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## PHARMACEUTICAL DRUG PRICING: THE INTERNET AS A SOLUTION FOR THIS HEALTH ISSUE TURNED FINANCIAL ISSUE

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# PHARMACEUTICAL DRUG PRICING: THE INTERNET AS A SOLUTION FOR THIS HEALTH ISSUE TURNED FINANCIAL ISSUE

## ABSTRACT

*Over the course of five decades, American annual expenditure on pharmaceutical drugs has increased by more than \$350 billion. This drastic increase has led many patients to struggle to afford their necessary, and potentially life-saving, medications. Today's high pharmaceutical prices are largely due to the fact that name-brand drug manufacturers have few restrictions on how much they can charge for their products. Additionally, name-brand manufacturers are able to monopolize the manufacture of their drugs because patent laws prevent other manufacturers from using the formula of these drugs for two decades. To combat these high prices, this Note proposes a partnership between telemedicine companies and online pharmacies that promotes the prescription of cheaper, generic-brand drugs. By combining the cheaper, mobile services of telemedicine with generic-brand drugs offered by online pharmacies, this partnership can increase access and quality of healthcare while driving down price.*

## INTRODUCTION

“You are such a moron.”<sup>1</sup> This was the response from the questionable hedge fund manager, and now convicted felon, Martin Shkreli,<sup>2</sup> when he was asked about acquiring the rights to market Thiola<sup>3</sup> and increasing its price from less than \$15 per pill to \$750 per pill.<sup>4</sup> Although pharmaceutical drug prices have been rising for decades, the issue of outrageously overpriced drugs was not thrust into the spotlight until Shkreli hiked Thiola's price by 2000%.<sup>5</sup> While Shkreli's exorbitant price hike may be an “outrageous” outlier, it helps shed light on this combined health and financial issue.<sup>6</sup> The Thiola situation exposes that pharmaceutical

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1. John Carroll, *Why Would Martin Shkreli Hike an Old Drug Price by 5000%? Only a 'Moron' Would Ask*, FIERCEBIOTECH (Sept. 20, 2015, 12:08 PM), <https://www.fiercebiotech.com/biotech/why-would-martin-shkreli-hike-an-old-drug-price-by-5000-only-a-moron-would-ask>.

2. Matthew Herper, *You Hate Martin Shkreli. That's Sort of a Problem*, FORBES (Mar. 9, 2018), <https://www.forbes.com/sites/matthewherper/2018/03/09/you-hate-martin-shkreli-thats-sort-of-the-problem/#5bca7e6238af>.

3. “THIOLA tablets is a prescription medicine. It is used in combination with high fluid intake, alkali (low acid), and dietary changes to help prevent the formation of one type (cystine) of kidney stones in certain adult and pediatric patients that weigh at least 44 pounds (20 kg) and who do not respond to these measures alone.” *How Does THIOLA Work?*, THIOLA.COM, <https://www.thiola.com/about-thiola> (last visited Sept. 18, 2019).

4. Carroll, *supra* note 1.

5. Lydia Ramsey, *The CEO Who Jacked up the Price of a Drug by 5,000% Has Done This Before*, BUS. INSIDER (Sept. 23, 2015, 2:22 PM), <https://www.businessinsider.com/martin-shkreli-history-of-price-hikes-2015-9>.

6. *Id.*

companies retain the ability to raise prices in a manner similar to Shkreli because he was convicted of securities charges, none of which had anything to do with his price hikes.<sup>7</sup> Some solutions, such as transparency legislation, have been enacted in order to promote price reduction, but only minimal change has been observed because transparency legislation and other solutions have encountered successful pushback from the pharmaceutical industry.<sup>8</sup>

This Note argues that combining the growing markets of telemedicine and online pharmacies can increase medicinal quality and access, while driving down the cost of pharmaceutical drugs. In other words, the partnership between the two markets will increase drug pricing competition while providing greater access to quality care and a wider range of cheaper, off-brand pharmaceuticals, thus driving down drug pricing.

Part I of this Note provides a brief history of pharmaceutical pricing in the United States, followed by Part II's review of previously proposed solutions to America's high drug prices. Part III will provide a description of telemedicine, online pharmacies, and United States internet use. Additionally, Part III details the business structure of this Note's proposed partnership. Part IV will then tackle the most pressing legal issues facing the proposed combination, such as Anti-trust and privacy laws. Lastly, Part V discusses Ro, a small-scale telemedicine-online pharmacy, in order to support the viability of this Note's proposed solution.

## I. BACKGROUND

Prescription drug spending in the United States has been on the rise for nearly six decades, with the most significant increases during the past twenty years.<sup>9</sup> In 1960, for example, the United States expenditure on prescription drugs was \$2.7 billion.<sup>10</sup> By 1990, American drug expenditure increased to \$40.3 billion, and then increased further to \$205.3 billion by 2005.<sup>11</sup> The current projection for 2019 is \$360.3 billion.<sup>12</sup> Drug pricing outside of the United States has been, and continues to be, significantly less.<sup>13</sup> Many American consumers have turned to Canadian pharmacies as a

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7. Herper, *supra* note 2.

8. Thomas Huelskoetter, *State Policies to Address Prescription Drug Prices*, CTR. FOR AM. PROGRESS (May 31, 2018, 9:00 AM), <https://www.americanprogress.org/issues/healthcare/reports/2018/05/31/451170/state-policies-address-prescription-drug-prices/>

9. See *Prescription Drug Expenditure in the U.S. 1960-2019*, STATISTA, <https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/> (last visited Oct. 24, 2019).

10. *Id.*

11. *Id.*

12. *Id.*

13. See Robert Langreth, *Drug Prices*, BLOOMBERG (Feb. 5, 2019, 10:39 AM), <https://www.bloomberg.com/quicktake/drug-prices> (illustrating that the United States ranks first in per capita spending on prescription drugs and indicating that Canada is not even in the world's top ten).

source for their vitally needed prescription medicine, but United States legislatures have made efforts to prevent this “bargain hunting.”<sup>14</sup>

A simple, yet telling approach to gauge the effectiveness of a healthcare system is to imagine the system as a three-legged stool.<sup>15</sup> The first leg represents quality of care, the second leg is access to care, and the third leg is cost of care.<sup>16</sup> In order to drive down drug prices and balance the stool, the quality and access legs must have telemedicine and internet pharmacies at their core. The quality of United States healthcare has been extensively scrutinized by the general population with many critics still remaining, but the implementation of new technology has received a positive response from many patients.<sup>17</sup> More and more patients now rate their overall quality of care considerably higher than in recent years.<sup>18</sup> Still, the ‘healthcare stool’ becomes wobbly when many medical developments are hindered or underutilized due to the lack of efficient access to healthcare as a result of “budget constraints”<sup>19</sup> and insurance companies becoming less likely to cover or offer many benefits as they once did.<sup>20</sup> With less insurance coverage, the high costs of healthcare treatment are being shifted to the patient,<sup>21</sup> which creates instability for the third leg of the healthcare stool. Higher healthcare costs deter patients from seeking treatment, and this reluctance has placed many rural medical facilities in a position where they struggle to meet operating costs.<sup>22</sup> A positive assessment of healthcare quality means little when high costs and limited access prevent this quality healthcare from being utilized.

The United States is also an outlier among other developed countries<sup>23</sup> in regard to drug pricing, which results in many patients becoming angered by continuously increasing prices.<sup>24</sup> A study comparing the United States

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14. Steven Morgan & Jeremiah Hurley, *Internet Pharmacy: Prices on the Up-and-Up*, CMAJ GROUP (Mar. 16, 2004), <http://www.cmaj.ca/content/170/6/945.full?etoc=>.

15. Audiotape: Representing Hospitals, held by Professor Salvatore J. Russo (Oct. 4, 2018) (on file with Brooklyn Law School).

16. *Id.*

17. Ruben Castaneda, *How Technology Helps Patients and Other Visitors Navigate Hospitals*, US NEWS (Jan. 18, 2017, 4:57 PM), <https://health.usnews.com/wellness/articles/2017-01-18/how-technology-helps-patients-and-other-visitors-navigate-hospitals>; Justin McCarthy, *Most Americans Still Rate Their Healthcare Quite Positively*, GALLUP (Dec. 7, 2018), <https://news.gallup.com/poll/245195/americans-rate-healthcare-quite-positively.aspx>.

