DEP’T OF JUSTICE, UNITED STATES ATTORNEYS’ MANUAL § 113 (1997), http://www.justice.gov/usao/eousa/foia_reading_room/usam/title4/civ00113.htm.

181. 21 U.S.C. § 353(e)(2)(A); 21 C.F.R. §§ 205.4, 205.5, 205.50; U.S. FOOD & DRUG ADMIN., PRESCRIPTION DRUG MARKETING ACT OF 1998: CHAPTER 2 FDA AUTHORITY, REGULATORY PROCEDURES MANUAL § 2-2-27 (July 2012), <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074340.pdf>.

182. “The term ‘product identifier’ means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.” 21 U.S.C. § 360eee(14) (2012).

183. See 21 U.S.C. §§ 582(b)–(e) (2012).

184. *Id.*

D. Health Care Fraud

The federal criminal health care fraud statute, which is part of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), prohibits,

[K]nowingly and willfully execut[ing], or attempt[ing] to execute, a scheme . . . to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services¹⁸⁵

This statute covers fraud upon private payers and public insurers, such as Medicaid, Medicare, and other state-funded health programs.¹⁸⁶

Government-funded health care programs, such as Medicare and Medicaid, as well as most state-funded health care programs, do not cover non-FDA-approved new drugs or misbranded drugs.¹⁸⁷ Physicians and health care providers must submit claims for reimbursement for administered or dispensed drugs that represent that such drugs were FDA-approved drugs.¹⁸⁸ If a physician submits such a form for a non-FDA-approved new or misbranded drug to a Medicare or Medicaid program and certifies that such drug is an FDA-approved drug, he is making a false statement. Moreover, if he obtains the drug at a discounted price and submits a claim for the FDA-approved drug, which sells at a higher price, he is using fraudulent pretenses to obtain money from a health care benefit program in connection with the delivery of, or payment for, health care benefits, items, or services.

In *United States v. Shrum*,¹⁸⁹ Dr. Kelly Dean Shrum, a physician licensed to practice in Arkansas, was convicted of health care fraud. Dr. Shrum purchased non-FDA-approved intrauterine devices (“IUDs”) from purported Canadian internet pharmacies at deeply discounted prices, administered such devices to patients, and billed the Arkansas Medicaid Program for the FDA-approved version, making a profit in reimbursements.¹⁹⁰ The claims he submitted to the Arkansas Medicaid Program included false representations.¹⁹¹ Therefore, the court found that he knowingly and willfully executed a scheme to defraud the Arkansas Medicaid Program and obtained, by means of fraudulent pretenses and representations, money under the custody and control of

185. 18 U.S.C. § 1347(a) (2012).

186. ROBERT FABRIKANT & PAMELA H. BUCY, HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE § 3.02[12A] (2013).

187. 42 U.S.C. §§ 1396r-8(k)(2)–(3), (6) (2012); 42 U.S.C. § 1395w-102(e)(4)(A)(ii) (2012); *United States ex rel. Palmieri v. Alparma, Inc.*, 928 F. Supp. 2d 840, 843 (D. Md. 2013).

188. Plea Agreement at 4, *United States v. Kincaid*, 2:12-cr-00116 (E.D. Tenn. Nov. 15, 2012).

189. *United States v. Shrum*, No. 4:09cr00295-01 JMM, 2011 WL 4903082 *1 (E.D. Ark. Oct. 3, 2011).

190. *Id.* at *2, 6.

191. *Id.* at *6.

the Arkansas Medicaid Program in connection with the delivery of or payment for health care benefits, items, or services.¹⁹² As a result, he was ordered to forfeit \$75,000 of proceeds from the health care fraud.¹⁹³ Additionally, the FDA permanently debarred him from providing medical services to patients in any capacity with prescription drugs.¹⁹⁴

Similarly, Dr. Isabella Martire, a Maryland-licensed physician, was charged with introducing a misbranded drug into interstate commerce and health care fraud because she administered cancer drugs that were manufactured in the United Kingdom and intended for distribution in Turkey, but billed US government health care programs for the FDA-approved drug.¹⁹⁵ Dr. Martire sought reimbursement from Medicare, Medicaid, Tricare, federal employee health benefit plans, and private health insurers for the cost of the drugs, making a profit of at least \$790,600.¹⁹⁶ Dr. Martire was forced to repay \$514,000 to government health care programs.¹⁹⁷

E. *Other Charges*

In addition to charges under the FDCA, the PDMA, and the health care fraud statute, physicians and pharmacists who participate in the gray market may be criminally charged with conspiracy; bank, mail, or wire fraud; and false statements.

1. Conspiracy

It is a federal offense for two or more persons to conspire either to commit any offense against the United States or to defraud the United States, or any agency thereof, in any manner or for any purpose.¹⁹⁸ The penalty for such act is a maximum fine of \$250,000, a maximum prison sentence of five years, or both.¹⁹⁹ In *Hammerschmidt v. United States*, the Supreme Court defined “defraud” as follows:

To conspire to defraud the United States means primarily to cheat the Government out of property or money, but it also means to interfere with or obstruct one of its lawful governmental functions

192. *Id.*

193. Press Release, U.S. Dep’t of Justice, E. Dist. of Ark., Pine Bluff Doctor Convicted of Misbranding and Health Care Fraud, (Nov. 17, 2010), http://www.justice.gov/usao/arc/news/2010/November/shrumguilty_HCF_111710.pdf.

194. Kelly Dean Schrum: Debarment Order, 77 Fed. Reg. 51030, 51031 (Aug. 23, 2012) (Order).

195. STATE OF MD, ANNUAL REPORT OF THE MEDICAID FRAUD CONTROL UNIT AND OFFICE OF THE INSPECTOR GENERAL, 8 (2012), [http://dlslibrary.state.md.us/publications/Exec/DHMH/HG2-611\(a\)_2012.pdf](http://dlslibrary.state.md.us/publications/Exec/DHMH/HG2-611(a)_2012.pdf); Press Release, U.S. FOOD & DRUG ADMIN. Office of Criminal Investigations, Laurel Oncologist Pleads Guilty to Purchasing Misbranded Drugs, (Aug. 8, 2011), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm267356.htm>.

196. Press Release, U.S. FOOD & DRUG ADMIN. Office of Criminal Investigations, *supra* note 195.

197. *Id.*

198. 18 U.S.C. § 371 (2012).

199. *Id.*

by deceit, craft or trickery, or at least by means that are dishonest. It is not necessary that the Government shall be subjected to property or pecuniary loss by the fraud, but only that its legitimate official action and purpose shall be defeated by misrepresentation, chicane or the overreaching of those charged with carrying out the governmental intention.²⁰⁰

Therefore, proof that the United States has been defrauded under this section does not require any showing of monetary or proprietary loss.²⁰¹ If the defendant and others have engaged in dishonest practices in connection with a program administered by an agency of the government, it constitutes a fraud on the United States.²⁰²

The element of intent is met if the defendant possesses the intent (a) to defraud, (b) to make false statements or representations to the government or its agencies in order to obtain property of the government, or (c) that the defendant performed acts or made statements that he knew to be false, fraudulent or deceitful to a government agency, which disrupted the function of the agency or of the government.²⁰³ The government is not required to prove the statements ultimately resulted in any actual loss to the government of any property or funds, only that the defendant's activities impeded or interfered with legitimate governmental functions.²⁰⁴

In *United States v. Gallant Pharma International, Inc.*, the defendants were charged with conspiracy, among other things.²⁰⁵ The defendants included Gallant Pharma International, an unlicensed distribution company located in Virginia, and all of Gallant's employees, which included two directors, four sales representatives, and two office managers, as well as a physician who purchased misbranded biologics from Gallant.²⁰⁶ Gallant held itself out as a Canadian company but obtained botulinum toxin type A, cancer biologics, and other prescription drugs from Switzerland, Turkey, and the United Arab Emirates, selling the misbranded drugs in the United States.²⁰⁷

Defendant Anoushirvan Sarraf, a Virginia-licensed physician, allowed the other defendants to (1) lease office space within his medical practice, (2) ship the misbranded drugs to Dr. Sarraf's office, and (3) ship the misbranded drugs to physicians, medical practices, and

200. *Hammerschmidt v. United States*, 265 U.S. 182, 188 (1924).

