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## Pharming Out Data: A Proposal for Promoting Innovation and Public Health through a Hybrid Clinical Data Protection Scheme

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# Pharming Out Data: A Proposal for Promoting Innovation and Public Health through a Hybrid Clinical Data Protection Scheme

## ABSTRACT

*The pharmaceutical industry, one of the largest industries in the world, is rapidly becoming globalized. Clinical trials, which are required for drugs to be approved for human use, are increasingly performed outside of the pharmaceutical company's home country in an attempt to save money. This is mainly due to drug development's steep costs, and the high risks involved in an industry where only 12 percent of products that begin development ever make it to market. In order to help offset these risks and encourage innovation, many countries offer clinical trial data certain protections through patents, market exclusivity, or trade secret protection. However, regulations and clinical data protection often do not align between the originator country and the location of the clinical trial. This leads to confusion and undermines the goals of providing clinical data protection. Additionally, providing too much protection to test data can negatively affect consumers, who will not be able to access cheaper generic versions of drugs. While it is commonly accepted that clinical data protection must be standardized on a global level, it is less clear what level and type of protection is appropriate. This Note proposes a hybrid system of clinical data protection that offers one year of data exclusivity, followed by a four-year period of cost sharing, during which generic competitors must pay a fee to rely on the originator company's data. Such a scheme would properly balance the need to encourage pharmaceutical companies to undertake the risky business of innovating with the need to provide easy access to affordable medications.*

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## I. INTRODUCTION TO DRUG DEVELOPMENT AND THE PROBLEM OF CLINICAL DATA PROTECTION

The pharmaceutical industry is a formidable beast, both in the United States and worldwide. In 2014, an estimated 48.9 percent of people in the United States had used at least one prescription drug in the past thirty days.<sup>1</sup> This represents a marked increase from just two decades earlier, when only 37.8 percent of survey respondents answered the same question in the affirmative.<sup>2</sup> Globally, pharmaceutical revenues exceeded \$1 trillion for the first time in 2014, and have continued to increase accordingly, with US-based pharmaceutical companies accounting for approximately half of the market revenues.<sup>3</sup> In 2017, the world pharmaceutical market value was estimated to be \$1.2 trillion.<sup>4</sup>

However, drug development is also a highly risky business. It can cost anywhere from \$650 million to \$2.7 billion to put a drug on the market in the United States.<sup>5</sup> When as few as one in ten thousand

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1. U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH, UNITED STATES, 2016: WITH CHARTBOOK ON LONG-TERM TRENDS IN HEALTH 293 (2017), <https://www.cdc.gov/nchs/data/abus/abus16.pdf> [<https://perma.cc/269T-52SJ>] (archived Sept. 15, 2018).

2. *Id.* The cause of this increase has not been definitively determined.

3. *Global Pharmaceutical Industry—Statistics & Facts*, STATISTA, <https://www.statista.com/topics/1764/global-pharmaceutical-industry/> (last visited Oct. 11, 2018) [<https://perma.cc/KXH6-QFKS>] (archived Aug. 25, 2018) [hereinafter STATISTA].

4. Ellen 't Hoen, *Wrapping Up 2017—some noteworthy medicines law and policy events*, MEDICINES LAW & POLICY (Dec. 31, 2017), <https://medicineslawandpolicy.org/2017/12/wrapping-up-2017-some-noteworthy-medicines-law-and-policy-events/> [<https://perma.cc/YTV9-8T93>] (archived Sept. 15, 2016).

5. Compare Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTEL. PROP. L. REV. 1, 5 (Winter 2009) (citing figures between \$800 million and \$1 billion per approved drug), with Richard Harris, *R&D Costs for Cancer Drugs are Likely*

compounds eventually becomes a marketable product—only twenty-two novel drugs were approved by the Food and Drug Administration (FDA) in 2016<sup>6</sup>—it would be smarter to buy a lottery ticket. Further, although pharmaceutical-company expenditures on research and development continue to grow, only 30 percent of the drugs that do make it to market recoup enough money to meet or exceed the average cost of development.<sup>7</sup>

To truly understand the costs involved in getting a drug to market, it is also important to understand the drug development process.<sup>8</sup> The first step is researching in a laboratory to discover new compounds or find new uses for drugs that are already approved.<sup>9</sup> Molecules that show a potential therapeutic indication move on to the preclinical research stage, the goal of which is to determine the maximum dosage that can be given to humans without toxicity, if such a dose exists.<sup>10</sup> Preclinical research can be conducted *in vitro*, but is most commonly done using animals such as mice, rats, dogs, and monkeys.<sup>11</sup> The FDA requires a specific set of preclinical studies before drugs may be tested on humans.<sup>12</sup>

After the requisite preclinical studies are conducted and maximum safe dosages are determined, pharmaceutical companies file

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*Much Less than Industry Claims, Study Finds*, NPR: ALL THINGS CONSIDERED (Sept. 11, 2017, 1:10 PM), <https://www.npr.org/sections/health-shots/2017/09/11/550135932/r-d-costs-for-cancer-drugs-are-likely-much-less-than-industry-claims-study-finds> [<https://perma.cc/J3H6-FQSD>] (archived Sept. 15, 2018) (citing one study that found it costs \$650 million to develop a new cancer drug, and also pointing out that the pharmaceutical industry asserts the cost to develop a new drug is \$2.7 billion).