18. McCarthy, *supra* note 17.

19. INST. OF MED., ACCESS TO HEALTHCARE IN AMERICA 1, 19 (Michael Millman ed., 1993).

20. *Id.* at 19–20.

21. *Id.*

22. *Id.* at 20.

23. A developed country is “a country with a lot of industrial activity and where people generally have high incomes.” *Developed Country*, CAMBRIDGE BUSINESS ENGLISH DICTIONARY (2011), <https://dictionary.cambridge.org/us/dictionary/english/developed-country>.

24. Dana O. Sarnak et al., *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, THE COMMONWEALTH FUND (Oct. 5, 2017), <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier>.

monthly pricing of six top-selling prescription drugs to that of other countries found American pricing to be significantly higher.<sup>25</sup> The study accounts for the “confidential discounts”<sup>26</sup> given to United States healthcare plans, and the difference remains staggering with some drugs selling for hundreds of dollars more than the next priciest country.<sup>27</sup> A separate study also shows that almost 15% of insured Americans fail to take or refill prescriptions due to high cost, compared to the next highest country at 10%.<sup>28</sup>

The stark drug price difference between America and other countries is due, in part, to the few price-controlling regulations, and in some cases regulations that allow drug manufactures to negotiate directly with payers.<sup>29</sup> Drug manufacturers tend to justify their pricing by linking it to the cost of “research, development and manufacturing.”<sup>30</sup> However, there is mounting evidence showing that this justification is inaccurate because the true source of the high pricing is the ability of drug manufacturers to set their prices as high as the United States market will allow without legislative restriction or guidance.<sup>31</sup> This lack of legislative restriction is largely due to the fact that pharmaceutical manufacturers have market information at their disposal that is unavailable to the public.<sup>32</sup> Thus, an accurate market price cannot be discerned, which allows drug manufacturers to set their own, unverified market price.<sup>33</sup> However, as this Note will explore, even if laws are enacted to mandate disclosure of this market information, price reduction is still unlikely to occur.

## II. PREVIOUSLY PROPOSED SOLUTIONS

Over the last few decades, scholars and legislators have proposed solutions to the drug pricing issue.<sup>34</sup> Some federal and state legislation has

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25. American pricing was 5% to 117% higher than prices in the other examined countries. *Id.*

26. Confidential discounts are negotiated prices between insurers, both public and private, and pharmaceutical manufacturers. The discounts remain confidential so that pharmaceutical manufacturers can charge different prices in different markets. Insurers abide by this confidentiality in order to receive better discounts. Steven G. Morgan et al., *Payers' Experiences with Confidential Pharmaceutical Price Discounts: A Survey of Public and Statutory Health Systems in North America, Europe, and Australasia*, 121 HEALTH POL'Y 354, 354–55 (2017).

27. Samak et al., *supra* note 24.

28. *Id.*

29. *Id.*

30. Aaron Berman et al., *Curbing Unfair Drug Prices: A Primer for States*, GLOB. HEALTH JUST. P'SHIP. (Aug. 2017), [https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing\\_unfair\\_drug\\_prices-policy\\_paper-080717.pdf](https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf).

31. *Id.*

32. See Lutz Heinemann, *Biosimilar Insulin and Costs: What Can We Expect?*, 10(2) J. OF DIABETES SCI. AND TECH. 457, 458 (2016).

33. *Id.*

34. Benjamin E. Brown, Note, *Decreasing Prescription Drug Prices: Can Effective Policy Incentivize Cooperation Between Previously Antithetic Sectors?*, 14 IND. HEALTH L. REV. 162, 165 (2017).

been enacted to increase competition and transparency among drug manufacturers, but pitfalls within such laws and regulations led to limited success.<sup>35</sup> This section will address four previously proposed solutions: (1) transparency regulations, (2) changes to patent laws, (3) drug importation, and (4) mandated caps on drug pricing.

#### A. TRANSPARENCY REGULATIONS

With the rising cost of pharmaceutical drug prices and the increased media coverage, thirty states,<sup>36</sup> including New York, felt pressure to respond with proposed legislation.<sup>37</sup> One such 2019 bill, in committee, is Senate Bill S5338A: New York’s Pharmaceutical Cost Transparency Act (NYPCTA)—requiring the disclosure of the costs associated with drug manufacturing.<sup>38</sup> The NYPCTA applies to drug manufacturers that have “a wholesale acquisition cost of ten thousand dollars (\$10,000) or more annually.”<sup>39</sup> The NYPCTA requires these drug manufacturers to disclose costs for:

production; research and development; clinical trials and other regulatory costs; materials, manufacturing and administration; costs paid by other entities, including federal, state or other governmental programs; other costs to acquire the drug; total marketing and advertising costs; a cumulative annual history of the average wholesale price; total profits derived from the sale of the drug; and the total amount of financial assistance provided by the manufacturer, if available.<sup>40</sup>

By mandating drug manufacturers to disclose the above costs, the New York Senate believes the costs of pharmaceuticals may be rationalized or, more likely, seen as unwarranted because of the drastic difference between production and sale cost.<sup>41</sup>

Transparency regulations certainly provide benefits, specifically these regulations indirectly impose a requirement of morality. If drug manufacturers reveal their pricing to be grossly higher than the costs required to bring the drug to market, then society is likely to view such actions as morally wrong leading to social pushback. Transparency regulations also serve as a means for “policymakers, government agencies

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35. *Id.* at 167–69.

36. Trevor Flynn & Jerin Philip, *Lowering Drug Costs: Transparency Legislation Sets Off Flurry of New State Approaches*, NAT’L ACAD. FOR ST. HEALTH POL’Y (Aug. 22, 2017), <https://nashp.org/lowering-drug-costs-transparency-legislation-sets-off-flurry-of-new-state-approaches/>.

37. John G. Curran, Note, *The New York Pharmaceutical Cost Transparency Act: How a Narrow View of the Prescription Drug Pricing Puzzle Renders a Well-Intentioned Bill Irrational*, 82 BROOK. L. REV. 315, 316 (2016).

38. *Id.*

39. S. 5338A, 2015-2016 Reg. Sess. (N.Y. 2015).

40. *Id.*

41. Curran, *supra* note 37, at 316–17.

and others” to make important public sector decisions,<sup>42</sup> such as setting price caps on certain prescription drugs.<sup>43</sup>

While transparency regulations are backed with financially favorable intentions, this type of legislation is susceptible to pitfalls rendering it ineffective. One such pitfall is that legislation, such as the NYPCTA, neglects to require disclosure of costs associated with failure.<sup>44</sup> Failure refers to drugs that never make it to market but accrue considerable costs. Yet, the NYPCTA does not require disclosure of failed drugs because these unsuccessful drugs could not possibly accrue an annual wholesale value of \$10,000.<sup>45</sup> Pharmaceutical companies are businesses, and like any other business, they must find a way to recoup the loss of failed probes. This loss-recoupment could help justify higher prescription costs, but its exclusion could undermine the “trustworthiness” that transparency legislation seeks to provide.<sup>46</sup> By failing to require the disclosure of unsuccessful drugs, legislatures may indirectly foster public misconceptions about drug pricing.<sup>47</sup> Even if legislatures were to remedy this omission of recoupment costs, the transparency statutes would still prove ineffective because much of the public may concede that drug prices are reasonable given the built-in financial recoupment.

A second, and possibly more significant, drawback of pharmaceutical drug transparency law is that it tends to lack enforceable penalties or any discipline at all.<sup>48</sup> Some legislatures have included penalties for excessive “price gouging,” but these penalties have faced constitutional challenges.<sup>49</sup> In *Association for Accessible Medicine v. Frosh*,<sup>50</sup> Maryland’s pharmaceutical transparency and anti-price gouging law required the disclosure and justification of costs associated with the production of prescription drugs.<sup>51</sup> The law goes further than merely requiring disclosure of costs; in addition to requiring price justification, a penalty of \$10,000 per violation is applicable if the drug manufacturer sets “an unconscionable increase in the price of a prescription drug.”<sup>52</sup> The plaintiff in *Association for Accessible Medicine* operated production plants throughout the United States, not solely in Maryland.<sup>53</sup> The plaintiff argued that the anti-gouging law was unconstitutional because it violated the dormant commerce clause

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42. S. 5338A.