201. *United States v. Conover*, 772 F.2d 765, 770 (11th Cir. 1985).

202. *United States v. Gallup*, 812 F.2d 1271, 1276 (10th Cir. 1987).

203. *See United States v. Puerto*, 730 F.2d 627 (11th Cir. 1984); *United States v. Tuohey*, 867 F.2d 534 (9th Cir. 1989); *United States v. Sprecher*, 783 F. Supp. 133, 156 (S.D.N.Y. 1992).

204. *See Sprecher*, 783 F. Supp. at 156.

205. *United States v. Gallant Pharma Int'l, Inc.*, Indictment, Criminal No. 1:13-CR-130, at *1 (E.D. Va. Mar. 27, 2013). Other charges included importation contrary to law, introduction of misbranded drugs, unlicensed medical wholesaling, wire fraud, and monetary transactions with criminally derived proceeds. *Id.*

206. *Id.* at *1, 7-9.

207. *Id.* at *1, 5.

hospitals throughout the country from his office.²⁰⁸ Dr. Sarraf also purchased drugs from Gallant to administer to his patients.

The other defendants sent solicitations advertising brand-name drugs at deeply discounted prices, an example of which is in Figure 2 below, but they actually sold and delivered misbranded medications.²⁰⁹ The court found that the defendants conspired to: (a) fraudulently and knowingly import misbranded drugs into the U.S. in violation of the FDCA; (b) engage in wholesale distribution without a Virginia license; (c) introduce misbranded drugs into interstate commerce with the intent to defraud; (d) knowingly and with the intent to defraud, devise a scheme and artifice to defraud, and obtain money and property by false or fraudulent pretenses, and transmit wire communications in interstate and foreign commerce; and (e) defraud the United States by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public.²¹⁰ As a result, all but two of the defendants were indicted and pleaded guilty, and sentencing is still pending as of March 2014.²¹¹ They could face the following sentences based on their convictions:²¹²

Importation contrary to law	Maximum of 20 years
Wire fraud	Maximum of 20 years
Monetary transactions with criminally derived proceeds	Maximum of 10 years
Defraud of the FDA	Maximum of 5 years
Introduction of misbranded drugs into interstate commerce	Maximum of 3 years
Unlicensed medical wholesaling	Maximum of 3 years

On May 7, 2014, the two defendants who did not plead guilty, Anoushirvan Sarraf and Eva Pritchard, were convicted by a federal jury on charges of conspiracy related to their roles in the diversion scheme.²¹³

Therefore, physicians and pharmacists should be skeptical of solicitations offering medications below market price and contact manufacturers when doubts arise as to distributor or product legitimacy.

208. *Id.* at *12.

209. *Id.* at *14.

210. *Id.* at *10–11.

211. *Id.* at *1.

212. Press Release, U.S. Att’y’s Office, Eastern District of Virginia, Eleven Charged in Alleged Illegal Pharmacological Import and Distribution Scheme, (Aug. 7, 2013), *available at* <http://www.justice.gov/usao/vae/news/2013/08/20130807hudanr.html>.

213. Press Release, U.S. Dep’t of Justice, Aphrodite Advanced Esthetic & Skin Care Clinic Received Illegal Imports For Gallant Pharma, Which Sold Over \$10 Million Of Non-FDA-Approved Chemotherapy And Cosmetic Drugs In The U.S., (May 7, 2014), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm397123.htm>.

2. Bank, Mail, and Wire Fraud

Bank fraud, which is a federal offense against the United States, occurs if an individual “knowingly executes or attempts to execute a scheme . . . to defraud a financial institution[] or to obtain any of the money[], funds, credits, assets, . . . or other property owned by the bank by means of false or fraudulent pretenses”²¹⁴ The sentence for bank fraud is a maximum fine of \$1,000,000, a maximum prison sentence of 30 years, or both.²¹⁵

Mail fraud, which is a federal offense against the United States, occurs if an individual devises or intends to devise a scheme to defraud or obtain money or property by means of false or fraudulent pretenses, representations, or promises by utilizing the mail.²¹⁶ The sentence for such an act is a maximum fine of \$250,000, a maximum of 20 years imprisonment, or both.²¹⁷

Wire fraud, which is a federal offense against the United States, occurs if an individual devises or intends “to devise a scheme to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises,” and “transmits or causes to be transmitted by means of wire . . . in interstate . . . commerce, any writings . . . for the purpose of executing such scheme”²¹⁸ The sentence for such an act is a maximum fine of \$1,000,000, imprisonment of not more than 30 years, or both.²¹⁹ Charges of conspiracy, and bank, mail, and wire fraud are common as a result of gray market schemes due to the multiple parties involved and transactions entailing payment in exchange for shipment of goods.

For instance, pharmacist Andrew J. Strempler was charged with both conspiracy to commit mail fraud and wire fraud, for actually committing mail fraud and wire fraud, and for selling misbranded pharmaceuticals from his Canadian pharmacy, RxNorth. RxNorth was an internet, mail, and telephone order pharmacy that sold to residents of the United States.²²⁰ Although the FDA warned Strempler that sales of drugs were illegal in the United States unless the drugs were FDA-approved,²²¹ Strempler continued to sell the drugs in the United States, falsely representing that RxNorth was selling safe medications in compliance with US regulations. In reality, Strempler obtained the drugs from other countries without properly ensuring safety or authenticity, filled prescriptions for US consumers in the Bahamas, and then had the packages shipped to the United States.²²²

214. 18 U.S.C. § 1344 (2012).

215. *Id.*

216. 18 U.S.C. § 1341 (2012).

217. *Id.*

218. 18 U.S.C. § 1343 (2012).

219. *Id.*

220. Press Release, U.S. FOOD & DRUG ADMIN. Office of Criminal Investigations, Internet Pharmacy Owner Charged in \$95 Million Fraud Scheme (June 14, 2012), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm309438.htm>.

221. *Id.*

222. *Id.*

3. False Statements

Under the federal false statements statute, individuals are prohibited from knowingly and willfully making material false statements on matters within the jurisdiction of the executive, legislative, or judicial branch of the federal government.²²³ A matter is considered “material” if “it has a natural tendency to influence, or is capable of influencing, the decision of the [individual or entity] to [whom] it [is] addressed.”²²⁴ A matter is “within the jurisdiction of” a federal entity “when it has the power to exercise authority in a particular situation” and “may exist when false statements [are] made to state or local government agencies receiving federal support or subject to federal regulation.”²²⁵ A violation of this provision is punishable by imprisonment for not more than five years and a fine of not more than \$250,000 for individuals or \$500,000 for corporations.²²⁶

Dr. Gayle Rothenberg, a physician licensed in Texas, was convicted of making false statements to an agent of the United States government, in addition to misbranding a biologic while it was being held for sale with intent to defraud or mislead.²²⁷ Dr. Rothenberg ordered and administered misbranded botulinum toxin type A to more than 170 patients despite the fact that it was labeled with the warning “For Research Purposes Only, Not for Human Use.”²²⁸ Dr. Rothenberg also misrepresented to patients that they were receiving injections of the FDA-approved drug.²²⁹ On January 20, 2005, FDA agents traveled to Dr. Rothenberg’s clinic and spoke to her about whether any of the misbranded medication had been ordered and used on patients in her medical clinic.²³⁰ In response, Dr. Rothenberg confirmed that the non-approved product had been ordered but falsely stated that it had only been administered to friends and family.²³¹ During a second visit from FDA agents, Dr. Rothenberg stated that the product had been used on approximately 210 of her patients without her knowledge or approval. However, the FDA found that Dr. Rothenberg was aware all along that her patients were receiving a non-FDA-approved version of the biologic that was not intended for human use.²³² As a result, Dr.

