"Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem"

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I. INTRODUCTION

"Love you, Mom."[1] Those were the last words Ryan Haight said to his mom before he overdosed on a prescription drug he obtained from an online pharmacy.[2] Ryan Haight never even saw the doctor who wrote his prescription for the drugs.[3] Worse yet, the creator of the online pharmacy and the doctor signing the prescriptions made millions of dollars on their scheme before Ryan Haight died.[4] Although these individuals have been convicted of applicable crimes,[5] the nefarious framework facilitating their misdeeds remains intact.[6]

At the time of his death, Ryan Haight's mother was a registered nurse and his father was a physician.[7] His parents' professional experience with prescription medications was one of stringent inventory procedures and diligent recordkeeping.[8] Therefore, they were shocked at how easily their son had acquired prescription medication and were surprised that online pharmacies apparently operated with virtually nonexistent standards.[9]

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1. Francine Haight, Presentation, *Illegal Sales of Pharmaceuticals on the Internet*, 16 ALB. L.J. SCI. & TECH. 565, 566 (2006).
2. *Id.*
3. *Id.*
4. *Id.* at 567; *see also* DRUG ENFORCEMENT AGENCY, *Local Pharmacist and Stepfather Sentenced in Internet Pharmacy Case* (Mar. 17, 2005), http://www.justice.gov/dea/pubs/states/newsrel/dallas031705.html (noting that the pharmacist involved in Ryan Haight's tragedy, Clayton H. Fuchs, made over $8 million dollars operating two online pharmacies).
5. U.S. v. Fuchs, 467 F.3d 889, 896, 912 n.2 (5th Cir. 2006) (affirming Clayton Fuchs's appeal of his conviction on six counts—"includ[ing] conspiracy to dispense a controlled substance"—following a jury trial and noting that the doctor involved in Ryan Haight's tragedy, Robert Ogle, was not a party to the appeal although he had been convicted on two counts—including "conspiracy to illegally distribute a controlled substance"—in a jury trial); *see also Local Pharmacist and Stepfather Sentenced in Internet Pharmacy Case, supra* note 4.
6. *See infra*, Part III-C.
7. Haight, *supra* note 1, at 566.
8. *Id.* at 566–67.
9. *Id.*; *see also* Kristin Yoo, Note, *Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet*, 20 J. MARSHALL J. COMPUTER & INFO. L. 57, 60, 68–69 (2001) (noting that although the NABP has attempted to provide some standards for online pharmacies, these standards have not affected a vast number of pharmacies because they are not compulsory).

Their concerns were not unfounded; according to one report, buying prescription drugs online can be just as easy as buying candy online.[10]

There is an unaddressed anomaly with respect to regulating online pharmacies when compared with traditional pharmacies.[11] Online pharmacies serve the same ends as traditional brick and mortar pharmacies, i.e., to bring medication to consumers as a part of a profitable business. The *raison d'être* of traditional pharmacy regulation—to protect consumers[12]—should logically apply to online sources of the same inherently dangerous pharmaceuticals. However, traditional pharmacies are regulated, while online pharmacies have long eluded effective regulation and now constitute a lawless source of purchase and abuse that is far from real physician control, effective standards, or accountability.[13]

Ryan Haight is unfortunately not the only person to have easily obtained prescription drugs online and subsequently die from, or experience serious problems associated with, the drugs received.[14] Thus, there has been a diverse call for consumer protection from online pharmacy abuse[15] from consumer advocacy groups, governments, and applicable experts.[16]

Notwithstanding the fact that many experts recognize the problem, implementing effective regulations has proven problematic due to inadequacies

10. Joseph A. Califano, Jr., NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY, *"You've Got Drugs!" Prescription Drug Pushers on the Internet: 2006 Update* (June 2006), http://static.scribd.com/docs/ed89hyvrez48g.swf?INITIAL_VIEW=width.%20From%20us%20pharmacist%20pdf.

11. *See* Sean P. Haney, *Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies*, 42 WM & MARY L. REV. 575, 575 (2000).

12. *See id.* at 587 (noting that a consumer's "health safety" is at issue when purchasing from some online pharmacies).

13. *See generally id.*; *see also* Barbara J. Williams, Note, *On-Line Prescription and Drug Sales: An Overview of Emerging Issues*, 1 HOUS. J. HEALTH L. & POL'Y 147, 148–49 (2001); *see also* Bryan A. Liang, *A Dose of Reality: Promoting Access to Pharmaceuticals*, 8 WAKE FOREST INTELL. PROP. L. J. 301, 340 (2008).

14. *See Illegal Online Pharmacies Providing Faulty Drugs*, FORTHEPEOPLE.COM, (Oct. 10, 2013), http://www.forthepeople.com/blog/illegal-online-pharmacies-providing-faulty-drugs (noting that many deaths due to overdosing after obtaining prescription drugs online go unnoticed); *see also* Williams, *supra* note 13, at 149.

15. *See* Jeff Karberg, Note, *Progress in the Challenge to Regulate Online Pharmacies*, 23 J.L & HEALTH 113, 114 (2010) (describing a "well documented" need for more regulation of online pharmacies).

16. Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L MED. & ETHICS 98, 99 (2000).

at the national level, coupled with the absence of international controls.[17] This inability to effectively regulate is due in large part to the very nature and characteristics of the internet, including anonymity, instantaneous communication, jurisdictional obscurity, and the diversity of governing bodies involved.[18] An emboldened representative of an online pharmacy articulated this difficulty by declaring, "I [do not] think the politicians are going to be able to do anything to us . . . [it is] kind of like trying to nail Jell-O to a wall."[19]

This problem must be addressed immediately and thoughtfully before more lives are needlessly ruined or ended. The solution must include an evolved understanding of not only the reprehensible elements of some online pharmacy operations, but also the legitimate ends that some online pharmacies fulfill.[20] Also, given the burgeoning international nature of the internet, an effective solution to this problem can no longer be restricted to just the nation state, it must be a collaborative international effort with committed participation from multiple nations.[21]

Following this introduction, Part II of this Comment will establish a foundation for analyzing the problem by describing online pharmacies in the marketplace today. Part III will describe how the international community has thus far attempted to address the problem of online pharmacies. Part IV will address how the United States has approached the problem, including a specific analysis of the strengths and weaknesses of the Ryan Haight Online Consumer Protection Act of 2008 ("Ryan Haight Act"). Part V will summarize the current problems still facing the global marketplace of consumers and citizens. Part VI will recommend a solution to the problem in the form of an international compact that draws upon the Ryan Haight Act and international approaches to date. Part VII will present the objectives and suggested content of such an international compact.

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17. *See generally* Yoo, *supra* note 9.

18. *Id.* at 60; Haney, *supra* note 11, at 575; *see also* Kim Zetter, *FBI Fears Bitcoin's Popularity With Criminals*, WIRED (May 9, 2012 at 10:51PM), http://www.wired.com/threatlevel/2012/05/fbi-fears-bitcoin/ (discussing the potential for bitcoins to facilitate the sale of illegal products online, largely due to the anonymity it offers purchasers).

19. John Richard Castronova, *Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking*, 27 J. LEGAL MED. 207, 213 (2006).

20. CENTERS FOR DISEASE CONTROL AND PREVENTION, *Prescription Drug Overdoses: An American Epidemic* (Feb. 18, 2011), http://www.cdc.gov/about/grand-rounds/archives/2011/01-February.htm.

21. Jeremy W. Hochberg, *Nailing Jell-O to a Wall: Regulating Internet Pharmacies*, 37 J. HEALTH L. 445, 468 (2004).

II. BACKGROUND

A. Types of Online Pharmacies

Not all online pharmacies are the same, and understanding the differences between the various types illuminates the problems they pose.[22] Online pharmacies are generally classified as a: (1) "traditional online pharmacy," (2) "prescribing-based site pharmacy," or (3) "rogue pharmacy."[23] The main difference among the pharmacies is the extent to which they require a prescription or physician-customer interaction. Traditional online pharmacies require a prescription issued from a customer's physician; prescribing-based sites provide a pro forma "cyber-consultation" to customers and, subsequently, write the prescription for the customer; and rogue pharmacies do not require a prescription at all before dispensing prescription drugs.[24]

Traditional online pharmacies are functionally similar to traditional brick and mortar pharmacies.[25] In fact, these pharmacies are often "an online extension" of existing well-known brick and mortar pharmacies.[26] As such, they require a prescription from a physician before a customer's order will be processed and completed.[27] This prescription must be delivered to the pharmacy by the customer or by a physician on behalf of the customer.[28] Because these pharmacies do not prescribe medication themselves, their function is to simply "provid[e] another medium for one to fill existing prescriptions."[29]

Aside from properly requiring prescriptions, traditional online pharmacies typically implement rigorous self-imposed standards aimed at protecting consumers.[30] These types of online pharmacies have been