43. *See infra* Section II.B.

44. Curran, *supra* note 37, at 325–26.

45. *Id.* at 325.

46. Seth Whitelaw et al., *Drug Pricing—The Next Compliance Waterloo*, 44 MITCHELL HAMLINE L. REV. 1165, 1193–94 (2018).

47. Curran, *supra* note 37, at 327.

48. Whitelaw et al., *supra* note 46, at 1186–87.

49. *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018).

50. *Id.* at 664.

51. *Id.* at 666.

52. *Id.*

53. *Id.* at 667.

of the United States Constitution.<sup>54</sup> The court held that Maryland's transparency law was an attempt to regulate "wholly out-of-state commerce," which is a power expressly granted to the Federal Government via the Constitution.<sup>55</sup> Thus, the court found that Maryland's Act was unconstitutional because it violated the dormant commerce clause as it "directly regulates transactions that take place outside Maryland."<sup>56</sup>

While drug-pricing transparency laws intend to prevent the swindling of consumers, this legislation fails to address all circumstances factoring into drug pricing, such as the costs of failure. Additionally, transparency regulation merely imposes a moral burden. Many attempts to impose stricter, more significant penalties have faced abundant and successful constitutional challenges.<sup>57</sup>

## B. CHANGES TO PATENT LAW

In the realm of pharmaceutical drugs, a vital tool for manufacturers is a drug patent because it provides two decades of market exclusivity for the patented drug.<sup>58</sup> The general idea behind patent law is to prevent a "restraint of trade" while "promoting fair competition" by precluding other manufacturers from stealing a company's formula and profiting from it, in addition to providing protection from anti-competition laws.<sup>59</sup> Pharmaceutical companies, like any well-run business, look to the future and anticipate the impact of a "patent cliff."<sup>60</sup> Manufacturers expect a significant reduction in profits derived from patented drugs once their market exclusivity ends<sup>61</sup> because other companies have the opportunity to use the formerly patented formula for their own profit.<sup>62</sup> With the expectation of reduced profits in the future, pharmaceutical companies raise the price of their drugs during the patent period in order to offset this future decrease.<sup>63</sup>

Congress, in an effort to increase pricing competition and partially circumvent pharmaceutical drug patents, enacted the Drug Price Competition and Patent Term Restoration Act, (hereinafter the "Hatch-

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54. *Id.* at 666.

55. *Id.*

56. *Id.* at 674.

57. *See id.*

58. Brown, *supra* note 34, at 169.

59. *Id.* at 169–70.

60. "The period of increased prescription drug prices prior to patent expiration is known as the 'patent cliff.'" *Id.* at 169.

61. *Id.* at 169.

62. During a patent's term, only the owner of the patent can manufacture the invention (or formula in the case of pharmaceuticals). Once expired, the patent can be copied and marketed by all. Beverly Bird, *What Happens to a Patent When it Expires?*, LEGAL ZOOM, <https://info.legalzoom.com/happens-patent-expires-20317.html> (last visited Oct. 10, 2019).

63. Brown, *supra* note 34, at 169.



Waxman Act”).<sup>64</sup> The Hatch-Waxman Act is intended to allow manufacturers of a generic “bioequivalent” of a name-brand drug to bring the bioequivalent to market prior to the expiration of the exclusivity period.<sup>65</sup> Under the Hatch-Waxman Act, manufacturers of a bioequivalent complete an abbreviated new drug application (ANDA) in order to be protected from patent infringement penalties.<sup>66</sup> If the application is approved by the Food and Drug Administration (FDA), a 180-day stay goes into effect that prevents the FDA from approving ANDAs—for the bioequivalent at issue—from other generic manufacturers.<sup>67</sup> The Hatch-Waxman Act facilitates more drug-pricing competition because a bioequivalent averages 60% cheaper than its name-brand counterpart.<sup>68</sup>

The Hatch-Waxman Act has been successful in certain aspects, but it has failed in one key way: it has not reduced pharmaceutical prices. The Hatch-Waxman Act was enacted in 1984<sup>69</sup> when United States expenditure on prescription drugs was between twelve and forty billion dollars.<sup>70</sup> Today’s expenditure on prescription drugs is estimated to be \$360.3 billion, almost nine times greater than that of 1980-1990, and still more than three times greater when accounting for inflation.<sup>71</sup> A possible explanation for the Hatch-Waxman Act’s ineffectiveness is the pharmaceutical tax under the Affordable Care Act.<sup>72</sup> The pharmaceutical tax of the Affordable Care Act applies to branded prescription drugs, also known as name-brand drugs, while excluding generic-brand drugs.<sup>73</sup> The collected tax is then funneled through the United States Treasury Department to the Federal Supplementary Medical Insurance Trust Fund to help “support health insurance coverage.”<sup>74</sup>

This pharmaceutical tax, in theory, would allow for more competition from generic-brand drug manufacturers, while encouraging name-brand

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64. Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <https://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809>.

65. The term “bioequivalent” is used to describe a drug that is chemically the same as a name-brand drug. 21 U.S.C. § 355 (2012).

66. Rumore, *supra* note 64, at 165.

67. *Id.*

68. Brown, *supra* note 34.

69. 21 U.S.C. § 355 (2012).

70. STATISTA, *supra* note 9.

71. *Id.*

72. Peter S. Reichertz, *New Taxes for Pharmaceutical and Medical Device Manufacturers/Importers/Distributors*, SHEPPARD MULLIN: FDA L. UPDATE BLOG (Apr. 19, 2010), <https://www.fdalawblog.com/2010/04/articles/legislation/new-taxes-for-pharmaceutical-and-medical-device-manufacturersimportersdistributors/>.

73. *Id.*

74. A manufacturer with an annual aggregate revenue of \$100 million would pay \$10 million in taxes during the first year, then an increasing tax rate each year until 2019. As a manufacturer’s aggregate revenue increases, so does the manufacturer’s tax rate. *Id.*

drug manufacturers to reduce costs in order to avoid a higher tax rate. Nevertheless, name-brand manufacturers have retained a large consumer base that is still willing to pay for the more expensive drug.<sup>75</sup> This preservation of higher drug prices is largely due to “average sales price plus six percent” or ASP+6.<sup>76</sup> ASP+6 is the means by which Medicare pays for prescription drugs.<sup>77</sup> Medicare will reimburse the average price of the prescription drug plus six percent of the average price “to cover overhead costs.”<sup>78</sup> ASP+6 unintentionally incentivizes the prescription of more expensive drugs because the physician will be paid a greater overhead percentage.<sup>79</sup> For example, if two bioequivalent drugs produce “clinically equivalent benefits,” but the name-brand drug costs \$2,000 while the generic-brand costs \$50, then a physician has more incentive to prescribe the name-brand drug.<sup>80</sup> In this example, the physician would receive a \$120 profit in overhead reimbursement for the name-brand drug and only a \$3 profit for the generic-brand drug.<sup>81</sup> Instead of being used to effectively reduce prescription payments, the Affordable Care Act’s pharmaceutical tax is likely reimbursing costs for name-brand drugs and, in turn, negating the intended benefits of the tax.

Lastly, changes to patent laws cannot change name-brand recognition with consumers.<sup>82</sup> Pharmaceutical companies market to their consumer base in a different manner than many other industries, but, like almost all industries, the companies with the most money have the most name recognition.<sup>83</sup> Generally, pharmaceutical companies do not promote the company itself, rather they promote a product of the company, such as Viagra manufactured by Pfizer.<sup>84</sup> The formula for brand recognition is quite simple: identify an illness that much of the population is susceptible to, offer an “insert pill name here” as the best remedy for the illness, then warn of side-effects.<sup>85</sup> The drug manufacturers behind “blockbuster drugs,” like Viagra, can bolster their remedy drug’s name through more platforms and

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75. Isaac D. Buck, Note, *The Cost of High Prices: Embedding an Ethic of Expense into the Standard of Care*, 58 B.C. L. REV. 101, 129 (2017).