223. 18 U.S.C. § 1001 (2012).

224. *United States v. Staad*, 636 F.3d 630, 638 (D.C. Cir. 2011) (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999)); *see also* *United States v. Garcia-Ochoa*, 607 F.3d 371, 375 (4th Cir. 2010).

225. *United States v. Ford*, 639 F.3d 718, 720 (6th Cir. 2011) (quoting *United States v. Rodgers*, 466 U.S. 475, 479 (1984)) (internal quotation marks omitted).

226. 18 U.S.C. § 1001 (2012).

227. Press Release, U.S. Att’y’s Office, S. Dist. of Tex., Local Physician Sentenced for Injecting Patients with Fake Botox (Apr. 16, 2010), <http://www.justice.gov/usao/txs/1News/Releases/2010%20April/041610%20Rothenberg.htm>.

228. *Id.*

229. *Gayle Rothenberg: Debarment Order*, 76 Fed. Reg. 69,272, 69,273 (Nov. 8, 2011) (order).

230. *Id.*

231. *Id.*

232. *Gayle Rothenberg: Proposal to Debar, Notice of Opportunity for Hearing*, Docket No. FDA-2011-N-0444 (July 29, 2011).

Rothenberg was sentenced to five and a half months in federal prison, three years of supervised release, and \$96,426 in restitution to her patients.²³³ In addition, the FDA permanently debarred Dr. Rothenberg from providing services in any capacity to a person with an approved or pending drug product based on her felony convictions related to the regulation of a drug product under the FDCA.²³⁴

In sum, while a simple misbranding charge is only a misdemeanor, it is possible for a physician or pharmacist to be charged with various felonious offenses simultaneously, resulting in imprisonment, steep monetary fines, and debarment, regardless of whether their actions were profit-driven, as in the case of Gallant Pharma, or altruistic, as in the case of Dr. Patwardhan. Given that the FDA has stated that it does not have the resources to adequately pursue gray market bad actors, states must undertake their own investigations and prosecutions.

IV. EFFORTS TO PROTECT PATIENTS FROM GRAY MARKET BIOLOGICS: RECOMMENDATIONS FOR EDUCATION AND ENFORCEMENT

Although the FDA is responsible for protecting the health and safety of Americans by regulating drug approval and distribution in the United States, it cannot manage all aspects of the supply chain. FDA efforts to implement and enforce federal laws are well-intentioned; however, they inadequately reduce the threat posed by gray markets. States have broad police powers in regulating health professionals' dispensing and administering of drugs.²³⁵ Where there are weaknesses in enforcement at the federal level, states and professional groups should intervene, drawing lessons and resources from state and professional responses to controlled substance diversion.

Prescription drug abuse often results from improper prescribing or dispensing by physicians and pharmacists, either due to a lack of education on controlled substances or intentional bad behavior. As a result, many state legislatures or medical boards have required prescriber education in safe prescribing and abuse prevention.²³⁶ States have also increased investigation and enforcement efforts, including prosecuting intentional bad actors and implementing professional sanctions and rehabilitation for negligent actors. Additionally, professional associations have released best practice guidelines for health care practitioners and have instituted consumer awareness campaigns.²³⁷ These combined federal, state, professional, and corporate efforts have yielded reductions in diversion, abuse, and consumer harm.²³⁸ As manufactur-

233. Press Release, U.S. Att'y's Office, S. Dist. of Tex., *supra* note 7.

234. Gayle Rothenberg: Debarment Order, 76 Fed. Reg. at 69,273.

235. *Robinson v. California*, 370 U.S. 660, 664–65 (1962); *Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921).

236. See STRATEGIES TO STOP THE EPIDEMIC, *supra* note 9.

237. NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS, PRESCRIPTION DRUG ABUSE, ADDICTION AND DIVERSION: OVERVIEW OF STATE LEGISLATIVE AND POLICY INITIATIVES 7 (2014), available at <http://www.namsdl.org/library/6D4B39ED-65BE-F4BB-A67AEA9E53B140A9/>.

238. See *supra* note 10 and accompanying text.

ers produce alternatives to controlled substances that are less appealing to would-be abusers, such as biologics, states and professionals must take parallel action to reduce the proliferation of the gray market for biologics. Many of the activities can be adjusted and applied to address the diversion of biologics to the gray market.

A. *State Intervention*

As states work to stem the epidemic of controlled substance diversion and abuse, law enforcement, public health agencies, and health care providers must cooperate to simultaneously establish and enforce clear rules supported by meaningful professional and criminal penalties, in order to effectively deal with gray market biologics.²³⁹ State law enforcement and licensing boards are an important component of pressuring gray market participants to cease trafficking in gray market medications and educating licensed health care providers about the dangers of gray market medications.²⁴⁰ States are in the best position to deal with potential drug-related health and safety threats and may employ a combination of federal and state laws to patch holes in the closed system of distribution of biological pharmaceuticals.²⁴¹

1. *Mandatory Education*

No health care practitioner should purchase gray market medications because the risk is too high. However, many simply are not properly educated on the risks involved or even how to spot a gray market biologic. States have the authority to impose requirements on licensed professionals in order to protect the health, safety, and welfare of the public, including the right to mandate education.²⁴²

Many states have adopted, through legislation or regulation, education requirements regarding pain management, safe prescribing of controlled substances, screening for substance use disorders, substance abuse prevention, and use of state prescription monitoring programs in order to reduce the prescription drug abuse epidemic.²⁴³ For instance, Kentucky-licensed physicians complete 7.5 percent of their required continuing education courses on the use of prescription drug monitoring programs, pain management, or addiction disorders.²⁴⁴ Massachusetts requires all prescribers to complete education relating to “effective pain management, identification of patients at high risk for substance

239. Liang, *supra* note 30, at 312–313.

240. *Gray Market, Black Heart*, *supra* note 32.

241. Kane, *supra* note 33 (noting that the FDA’s Office of Criminal Investigations looks into complaints about blatant safety concerns in the gray market but the agency defers to the states to do the bulk of regulation).

242. *United States v. E. C. Knight Co.*, 156 U.S. 1, 11 (1895).

[T]he power of a State to protect the lives, health, and property of its citizens, and to preserve good order and the public morals . . . is a power originally and always belonging to the States, not surrendered by them to the general government, nor directly restrained by the Constitution of the United States, and essentially exclusive.

243. *PRESCRIPTION NATION*, *supra* note 36.

244. Ky. Rev. Stat. Ann. § 218A.205 (LexisNexis 2013).

abuse, and counseling patients on the side effects, addictive nature, and proper storage and disposal of prescription medications.”²⁴⁵ Courses on the risks of biologic fraud and diversion may readily be incorporated into existing course offerings, which already address other forms of fraud and diversion.