22. David Mills, *Cybermedicine: The Benefits and Risks of Purchasing Drugs Over the Internet*, 5 J. TECH. L. & POL'Y 1, para. 5 (2000).
23. Karberg, *supra* note 15, at 115; Ludmila Bussiki Silva Clifton, *Internet Drug Sales: Is it Time to Welcome "Big Brother" Into Your Medicine Cabinet?*, 20 J. CONTEMP. HEALTH L. & POL'Y 541, 546 (2004).
24. Kerry Toth Rost, Note, *Policing the "Wild West" World of Internet Pharmacies"*, 76 CHI.-KENT L. REV. 1333, 1334 (2000).
25. Karberg, *supra* note 15, at 115.
26. *Id.*
27. *Id.*
28. Yoo, *supra* note 9, at 64.
29. Joanna M. Carlini, Note, *Liability on the Internet: Prescription Drugs and the Virtual Pharmacy*, 22 WHITTIER L. REV. 157, 171 (2000).
30. Karberg, *supra* note 15, at 115.

considered "a valuable addition to the healthcare consumer industry."[31] Accordingly, they are neither part of the online pharmacy problem, nor do they warrant the implementation of new regulations.[32]

The second type of online pharmacies, prescribing-based site pharmacies, presents some problems for consumer safety.[33] These pharmacies provide both the prescription and the medication to customers who visit the site.[34] The prescription-writing process usually entails a pharmacy providing the consumer with a consultation that consists of little more than a questionnaire.[35] Then, a doctor reviews the results of the consultation and, if approved, the doctor writes the prescription.[36] There is no actual physical examination of the patient in these scenarios, because the entirety of the "examination" occurs online.[37]

One obvious problem with these types of pharmacies is that online questionnaires are simply not comparable to either a thorough medical history report or to an actual physical examination.[38] Patients can, and often do, provide inaccurate information on these questionnaires, a feat they would have a harder time accomplishing at a brick-and-mortar pharmacy during an in-person examination with a doctor or medical professional.[39] Furthermore, these questionnaires do not ask the detailed or critical questions that are necessary for a proper determination of the appropriate medication for a particular ailment.[40]

Another problem with prescribing-based online pharmacies is the high rate of approval for desired medications, possibly influenced by the fact that many consulting doctors employed by this type of online pharmacy get paid by the prescription.[41] Furthermore, these types of pharmacies may

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31. Rost, *supra* note 24, at 1334.

32. Bethany Lipman, Note, *Prescribing Medicine For Online Pharmacies: An Assessment of the Law and a Proposal to Combat Illegal Drug Outlets*, 50 AM. CRIM. L. REV. 545, 549 (2013).

33. *See* Karberg, *supra* note 15, at 116.

34. *Id.*

35. *See id.*

36. Lipman, *supra* note 32, at 550.

37. Williams, *supra* note 13, at 151.

38. Mills, *supra* note 22, at 6.

39. Ann M. Alexander, *Buying Drugs over the Internet: Who is Regulating Pharmacies on the World Wide Web*, 13 SYRACUSE SCI. & TECH. L. REP. 1, 3 (2006); *see also* Hochberg, *supra* note 22, at 446 (noting that those with addictions to a pharmaceutical may go online for the purpose of avoiding the traditional brick-and-mortar physician-patient interaction).

40. Alexander, *supra* note 39, at 1.

41. Karberg, *supra* note 15, at 116; *see also* Ancier v. State, Dept. of Health, 140 Wash. App. 564, 568 (2007) (where a doctor reviewed 200,000 prescriptions over the course of three years and approved 180,000 of them); United States v. Fuchs, 467 F.3d

appear to be legitimate, but the physicians providing the imprimatur are not acting in accordance with the accepted standards of the medical profession.[42] For instance, one website advertised that it had a licensed physician reviewing patient questionnaires; however, the website failed to mention that his license had been revoked in two states.[43]

The third category, "rogue" online pharmacies, poses additional dangers to consumers.[44] Rogue online pharmacies dispense prescription medications without first receiving a prescription, offering a questionnaire, or performing an examination to determine a medical need for the drugs sought.[45] These sites merely require a prospective customer to fill out an order form and select both the drug and quantity desired.[46] In order to receive the drugs, customers simply pay with a credit card online or promise to furnish cash when receiving the drugs.[47]

Rogue online pharmacies generally operate illegally, because only licensed healthcare practitioners are authorized to dispense pharmaceutical drugs, and they must do so in accordance with a valid prescription.[48] Rogue pharmacies may also operate illegally by selling drugs that are banned categorically for sale by certain governments.[49] As such, they have been analogized to street drug dealers[50] and are widely considered to be extremely dangerous.[51] Nevertheless, this third category of online pharmacies has proliferated widely.[52]

There are currently more than "40,000 active rogue [online] pharmacies."[53] Adding to public safety concerns, the World Health Organization ("WHO") has found that up to 50% of the medicine sold on

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889, 898 (5th Cir. 2006) (where one pharmacist received $40 per prescription approved and another between $40–70 per prescription approved).

42. Lipman, *supra* note 32, at 550.
43. Williams, *supra* note 13, at 151.
44. Clifton, *supra* note 23, at 546.
45. Yoo, *supra* note 9, at 65.
46. *Id.*
47. Lipman, *supra* note 32, at 550.
48. *Id.*
49. *See id.*
50. Karberg, *supra* note 15, at 117.
51. *Online Rogue Pharmacies Still Booming*, ASSOCIATED PRESS, (Aug. 23, 2007), http://www.nbcnews.com/id/20409515/#.UmhOiBbvyqQ.
52. *Id.*
53. *Frequently Asked Questions*, LEGITSCRIPT, (last visited Mar. 4, 2015) https://www.legitscript.com/about/faq/.

these sites is fake.[54] This evidences that consumers are in danger of receiving harmful drugs in addition to failing to receive the drugs they need.[55]

Oversight of rogue internet pharmacies is very difficult, as these sites often diversify the locations of their operations.[56] For example, one rogue pharmacy utilized a domain name registered in Russia, web servers located in China and Brazil, processed its expenditures through a bank in Azerbaijan, and shipped its products from India.[57] Due to the extreme risks to patient health posed by "rogue" pharmacies, regulators have, understandably, largely focused on this "rogue" type of pharmacy.[58]

B. Benefits of Online Pharmacies

"The beneficial potential of online pharmacies is significant."[59] The economic incentive to sell pharmaceuticals online is clear. The global pharmaceutical industry earned over $980 billion dollars in revenue in 2013, up from the $390 billion earned in 2001, and is expected to continue growing to just under $1.3 trillion by 2017.[60] Additionally, over 2.4 billion of the world's 7 billion inhabitants are internet users.[61] Therefore, because internet communication costs are essentially negligible, online pharmacies are an economically attractive proposition to sellers.[62]

Online pharmacies are not only economically attractive from a seller's perspective, but they are also attractive from a buyer's perspective.[63] These sites often offer consumers lower costs due to increased competition[64]

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54. *WHO and Partners Accelerate Fight Against Counterfeit Medicines*, WORLD HEALTH ORGANIZATION, http://www.who.int/mediacentre/news/releases/2006/pr69/en/index.html (last visited Mar. 4, 2015).

55. *See id.*

56. Yoo, *supra* note 9, at 66; *see*, *e.g.*, Liang, *supra* note 13, at 340 (noting "the nature of online pharmacies and the inability of key [U.S.] agencies to provide even rudimentary controls over rogue internet pharmacies").

57. *Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad*, GOVERNMENT ACCOUNTABILITY OFFICE (July 2013), http://www.gao.gov/assets/660/655751.pdf.

58. Lipman, *supra* note 32, at 550.

59. Haney, *supra* note 11, at 582.

60. *Statistics and facts about the pharmaceutical industry worldwide*, STATISTA, http://www.statista.com/topics/1764/global-pharmaceutical-industry/ (last visited Mar. 4, 2015).

61. *Internet Users in The World Distribution by World Regions—2012 Q2*, INTERNET WORLD STATS (June 30, 2012), http://www.internetworldstats.com/stats.htm.

62. Clifton, *supra* note 23, at 541.

63. Rost, *supra* note 24, at 1337–38; *see also Drug Sales Over the Internet*, U.S. FOOD AND DRUG ADMINISTRATION (June 30, 1999), http://www.fda.gov/NewsEvents/Testimony/ucm115047.htm.

64. Rost, *supra* note 24, at 1337.

and lower overhead.[65] Consumers may also benefit from comparative shopping, greater availability of drugs, ease of purchase, and convenience.[66] Shoppers also gain the convenience and privacy of ordering drugs online and having them delivered directly to their doors.[67] And, in terms of legitimate functioning, online pharmacies allow "online prescription transmission and electronic consults within narrowly defined circumstances,"[68] which may not pose a consumer protection issue in certain circumstances.

Considering the benefits that online pharmacies may provide to both sellers and consumers, it is clear that online pharmacies have the potential to provide a significant benefit to global society.[69] However, with these tremendous benefits comes a great potential for abuse.