76. Lola Butcher, *ASP+6 Should Go, but What’s Next?*, ONCOLOGY TIMES (June 25, 2015), [https://journals.lww.com/oncology-times/fulltext/2015/06250/ASP\\_6\\_Should\\_Go,\\_But\\_What\\_s\\_Next\\_.8.aspx](https://journals.lww.com/oncology-times/fulltext/2015/06250/ASP_6_Should_Go,_But_What_s_Next_.8.aspx).

77. *Id.*

78. ASP+6 is actually the average sales price plus 4.3% after a 2012 budget cut, but it is still referred to as ASP+6. The use of ASP+6 has been extended through 2024. *Id.*

79. Buck, *supra* note 75, at 128–29.

80. *Id.*

81. *Id.* at 129.

82. See Sarah Hand, *How Pervasive is Brand Recognition in the Pharmaceutical Industry?*, XTALKS (Jan. 19, 2017), <https://xtalks.com/brand-recognition-pharmaceutical-industry/>.

83. *Id.*

84. *Id.*; *Our Products*, PFIZER, <https://www.pfizer.com/products/product-detail/viagra> (last visited Oct. 11, 2018).

85. Hand, *supra* note 82.

with more frequency than a generic bioequivalent could.<sup>86</sup> Ultimately, the pharmaceutical companies with more money and more brand recognition will attract more consumers than generic bioequivalent manufacturers.

### C. DRUG IMPORTATION

On average, United States drug pricing is three times more expensive than in foreign countries because the United States has seen a slow increase in generic drug competition compared to the United Kingdom and Europe due to the aforementioned patent laws.<sup>87</sup> This price difference is financially enticing to many struggling patients and has created a push to allow drug importation, specifically from Canada due to its proximity to the United States.<sup>88</sup> In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was signed into law.<sup>89</sup> Under the MMA, cheaper drugs from Canada may be imported with the approval of the Health and Human Services Secretary (Secretary).<sup>90</sup> In order for importation to receive approval, a series of requirements must be satisfied, including a certification that the drug to be imported is cheaper than those available in the United States and a determination by the Secretary that the drug poses no health risks.<sup>91</sup> However, the Secretary has yet to approve the importation of any drug, likely due to the pushback from American pharmaceutical companies.<sup>92</sup>

Despite the lack of any certification from the Secretary, Vermont has recently passed legislation allowing wholesale prescription drug importation.<sup>93</sup> Allowing drug importation for Vermont citizens will alleviate a great portion of the financial burden associated with prescription drugs while likely creating a pocket of increased drug competition within the state. While fruitful in theory, the Vermont statute is almost certain to face federal opposition and likely to be defeated.<sup>94</sup> In *Vermont v. Leavitt*,<sup>95</sup> Vermont challenged the FDA's denial of the state's petition to allow individual importation of prescription drugs from Canada under the

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86. *Id.*

87. Ben Hirschler, *How the U.S. Pays 3 Times More for Drugs*, REUTERS (Oct. 13, 2015), <https://www.reuters.com/article/us-pharmaceuticals-usa-comparison/exclusive-transatlantic-divide-how-u-s-pays-three-times-more-for-drugs-idUSKCN0S61KU20151012>.

88. Vaishali V. Shah, Note, *Prescription Drugs in America: The Pain of Pricing Has An Unpromising Cure*, 2006 U. ILL. L. REV. 859, 863 (2006).

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. Thomas Sullivan, *Vermont's Next Act: Wholesale Prescription Drug Importation Program*, POL'Y & MED. (May 21, 2018), <https://www.policyandmed.com/2018/05/vermonts-next-act-wholesale-prescription-drug-importation-program.html>.

94. *Id.*

95. *Vermont v. Leavitt*, 405 F.Supp.2d 466, 466 (D. Vt. 2005).

MMA.<sup>96</sup> Vermont also claimed that the MMA itself was in violation of the United States Constitution because it granted power to the Executive Branch that should have been delegated to the Legislative Branch.<sup>97</sup> The United States District Court dismissed Vermont's claims because the Vermont petition was for an illegal program under the MMA, which allows for approved "wholesale" importation, not "individual" importation.<sup>98</sup> Relying on this precedent, challenges to the Vermont legislation will likely preclude the importation of prescription drugs from Canada.

Aside from legislation, there are also risks that will likely prevent drug importation from becoming a viable solution for the prescription pill financial issue. One of these risks is a lack of foreign safeguards against poor quality and dangerous drugs being imported.<sup>99</sup> Exporting countries have regulations for drugs purchased by their own citizens, but some, such as Canada, concede that their regulations are not as strict for their exported drugs.<sup>100</sup> Additionally, many countries that export drugs, import those same drugs from other regions of the world.<sup>101</sup> This chain of multiple importations not only raises serious regulatory questions, but also increases the probability of drug alteration due to the multiple transfers and environment changes.<sup>102</sup> An additional risk associated with drug importation is a higher likelihood of counterfeit drugs.<sup>103</sup> Counterfeiters have ample resources to recreate labels identical to name-brand drugs, that not only swindle patients out of their money, but also put patients in danger of laced or ineffective drugs.<sup>104</sup>

Federal reluctance to allow drug importation is not merely based in theory, but it has support from cases such as Thalidomide.<sup>105</sup> During the mid-twentieth century, a drug known as Thalidomide was developed to help patients fall asleep and ease the pain of morning sickness for pregnant women.<sup>106</sup> Thalidomide was prescribed quite frequently in Europe. By 1960, it was even sold over-the-counter in Germany, but the United States

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96. *Id.* at 469–70.

97. *Id.* at 470.

98. The holding in this case has not been appealed, nor has it received negative treatment. *Id.* at 479.

99. Holly Campbell, *4 Facts on why Drug Importation Is Bad for Patients*, PHRMA (Oct. 6, 2018), [https://catalyst.phrma.org/4-facts-on-why-drug-importation-is-bad-for-patients#\\_ftn1](https://catalyst.phrma.org/4-facts-on-why-drug-importation-is-bad-for-patients#_ftn1).

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. Linda Bren, *Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History*, U.S. FOOD AND DRUG ADMIN. (Mar.–Apr. 2001), [http://www.fda.gov/fdac/features/2001/201\\_kelsey.html](http://www.fda.gov/fdac/features/2001/201_kelsey.html) [[https://web.archive.org/web/20090512235601/http://www.fda.gov/fdac/features/2001/201\\_kelsey.html](https://web.archive.org/web/20090512235601/http://www.fda.gov/fdac/features/2001/201_kelsey.html)].

106. *Id.*

was still reluctant to allow its use.<sup>107</sup> The FDA's reluctance to allow Thalidomide was largely due to the suspicions of FDA Medical Reviewer, Frances Oldham Kelsey.<sup>108</sup> Fortunately for many Americans, Kelsey was proven correct when a report revealed that more than 10,000 children across forty-seven countries were born with deformities due to Thalidomide use by their mothers.<sup>109</sup> If Thalidomide or a similar defective drug was imported to the United States, the health and financial effects would be devastating.

Importing prescription drugs from other countries would certainly decrease the financial burden for many American patients. However, in weighing the financial benefits against the risks of importing possibly counterfeit and defective drugs, the scale is disproportionately tipped against drug importation.

#### D. MANDATED CAPS ON PRESCRIPTION DRUG PRICES

Lastly, solutions have been proposed that would allow federal or state legislatures to enact laws that place a cap on the price pharmaceutical manufacturers can charge for their products.<sup>110</sup> These price cap proposals suggest valuating prescription drugs according to accepted standards, and other computable measures in order to deduce a fair price cap.<sup>111</sup> Some price capping solutions would allow buyers, such as pharmacies, to combine their "purchasing power" and negotiate as a single group in order to enforce a price cap.<sup>112</sup> The application of price caps could save patients tens of thousands of dollars per year, while saving the federal government billions of dollars annually.<sup>113</sup>

Pharmaceutical companies adamantly oppose price capping for many reasons, mainly because price capping negatively impacts innovation.<sup>114</sup> While manufacturers could reduce prices if they only produced a set number of drugs, pharmaceutical companies argue that large sums of money are needed to innovate, and the only way to acquire the money needed to innovate is by maintaining the current pricing system.<sup>115</sup> Additionally, pharmaceutical companies argue that the innovative process

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107. *Id.*

108. *Id.*

109. Only seventeen American children experienced birth-defects as a result of Thalidomide. *Id.*

110. See Ezekiel J. Emanuel, *The Solution to Drug Prices*, N.Y. TIMES (Sept. 9, 2015), <https://www.nytimes.com/2015/09/09/opinion/the-solution-to-drug-prices.html>.