Similarly, as other states enact education mandates to reduce controlled substance diversion and abuse, they must ensure the requirement and curricula address fraud, diversion, and patient safety related to the gray market for biologics. Such topics could be included in ethics courses or as part of safe prescribing and fraud and abuse detection requirements.²⁴⁶ Virginia mandates that physicians complete sixty hours of “continued competency requirements” every two years.²⁴⁷ Thirty of these hours may be in areas such as ethics, standards of care, patient safety, and patient communication, all of which lend themselves well to a discussion of gray market biologics.²⁴⁸ Such specific training surrounding the physician and pharmacist role in ensuring the safety and proper use of medications, including biologics, is needed in all states.

It is equally important that education for physicians and pharmacists also address the adulteration of prescription drugs. They must remain vigilant and mindful to the concerns brought to them by patients. If a drug is not having the positive effects that it once had, or a medicine tastes different than it has in the past, or an injection suddenly begins to hurt, physicians and pharmacists must consider that the drug may be spoiled or counterfeit.²⁴⁹

Once professionals are educated, professional boards must revoke professionals’ licenses for dispensing or administering gray market biologics because, at that point, professionals are aware of the risks. Their actions become intentional and knowing. Therefore, they must be prosecuted.

2. Investigation and Professional Sanctions

State pharmacy and medical boards are responsible for overseeing the entities that buy, sell, prescribe, and dispense prescription drugs, including pharmacists, distributors (in states in which licensure is required), and physicians. They serve a judicial function by conducting investigations and hearings on alleged wrongdoings. Hearings resem-

245. MASS. GEN. LAWS ch. 94C, § 18(e) (2013).

246. See, e.g., N.M. STAT. ANN. § 24-2D-5.2 (2012) (requiring quarterly prescription drug misuse and overdose prevention and pain management advisory council meetings to discuss education of professional prescribers in New Mexico, among other issues).

247. Continued Competency Requirements for Renewal of an Active License, 18 VA. ADMIN. CODE § C85-20-235(A) (2012).

248. *Id.*

249. Louis A. Ling, *While We Are Waiting: Imagining and Creating a Safe Drug Supply While We Await the Coming of the Radio Frequency Identification Track-and-Trace System*, 19 J. PHARMACY PRAC. 153, 158–59 (2006).

ble civil and criminal court proceedings,²⁵⁰ or, at the very least, an administrative hearing, when deciding to revoke or suspend the license of a pharmacist or physician. They must investigate wrongdoers and determine the proper punishment in order to deter future bad acts. If an investigation shows that a gray market participant has acted negligently, at a minimum, the practitioner must receive professional sanctions, such as a revocation of a license or suspension and rehabilitation.

After being involved in both gray market biologic diversion and controlled substance diversion, Erick Falconer, a physician licensed in Missouri, Illinois, and Arizona, pleaded guilty to making false statements to federal agents regarding his purchase of misbranded botulinum toxin type A from a foreign unlicensed drug wholesaler, some of which had counterfeit packaging.²⁵¹ Dr. Falconer made over fifty separate purchases of the Turkish version of botulinum toxin type A at a discounted price that was over thirty percent below the US market rate.²⁵² However, during an interview with FDA special agents, Dr. Falconer said he only made three purchases of the illegal drugs from this unlicensed foreign wholesaler. After receiving notice that Dr. Falconer would be charged with making a material false statement and representation to special agents of the FDA, the Illinois Department of Financial and Professional Regulations (“Illinois board”) found that Dr. Falconer’s continued practice of medicine constituted an immediate danger to the public, and on December 3, 2013, the Illinois board suspended Dr. Falconer’s license.²⁵³ Ten days later, it issued a temporary restraining order, which reinstated his medical license, but restricted him to the practice of emergency medicine only.²⁵⁴ He was also prohibited from administering botulinum toxin type A.²⁵⁵

Additionally, the Missouri State Board of Registration for Healing Arts has a formal complaint pending against Dr. Falconer, alleging that, in addition to making false statements, he repeatedly failed to meet the

250. In an administrative disciplinary action, the burden of proof varies in different states. Some states require a preponderance of the evidence standard in order to sustain an administrative prosecution. Preponderance of the evidence occurs when the fact-finder is satisfied that the facts are more likely true than not true. Other states require a stronger clear and convincing evidence standard to prove administrative violations. In a clear and convincing evidence standard, the fact-finder must have a firm believe that the allegations are true, although reasonable doubt may still exist. See Dale J. Atkinson, *Legal Briefs: Burden May Be Burdensome*, NAT’L ASS. OF BDS. OF PHARMACY (Mar. 21, 2012, 4:06 PM), <http://www.nabp.net/news/legal-briefs-burden-may-be-burdensome> (last visited Feb. 17, 2014); see also 29 AM. JUR. 2d, Evidence § 173.

251. Press Release, U.S. Att’y’s Office, E. Dist. of Mo., Local Doctor Pleads Guilty to Making False Statement to Agent (Nov. 6, 2013), http://www.justice.gov/usao/moe/news/2013/november/falconer_erick.html.

252. *Id.*

253. In the Matter of Erick A. Falconer, MD-13-1181, Order Rescinding Summary Suspension and Interim Findings of Fact, Conclusion of Law and Order for Summary Practice Restriction, Ariz. Med. Bd., <http://azmd.gov/GLSuiteWeb/Repository/0/0/2/9/a3d897c3-a290-4947-8209-fd2d65a78361.pdf>.

254. *Id.* at 3.

255. *Id.*

standard of care.²⁵⁶ He was also previously disciplined by the Missouri Bureau of Narcotics and Dangerous Drugs for “multiple violations relating to safeguarding, dispensing, record-keeping, and failing to provide effective controls to guard against the diversion of controlled substances”²⁵⁷ As a result, the Missouri board also suspended Dr. Falconer’s license. Arizona’s board took into consideration the Illinois and Missouri board decisions, and found that Dr. Falconer’s actions constituted unprofessional conduct under Arizona law.²⁵⁸ Although the Arizona board summarily suspended Dr. Falconer’s license to practice medicine in Arizona, the Board later removed its suspension but restricted Dr. Falconer’s license so that he could only practice emergency medicine through his practice group and was prohibited from administering botulinum toxin type A.²⁵⁹ It is surprising and disconcerting that, given the egregious nature of Dr. Falconer’s activities, his license was not revoked in all three states.

State legislatures must ensure that professional licensing boards have adequate resources for carrying out their investigation and enforcement responsibilities and that they be held accountable for fulfilling their responsibilities to vigilantly protect the public from the harms associated with gray market biologics.

3. Criminal Enforcement

To curb the dangerous practices of non-compliant pharmacists and physicians and eventually drive them out of the market, meaningful criminal sanctions must be imposed on intentional bad actors.

When law enforcement or licensing boards investigate and discover that they are dealing with a non-compliant physician or pharmacist whose behavior is knowing and willful, the next step should be to refer the case for prosecution to the full extent of the law. When state law requires physicians and pharmacists to be properly educated regarding the risks and harms to consumers associated with the gray market, the incidences of unknowing, negligent gray market participation can be expected to decline to near zero. It is likely that only the egregious actors who knowingly and intentionally participate in gray market activi-

256. *Id.* Additionally, Dr. Falconer allegedly (1) “repeatedly enticed and misled patients into false expectations to solicit business;” (2) “repeatedly failed to use the degree of skill used under similar circumstances by members of his profession;” (3) “repeatedly abused the professional trust of the physician-patient relationship for the purpose of engaging in sexual activity;” (4) “lied on his Missouri medical license renewal application;” and (5) “did not appropriately treat a patient in the course of his duties as an Emergency Room physician ultimately leading to a patient’s death.” *Id.* at 2–3.

257. *Id.* at 3.