C. Dangers of Some Types of Online Pharmacies

Online pharmacies pose dangers for consumers in many different ways, as follows:

(a) The illegitimate pharmaceutical industry is growing alongside the legitimate industry.[70]
(b) It may be very hard for consumers to distinguish between a legitimate online pharmacy and an illegitimate or rogue pharmacy.[71]
(c) Consumers have easy access to low-quality, expired, counterfeit, or unapproved drugs.[72]
(d) Online pharmacies have begun implementing persistent advertising strategies in an effort to convince patients to self-diagnose their medical ailments and purchase drugs they may not need.[73]

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65. Castronova, *supra* note 19, at 209.
66. *Id.* at 210.
67. Carlini, *supra* note 29, at 157.
68. Haney, *supra* note 11, at 583.
69. Yoo, *supra* note 9, at 62 (recognizing that "legitimate prescription drug sales on the internet can provide tremendous benefits to consumers.").
70. *See Counterfeit Medicines*, WORLD HEALTH ORGANIZATION (Nov. 14, 2006), http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html containing a projection by the Centre for Medicines in the Public Interest that the worldwide sale of counterfeit pharmaceuticals would be $75 billion in 2010, an increase of 90% from 2005).
71. Rost, *supra* note 24, at 1338.
72. Castronova, *supra* note 19, at 211.
73. *Id.*

(e) Consumers are at a greater risk to have their confidential health information mismanaged and their privacy violated when dealing with online pharmacies.[74]
(f) Customers utilizing these sites often believe, incorrectly, that abusing prescription drugs "cannot be as harmful as abusing more conventional 'street' drugs."[75]
(g) Drugs purchased from foreign sites may have incorrect and dangerous labeling and packaging.[76]
(h) There may not be a patient-physician relationship.[77]

The lack of a physician-patient-pharmacist relationship sticks out as being especially troublesome. Before the emergence of online pharmacies, prescription drugs were—in the normal course of behavior—not available without a physician-patient physical interaction.[78] Now, prescribing-based and rogue online pharmacies do not require this relationship.[79] This is problematic because, "[n]ot only does the physician have no way of knowing the identity of his patient, but in many cases the patient has no way of knowing whether the physician or pharmacist with whom he is dealing is properly licensed."[80]

Further, customers receiving drugs without a physician-patient consultation or relationship are not afforded the same safeguards provided by physician and pharmacist reviews.[81] Risk is disproportionately allocated to these consumers, as they are required to learn on their own about the medication they receive, including proper utilization, potential side effects, and complications with mixing the medication with other drugs.[82] Essentially, "a patient can skip going to the doctor and can substitute a

74. *See* Karberg, *supra* note 15, at 132–35.
75. Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008; Final Rule, 74 Fed. Reg. 15,595, 15,596 (Apr. 6, 2009) (to be codified at 21 C.F.R. pt 1300, 1301, 1304, et. al.), http://www.gpo.gov/fdsys/pkg/FR-2009-04-06/html/E9-7698.htm [hereinafter Implementation of the Ryan Haight Act].
76. Michael Veronin, *Packaging and Labeling of Pharmaceutical Products Obtained from the Internet*, J. MED. INTERNET. RES. 2011 Jan–Mar. (2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3221344/ (recognizing that foreign sites are significantly noncompliant with FDA regulations on the labeling and packaging of pharmaceuticals, a critical means for patient safety).
77. Mills, *supra* note 22, at ¶¶ 17, 19.
78. Kara M. Friedman, *Internet Prescribing Limitations and Alternatives*, 10 ANNALS H. L. 139, 140 (2001).
79. *See* Rost, *supra* note 24, at 1334.
80. Hochberg, *supra* note 21, at 452.
81. Rost, *supra* note 24, at 1339.
82. *Id.*

click of the button for 6 years of medical school"[83] and additional years of residency training.

The following two examples vividly illustrate some of the most troublesome characteristics of online pharmacies, particularly the ease with which drugs may be obtained and the alarming lack of oversight. These examples would almost be comical were the life and death implications not so glaringly apparent.

First, an investigative journalist successfully obtained weight loss medication from an online pharmacy by inputting the information of a seven-year-old child into the website.[84] Secondly, another investigative journalist obtained Viagra for her cat from an online pharmacy.[85] This journalist simply filled out a questionnaire with the cat's information, including its exact height (six inches tall) and weight (fifteen pounds).[86] Further, in response to a question about prior surgeries, the journalist responded, "Neutered, 12/15/88."[87]

Not only did the pharmacies in these examples fill and deliver such ludicrous prescriptions, but they also did not question any of the inputted data.[88] This suggests neither a physician nor a pharmacist ever reviewed these orders in any meaningful sense.[89] The nonsensical and glaring failures that these two examples exemplify are disconcerting.[90]

The negative effects of some online pharmacies are substantial, as evidenced by the vast number of people who are getting sick or dying due to medications obtained through these types of pharmacies.[91] Action must be taken to improve the landscape of providing medication online, particularly international regulation, as national regulatory regimes inherently fall short of realizing a lasting solution due to the glaring holes in the regulatory schemes.[92]

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83. Carlini, *supra* note 29, at 173.
84. Castronova, *supra* note 19, at 207.
85. *Id.*
86. Williams, *supra* note 13, at 153.
87. Carlini, *supra* note 29, at 159.
88. Consumer News, *Congressional Panel Discusses Online Pharmacies*, 11 LOY. CONSUMER L. REV. 212, 213 (1999).
89. Carlini, *supra* note 29, at 159.
90. *See generally id*.
91. *WHO and Partners Accelerate Fight Against Counterfeit Medicines*, *supra* note 54.
92. Haney, *supra* note 11, at 612.

III. INTERNATIONAL APPROACHES

Many scholars and health organizations have called for a comprehensive, unified international approach to regulating online pharmacies, including establishing "standardized regulations, operations, and reporting infrastructures supported by serious criminal penalties."[93] Nevertheless, international approaches to solving the problem of regulating online pharmacies have thus far, at best, provided short-term relief, not a lasting solution.

A. World Health Organization

The WHO has explicitly recognized the potential for selling prescription drugs online to evade unilateral regulatory regimes and has noted that this poses a problem for consumers worldwide because it makes medical products that are "unapproved, fraudulent, unsafe, or ineffective" readily available.[94] In accordance with this recognition, the WHO has dedicated resources to address this problem beginning as early as 1997.[95]

For example, at the request of the Fiftieth World Health Assembly, the WHO created a group to gather information pertaining to the problems associated with online pharmacies.[96] This group collected data by collaborating with "drug regulatory agencies, national and international enforcement agencies, consumer groups, professional associations, and the pharmaceutical industry."[97] Subsequently, at the request of the Fifty-First World Health Assembly, the WHO investigated relevant "existing legislation, regulation, and guidelines."[98]

Thereafter, in a further effort to better understand how countries regulate the buying and selling of prescription medications online, the WHO sent a questionnaire to all 191 of its Member States and received responses from 58.[99] The results of the questionnaire "give good grounds for safety concerns."[100] The WHO received information that only five

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93. *See*, *e.g.*, Brian A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J. L. & MED. 279, 312 (2006).

94. Brian A. Liang & Tim Mackey, *Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales*, 35 AM. J. L. & MED. 125, 141 (2009).

95. *Id.*

96. Dr. Lembit Rägo, *Overview of activities by the World Health Organization*, WORLD HEALTH ORGANIZATION 7 (Sept. 24–25, 2001) http://apps.who.int/medicinedocs/pdf/h2960e/h2960e.pdf.

97. *Id.*

98. *Id.*

99. *Id.* at 7–8.

100. *Id.* at 8.

countries "specifically regulate the promotion and sale of pharmaceuticals through the internet."[101]

The apparent dearth of national solutions evinced by this questionnaire, coupled with the other relevant data the WHO had previously obtained, resulted in the WHO's attempt to provide Member States with templates capable of being implemented locally.[102] These templates include an informational guidebook and a draft website for drug regulatory authorities.[103]

Specifically, the WHO guidebook, entitled *Medical Products and the Internet*: *A Guide to Finding Reliable Information*, serves as an educational tool for nations to present to their citizens.[104] The guidebook seeks to educate consumers on a variety of topics, including being able to locate warning signs on online pharmacies, such as: (1) advertisements that claim scientific breakthroughs, (2) advertisements claiming to be the exclusive source for a drug (and that it can only do so for a limited time), and (3) statements that the drugs pose no risks whatsoever.[105] The guidebook also includes a top-ten list of how prescription drugs can be dangerous and ways consumers can spot a legitimate online pharmacy.[106] This list includes tips about what to look for, including active ingredients, instructions on proper use, and warnings about possible negative side effects.[107]

The WHO has also endeavored to educate consumers worldwide about purchasing drugs online via its cooperation with the International Conference of Drug Regulatory Agencies ("ICDRA").[108] ICDRA conferences provide a forum for the regulatory bodies of the WHO Member States to share information and collaborate with one another

101. *Id.*
102. *Id.*
103. *Id.*
104. Ivette P. Gomez, Note, *Beyond the Neighborhood Drug Store: U.S. Regulation of Online Prescription Drug Sales by Foreign Business*, 28 RUTGERS COMPUTER & TECH. L.J. 431, 454–55 (2002).
105. *Id.* at 455.
106. *Id.*
107. *Id.*
108. Liang & Mackey, *supra* note 94, at 143.

about how to regulate online pharmacies.[109] The goal of these conferences is ultimately to harmonize regulations.[110]

The WHO has taken more directed action through the WHO International Medical Products Anti-Counterfeiting Taskforce ("IMPACT").[111] IMPACT "aims to build coordinated networks across and between countries in order to halt the production, trading, and selling of fake medicines around the globe."[112] Comprised of "international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations, and drug and regulatory agencies," IMPACT recognizes the need for "an international multi-stakeholder" coordinated approach to solve these problems and protect consumers.[113] IMPACT presents "guiding principles for model legislation" to help countries better align their laws with the policy of punishing or deterring this activity.[114]

B. Internet Healthcare Coalition

Another international organization that has attempted to combat the negative effects of online pharmacies is the Internet Healthcare Coalition ("IHC").[115] The IHC is an international non-profit organization that consults with many government agencies and holds a yearly conference to discuss the problems regarding, *inter alia*, providing prescription medications online.[116] The specific aims of the organization are to: 1) educate parties involved in healthcare about providing healthcare online, 2) provide "models . . . of good and bad sources of online healthcare information and services," 3) promote pre-existing resources and create new resources pertaining to providing healthcare online, and 4) serve "as a representative . . . before public policymakers and with the media."[117] The IHC has become a "global leader" in educating people about using the internet for healthcare purposes.[118]

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109. *International Conference of Drug Regulatory Authorities*, WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/.