111. *Id.*

112. *Id.*; Emily K. White, *Killing U.S. Slowly: Curing the Epidemic Rise of Cancer Drug Prices*, 72 FOOD AND DRUG L. J. 189, 214–15 (2017).

113. Emanuel, *supra* note 110.

114. Peter B. Bach, *Could Higher Drug Prices Be Bad for Innovation?*, FORBES (Oct. 3, 2014, 9:51 AM), <https://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation/#13254cd95a80>.

115. *Id.*

involves failures,<sup>116</sup> making the price of innovation even greater than many anticipate.<sup>117</sup> Those who support a free market argue that price capping and increased government regulation may only make the problem worse,<sup>118</sup> possibly expanding the issue outside of the healthcare and financial realm. In addition, price capping would likely have to take place at the federal level in order to avoid violation of the commerce clause of the United States Constitution.<sup>119</sup> The power to regulate foreign and interstate commerce rests with the federal government<sup>120</sup> and convincing a majority of the United States Congress to enact a law restricting the free market in a free market system is likely quite difficult. Unless a drug manufacturer operates and sells within the borders of a single state, state attempts to enforce price caps will likely be preempted via the commerce clause.<sup>121</sup>

### III. A NEW SOLUTION: COMBINING TELEMEDICINE WITH INTERNET PHARMACIES

Combining telemedicine with internet pharmacies will increase access to quality medical opinions and treatment, which, in turn, will drive down the price of prescription drugs. Drug prices will decrease because this combination will provide greater access to cheaper, yet effective prescription drugs for those struggling to meet the financial burdens of their medical treatment. This solution will set a base for increased market competition that promotes innovation over profit. Before delving into the relationship between telemedicine and internet pharmacies, it is important to understand the concept behind each.

#### A. TELEMEDICINE/TELEHEALTH

As currently implemented, telemedicine allows home-ridden patients and patients without local medical facilities to receive medical opinions remotely via the internet.<sup>122</sup> Health services are facilitated through video conferences, phone calls, and the e-mailing of medical records and other necessary information.<sup>123</sup> In addition to information sharing, telemedicine provides necessary monitoring equipment that will provide physicians with

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116. See *supra* notes 44–47 and accompanying text.

117. Curran, *supra* note 37, at 325–26.

118. Jennifer Boeder, *Should the Government Cap Prescription Drug Prices?*, TYLT, <https://thetylt.com/politics/government-cap-prescription-drug-prices> (last visited Oct. 24, 2019).

119. U.S. CONST. art. I, § 8, cl. 3.

120. *The Commerce Clause as a Restraint on State Powers*, LEGAL INFO. INST., <https://www.law.cornell.edu/constitution-conan/article-1/section-8/clause-3/the-commerce-clause-as-a-restraint-on-state-powers> (last visited Oct. 18, 2018).

121. *Id.*

122. Kimberly Lovett Rockwell, *The Promise of Telemedicine: Current Landscape and Future Direction*, 96 MICH. B.J. 38 (2017).

123. *Id.*

feedback even if direct communication is not feasible.<sup>124</sup> Telemedicine is an expanding market and is expected to be worth \$13 billion in 2020, a \$12.5 billion increase from the 2014 market value.<sup>125</sup> This financial growth spurt is a result of, not only technological advances, but the prospect of a growing consumer base.<sup>126</sup> Hospitals and insurance companies can now serve populations that have previously been hindered from receiving the benefits of clinics and health coverage.<sup>127</sup>

When the application of telemedicine was introduced during the 1990s, reaching remotely located patients and providing access was the main focus, but it became apparent that telemedicine could reduce healthcare costs as well.<sup>128</sup> Telemedicine savings are not limited to remotely located patients, but it can be experienced by most of the world, as it is estimated that “[90%] of the world population [will] have a smartphone by 2020.”<sup>129</sup> In the United States alone, 96% of adults own any type of cellphone and 81% own a smartphone.<sup>130</sup> These ownership percentages have been consistently trending upwards along with an upward trend in smartphone dependency, currently calculated at 20% of American adults.<sup>131</sup> The suggested savings<sup>132</sup> associated with telemedicine and the potential for more than three-quarters of American adults to utilize telemedicine services make it a fitting match for an online pharmacy—a business based on wireless connectivity.

## B. INTERNET/ONLINE PHARMACIES

Generally, internet pharmacies operate in a similar manner to that of a physical pharmacy.<sup>133</sup> Once the internet pharmacy receives an official prescription from a physician, the company ships the pharmaceuticals to the patient, thus saving the patient the hassle of traveling to and from the pharmacy.<sup>134</sup> While this form of online pharmacy may be the most common, it is one of three acknowledged categories of online

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124. *Id.* at 39.

125. *Id.* at 38.

126. E. Ray Dorsey & Eric J. Topol, *State of Telehealth*, 375 NEW ENG. J. MED 154, 154 (July 14, 2016).

127. *Id.*

128. *Id.*

129. Lovett Rockwell, *supra* note 122, at 39.

130. *Mobile Fact Sheet*, PEW RESEARCH CTR. (June 12, 2019), <http://www.pewinternet.org/fact-sheet/mobile/>.

131. In this study, cellphone dependency was determined by the amount of smartphone users that do not have a “traditional home broadband service.” *Id.*

132. Dorsey & Topol, *supra* note 126, at 155.

133. See Shah, *supra* note 88, at 873 (explaining that the goal of many online pharmacies is to accept and dispense valid prescriptions, just like traditional pharmacies, in a more convenient fashion).

134. See Trisha Torrey, *How to Safely and Legally Buy Drugs from Online Pharmacies*, VERYWELLHEALTH (Sept. 8, 2019), <https://www.verywellhealth.com/safely-and-legally-buying-drugs-from-online-pharmacies-2615035>.

pharmacies.<sup>135</sup> A second category of online pharmacy provides “online consultation” in which patients merely submit a questionnaire-style form to be reviewed by a physician who then decides whether to prescribe medicine.<sup>136</sup> This second category of online pharmacy may seem similar to this Note’s solution, but notably, category two pharmacies do not involve face-to-face contact and have been all but eliminated because of the illegitimate prescription of drugs based solely on an online questionnaire.<sup>137</sup> Additionally, prosecutions against “category two” online pharmacies have been so successful that, in 2008, “Congress amended the Controlled Substance Act...to explicitly prohibit dispensing and distributing controlled substances based solely on an online questionnaire.”<sup>138</sup> Lastly, the third category of internet pharmacy is known as “rogue internet pharmacies,” which sell prescription drugs to anyone, even those without prescriptions.<sup>139</sup> Rogue internet pharmacies operate “in direct violation of federal and state law,” and even “sell drugs the Food and Drug Administration bans.”<sup>140</sup> Not only will online pharmacies provide cheaper pharmaceutical prices when combined with telemedicine, the face-to-face aspect of telehealth will help achieve the much-desired decrease of federally “illicit” rogue internet pharmacies.<sup>141</sup>

### C. WHY ONLINE PHARMACIES AND TELEMEDICINE ARE A PERFECT ‘PARE’ FOR DRUG PRICES

As of March 2019, the United States had 292.89 million internet users.<sup>142</sup> The current estimated population of the United States is 329.56 million people,<sup>143</sup> meaning that more than 88% of Americans are internet users. Additionally, as of 2017, 96% of internet-using adults shop online, with 82% of internet-using adults shopping online via their mobile

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135. 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, 549–50 (2013).

136. *Id.* at 550.

137. *Id.* at 553.

138. *Id.* at 550.

139. *Id.*

140. *Id.*

141. *The Internet Pharmacy Market in 2016*, CTR. FOR SAFE INTERNET PHARMACIES 1, 2 (Jan. 2016), <http://safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf>.