258. *Id.* at 4 (citing ARIZ. REV. STAT. § 32-1401(27)(d) (2013), which involves “committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude” and ARIZ. REV. STAT. § 32-1401(27)(o) (2013), which involves “action that is taken against a doctor of medicine by another licensing or regulatory jurisdiction due to that doctor’s . . . medical incompetence or for unprofessional conduct as defined by that jurisdiction and that corresponds directly or indirectly to an act of unprofessional conduct . . .”).

259. *Id.* at 5.

ties will remain. These are the individuals who should face vigorous criminal prosecution; and as these prosecutions become more prevalent, they will serve as eye-opening deterrents from gray market activity in that state and within that profession more broadly.

The national market will benefit from coordination among states in the consistent enforcement of state laws with similar provisions aimed at crippling the gray market for biologics. Otherwise, bad actors will relocate to states with less scrutiny and continue to feed the illicit supply.

Florida and Georgia provide a telling example, in the prescription opioid context, of criminal actors relocating to states where federal laws are less rigorously enforced and state laws are less aggressive in protecting public health and safety.²⁶⁰ Florida successfully reduced prescription opioid diversion, abuse, and resultant overdose deaths thanks to a combination of enforcement of federal and state controlled substance laws and legislative actions designed to improve public health and safety by cracking down on pill mills and rogue prescribers.²⁶¹ Measures included professional education requirements, revoking licenses to dispense controlled substances,²⁶² charging prescribers under the CSA, or charging the most extreme physicians with murder when their patients died of overdoses.²⁶³ Pam Bondi, Florida's Attorney General, described such physicians as "drug dealers wearing white coats."²⁶⁴ As a result of Florida's success, bad actors relocated to Georgia, leading to a surge in pill mills in that state.²⁶⁵ Such consequences can be avoided by properly enforcing federal and state pharmaceutical commerce laws and implementing new health and safety requirements, including professional education mandates, consistently throughout the states.

B. *Best Practices for Health Care Organizations*

The health care industry must be made aware of the dangers of gray market biologics. Health care providers should implement best policies and practices regarding gray market biologics, as they have done with prescribing opioids. For instance, various patient advocacy

260. *Florida Combats Prescription Drug Abuse with Laws and Enforcement*, DRUGFREE.ORG (Apr. 8, 2013), <http://www.drugfree.org/join-together/community-related/florida-combats-prescription-drug-abuse-with-laws-and-enforcement> [hereinafter *Florida Combats Prescription Drug Abuse*].

261. See FLA. DEP'T OF LAW ENFORCEMENT, DRUGS IDENTIFIED IN DECEASED PERSONS BY FLORIDA MEDICAL EXAMINERS: 2012 INTERIM REPORT ii (Mar. 2013), <http://www.fdle.state.fl.us/Content/getdoc/9c4df7c2-4b07-4f7a-acfb-6461719c0e44/2012-interim-drug-reportFINAL.aspx> (showing a decrease in overdose deaths from 2011 to 2012).

262. *Florida Combats Prescription Drug Abuse*, *supra* note 260.

263. FLA. OFFICE OF DRUG CONTROL, FLORIDA'S PRESCRIPTION DRUG DIVERSION AND ABUSE ROADMAP 2012-2015 17 (Apr. 2, 2012), [http://myfloridalegal.com/webfiles.nsf/WF/KGRG-8T8L5K/\\$file/PrescriptionDrugDiversionAndAbuseRoadmap.pdf](http://myfloridalegal.com/webfiles.nsf/WF/KGRG-8T8L5K/$file/PrescriptionDrugDiversionAndAbuseRoadmap.pdf).

264. Lizette Alvarez, *Florida Shutting 'Pill Mill' Clinics*, N.Y. TIMES (Aug. 31, 2011), <http://www.nytimes.com/2011/09/01/us/01drugs.html?pagewanted=all>.

265. Timothy W. Martin, *Florida "Pill Mill" Crackdown Sets Off a Rush into Georgia*, WALL ST. J., Dec. 25, 2012, <http://online.wsj.com/news/articles/SB10001424127887324478304578173341194754984>.

groups, hospitals, and practice groups have voluntarily adopted opioid safe prescribing and treatment monitoring guidelines. Similarly, when dealing with potential gray market biologics, health care administrators should consult with the institution's risk management and legal team in order to understand the differences between a legal and an illegal distribution operation and establish internal policies based on best practices.²⁶⁶ Purchasers must plan ahead to determine the impact on scheduling treatments and the availability of other agents in the same class, so they are not left without solutions when a drug shortage happens.²⁶⁷ Johns Hopkins Hospital, for example, has developed a strict policy against purchasing prescription drugs on the gray market, regardless of whether there is a shortage.²⁶⁸ At Hopkins, a coordinated task force of clinicians, pharmacists, drug purchasers, and other stakeholders meets frequently to discuss current and future drug shortages based on the volume of patients.²⁶⁹ Given that tracking the availability of prescription drugs is a time-consuming task, some hospitals have hired technicians to track and follow medications on backorder.²⁷⁰ The cost of tracking outweighs the cost of adverse events caused by harmful gray market drugs.

Before making a purchase, the pharmacy director should confirm with the state board of pharmacy that the seller is a properly licensed distributor.²⁷¹ If the distributor is not properly licensed, then no purchase should be made. Additionally, no purchase should be made unless the shipment contains an entire transaction history for the medications.²⁷² A legitimate drug cannot be profitably sold more than once or twice, so if the transaction history reflects three or more preceding sales, the shipment should be declined.²⁷³

Providers should exhibit due diligence in purchasing high-quality pharmaceuticals, and they must thoroughly inspect products to ensure that they are, in fact, what they are purported to be.²⁷⁴ If purchasing from a new supplier, providers should compare and scrutinize the package, label, and contents; and should not use a drug if there is any cause for suspicion or concern. A drug is suspicious, for example, if a label contains a foreign language or lacks "for Rx use only," or the package

266. See CHERICI ET AL., *supra* note 74, at 5–6.

267. Greg Rienzi, *Essential Drugs, Short Supplies*, *JOHNS HOPKINS MAG.* (June 3, 2013), <http://hub.jhu.edu/magazine/2013/summer/drug-shortage-task-force>.

268. *Id.*

269. *Id.*

270. See Jaimy Lee, *Providers Fuel Gray Market: Some Sell While Others Buy During Drug Shortage*, *MODERN HEALTHCARE* (Sept. 5, 2011), <http://www.modernhealthcare.com/article/20110905/MAGAZINE/309059980>.

271. See CHERICI ET AL., *supra* note 74, at 6.

272. See *id.*

273. Ling, *supra* note 249, at 157.

274. Marv Shepherd, *Tips for Pharmacists in Detecting Counterfeit Medications*, *CURRENT CONCEPTS IN PHARMACY MGMT., U. OF ARIZ. HEALTH SCI. CTR.*, Summer 2011, [available at http://www.ccpharm.com/01_counterfeit_meds.php](http://www.ccpharm.com/01_counterfeit_meds.php).

appears tampered with.²⁷⁵ Practitioners can also check manufacturers' websites for alerts describing how to identify misbranded drugs.²⁷⁶ For example, when the manufacturer of botulinum toxin type A became aware of gray market distribution of its product, the company provided a video for botulinum toxin type A purchasers, which described packaging conventions that distinguished real botulinum toxin type A from its illegal counterparts.²⁷⁷

Providers must understand and account for the risks to their practice and the risks to the patients they serve by seeking legal and risk management counsel.²⁷⁸ They must (1) develop and widely communicate policies for decisions regarding purchases, (2) confirm with the state board of pharmacy or department of health that a distributor is appropriately licensed and not subject to any current investigations, and (3) request drug history documents.²⁷⁹ They should keep records of sellers they have refused to do business with and the reasons why.²⁸⁰ Finally, they should report any suspicious supplier to the appropriate local, state, and national authorities and to the product manufacturer.²⁸¹

C. Consumer Awareness

Consumers must be made aware of the harms involved in taking gray market biologics. Yet, recent federal and state actions have yielded contradictory messages.