110. *Id.*

111. Liang & Mackey, *supra* note 94, at 143.

112. *About Us*, INTERNATIONAL MEDICAL PRODUCTS ANTI-COUNTERFEITING TASKFORCE, http://www.who.int/impact/about/en/.

113. *Id.*

114. *WHO and Partners Accelerate Fight Against Counterfeit* M*edicines*, *supra* note 54.

115. Gomez, *supra* note 104, at 456.

116. John Mack, *The Internet Healthcare Coalition*, U.S. NATIONAL LIBRARY OF MEDICINE NATIONAL INSTITUTES OF HEALTH (Mar. 5, 2000), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1761844/.

117. *Id.*

118. Gomez, *supra* note 104, at 457.

In 2000, the IHC partnered with other organizations to formulate the "e-Health Ethics Initiative" ("the Initiative").[119] The purpose of the Initiative was to "creat[e] a universal ethical code of conduct for health and medical websites."[120] The Initiative aimed to enable consumers to make better and more informed decisions by generating information that would help consumers understand the statements online pharmacies present on their websites.[121]

C. INTERPOL

INTERPOL has also recognized the problems of illicit online pharmacies and has created many task forces aimed at the enforcement of crimes, global education, and cooperation.[122] For instance, one of INTERPOL's flagship operations, Operation Pangea, is dedicated to targeting and intervening against the sale of illegal drugs online.[123] The operation conducts one mission annually consisting of a week of coordinated efforts among "customs, health regulators, national police, and the private sector."[124] Operation Pangea achieves its success by targeting the following: "internet service providers, payment systems, and the delivery service" utilized by illegal online pharmacies.[125]

Although only ten countries participated in the operation's inaugural year, 2008, the most recent phase in 2013 brought together about 100 countries.[126] There have been six phases of Operation Pangea to date and, collectively, they have identified and shut down a great number of websites engaged in illegal activity and have resulted in multiple arrests of those affiliated with the sale of illegal drugs online.[127]

In the most recent phase of Operation Pangea, Pangea VI, INTERPOL confiscated 10.1 million illicit and counterfeit pills worth about $36

119. *Id.*
120. *Id.*
121. *Id.*
122. *See* Judy Siegel-Itzkovich, *Global Crackdown on Illicit Online Pharmacies*, PERMANENT FORUM ON INT'L PHARMACEUTICAL CRIME (July 2, 2014), http://pfipc.org/news1/9-global-crackdown-on-illicit-online-pharmacies.
123. *Operations*, INTERPOL, http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea (last visited Jan. 13, 2013).
124. *Id.*
125. *Id.*
126. *Id.*
127. *See id.* (providing information about each Operation Pangaea mission to date).

million dollars, destroyed over 13,700 websites, either investigated or arrested about 213 individuals, and inspected over 500,000 packages, resulting in the confiscation of 41,000.[128] Major market players were involved in Pangea VI, including the United States, the United Kingdom, China, India, Japan, and Canada.[129]

In addition to Operation Pangea, INTERPOL has recently established another unit, the Medical Products Counterfeiting and Pharmaceutical Crime unit ("MPCPC"), which is designed to engage in the international enforcement of illicit online pharmacies.[130] This unit was created to support WHO-IMPACT in combatting online pharmaceutical crime.[131]

D. National Association of Boards of Pharmacy

There are also smaller organizations dedicated to educating consumers about illegal online pharmacies.[132] One such organization is the National Association of Boards of Pharmacy ("NABP").[133] The NABP has been active in addressing the problems associated with online pharmacies. For instance, the NABP maintains a database with information about pharmacies and pharmacists.[134] Additionally, the NABP hosts a global certification program—Verified Internet Pharmacy Practice Site ("VIPPS")—that verifies online pharmacies as being legitimate.[135] The purpose of the VIPPS program is to put consumers on notice that an online pharmacy with a VIPPS certification has passed an independent inspection.[136]

This VIPPS program was established due to mounting public concern about the problems online pharmacies may pose to consumers, and it allows online pharmacies to boast a seal of approval on their website, should they satisfy the VIPPS requirements.[137] These requirements include "compliance with standards of privacy and authentication and security of

128. *Id.*

129. *International Operation Targets Online Sale of Illicit Medicines*, INTERPOL (June 27, 2013), http://www.interpol.int/News-and-media/News-media-releases/2013/PR077 (last visited Jan. 13, 2014).

130. *INTERPOL applauds Southeast Asia Operation Storm II's Success in Disrupting Trade of Counterfeit Medical Products*, INTERPOL (Jan. 27, 2010), http://www.interpol.int/News-and-media/News-media-releases/2010/PR007.

131. *Id.*

132. *See*, *e.g.*, *Who We Are*, ALLIANCE FOR SAFE ONLINE PHARMACIES, http://safeonlinerx.com/about-us/who-we-are/ (last visited Jan. 13, 2014).

133. *See About*, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, http://www.nabp.net/about (last visited Jan. 13, 2014).

134. Williams, *supra* note 13, at 181.

135. *Id.* at 181–82.

136. Castronova, *supra* note 19, at 220.

137. Oliver, *supra* note 16, at 99.

prescriptions, adhere[nce] to quality assurance policy, and provid[ing] meaningful consultation between patients and pharmacists."[138]

Currently, there are thirty-five VIPPS certified pharmacies, eleven of which require membership in order to obtain medication, while the remaining twenty-four are open to all customers.[139] Although this program was the first attempt to establish a set of minimum standards for the online pharmacy industry, its effect has not been very successful, because participation is voluntary[140] and stricter regulation is needed.[141]

The NABP is also responsible for a more recent development in the international approach to regulating online pharmacies.[142] The NABP proposed to establish and become the official registry for a new domain name for buying pharmaceutical medications online, so that consumers can be confident in the safety of the drugs they are obtaining.[143] NABP promulgated this suggestion at the 2013 International Pharmacy Federation World Congress, where it further explained the uniform domain—".PHARMACY."[144] The uniform domain would ensure that accepted pharmacies "meet all the applicable regulatory standards . . . in the jurisdictions where they are based and where they serve patients."[145] These oversight standards would include "pharmacy licensure, drug authenticity, and valid prescription requirements."[146]

However, this proposal has faced a strong opposition that seeks to prevent it from being implemented.[147] Among the opponents to NABP

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138. *VIPPS*, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, http://www.nabp.net/programs/accreditation/vipps (last visited Jan. 13, 2014).

139. *Find a VIPPS Pharmacy Online*, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/ (last visited Jan. 13, 2014).

140. Yoo, *supra* note 9, at 69.

141. Alexander, *supra* note 39.

142. *See NABP Shares Online Pharmacy Safety Information at International Pharmaceutical Federation World Congress*, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (Sept. 18, 2013 5:40 PM), https://www.nabp.net/news/nabp-shares-online-pharmacy-safety-information-at-international-pharmaceutical-federation-world-congress.

143. *Id.*

144. *Id.*

145. *.PHARMACY and NABP*, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, http://www.nabp.net/programs/pharamcy/pharmacy-and-nabp (last visited Jan. 13, 2014).

146. *Id.*

147. *See*, *e.g.*, *Public Citizen, Demand Progress and RXRights.org Join Others Opposing U.S. Pharmacy Industry Group From Controlling "Pharmacy" Domain Registration*, PRWEB (May 30, 2013), http://www.prweb.com/releases/oppose/NABP-ICANN/prweb10780126.htm.

controlling the ".PHARMACY" domain are Public Citizen, Demand Progress, and RxRights.org.[148] These opponents of NABP's proposal claim the operation will sacrifice consumer access to affordable medication in order to benefit pharmaceutical companies.[149]

E. Conclusion About International Approaches

Although these aforementioned international approaches have seen some success, they have not had lasting effects on the online pharmacy industry. The problem requires more than education campaigns and short bursts of sporadic enforcement. Without re-directed efforts, there are still too many avenues for online pharmacies to exploit.