142. *Countries with the Highest Number of Internet Users 2019*, STATISTA, <https://www.statista.com/statistics/262966/number-of-internet-users-in-selected-countries/> (last visited Oct. 24, 2019).

143. *Total Population of the United States 2024*, STATISTA, <https://www.statista.com/statistics/263762/total-population-of-the-united-states/> (last visited Oct. 24, 2019).



device.<sup>144</sup> The growth of online shopping has outpaced brick-and-mortar shopping by \$1.7 billion as illustrated by online shopping's growth of \$2.4 billion in 2017 and brick-and-mortar's growth of only \$619 million.<sup>145</sup> These statistics indicate a vast majority of the United States' population have online access and are more likely to engage in online purchases as opposed to brick-and-mortar purchases. Furthermore, statistics show that many internet-using Americans prefer to shop online, as opposed to in-store, for the sake of convenience and pricing.<sup>146</sup> With so many people connected and shopping digitally, combining telemedicine and internet pharmacies creates an excellent platform for patients to wirelessly connect to physicians, while saving the trip to the brick-and-mortar pharmacy by purchasing their prescription drugs online.

In addition to a noticeable increase in mobile device use, Americans have embraced the use of mobile health applications, or mHealth.<sup>147</sup> The current estimated market size for mHealth is \$18.4 billion with its five-year projection listed at \$85.5 billion.<sup>148</sup> These figures represent just a portion of the digital health market which includes mHealth, digital health systems, health analytics, and telehealth.<sup>149</sup> Combined, the entire United States digital health market is estimated to be \$44.3 billion with its projected 2024 valuation at \$155.7 billion.<sup>150</sup> This projected growth in value indicates that telehealth and digital health use will continue to grow as mobile device use increases.<sup>151</sup>

Convenient access to prescription drugs is one aspect of the telehealth and online pharmacy combination, but the main goal of reducing drug costs will be achieved through the prescription and marketing of cheaper drugs through the telemedicine and internet pharmacy platform. Under this proposed solution, a telehealth company would enter into a contractual

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144. *U.S. Online Shopping Reach as of December 2017, by Device*, STATISTA, <https://www.statista.com/statistics/809665/us-online-users-shopping-reach-by-device/> (last visited Oct. 24, 2019).

145. *Growth of Grocery Sales for E-commerce and Brick-and-Mortar in U.S. 2017*, STATISTA, <https://www.statista.com/statistics/764378/grocery-sales-growth-ecommerce-brick-and-mortar-us/> (last visited Oct. 24, 2019).

146. 62% of American internet users order online for the sake of pricing and convenience as compared to 17% of American internet users that rarely/never make online purchases. *U.S. Online User Primary Reasons to Make Online Purchases 2018*, STATISTA, <https://www.statista.com/statistics/826773/primary-reasons-internet-users-make-digital-purchases/> (last visited Oct. 24, 2019).

147. *U.S. Digital Health Market Size by Technology Forecast 2014-2024*, STATISTA, <https://www.statista.com/statistics/938594/digital-health-market-size-forecast-united-states-by-technology/> (last visited Oct. 24, 2019).

148. *Id.*

149. *Id.*

150. *Id.*

151. *mHealth Market Worth \$23 Billion in 2017 and Estimated to Grow at a CAGR of More than 35% Over the Next Three Years*, REUTERS (Apr. 18, 2017), <https://www.reuters.com/brandfeatures/venture-capital/article?id=4640>.

partnership with an online pharmacy. This partnership would require the telehealth physicians to consult and diagnose patients via video conferences, as they usually do, but it would also require the physician to use his or her best effort to prescribe lower cost drugs from the partnered internet pharmacy's store. The professional services, provided by the telehealth physician, would be reimbursed through accepted insurance such as Medicare, Medicaid, and private insurance companies.<sup>152</sup> Prescription drug costs could be paid in the same manner as the aforementioned professional services<sup>153</sup> or out-of-pocket via an online payment system. The partnership would also provide salaries—paid out of the combined revenue from the telemedicine and online pharmacies services—for the telehealth physicians in exchange for the physicians' loyalty to the partnership. This salary would be calculated based on fair and reasonable market standards with no bonus incentives based on the brand or price of the drugs prescribed as to avoid statutory violations.<sup>154</sup> The physicians will be responsible for personally entering their prescriptions into the online pharmacy system, which will then allow the prescription to be dispensed. This responsibility will provide convenience for patients, but more importantly, it will prevent falsified prescriptions from entering the system and avoid the creation of a "rogue internet pharmacy."<sup>155</sup> The online pharmacy portion of the partnership will, of course, maintain an inventory of name-brand drugs for situations where the name-brand drug is the only available pharmaceutical on the market to treat certain ailments, or if the name-brand manufacturer has market exclusivity via patent.<sup>156</sup>

The Telemedicine-Online Pharmacy partnership will be able to profit through deals with generic-brand manufacturers. Generic-brand manufactures are likely to be fond of the idea that the proposed partnership specifically promotes generic-brand drugs. With the knowledge of this promotional scheme, generic-brand manufactures will likely be more willing to negotiate a cheaper price for the partnership when the partnership orders in bulk. This will make the already cheaper generic-brand drugs<sup>157</sup> even more affordable for financially struggling patients, while allowing the Telemedicine-Online Pharmacy partnership to profit.

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152. James Roland, *17 Best Telemedicine Companies*, HEALTHLINE (Oct. 27, 2015), <https://www.healthline.com/health/best-telemedicine-companies#1>.

153. *Id.*

154. *See infra* Section IV.A.

155. Lipman, *supra* note 135, at 550.

156. Brown, *supra* note 34, at 169.

157. *Id.* at 165.

#### IV. LEGAL ANALYSIS OF THE TELEMEDICINE-ONLINE PHARMACY SOLUTION

##### A. ANTI-KICKBACK STATUTE AND STARK LAW

The Anti-Kickback statute<sup>158</sup> was enacted to prevent physician “remuneration.”<sup>159</sup> For example, if a pharmaceutical company offered a physician money, sports tickets, hotel stays, or other forms of payment in exchange for the physician’s promise to prescribe the company’s drug to patients, the physician and the pharmaceutical company would be criminally liable.<sup>160</sup> Stark Law<sup>161</sup> is designed to prevent physicians from referring their Medicare and Medicaid patients to “entities with which the physician or an immediate family member has a financial relationship.”<sup>162</sup> Stark Law is typically implicated when a referring physician has an ownership stake in a designated health service such as a clinical laboratory or a prescription drug provider.<sup>163</sup>

On its face, it may seem as though the Telemedicine-Online Pharmacy partnership creates a situation in which the Anti-Kickback Statute and Stark Law may easily be violated. Under the Anti-Kickback Statute, if a physician “knowingly and willfully solicits or receives any remuneration...directly or indirectly,” he or she is criminally liable.<sup>164</sup> Physicians working with the Telemedicine-Online Pharmacy knowingly and willfully accept remuneration, via salary, for their prescription of pharmaceuticals listed on the partnership’s web store. Additionally, the physicians salaries from the Telemedicine-Online Pharmacy establish a “financial relationship.”<sup>165</sup> Under Stark Law, where a financial relationship exists, a physician may not make a referral to the entity with which he or she has the relationship.<sup>166</sup> However, the Telemedicine-Online Pharmacy would not violate these laws because they include exclusions and “safe harbors” that provide a legal and viable plan for the partnership to follow.<sup>167</sup>

In order to fall within an Anti-Kickback Statute safe harbor, the Telemedicine-Online Pharmacy must draft “personal services and

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158. Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b) (2019).

159. Remuneration is payment, or some form of consideration, in exchange for a service. *A Roadmap for New Physicians: Fraud and Abuse Laws*, U.S. DEP’T OF HEALTH AND HUMAN SERVS. (2018), <https://oig.hhs.gov/compliance/physician-education/01laws.asp>.

160. *Id.*

161. Stark Law is also known as Physician Self-Referral Law or 42 U.S.C. § 1396nn. *Physician Self Referral*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 5, 2015, 10:59 AM), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html>.