1. Consistent Messages to Consumers

Although it is illegal for foreign pharmacies to distribute drugs to individuals in the United States for personal use in most circumstances, the FDA has adopted a narrow policy exception in which it will allow consumers to import non-FDA-approved medications.²⁸² For the exception to apply, all of the following factors must be met:

- 1) The drug is for a serious condition for which effective treatment is not available in the United States;
- 2) There is no commercialization or promotion of the drug to U.S. residents;
- 3) The drug is considered not to represent an unreasonable risk;

275. Press Release, Premier Healthcare Alliance, Drug Shortages Leading to Price Gouging, Possible Safety Issues, According to Research (Aug. 16, 2011), <http://www.reuters.com/article/2011/08/16/idUS172348+16-Aug-2011+BW20110816>.

276. McKenzie & Kelly, *supra* note 140.

277. *Id.*

278. Press Release, Premier Healthcare Alliance, *supra* note 275.

279. *Id.*

280. *Id.*

281. *Id.*

282. ABOUT FDA, *Is It Legal for Me to Personally Import Drugs?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm> (last updated Nov. 18, 2014).

4) The individual importing the drug verifies in writing that it is for his or her own use, and provides contact information for the doctor providing treatment or shows the product is for the continuation of treatment begun in a foreign country; and

5) Generally, not more than a three-month supply of the drug is imported.²⁸³

Giving the impression that importation of Canadian pharmaceuticals from online pharmacies may be acceptable, Congress enacted amendments to the FDCA in 2001 and 2003, entitled the Medicaid Prescription Drug, Improvement, and Modernization Act (“MMA”), which allowed limited importation of certain prescription drugs from Canada by pharmacists, wholesalers, and consumers. The MMA required the Secretary of HHS to first certify that the importation would “pose no additional risk to the public’s health and safety.”²⁸⁴ All four of the Secretaries of HHS who have served since the amendment was enacted have declined to make the requisite certifications.²⁸⁵

Policies like these lead consumers to believe that purchasing medications online, including biologics, is not risky. For instance, in 2006, a group of consumers and organizations joined together to bring a class action anti-trust lawsuit against various pharmaceutical manufacturers under the Clayton Act.²⁸⁶ They argued that the drug manufacturers unlawfully conspired to suppress the importation of Canadian prescription drugs for personal use by engaging in “a concerted course of conduct designed to prevent brand name prescription drugs purchased from Canadian pharmacies from entering the United States” and causing American consumers to pay higher drug prices.²⁸⁷

In *In re Canadian Import Antitrust Litigation*, the Eighth Circuit affirmed the district court’s grant of a motion to dismiss, finding that the FDCA prohibits virtually all importation of prescription drugs into the United States by individual consumers for personal use.²⁸⁸ Such

283. *Id.*

284. 21 U.S.C. § 384(l)(1)(A) (2012).

285. 21 C.F.R. §§ 200–369 (2002); *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006) (stating that all three secretaries between 2001 and 2006 declined to make this certification. This case was decided in 2006, before current Secretary Kathleen Sebelius took the position. Secretary Sebelius also has not made the certification). The Secretaries who declined to make this certification include Donna Shalala (1993–2001), Tommy G. Thompson (2001–2005), Michael O. Leavitt (2005–2009), and Kathleen Sebelius (2009–present).

286. *In re Canadian Import Antitrust Litig.*, 470 F.3d at 787.

287. *Id.* at 788. The plaintiffs argued that the defendant drug companies engaged in anticompetitive conduct, including:

1) Requiring Canadian pharmacies to certify that they were not selling prescription drugs to persons whom the pharmacies knew or should have known were taking the drugs outside the country,

2) Monitoring orders of Canadian pharmacies and limiting their purchases to historical levels,

3) Creating “blacklists” of pharmacies that were suspected of selling drugs to American consumers and directing wholesalers not to sell to the blacklisted pharmacies, and

4) Cutting off supplies to wholesalers who did not comply with their policies.

288. *Id.* at 788–89.

drugs violate the FDCA because they are predominantly unapproved new drugs, are misbranded because they are not labeled in accordance with federal requirements, or are dispensed without a valid prescription.²⁸⁹ Many illicit online pharmacies do not require the consumer to provide a prescription in order to purchase the medication, as is required by the FDCA.

In particular, the Eighth Circuit ruled that the Canadian prescription drugs at issue were misbranded.²⁹⁰ Prescription drugs dispensed by Canadian pharmacies are labeled “Pr,” as opposed to the required “Rx only.”²⁹¹ Whereas the plaintiffs argued that the Canadian symbol was the “functional equivalent” of “Rx only,” the court found that federal law does not provide for functional equivalence in labeling.²⁹² Given that foreign labeling differs from domestic labeling, approval granted to a specific manufacturer for a particular product to be distributed in the United States does not constitute approval of another drug—even one with the same chemical composition—that is distributed in Canada with different labeling, and then imported into the United States.²⁹³ This precise labeling requirement is a manifestation of Congress’s intent to create a “closed system” designed to guarantee safe and effective drugs for consumers in the United States.²⁹⁴ Therefore, it is per se illegal to import Canadian drugs into the United States for personal use, or drugs from any other country for that matter, except in cases that fit the narrow exception created by the FDA.²⁹⁵ Despite the ruling in *In re Canadian Import Antitrust Litigation* and the decision not to certify importation under the MMA, the FDA has been unable to adequately enforce the legal prohibition on personal importation of foreign drugs.²⁹⁶

State courts, nevertheless, have upheld the personal right to choose what may be a “suicidal medical course,”²⁹⁷ including choosing to use non-FDA-approved medications imported from abroad and the right to use a nontoxic substance in connection with one’s own personal health care.²⁹⁸ The issue of toxicity begs the question that Con-

289. *Id.* (citing 21 U.S.C. §§ 352, 353(b)(1), 355 (2006)).

290. *Id.* at 789.

291. *Id.*

292. *Id.*

293. *Id.* at 790.

294. *Id.*

295. *Id.* at 790–91. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating [a] comprehensive regulatory system . . . , Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384.

296. *Id.* at 791.

297. *People v. Privitera*, 141 Cal. Rptr. 764, 770 (Ct. App. 1977); *Matter of Erickson v. Dilgard*, 252 N.Y.S.2d 705 (Sup. Ct. 1962); *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914).

298. *Privitera*, 141 Cal. Rptr. at 783, *rev’d*, 591 P.2d 919, 945 (Cal. 1979) (finding that although the FDA had not approved a certain cancer medication yet, the patient still has “the choice of ‘state sanctioned’ treatment by the doctor or no treatment from the doctor at all”); *Rutherford v. United States*, 438 F. Supp. 1287, 1301 (W.D. Okl. 1977).

gress has answered through the FDCA's drug approval and labeling requirements.