IV. UNITED STATES APPROACH

A. Background

The United States presents a domestic regulatory scheme illustrative of a unilateral, national approach to regulating online pharmacies. Traditionally, each state individually regulates pharmacies.[150] However, online pharmacies are regulated largely by the Food and Drug Administration ("FDA") and the Drug Enforcement Administration ("DEA").[151] The FDA regulates online pharmacies through the Federal Food, Drug, and Cosmetic Act ("FDCA"), while the DEA regulates online pharmacies through the Controlled Substances Act ("CSA").[152] Although the two agencies often work together, the FDA focuses on what has been categorized as "non-controlled substances", while the DEA focuses on what has been categorized as "controlled substances."[153]

With this infrastructure in place, the distribution of prescription drugs in the United States has been "one of the safest systems in the world."[154] However, with the emergence of online pharmacies, the United States has been forced to change its model and adapt its regulations to accommodate

148. *Id.*
149. *Id.*
150. Oliver, *supra* note 16, at 99.
151. Karberg, *supra* note 15, at 118.
152. *Id.*
153. *Id.*
154. Clifton, *supra* note 23, at 544; *but cf.* Geoffrey Kabat, *Natural Does Not Mean Safe*, SLATE, http://www.slate.com/articles/health_and_science/medical_examiner/2012/11/herbal_supplement_dangers_fda_does_not_regulate_supplements_and_they_can.1.html (last visited Jan. 17, 2014) (recognizing that there are still problems with such regulations, including the health risks associated with the exemptions from FDA regulation afforded to "dietary and herbal supplements").

the benefits of online pharmacies, while also attempting to eliminate the harms.[155]

One way in which the DEA has attempted to combat illicit online pharmacies was by creating a database named the Automation of Reports and Consolidated Orders System ("ARCOS").[156] This program requires manufacturers and distributors of pharmaceuticals to provide the DEA with information about narcotic substances.[157] The goal is to allow the DEA to utilize this data to pursue investigative leads where consumers were purchasing abnormally high volumes of controlled substances.[158] Furthermore, the DEA implemented the "Internet Distributor Initiative" and the "Internet Industry Initiative" in an attempt to make distributors accountable for their misdeeds and raise awareness among other parties who are involved in the misdeeds, including delivery services and credit card companies.[159]

These initiatives may have brought about some success.[160] A study performed by the National Center on Addiction and Substance Abuse at Columbia University indicated that rogue internet pharmacies decreased 25% from 2004 to 2008.[161] However, a regulatory framework was needed to further combat online pharmacies, and that need that was realized in 2008 with the passage of the Ryan Haight Online Consumer Protection Act of 2008.

B. The Ryan Haight Online Consumer Protection Act of 2008

Ryan Haight's story motivated Congress to amend the Controlled Substances Act ("CSA") by passing the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act").[162] This piece of legislation is essentially the first in the United States to specifically attack the problem of online pharmacies.[163] The act explicitly prohibits distributing

155. *See generally* Kabat, *supra* note 154, at 544.
156. Monica Kim Sham, Note, *Down on the Pharm: The Juvenile Prescription Drug Abuse Epidemic and the Necessity of Holding Parents Criminally Liable for Making Drugs Accessible in Their Homes*, 27 J. CONTEMP. HEALTH L. & POL'Y 426, 440 (2011).
157. *Id.*
158. *Id.*
159. *Id.*
160. *Id.* at 440–41.
161. *Id.*
162. *See* Karberg, *supra* note 15, at 114, 122.
163. *Id.* at 122.

controlled substances online without a doctor-patient physical examination.[164] Accordingly, the online pharmacies that already require a doctor-patient examination—the traditional online pharmacies—are not targeted, while prescribing-based and rogue pharmacies are the subject of the Act.[165] The purpose of the Ryan Haight Act has been described as a means "to protect consumers by ensuring that only legitimate, law-abiding Web sites dispense controlled substances via the Internet."[166]

The Ryan Haight Act specifically states, "[n]o controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the internet without a valid prescription."[167] A valid prescription is defined as "a prescription that is issued for a legitimate medical purpose in the course of professional practice by—(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner."[168] A covering practitioner is one who:

> conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous 24 months; and (ii) is temporarily unavailable to conduct the evaluation of the patient.[169]

Moreover, the Ryan Haight Act mandates a new DEA registration for online pharmacies.[170] This registration allows the DEA to better recognize and keep track of the misdeeds of online pharmacies.[171]

Not only must an online pharmacy now register with the DEA in order to operate legally, but it must also report the amount of controlled substances it distributes, by any means, during a given month, if the amount it has distributed is above the given threshold requirements.[172] The threshold requirements are as follows: "(A) 100 or more prescriptions dispensed. (B) 5,000 or more dosage units of all controlled substances combined."[173]

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164. Lipman, *supra* note 32, at 552; Controlled Substances Act (CSA), 21 U.S.C. § 829(e)(2)(A)(i) (2012).

165. *See* Sarah Rubenstein, *New Bill Targets Rogue Druggists on the Internet*, WALL ST. J. (Oct. 9, 2008 12:01 AM), http://online.wsj.com/news/articles/SB12235152 1815117817.

166. Implementation of the Ryan Haight Act, *supra* note 75, at 15,609.

167. 21 U.S.C. § 829(e)(1).

168. 21 U.S.C. § 829(e)(2)(A).

169. 21 U.S.C. § 829(e)(2)(C).

170. Implementation of the Ryan Haight Act, *supra* note 75, at 15,599; *see also* Karberg, *supra* note 15, at 124–25.

171. Karberg, *supra* note 15, at 124–25.

172. Implementation of the Ryan Haight Act, *supra* note 75, at 15,601; 21 U.S.C. § 827(d)(2).

173. 21 U.S.C. § 827(d)(2)(A); 21 U.S.C. § 827(d)(2)(B).

The Ryan Haight Act also requires an online pharmacy to display specific information about its operations on its website.[174] First, the online pharmacy must post a statement and declaration of compliance with the new regulations.[175] Second, the online pharmacy must prominently display the following information: "[t]he name and address of the pharmacy, [t]he pharmacy's telephone number and email address," the qualifications and contact information of the pharmacist in charge, "[a] list of the states in which the pharmacy is licensed to dispense controlled substances," a certificate of registration to distribute controlled substances, the qualifications and contract information of the person who will provide medical evaluations or issue prescriptions for controlled substances, and a statement of notice.[176]

The Ryan Haight Act also adds two new crimes to the existing CSA regulatory framework.[177] Specifically, the Ryan Haight Act provides that, "[i]t shall be unlawful for any person to knowingly or intentionally—(A) deliver, distribute, or dispense a controlled substance by means of the internet, except as authorized by this subchapter; or (B) aid or abet . . . any activity described in subparagraph (A) that is not authorized by this subchapter."[178]

The Ryan Haight Act also broadens the civil liability for violations by allowing states to bring a civil action in federal court.[179] Specifically, the Act provides, "[i]n any case in which the State has reason to believe that an interest of the residents of that State has been or is being threatened or adversely affected by the action of [sic] [an] Internet site" may bring an action in a federal district court.[180] Relief in these instances is not limited to equitable damages; legal damages are also available.[181]

The DEA attempted to articulate, in a press conference, the most important features of the Ryan Haight Act as: 1) requiring at least one face-to-face medical examination between a patient and a doctor a prescription

174. Implementation of the Ryan Haight Act, *supra* note 75, at 15,602–03; 21 U.S.C. § 831.
175. 21 U.S.C. § 831(a); 21 U.S.C. § 831(e).
176. 21 U.S.C. § 831(c).
177. Implementation of the Ryan Haight Act, *supra* note 75, at 15,602–03; 21 U.S.C. § 841(h) (2010).
178. 21 U.S.C. § 841(h).
179. Implementation of the Ryan Haight Act, *supra* note 75, at 15,602; 21 U.S.C. § 882(c) (2009).
180. 21 U.S.C. § 882(c).
181. *See id.*

for a controlled substance to be valid, 2) requiring a DEA endorsement before an online pharmacy may distribute controlled substances online, 3) deterring the sale of certain drugs by increasing the penalties associated with selling such drugs, 4) prohibiting advertising the illegal sale of controlled substances online, 5) requiring an online pharmacy to post truthful information about its operation, and 6) allowing a civil state cause of action for state attorney generals.[182]

1. Strengths of the Ryan Haight Act

The Ryan Haight Act is not a perfect example of domestic regulation; nevertheless, there are some merits in its approach to regulating online pharmacies, as it embraces the right policies and is capable of serving as a good model for expansion.[183] Although still new in its implementation, the Ryan Haight Act has been recognized as having had a significant impact on reducing the number of domestic online pharmacies operating illegally.[184] Specifically, the Ryan Haight Act has had the greatest influence on combatting prescribing-based online pharmacies, both through prosecutions for noncompliance and through the deterrent effect it has, because of the clear message it sends to operators of online pharmacies about what is and is not legal.[185] In fact, five years after the Ryan Haight Act passed, prescribing-based online pharmacies have been "largely eliminated" in the United States.[186]

Arguably the most prominent strength of the Ryan Haight Act is that it requires online pharmacies to obtain a valid prescription in order to distribute drugs, which must consist of at least one face-to-face doctor-patient interaction.[187] This requirement, at least in theory, puts an end to prescribing-based and "rogue" online pharmacies[188] and has led to the government prosecuting the operators of such pharmacies.[189] Unfortunately, although this new requirement is necessary for compliance, it is not

182. *Congress Passes Ryan Haight Online Consumer Protection Act*, DRUG ENFORCEMENT AGENCY (Oct. 1, 2008), http://www.justice.gov/dea/pubs/pressrel/pr100108.html.