162. U.S. DEP’T OF HEALTH AND HUMAN SERVS., *supra* note 159.

163. *See id.*

164. 42 U.S.C. § 1320a-7(b)(1) (2019).

165. 42 U.S.C. § 1395nn(a) (2019).

166. *Id.*

167. U.S. DEP’T OF HEALTH AND HUMAN SERVS., *supra* note 159.

management contracts”<sup>168</sup> between the online pharmacy and the physicians. These contracts must include seven codified elements in order to satisfy the exclusion.<sup>169</sup> The agreement must: (1) be in writing, (2) include the services to be provided by both parties, (3) specify the length of service, if not full-time, (4) have a term longer than one year, (5) in advance, set an aggregate compensation that conforms to fair market value<sup>170</sup> and does not consider “the volume or value of any referrals,” (6) not promote any business practice in violation of state or federal law, and (7) specify that the aggregate services being agreed to are reasonably necessary to run the business in a justifiable manner.<sup>171</sup> The first four requirements are quite clear-cut and, in this proposed solution, are likely satisfied with ease. The fifth requirement calls for the Telemedicine-Online Pharmacy to diligently calculate fair market compensation. Under this calculation, the partnership must ensure that its physicians’ compensation be comparable to that of other physicians performing the same “type, quality, and quantity” of services.<sup>172</sup> To satisfy the sixth requirement, the partnership must have specific checks and balances in place to avoid violating state and federal laws. One such check could be a hiring an outside lawyer or in-house counsel tasked with, among other things, ensuring the business’s objectives are in compliance with state and federal laws.<sup>173</sup> Another similar check could be the establishment of a compliance department, which, in addition to ensuring compliance with state and federal laws, would ensure conformity with acceptable professional, internal, and business standards.<sup>174</sup> Lastly, the seventh requirement can be satisfied by contracting only for services deemed necessary to the operation of the Telemedicine-Online Pharmacy. These services are likely to include the regular activities that telemedicine companies and online pharmacies perform individually, in addition to the referrals within the partnership.

The Telemedicine-Online Pharmacy’s contracted physicians could be seen as employees, thus raising further issues of possible Anti-Kickback Statute violations. However, the safe harbors of the statute include

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168. 42 C.F.R. § 1001.952(d) (2019).

169. *Id.*

170. “Fair market value means the value in arm’s-length transactions, consistent with the general market value. ‘General market value’ means the price that an asset would bring as the result of *bone fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party.” 42 C.F.R. § 411.351 (2019).

171. 42 C.F.R. § 1001.952(d) (2019).

172. 42 C.F.R. § 411.351 (2019).

173. Pervin R. Taleyarkhan, *The Attorneys on the Inside: Functions and Goals of In-House Legal Counsel*, A.B.A. (Aug. 9, 2017), [https://www.americanbar.org/groups/young\\_lawyers/publications/tyl/topics/in-house-counsel/attorneys-inside-functions-goals-in-house-legal-counsel/](https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/in-house-counsel/attorneys-inside-functions-goals-in-house-legal-counsel/).

174. *The Role of A Compliance Officer*, ROBERT WALTERS (2019), <https://www.robertwalters-usa.com/career-advice/the-role-of-a-compliance-officer.html>.

employees in a “bone fide employment relationship with the employer.”<sup>175</sup> Therefore, if the physicians under the partnership are deemed to be employees, as opposed to contractors for personal services and management, then the Telemedicine-Online Pharmacy will still fall within an Anti-Kickback Statute safe harbor.

Stark Law prohibits physicians from referring patients to a designated health services<sup>176</sup> entity with which the physician has a “financial relationship.”<sup>177</sup> A financial relationship includes a compensation agreement,<sup>178</sup> as would be present in the Telemedicine-Online Pharmacy partnership. However, like the Anti-Kickback Statute, Stark Law provides exceptions for bone fide employment relationships and personal service arrangements.<sup>179</sup> If the relationship between the physicians and the online pharmacy is deemed to be that of employment, then three conditions must be met: (1) the services performed must be identifiable, (2) the amount of remuneration must be consistent with fair market value and not take into account the amount and value of any referrals, and (3) the compensation provided must be considered reasonable even if no referrals are made.<sup>180</sup> Stark Law applies a strict liability standard, which means there is no requirement of a *mens rea*<sup>181</sup> to establish a violation.<sup>182</sup> The strict liability standard may seem to increase the risk of non-compliance. However, the three conditions, set forth in the statute, are easily met if one is to look back to the Anti-Kickback safe harbors. The requirements for the Stark Law exclusion are also covered via the Anti-Kickback exclusions. The Telemedicine-Online Pharmacy must identify the responsibilities of the physicians, calculate the physicians’ salaries based on fair market standards, and the salary must be considered reasonable and not account for referrals made. Thus, if the Telemedicine-Online Pharmacy falls within the aforementioned Anti-Kickback safe harbors, then the partnership is likely to avoid a violation of Stark Law as well.

If, on the other hand, the physician’s relationship with the online pharmacy more closely resembles a personal service arrangement, then six conditions, under Stark Law, must be met: (1) the arrangement must be in signed writing and specify services to be covered, (2) the arrangement must

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175. 42 C.F.R. § 1001.952(i) (2019).

176. Stark Law specifies ten designated health services. For the purpose of this note, focus should be placed on the ninth designated health service: outpatient prescription drugs. 42 C.F.R. § 411.351(1)(ix) (2019).

177. 42 U.S.C. § 1395nn(a) (2019).

178. *Id.* at (a)(2)(B).

179. 42 C.F.R. § 411.357(c) (2011); 42 C.F.R. § 411.357(d) (2019).

180. *Id.* at (c).

181. “*Mens rea* refers to criminal intent.” *Mens Rea*, LEGAL INFO. INST., [https://www.law.cornell.edu/wex/mens\\_rea](https://www.law.cornell.edu/wex/mens_rea) (last visited Nov. 20, 2018).

182. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 710 (Abridged 8th ed. 2018).

specifically identify the services furnished by the physician, (3) the aggregate amount of services must be reasonably necessary for the business's purposes, (4) the agreement be no shorter than one year, (5) the compensation must be consistent with fair market value, and (6) the services provided do not violate State or Federal law.<sup>183</sup> These conditions are strikingly similar to those codified in the Anti-Kickback safe harbors. Similar to an employment relationship, if all requirements for personal service arrangements are met in the same manner as the Anti-Kickback safe harbors, then a Stark Law violation is likely to be avoided. Therefore, if the Telemedicine-Online Pharmacy abides by the exclusions codified in the Anti-Kickback and Stark Law Statutes, then the partnership will avert statutory violation.

## B. HIPAA AND PRIVACY ISSUES

The Telemedicine-Online Pharmacy must comply with the regulations of the Health Insurance and Portability and Accountability Act (HIPAA) because the partnership provides healthcare and transfers health information via an electronic platform.<sup>184</sup> Both pharmacies and telehealth companies are covered entities under HIPAA,<sup>185</sup> meaning the telemedicine company and online pharmacy would already be in compliance with HIPAA prior to any formation of a partnership. Still, a possibly larger legal risk to health privacy is the danger of data breaches.

Many privacy laws and company policies have been enacted to protect consumer privacy both online and offline.<sup>186</sup> While numerous, these laws and policies do not cover all privacy risks, and many fail to provide proper notice or understanding to consumers as to what information is protected.<sup>187</sup> Additionally, with respect to the individual company policies, the policies are more akin to “corporate disclaimers, rather than consumer guarantees.”<sup>188</sup> Many company policies and enacted laws focus on the intentional release of data,<sup>189</sup> but many seem to neglect unintentional releases or data breaches. This privacy risk would be of great concern to the patients of the Telemedicine-Online Pharmacy because the patients would be protected against intentional data release, but they would seem to have no remedy for unintentional releases. Fortunately, an important legal shift is taking place that would allow for even greater protection of consumer and

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183. 42 C.F.R. §411.357(d) (2019).

184. 45 C.F.R. § 160.102(a)(3) (2019).

185. 45 C.F.R. § 160.300 (2019).

186. Lindsey Barrett, *Model(ing) Privacy: Empirical Approaches to Privacy Law & Governance*, 35 SANTA CLARA HIGH TECH. L.J. 1, 10–11 (2018).