At least one state has enacted its own legislation explicitly permitting importation of prescription drugs for personal use. On June 27, 2013, Maine became the first state to legalize importation of prescription medications from pharmacies in Canada, the UK, New Zealand, and Australia (the "Importation Law").²⁹⁹ According to Maine's Importation Law, a licensed retail pharmacy in one of those countries may export prescription drugs to a resident of Maine for the resident's personal use.³⁰⁰ Consumers who take prescription drugs shipped into Maine by foreign pharmacies pursuant to the Importation Law do not benefit from the quality and safety controls put into place by the federal government.³⁰¹ What's more, consumers in the United States tend to be particularly trusting of online pharmacies purporting to be Canadian pharmacies even though many of these pharmacies are actually located in countries other than Canada and sell drugs that are not manufactured or approved for sale in Canada.³⁰²

Importation and re-importation are prohibited under the FDCA and PDMA, and state laws that are contrary send a mixed message to citizens, propagating a notion that drugs from foreign countries are as safe and effective as medications approved and labeled for use in the United States.³⁰³ Furthermore, such state laws are preempted by federal law under the Supremacy Clause of the US Constitution. Pursuant to the preemption doctrine, federal law preempts state law if it contains "express" language overruling state law or to the extent that the laws conflict, whereby following the state law would violate the federal law.³⁰⁴ The Maine law is preempted by the MMA, which does not allow for the importation of prescription drugs from Canada by pharmacists until the Secretary of HHS first certifies that the importation would

299. Julie Rovner, *Maine Once Again Allows Mail-Order Canadian Drugs to Cut Costs*, NPR (June 27, 2013, 5:00 PM), <http://www.npr.org/blogs/health/2013/06/27/196325173/maine-once-again-allows-mail-order-canadian-drugs-to-cut-costs>.

300. ME. REV. STAT. tit. 32, § 13731(1)(B) (2013).

301. Complaint at 1, *Ouellette v. Mills*, No. 1:13-CV-00347-NT, 2014 WL 1975438 (D. Me. May 15, 2014).

302. *Deceptive Practices*, *supra* note 93.

303. *Save Money by Ordering Drugs from Canada? Not So fast*, CONSUMER REPORTS NEWS (Oct. 27, 2011, 6:08 AM), <http://www.consumerreports.org/cro/news/2011/10/save-money-by-ordering-drugs-from-canada-not-so-fast/index.htm> (noting that most Canadian websites are not actually Canadian pharmacies after all).

304. *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983) (noting that Congress may, if acting pursuant to its Constitutional authority, preempt state law "by so stating in express terms"). In addition, there are certain areas of the law where the federal interest deemed to have preempted the entire "field" of regulations. *Id.* However, despite the existence of some federal laws regulating prescription drugs, the states have broad authority to regulate practices impacting the health of their citizens. *See United States v. Lopez*, 514 U.S. 549, 594 (1995) (Thomas, J., concurring) ("That the internal commerce of the States and the numerous state inspection, quarantine, and health laws had substantial effects on interstate commerce cannot be doubted. Nevertheless, they were not 'surrendered to the general government.'"); *see also Barnes & Arndt*, *supra* note 48 (noting that both the federal government and the states regulate prescription drugs concurrently).

“pose no additional risk to the public’s health and safety.”³⁰⁵ This certification has yet to happen. Moreover, the Importation Law is an encroachment by the state of Maine on the federal government’s exclusive power to regulate foreign commerce, as affirmed by the US Supreme Court in 2005 in its *Gonzalez v. Raich* decision.³⁰⁶

States should not follow Maine’s lead in allowing importation of pharmaceuticals, including gray market biologics, from online “Canadian” pharmacies. Instead, states should crack down on entities dealing in gray market biologics, as states like Florida have done with entities that divert controlled substances. States must provide clear messages to consumers regarding the dangers of gray market biologics as they have with the dangers of controlled substance diversion and abuse.

In another case in which opioid diversion and gray market activity overlap, Texas’s Attorney General prosecuted pharmacist Rakesh Jyoti Saran for his elaborate involvement with a rogue internet pharmacy scheme that involved gray market diversion of controlled substances to drug-seekers.³⁰⁷ Mr. Saran operated twenty-three Texas-incorporated pharmacies and purchased various controlled substances at significantly discounted prices by fraudulently claiming his purchases were for institutional pharmacies.³⁰⁸ He then sold the controlled substances illegally to individuals without valid prescriptions at four times the cost of market price.³⁰⁹ He played an integral role in providing hydrocodone, alprazolam, and promethazine cough syrup with codeine to individuals who illegally sold the drugs “on the street.”³¹⁰ Mr. Saran pleaded guilty to conspiracy to commit health care fraud, two counts of mail fraud, and one count of conspiracy to distribute controlled substances.³¹¹ He was sentenced to twelve years in federal prison and ordered to pay \$68 million in restitution.³¹² This is a case of excessive wrongdoing, in which the penalty should be steep. Consumers must be protected from this kind of behavior.

More attorney generals and state prosecutors should take actions against rogue pharmacies that traffic in diverted medications and jeopardize public health and safety. It is important that professionals and consumers receive a consistent message about the dangers of drugs that circulate outside the lawful distribution chain. Authorizing the illegal importation of drugs for personal use, as Maine has done, blurs this

305. 21 U.S.C. § 384(l)(1)(A) (2012).

306. Complaint at 2, *Ouellette v. Mills*, No. 1:13-CV-00347-NT, 2014 WL 1975438 (D. Me. May 15, 2014); see *Gonzalez v. Raich*, 545 U.S. 1, 9 (2005) (holding that federal law that criminalizes cannabis use is a valid exercise of federal power and therefore supersedes California state law decriminalizing cannabis use in medical treatment).

307. Press Release, U.S. Dep’t of Justice, Lead Defendant in Health Care Fraud and Rogue Internet Pharmacy Scheme Sentenced to 12 Years in Federal Prison and Ordered to Pay \$68 Million in Restitution (Dec. 11, 2009), http://www.justice.gov/usao/txn/PressRel09/saran_sen_pr.html.

308. *Id.*

309. *Id.*

310. *Id.*

311. *Id.*

312. *Id.*

important message, undermines federal supremacy of laws, and places patient safety at risk.

1. Consumer Awareness Campaign

One of the most important players in reducing the demand for gray market pharmaceuticals is the consumer. Unfortunately, many appear unaware of the dangers that lurk in the prescription drug supply chain. For example, a survey of US patients found that fifteen percent of respondents had purchased drugs online.³¹³ However, the vast majority, ninety-three percent, of these respondents who had purchased prescription drugs online never suspected that the products might be counterfeit.³¹⁴ Furthermore, many adults lack basic knowledge regarding the illegality of pharmaceutical importation, as demonstrated by one survey in which forty-five percent of consumer respondents perceived drug importation practices to be legal, while thirty-three percent were unsure.³¹⁵ Even if patients are aware of the illegality of importing prescription drugs, many patients still look to purchase their medications at lower cost from foreign or illegitimate online suppliers.³¹⁶ It is not only important that patients learn to recognize the safety concerns associated with purchasing drugs from the gray market via the internet or a trip to another country, but that they also understand that even the prescriptions bought from a local pharmacy or administered by their health care provider are at risk of having been adulterated if purchased on the gray market.

Patients should closely examine the appearance of the package and drug each time they receive it and compare it to the original manufacturer's packing available online.³¹⁷ Patients should also feel and take note of the drug's taste or the way the injection site feels.³¹⁸ They must evaluate how their bodies react over the course of the treatment and consult with a pharmacist or physician on what they should expect to feel.³¹⁹ If something feels wrong after the administration of the prescription, patients should immediately write down their symptoms and call their physician.³²⁰ Individuals should report any quality concerns to their state board of pharmacy, the manufacturer, and the FDA's Drug Quality Reporting System ("DQRS"), where it will be classified and should be investigated.³²¹

313. Brian A. Liang, *A Dose of Reality: Promoting Access to Pharmaceuticals*, 8 WAKE FOREST INTELL. PROP. L.J. 301, 326 (2008).