183. *Drug Dealers on the Internet: Is the DEA enforcing the Ryan Haight Act?*, LEGITSCRIPT (June 2011), http://www.legitscript.com/download/LegitScript-DEA-Rogue-Internet-Pharmacy-Analysis.pdf (noting that the DEA has not effectively enforced the Ryan Haight Act).

184. *National Drug Control Strategy*, OFFICE OF NATIONAL DRUG CONTROL POLICY (2010), http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf.

185. Lipman, *supra* note 32, at 553.

186. *Id.*

187. *See* Karberg, *supra* note 15, at 126; 21 U.S.C. § 829 (2009).

188. Karberg, *supra* note 15, at 126.

189. Lipman, *supra* note 32, at 553.

sufficient because other regulations must be adhered to as well, such as the mandate that controlled substances "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[190]

Another strength of the Ryan Haight Act is the requirement that online pharmacies register with the DEA, in order to be authorized to dispense controlled substances online.[191] Such a requirement was previously in place for traditional brick-and-mortar pharmacies, and this new requirement helps put online pharmacies on "equal footing" with these traditional pharmacies.[192] Now, unregistered sites are illegal and, thus, the DEA can shut down any unregistered site and pursue both criminal and civil legal action.[193]

A beneficial corollary of this registration requirement is that it can simultaneously act as a database for legitimate online pharmacies.[194] In fact, one commentator has suggested that a list of DEA registered online pharmacies can set "the foundation for cooperation with other government agencies and business entities while also educating consumers as to the legitimacy of the pharmacies they visit online."[195]

Additionally, the Ryan Haight Act's requirement that each site discloses certain information about its operations is a very effective means of educating consumers about the legality of the drugs they purchase online.[196] The disclosure is effective, in part, due to the requirement that the information be conspicuously posted.[197]

Another strength of the Ryan Haight Act is the notice it gives to operators of online pharmacies, physicians, and pharmacists: all pharmacies, whether operating online or out of a storefront, are now going to be held to the same standards.[198] The Ryan Haight Act does this by setting a standard "baseline professional conduct" for doctors and pharmacists

190. Implementation of the Ryan Haight Act, *supra* note 76, at 15,599 (referring to 21 CFR 1306.04(a)).
191. Karberg, *supra* note 15, at 123–25.
192. *Id.* at 123
193. *Id.* at 125; *see also* Implementation of the Ryan Haight Act, *supra* note 75, at 15,599.
194. Karberg, *supra* note 15, at 125.
195. *Id.*
196. *Id.* at 125–26.
197. *Id.* at 126.
198. Implementation of the Ryan Haight Act, *supra* note 75, at 15,609–10; *see* also Karberg, *supra* note 15, at 125–26.

participating in the online pharmacy market.[199] This notice applies not only to the individuals who knowingly have been operating illegal sites, but also to those who were under the impression that their online prescribing or distribution practices were legitimate.[200] Accordingly, all involved in the online pharmacy market can no longer expect the disparate treatment online pharmacies had been receiving as compared with brick-and-mortar pharmacies, and they are effectively on notice that the United States has recognized the problems associated with illicit online pharmacies and has implemented more stringent regulations in response to those problems.

The Ryan Haight Act also features an increase in the severity of punishments for violations of the CSA.[201] Violators of the Ryan Haight Act face criminal penalties that could be double what they were prior to the passage of the Ryan Haight Act.[202] Furthermore, the Ryan Haight Act broadened the scope of civil liability by allowing states to bring a civil action on behalf of their citizens if they believe the citizens of their state are being negatively affected by an online pharmacy.[203] Remedies available under such a suit include legal damages and equitable relief.[204] These added penalties are beneficial, as they may deter illicit online pharmacy operators or preclude them from continuing their operations or starting new ones.

2. Weaknesses of the Ryan Haight Act

Despite its apparent successes, the Ryan Haight Act is not a comprehensive safeguard. Its scope is too narrow in addressing only "controlled substances," a small fraction of prescriptions dispensed in the United States.[205] This confined scope also leaves a gap in consumer protection, vis-a-vis foreign pharmacies, and does not protect patient privacy.[206]

Non-controlled substances also pose dangers for consumers.[207] Non-controlled substances include a wide variety of prescription drugs, from the erectile dysfunction drugs Viagra and Cialis, to the painkiller Celebrex,

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199. Karberg, *supra* note 15, at 126.
200. Lipman, *supra* note 32, at 553.
201. Karberg, *supra* note 15, at 122–23; *see also Congress Passes Ryan Haight Online Consumer Protection Act*, *supra* note 182.
202. *See Congress Passes Ryan Haight Online Consumer Protection Act*, *supra* note 182.
203. 21 U.S.C. § 882 (2013).
204. Karberg, *supra* note 15, at 128.
205. *Id.* at 131–32.
206. *Id.*
207. *Id.* at 131.

and the muscle relaxant Soma.[208] Unfortunately, online pharmacies target these and other excluded drugs.[209] In particular, drugs with weight-loss or erectile dysfunction appeal are internet marketed for the supposed "privacy" of the transaction.[210] Future regulations must also address non-controlled substances, because they pose some of the same quality concerns as many controlled substances and are potentially harmful.[211]

The same two senators who introduced the Ryan Haight Act to Congress, Dianne Feinstein and Jeff Sessions, have voiced their concern about the Act's insufficient scope in Congress.[212] These senators have unsuccessfully called for the passage of the Online Pharmacy Safety Act of 2011,[213] which essentially would have broadened the scope of the Ryan Haight Act to include regulation of all prescription drugs instead of merely addressing non-controlled substances.[214] The bill also called for an amendment to the FDCA and participation from the Secretary of Health and Human Services and the FDA in administering the law.[215]

The most serious failure of the Ryan Haight Act is its inability to address foreign-based rogue online pharmacies.[216] These foreign-based rogue sites are the principle offender in the realm of online pharmacies, yet the Ryan Haight Act essentially does not address them.[217] Not only does the Ryan Haight Act not address foreign pharmacies, its effectiveness in so doing would be suspect had it attempted to do so.[218]

Foreign pharmacies are elusive by their very nature, as they are not subject to domestic laws.[219] Therefore, the Ryan Haight Act, being that it

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208. Sarah Rubenstein, *New Bill Targets Rogue Druggists on the Internet*, WALL ST. J. (Oct. 9, 2008), http://online.wsj.com/news/articles/SB122351521815117817.

209. *See* Karberg, *supra* note 15, at 138.

210. *Id.*

211. *See id.*

212. *See* Dianne Feinstein, *Sessions Call for Stricter Online Pharmacy Rules*, FEINSTEIN.SENATE.GOV (Dec. 15, 2011), http://www.feinstein.senate.gov/public/index.cfm/press-releases?ID=9ac81372-466a-49e1-9d04-33da43cdb806.

213. *See S. 2002 (112th): Online Pharmacy Safety Act*, GOVTRACK.US (2011), https://www.govtrack.us/congress/bills/112/s2002#overview (indicating this bill has died in committee and is not currently under review by Congress).

214. Feinstein, *supra* note 212.

215. Online Pharmacy Safety Act, H.R. 4095, 112th Cong. (2012), http://beta.congress.gov/bill/112th/house-bill/4095.

216. Lipman, *supra* note 32, at 553.

217. Liang & Mackey, *supra* note 94, at 152.

218. *See generally id*.

219. *See* Karberg, *supra* note 15, at 135; *see also* Liang & Mackey, *supra* note 94, at 150.

is a domestic piece of legislation, implicitly has a substantial territorial application restriction.[220] To enforce such domestic legislation, the United States—and any other country for that matter—has little authority internationally, other than to request foreign governments get involved.[221] This may be difficult to achieve, as it is possible for a pharmacy to be in compliance with the laws of the foreign government in which it has based its operations, even if it does not comply with American regulations.[222]

Essentially the only impact the Ryan Haight Act has on foreign-based rogue internet pharmacies is that there are steeper penalties for distributing certain medications.[223] However, this impact is greatly minimized by the fact that operators of these sites know the likelihood of being caught and prosecuted for their behavior is minimal.[224] This is evidenced by the fact that nearly 97% of online pharmacies are still operating in non-compliance with state and federal laws or industry standards.[225]

The Ryan Haight Act also fails to establish standards that protect patient privacy.[226] "Identity theft, fraud, and patient privacy" are concerns for any internet transaction[227] and these concerns are amplified when dealing with sensitive information like medical records.[228] Thus, the legislature omitted what should be a necessary component of any regulation in this area when it failed to address patient privacy in the Ryan Haight Act.[229]

Rather than protecting consumers, it has also been argued that the "valid prescription" requirement provides illicit online pharmacies with another opportunity to exploit users.[230] As the argument goes, illicit online pharmacies may utilize the "valid prescription" requirement as another opportunity to charge their customers and collect more money from them.[231]

These problems should make American lawmakers realize that effectively regulating online pharmacies is an "inherently international crime problem."[232]

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220. *See* Karberg, *supra* note 15, at 135; *see also* Liang & Mackey, *supra* note 94, at 150.
221. Liang & Mackey, *supra* note 94, at 150.
222. Phil Ayers, *Prescribing a Cure for Online Pharmacies*, 72 TENN. L. REV. 949, 976 (2005).
223. Lipman, *supra* note 32, at 554.
224. *Id.*
225. *Id.* at 560–61.
226. Karberg, *supra* note 15, at 132.
227. *Id.*
228. *Id.*
229. *See id.*
230. Liang & Mackey, *supra* note 94, at 152.
231. *Id.*
232. Lipman, *supra* note 32, at 563.