187. *Id.* at 17–18.

188. *Id.* at 18.

189. *Id.* at 10–11.

patient information.<sup>190</sup> California recently passed a privacy law that will allow patients, as consumers, to sue for data breaches.<sup>191</sup> Many other states are likely to follow California's example because the "Golden State" has inspired other lawmakers with many of its progressive acts.<sup>192</sup> This law, if enacted throughout the United States, would allow patients of the Telemedicine-Online Pharmacy to recover for unintentional releases of data, providing an extra layer of assurance.<sup>193</sup> Additionally, the Telemedicine-Online Pharmacy would likely see this privacy law as an incentive to provide more effective and numerous buttresses against data leaks, thus providing greater legal protection for the partnership, in addition to providing greater privacy protection for its patients.<sup>194</sup>

### C. LEGAL BARRIERS AND THE REIMBURSEMENT MODEL

An issue facing the proposed Telemedicine-Online Pharmacy is the extent to which Medicare and Medicaid will reimburse its costs.<sup>195</sup> This issue has a greater impact on those using Medicare as a reimbursement system because Medicaid is silent in regard to categorizing telehealth as a distinct service, and the Centers for Medicare and Medicaid Services (CMS) promote "flexibility" in reimbursing telehealth through Medicaid.<sup>196</sup> On the other hand, CMS is more reluctant to reimburse telehealth companies through Medicare for services other than those used for direct communication, such as monitoring systems.<sup>197</sup> Additionally, limitations on reimbursement have been set that create an "eligible patient population . . . ." <sup>198</sup> To be within the eligible population, a patient must, among other factors, live a certain distance away from medical facilities and be enrolled

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190. Natalie Sherman, *How California Is Changing the US*, BBC NEWS (Oct. 16, 2018), <https://www.bbc.com/news/business-45767736>.

191. *Id.*

192. *Id.*

193. *Id.*

194. Cf. William H. Williams, Note, *On the Clock, Best Bet to Draft Cyberdefensive Linemen: Federal Regulation of Sports Betting from a Cybersecurity Perspective*, 13 BROOK. J. CORP. FIN. & COM. L. 539, 566, (2019) (explaining how data protection and cybersecurity are growing and important concerns for nascent industries in their attempt to gain legitimacy and consumer confidence).

195. Charles Townley & Rachel Yalowich, *Improving Behavioral Health Access & Integration Using Telehealth & Teleconsultation: A Health Care System for the 21st Century*, NAT'L ACAD. FOR ST. HEALTH POL'Y 1, 4 (Nov. 2015), <https://nashp.org/wp-content/uploads/2015/11/Telemedicine1.pdf>.

196. More "flexibility" is likely associated with Medicaid because states contribute to the Medicaid system as opposed to the completely Federal Medicare system. Since each state has its own reimbursement scheme, flexibility is required to accommodate each State's policy on telemedicine reimbursement. *See id.*

197. *Id.*

198. Latoya Thomas & Gary Capistrant, *50 State Telemedicine Gaps Analysis: Coverage & Reimbursement*, AM. TELEMEDICINE ASS'N 1, 7 (Jan. 2016).

in the correct payment plan.<sup>199</sup> These limitations would compound the issues facing the Telemedicine-Online Pharmacy because many patients would not receive full insurance coverage, or even qualify for any insurance coverage.<sup>200</sup>

Twenty-nine states have made an attempt to combat the limitations on reimbursement by enacting laws requiring private insurance companies to reimburse telemedicine services in the same manner as services provided by brick-and-mortar physician offices.<sup>201</sup> Telemedicine companies have also responded by contracting directly with employers to provide all telehealth services for a set fee.<sup>202</sup> While these private insurance laws and the direct contracting with employers improve the telehealth reimbursement system, they do not change Medicare's reluctance to cover all telemedicine services.<sup>203</sup> These changes in state private insurance law and telemedicine-employer contracting seem to create an optimistic belief that Medicare will eventually provide reimbursement for telehealth services in the same manner that it does for brick-and-mortar physician offices. Be that as it may, for the time being, many Medicare beneficiaries may be reluctant to utilize the Telemedicine-Online Pharmacy because of the limitations on reimbursement.

## V. A COMPARABLE COMPANY: RO

One company successfully using a business model similar to this Note's proposed solution is Ro, an online pharmacy that specializes in erectile dysfunction, hair loss, premature ejaculation, cold sores, and genital herpes for men.<sup>204</sup> Ro also focuses in eyelash loss, sex issues, and sleep issues for women,<sup>205</sup> as well as smoking cessation for men and women.<sup>206</sup> Under the Ro platform, a patient provides his or her medical history, communicates with a physician via online messaging or videoconference, then, if the physician deems acceptable, a prescription is provided.<sup>207</sup> The direct communication and online prescribing of medicine is similar to the Telemedicine-Online Pharmacy's model, but Ro is, in some ways, noticeably different from this Note's proposed solution. The main difference is that Ro only provides prescriptions for limited ailments,<sup>208</sup> as opposed to the various other prescriptions that would be available to

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199. *Id.*

200. *See id.*

201. *Id.* at 3, 29–79.

202. Lovett Rockwell, *supra* note 122, at 41.

203. *Id.* at 40.

204. *FAQ*, ROMAN, <https://www.getroman.com/faq/> (last visited Sept. 8, 2019).

205. *Frequently Asked Questions*, RORY, <https://www.hellorory.com/faqs/> (last visited Sept. 8, 2019).

206. *FAQ*, ZERO, <https://quitwithzero.com/faq/> (last visited Sept. 8, 2019).

207. ROMAN, *supra* note 204.

208. *Id.*



patients through the Telemedicine-Online Pharmacy. Additionally, Ro is merely a supplement to a patient's regular health plan and does not serve as the patient's primary physician.<sup>209</sup> This Note's proposed solution would serve as a patient's primary care center and would have the ability to prescribe medication for various ailments and conditions, including those covered by Ro. While Ro performs only a fraction of what the Telemedicine-Online Pharmacy would provide, it is a great small-scale indicator of the viability and profitability<sup>210</sup> of this Note's proposed solution.

## CONCLUSION

A Telemedicine-Online Pharmacy partnership is a possible means to drive down pharmaceutical drugs prices. The partnership would provide greater access to higher quality health care, while improving market competition among pharmaceutical companies. This increase in market competition can be achieved through Telemedicine-Online Pharmacies promoting generic-brand drugs in order to attract all patients, especially the ones that have been struggling to meet the cost of name-brand prescription drugs. If successful in creating greater market competition, then Telemedicine-Online Pharmacies will compel name-brand pharmaceutical companies to lower their prices in order to compete with the generic-brand prices, and even be promoted through telemedicine-online pharmacies, if prices are deemed affordable. Additionally, safeguards against poorly managed or illegal online pharmacies will promote the use of telemedicine-online pharmacies, while providing patients with information about the most reputable websites.<sup>211</sup> Not only do safeguards, such as the Center for Safe Internet Pharmacies, provide verification for online pharmacies, but they produce reports and blog updates pertaining to the best and fair online pharmacies as well as the worst, and likely illegal.<sup>212</sup> If Telemedicine-Online Pharmacies can effectively navigate the legal requirements imposed on healthcare companies<sup>213</sup> and promote lower priced pharmaceuticals, then financially struggling patients are likely to receive improved access to care and lower prescription prices.

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209. *Id.*

210. Josh Constine, *Erectile Pharmacy App Roman Raises \$88M to Launch 'Quit Smoking' Kit*, TECH CRUNCH (Sept. 18, 2018), <https://techcrunch.com/2018/09/18/roman-zero-quit-smoking/> (noting that Ro's Roman Health for men has a "revenue run-rate in the 10s of millions" of dollars).

211. *Mission, Goals & Objectives*, CTR. FOR SAFE INTERNET PHARMACIES, <https://safemedsonline.org/who-we-are/mission-goals-objectives/> (last visited Aug. 3, 2019).

212. *Id.*

213. *See* 42 U.S.C. § 1320a-7(b) (2019); 42 U.S.C. § 1396nn (2019).

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