314. *Id.*

315. Monali J. Bhosle & Rajesh Balkrishnan, *Drug Reimportation Practices in the United States*, 3 THERAPEUTICS & CLINICAL RISK MGMT. 41, 43 (2007).

316. *See supra* Part III.

317. *An 8-Step Checklist for Medicine Safety*, P'SHIP FOR SAFE MEDS., <http://www.safe-medicines.org/consumer/SAFEDRUG.pdf> (last visited Mar. 12, 2014).

318. *Id.*

319. *Id.*

320. *Id.*

321. FDA, REPORTING DRUG QUALITY PROBLEMS 2 (July 2009), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173143.pdf>.

As a result of the seemingly endless number of illegitimate online pharmacies, the National Association of Boards of Pharmacy (“NABP”) has created the “Verified Internet Pharmacy Practice Sites” (“VIPPS”) program.³²² If individuals insist on purchasing online medication, they should only do so from VIPPS accredited sites. In order for an online pharmacy to be VIPPS accredited to dispense pharmaceuticals, it must comply with state licensing and inspection requirements.³²³ VIPPS pharmacies must also demonstrate compliance with other criteria, including authentication and security of prescription orders, adherence to a quality assurance policy, and meaningful consultation between patients and pharmacists.³²⁴ Currently only thirty-five online pharmacies have been VIPPS-approved as safe and legitimate.³²⁵ This is a far cry from the hundreds of pharmacies that citizens are presented with when they utilize a search engine, making the process of ordering online much less intimidating.

V. CONCLUSION

Biologics are a significant medical advancement that improves the health of countless consumers. However, if improperly stored, handled incorrectly, expired, or diluted, they can become unsafe, ineffective, or both. Given that there is no guarantee of the safety and efficacy of gray market medications, physicians and pharmacists should never dispense or administer gray market biologics.

Yet, gray market activity is widespread in the health care industry. Bad actors exist throughout the entire system of distribution, but physicians and pharmacists can prevent dangerous, misbranded biologics from reaching patients. Those physicians and pharmacists who participate in the gray market, acting with knowing intent or mere negligence or ignorance, may face criminal liability under various legal doctrines. Given a purported lack of federal resources to adequately prosecute gray market participants, states must step in, not only to enact legislation or regulations requiring professional education, but also to rehabilitate or sanction negligent licensees. Once properly educated, the physicians and pharmacists with good intentions will know better than to purchase or dispense gray market biologics, and intentional wrongdoers will be isolated for vigorous prosecution. A strong deterrent message to would-be copycats will reduce the proliferation of the gray market for biologics. Additionally, health care groups must adopt best practices, and consumers must be made aware of the dangers of gray market biologics. In doing so, the risks of gray market biologics may decrease in a manner analogous to the risks of diverted controlled substances.

322. See generally *Verified Internet Pharmacy Practice Sites (VIPPS)*, NAT'L ASS'N OF BDS. OF PHARMACY (Mar. 3, 2014), <http://vipps.nabp.net/> (last visited Aug. 10, 2013).

323. *Id.*

324. *Id.*

325. See *Find a VIPPS Online Pharmacy*, NAT'L ASS'N OF BDS. OF PHARMACY, <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/> (last visited Aug. 10, 2013).

FIGURE 1. EXAMPLE OF THE TRADITIONAL SUPPLY CHAIN.

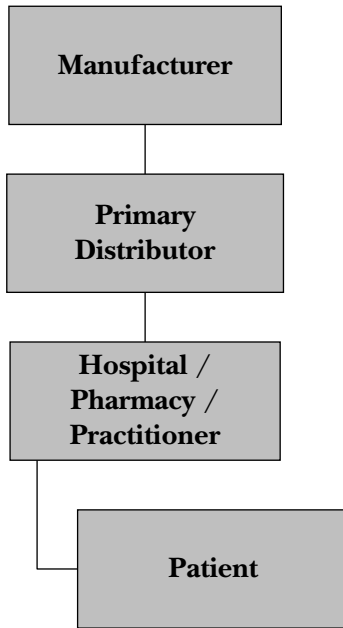


FIGURE 2. EXAMPLE OF A GRAY MARKET CHAIN OF DISTRIBUTION.

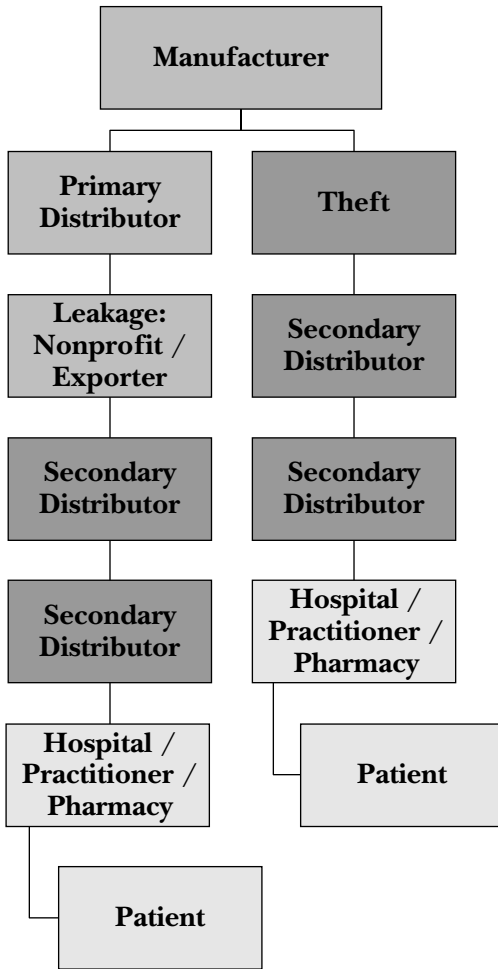


FIGURE 3. GRAY MARKET SOLICITATION FROM GALLANT PHARMACEUTICALS



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- Fax Transmission

To: [REDACTED] From: Lisa Coroniki
 Fax: [REDACTED] Date: 11/7/2012
 RE: Allergan, Medicis & Merz Pages: 1

Comments:

Hi Becky, its Lisa Coroniki, with Gallant Pharmaceutical. Weâ€™re a distributor, and youâ€™re probably not familiar with buying from a distributor. In a nutshell: tremendous savings- for the exact manufacturerâ€™s product youâ€™re buying from Big Pharma right now. Gallant buys from Allergan, Merz and Medicis. ALL whose product is manufactured in Europe. It is FDA approved. We offer free overnight shipping, enabling all product ordered by 4 PM EST to arrive the following day, via Fed Ex. We accept credit cards and guarantee pedigree with our customer satisfaction return policy. Compare our prices. Give us a try, an application is attached. Most small and mid size center city practices are saving thousands yearly by working with us, why shouldnâ€™t you?

I will personally do what it takes to earn your business. Please reach me on the office or cell number below.

ALLERGAN

Botox 100 IU \$425.00
 Juvederm Ultra 2 (2 x 0.55ml) \$289.00
 Juvederm Ultra 3 (2 x 0.8ml) \$369.00
 Juvederm Ultra 4 (2 x 0.8ml) \$379.00

QMEDI/MEDICIS

Dysport 500 IU \$450.00
 Perlane 1ml \$209.00
 Perlane 1ml w/ Lidocaine \$225.00
 Restylane 1ml \$189.00
 Restylane 1ml w/ Lidocaine \$204.00
 Restylane Touch \$150.00

MERZ

Xeomin \$400.00
 Radiesse 1.5cc \$295.00

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