C. Conclusions About the Approach of the United States

The Ryan Haight Act has been considered "a much needed first step toward meaningful regulation of online pharmacies."[233] Pharmacies in the international community could potentially benefit by applying some of the underlying principles behind the Ryan Haight Act to continue moving in the right direction toward solving the worldwide crisis of online pharmacy regulation.

V. THE CURRENT PROBLEM

As illustrated by the United States' legislation aimed at regulating online pharmacies and the international approaches to doing the same, there exists a deficiency in effective regulation. Domestic regulations fall short, as sovereign States do not have the unilateral ability to regulate foreign-based online pharmacies that sell medications to consumers within their borders. Similarly, international regulations fall short because they are too focused on education and short-term relief. Accordingly, consumers are not being protected, and a more comprehensive and cohesive international approach is necessary to prevent the proliferation of an epidemic that has already killed thousands of people.

Before addressing the purpose for which this article was written—to recommend a solution to the problems associated with certain online pharmacies via the implementation of a comprehensive international regulatory regime—the arguments against such a recommendation must be noted.

First, there is an argument that, although illicit online pharmacies have destroyed or greatly harmed people's lives, these same pharmacies have also saved lives. For example, an American woman named Nina spoke out after the United States government shut down numerous illicit online pharmacies.[234] Nina had become dependent upon a particular illegal online pharmacy after she lost her health insurance and could no longer afford to obtain a prescription through conventional means.[235] Instead, she

233. *See* Karberg, *supra* note 15, at 142.

234. Thomas Ginsberg, *Online Drug Bust is Casting a Wide Net[:] Some Customers with Valid Medical Needs Were Using the Internet Pharmacy. Experts Say Battling Sites Will Be Hard*, PHILA. INQUIRER (Apr. 22, 2005), http://articles.philly.com/2005-04-22/news/25426985 1internet-pharmacy-online-pharmacy-internet-site.

235. *Id.*

paid $45 a month for medication she obtained online.[236] Completely oblivious to the source of the medication, who operated the site, and who utilized the site, Nina was unfazed—"[i]t was that or nothing."[237]

Second, there is an argument against regulation due to the principle of customer autonomy.[238] As the argument goes, consumers should have the opportunity to decide for themselves where they obtain their medications without governmental interference on behalf of the public good.[239] Further, "[b]y allowing the market to control prices, free from excessive government interference, the result will be cheaper drugs for those who can least afford it."[240]

This argument is particularly powerful coming from the elderly, impoverished, uninsured, and underinsured who may not be able to see a doctor or otherwise obtain the drugs.[241] The argument for customer autonomy is also strong for people who want privacy with respect to the (embarrassing) drugs they wish to obtain.[242]

Third, there is an argument that attempts to regulate would only unduly burden legitimate online pharmacies and would not affect the troublesome pharmacies.[243] Regulators are therefore cautioned to tailor their regulatory schemes to address the problematic types of pharmacies and be wary not to cast too wide of a net that will place obstacles in the way of legitimate online pharmacies.[244] In fact, it has been suggested that governments should allow the natural forces of the online market to establish standards rather than establishing their own,[245] or focus instead on reducing the demand for pharmaceuticals.[246]

Lastly, it has been argued that the problems associated with the lack of a physician-patient relationship, a driving force being the call for

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236. *Id.*

237. *Id*. The fear that regulating online pharmacies may prevent people like Nina from obtaining the prescription medication they need is significantly weakened, at least in the United States, by the implementation of the Affordable Care Act. Regardless of the ultimate wisdom of the Act, "[m]ore than 16 million people have gained health insurance" under it, suggesting that people seeking prescription drugs for legitimate medical purposes may have another option besides resorting to illicit online pharmacies and, therefore, will not be negatively affected by regulating online pharmacies. *See Administration: 16M gained health coverage under ObamaCare*, THE HILL, (Mar. 16, 2015) http://thehill.com/policy/healthcare/235819-administration-16-million-people-gained-obamacare-coverage.

238. *See* Lipman, *supra* note 32, at 562.

239. *See id.*

240. Alexander, *supra* note 39.

241. *See id.*; *see also* Liang & Mackey, *supra* note 94, at 130.

242. *See* Alexander, *supra* note 39.

243. Williams, *supra* note 13, at 187.

244. *Id.*

245. *See* Carlini, *supra* note 29, at 161.

246. Castronova, *supra* note 19, at 221.

increased regulation, is misplaced because similar practices occur at traditional brick-and-mortar pharmacies.[247] Such critics contest that doctors prescribing medicine without a face-to-face interaction is not as anomalous an occurrence as those pushing for regulation postulate.[248] For example, many doctors at some point in their career have filled a prescription for a close friend or a family member of a longtime patient without actually seeing that person.[249] Accordingly, those who resist regulating online pharmacies accuse doctors who do criticize the practice of issuing prescription medications online without face-to-face consultation of engaging in "professional protectionism."[250]

Notwithstanding these arguments to the contrary, the rationale for more regulation—particularly where targeted at abusive practices—is more compelling. Ingestion of erroneous or improper dosages can be an issue of life or death. Furthermore, stopping the proliferation of illegitimate online pharmacies would curb the irresponsible use of prescription medicines. The responsible use of medicine, including proper identification and dosage, could lead to global annual savings of up to $500 billion dollars annually.[251] Such consumer protection should be a legitimate concern for governments across the world.[252]

Recognizing the problem and the need to address it is not enough, as additional issues arise in deciding how to effectively solve the problem. What type of international or multinational regulatory regime is appropriate and necessary to address this worldwide problem? What type of regulatory regime should be implemented?

VI. MULTINATIONAL REGULATORY SCHEME

Many scholars and commentators agree that the solution to the problems associated with some online pharmacies must involve international cooperation.[253] For example, the WHO Coordinator of IMPACT, Dr.

247. Mills, *supra* note 22, at 15 n.68.
248. *Id.*
249. *See id.*
250. See *id.*
251. *See* INTERNATIONAL PHARMACEUTICAL FEDERATION, https://www.fip.org (last visited Jan. 17, 2014).
252. *See* Liang, *supra* note 93, at 312–14.
253. *See*, *e.g.*, Hochberg, *supra* note 21, at 445; Gomez, *supra* note 104, at 462; Rost, *supra* note 24, at 1335; Lipman, *supra* note 32, at 564–65; Yoo, *supra* note 9, at 86; Williams, *supra* note 13, at 185.

Valerio Reggie, stated, "we need to coordinate action at a global level."[254] Scholars and other commentators are not short on giving this same advice.[255] For instance, one scholar noted, "[i]n both the short and long term, emphasis should be upon compacts, agreements, and accords among nations and between federal and state governments inter se."[256] In addition to calling for government cooperation, at least one scholar calls for a strategy that incentivizes private corporations to cooperate as well.[257]

It is clear that the market for illicit pharmaceutical distribution "does not respect international lines and hence, neither can efforts to eliminate it."[258] However, a multilateral international compact that transforms the successes and failures of the Ryan Haight Act into a cohesive and unified approach to regulating online pharmacies will effectively give sovereign States an opportunity to fill the previously incurable extraterritorial deficiencies in local regulation and provide consumers with the protection they need.

VII. INTERNATIONAL COMPACT

Ryan Haight became the face of online pharmacy reform in the United States. The United States legislation enacted in response to his story contains a workable framework for an international compact that addresses online pharmacy abuse. The Ryan Haight Act provides the content for a compact not only in its text, but also in that which critical analysis and hindsight reveal are missing from its text.

To begin, an international compact based upon the Ryan Haight Act (and other approaches to combating online pharmacies) should create a uniform body of law that is applicable to all online pharmacies operating within the borders of any country that is a signatory to the compact. The goal of the compact should be to protect consumers in the global marketplace, which will be accomplished through the multilateral enforcement of the compact's provisions.[259]

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254. *WHO and Partners Accelerate Fight Against Counterfeit Medicines*, *supra* note 55.

255. *See* Williams, *supra* note 13, at 185.

256. *Id.*

257. Lipman, *supra* note 32, at 568 (calling for governments to incentivize "payment intermediaries, search engines, and other private actors" to do their part).

258. Liang, *supra* note 93, at 313–14.

259. Effective enforcement of the compact may be most readily obtainable if each signatory incorporates the provisions of the compact into its domestic law, consistent with its state practice, through either "self-executing" means or by implementing additional domestic legislation. *See International Norms and Standards Relating to Disability*, UNITED NATIONS ENABLE, (2003–2004) http://www.un.org/esa/socdev/enable/comp101.htm

The drafters of the compact must be mindful of how the compact will affect the different types of online pharmacies. With this in mind, the compact should greatly emphasize reducing prescription medications that are distributed from rogue online pharmacies. This is a feat that has been largely unobtainable to date, and the Ryan Haight Act did not effectuate real change in this regard either.[260] In addition, the compact should target prescribing-based sites, and will feasibly be successful in eradicating such sites, just as the Ryan Haight Act did. Traditional online pharmacies should be subject to certain compliance measures, but should be the least emphasized of the three types of online pharmacies.

Moving to a more particularized view of the content the compact should contain, the underlying standard for the compact should be very similar to that of the Ryan Haight Act, but with a scope beyond "controlled substances." The broadened scope should embrace all prescription medications distributed online. Thus, the standard should make it illegal to "knowingly or intentionally . . . deliver, distribute, or dispense" any prescription medications online, or to "aid or abet" such activity, unless the activity is performed in accordance with the compact.[261] To comply with the compact, online pharmacies should at least be required to perform the following compliance measures: 1) register, 2) disclose information, 3) report information, and 4) require at least one doctor-patient in person examination.

First, online pharmacies should be required to register with their respective governments, just as the Ryan Haight Act requires registration with the DEA in the United States.[262] This registration requirement should be in place for any online pharmacy regardless of whether or not it dispenses medications known in the United States as "controlled substances." Furthermore, a list of all registered pharmacies should be kept on a central server that is maintained by, and is available to, all signatories. This registration requirement will serve many purposes. It will both aid in recognizing (and eliminating) noncompliant online pharmacies and will educate signatories' citizens about which online pharmacies are operating legitimately.[263] For guidance on registration and maintaining such a

(discussing the ways in which international treaty law may be incorporated into domestic law).

260. *See* Lipman, *supra* note 32, at 554.
261. *See* 21 U.S.C. § 841(h)(1) (2010).
262. *See* 21 U.S.C. §§ 823(f), 841(h)(1) (2010).
263. Karberg, *supra* note 15, at 125.

database, drafters of the compact may look to the NABP VIPPS program. However, whereas some criticize the NABP's VIPPS program for its voluntary nature,[264] this compact's registration requirement should be mandatory for all online pharmacies operating in a State that is a signatory.

Second, pharmacies must be required to display certain information on their websites, just as provided in the Ryan Haight Act.[265] The Ryan Haight Act provides a meaningful list of the type of information that should be disclosed, and the drafters of the compact should emulate such provisions. Further, if such information is properly displayed on an online pharmacy's website, and the website has effectively registered with its respective government, a "seal of approval" should be issued for the site to display. This will give consumers further indication that the site they are ordering prescription medications from is operating legitimately.

Third, online pharmacies should be required to submit reports to their respective governments, similar to the Ryan Haight Act's reporting provision.[266] The precise drugs and the quantity offered may be decided at a later date. There should be two triggers for mandatory reporting: surpassing a total volume of prescription medications dispensed, and surpassing a certain amount of "dangerous" substances dispensed. "Dangerous" substances would be those that provide some of the effects that the Mayo Clinic has identified as the causes of "prescription drug abuse," including getting high, relaxing, and feeding an addiction.[267] Drugs such as Vicodin, Oxycodone, Hydrocodone, Xanax, Adderall, Viagra, and Codeine should be included in such a category.[268]

The "dangerous" substance data submissions should also be utilized to maintain a database similar to California's Controlled Substance Utilization Review and Evaluation System ("CURES"), which makes information about the quantity of controlled substances a patient has previously purchased available to physicians and pharmacists.[269] The international compact should require its signatories to maintain such a database and, contrary to the CURES operation, make it mandatory for

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264. Yoo, *supra* note 9, at 69.

265. *See* 21 U.S.C. § 831(a).

266. *See* 21 U.S.C. § 827(d); 21 U.S.C. § 827(e); 21 U.S.C. § 827(h).

267. *See* Mayo Clinic Staff, *Prescription Drug Abuse*, MAYO CLINIC (Dec. 5, 2014), http://www.mayoclinic.com/health/prescription-drug-abuse/DS01079/DSECTION=causes.

268. *Commonly Abused Prescription Drugs Chart*, NATIONAL INSTITUTE ON DRUG ABUSE (Sept. 2002), http://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart (providing a detailed list of drugs that could constitute such a list).

269. Office of the Attorney General, *Controlled Substance Utilization Review and Evaluation System (CURES), California Prescription Drug Monitoring Program*, STATE OF CALIFORNIA DEPARTMENT OF JUSTICE, http://oag.ca.gov/cures-pdmp (last visited Jan.17, 2014).

physicians and pharmacists to inquire into the amount of "dangerous" substances a potential online customer has previously acquired to help determine the validity and medical necessity of the request.[270]

Fourth, registered online pharmacies should be banned from dispensing prescription medications without first being presented with a prescription that is based upon an in-person doctor-patient examination, just as the Ryan Haight Act does.[271] The language of the Ryan Haight Act's similar provision should be emulated here as well, including language that allows for "covering physician" prescriptions to be issued.[272]

In addition to establishing these compliance provisions, there should be both criminal and civil penalties implemented for violating the compact. There should be penalties not only for the operator of a noncomplying pharmacy, but also for the individual knowingly purchasing materials from a noncomplying pharmacy. This will deter illicit activities and broaden the scope of responsibility. There should also be a framework in place facilitating communication and cooperation among signatories to enforce these penalties.

In addition to the Ryan Haight Act, prior international actions should be incorporated into the compact as well. Signatories should be required to promote existing educational campaigns, including the proliferation of the WHO's *Medical Products and the Internet*: *A Guide to Finding Reliable Information*. For instance, all online pharmacies registered to operate under the compact should be required to include a link to such information (and other similar materials) on their websites. Additionally, signatories should be required to support INTERPOL's enforcement operation, Operation Pangea, if not already doing so.

Aside from the content of the compact, its adoption, proliferation, and enforcement should be discussed. While all States should be welcome to be a signatory, States with large numbers of online pharmacy consumers should be targeted to become signatories, because they have the greatest need for consumer protection.

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270. *See* Robert Glatter M.D., *Fighting Prescription Drug Abuse With a National Database*, FORBES (Feb. 16, 2012, 12:46 PM), http://www.forbes.com/sites/robertglatter/2012/02/16/fighting-prescription-drug-abuse-a-national-online-database-2/ (calling for a national database, similar to the CURES system, that is mandatory for physicians and pharmacists).

271. *See* 21 U.S.C. § 829(e)(2)(A).

272. *Id.*

The United States should be at the forefront of promoting the proliferation of the compact. As the United States' domestic regulation forms the basis for the compact, it only makes sense that the United States should promote the new international standard based thereon. Therefore, the United States should be the first to adopt the compact and show to the rest of the world its intellectual honesty in trying to solve this problem. The United States should call upon its allies and biggest trade partners to become signatories as well.

Aside from the United States acting to promote the adoption of the compact, international organizations like the WHO, IMPACT, and the IHC should promote its adoption as well. These are particularly well-suited avenues through which the compact should be promoted. This is critical because the potential impact of the compact increases as the number of signatories increases.

Lastly, such an international compact is feasible and enforceable. Consumers participating in the online pharmacy market make their purchases from within the borders of a nation state. Similarly, the products they purchase are imported into that nation State. Therefore, signatories have two distinct points at which they can enforce the compact: purchase and importation. For instance, signatories may seize the items imported or enforce the illegality of the purchase as outlined by the compact. Further, the registration requirement allows signatories to enforce the provisions of the compact against any unregistered or noncompliant site, even if the site is based in another country, provided that country is also a signatory to the compact.

VIII. CONCLUSION

Online pharmacies can be a powerful resource for consumers in an increasingly technological and fast paced global economy. However, the challenges they present must be dealt with by means of a unified stance against their fraudulent operation. This can, and should, be achieved in the form of an international compact as described above. The Ryan Haight Act was a tremendous step forward not only for the United States, but also for the global community. However, unilateral domestic regulations, though successful on some level, are inherently inadequate to address the core of the problem. The unintended consequence of the Ryan Haight Act is that it can serve as a framework by which the international community can formulate its own regulatory scheme to combat illicit online pharmacies.

"Love you, Mom."[273] Ryan Haight's mother should have had the opportunity to hear her son say these words many more times than she

273. Haight, *supra* note 1, at 566.

did. Now, she says, "I wish that something could be done so that no one has to go through this."[274] The aforementioned international compact is that something.

274. *Drugs and the Internet: A Deadly Combination*, DRUG ENFORCEMENT AGENCY, http://www.justice.gov/dea/prevention/francine-interview.shtml (last visited Jan. 17, 2014).