6. U.S. FOOD & DRUG ADMIN., 2016 NOVEL DRUGS SUMMARY 2 (2017), <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM536693.pdf> [<https://perma.cc/QJC2-8Z89>] (archived Sept. 15, 2018).

7. OLIVER GASSMANN ET AL., LEADING PHARMACEUTICAL INNOVATION: TRENDS AND DRIVERS FOR GROWTH IN THE PHARMACEUTICAL INDUSTRY 2 (2004).

8. For ease, the drug development process is explained through the lens of the regulations and procedures in the United States. This is because American-based drug companies represent over half of the industry's revenue, and therefore the United States' policies are the most widely applicable. See STATISTA, *supra* note 3. The drug development process in general is often similar in other developed countries, where most pharmaceutical companies are located, although not identical.

9. See *The Drug Development Process*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForPatients/Approvals/Drugs/default.htm> (last updated Jan. 4, 2018), [<https://perma.cc/3S3V-D3WZ>] (archived Sept. 15, 2018) [hereinafter *Drug Development Process*].

10. *Id.* Because the drugs are tested on animals in the preclinical stage, the FDA recommends that the maximum tolerated dose in animals be at least fifty times the expected clinical dose in humans. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: M3(R2) NONCLINICAL SAFETY STUDIES FOR THE CONDUCT OF HUMAN CLINICAL TRIALS AND MARKETING AUTHORIZATION FOR PHARMACEUTICALS 4 (2010), <https://www.fda.gov/downloads/drugs/guidances/ucm073246.pdf> [<https://perma.cc/TF7B-D4KM>] (archived Sept. 15, 2018).

11. See *Animals in Science/Research*, NEW ENG. ANTI-VIVISECTION SOC'Y, <https://www.neavs.org/research/biomedical> (last visited Oct. 11, 2018) [<https://perma.cc/4XGX-GPTW>] (archived Oct. 11, 2018); *Step 2: Preclinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm> (last visited Oct. 11, 2018) [<https://perma.cc/PF3G-YJAL>] (archived Oct. 11, 2018)

12. *Step 2: Preclinical Research*, *supra* note 11.

an Investigational New Drug (IND) application with the FDA.<sup>13</sup> In the application, the developer must include data from preclinical research, including information about toxicity and manufacturing, plans for future human clinical trials, and data from any prior human research involving the drug.<sup>14</sup> If the FDA is satisfied that the drug meets federal standards, the pharmaceutical company is allowed to proceed to clinical trials, where it administers the drug to humans.<sup>15</sup>

Phase I clinical trials are small in size and short in duration, and often involve healthy volunteers so scientists can assess safety, proper dosage, and potential side effects.<sup>16</sup> Approximately 70 percent of drugs advance to Phase II clinical trials, where several hundred patients with the target condition are given the drug for a few months to two years, depending on the particular trial.<sup>17</sup> The purpose of these trials is to determine whether the compound has the desired effect on the target disease, and if there are any new side effects in the target population.<sup>18</sup>

Thirty-three percent of molecules move on to Phase III clinical trials, which are designed to assess long-term effects of the drug in the target population.<sup>19</sup> Accordingly, these trials usually last between one and four years, with an average trial length of approximately twenty months.<sup>20</sup> After Phase III trials, the drug developer may file a New Drug Application (NDA) with the FDA, seeking approval to market the drug to the public.<sup>21</sup> The NDA includes reports on all studies and data collected up to the point of filing, as well as proposed labeling, patent information, and data from studies that were conducted outside of the United States.<sup>22</sup> The last phase of clinical research, Phase IV, assesses safety and efficacy in several thousand volunteers with the indicated condition.<sup>23</sup>

Although consumers often take for granted that their medications will be safe and will not cause excessive side effects, some may nevertheless view such extensive drug-development requirements as burdensome and overly expensive. However, a quick examination of the history behind the advent of clinical trials makes it clear why close regulation of pharmaceutical testing is necessary.

The birth of the modern clinical trial scheme goes back to the 1960s, when a German pharmaceutical company internationally

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13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*; see also Lisette Pregelj et al., *Changes in Clinical Trial Length*, 14 NATURE REVIEWS: DRUG DISCOVERY 307, 308 (2015).

21. *Drug Development Process*, *supra* note 9.

22. *Id.*

23. *Id.*

marketed a sedative called thalidomide.<sup>24</sup> The product was advertised as “completely safe,” even if used by pregnant women.<sup>25</sup> Doctors began to prescribe thalidomide not only as a sedative, but also as a treatment for morning sickness in expectant mothers, an off-label use discovered by an Australian physician.<sup>26</sup> This turned out to be a tragic mistake. Despite the manufacturer’s assurances, thalidomide was far from safe for pregnant women; in fact, it interfered with fetal development and caused severe birth defects, most commonly resulting in babies born with shortened or absent limbs.<sup>27</sup> The clinical trials for thalidomide were cursory at best—they involved over a thousand physicians administering the drug to twenty thousand patients, and did not require that the patients be tracked after taking the medication.<sup>28</sup>

Prior to these events, the United States had passed the Food, Drug, and Cosmetic Act (FDCA) of 1938, which required drug manufacturers to show that a drug was safe, and to submit an application to the FDA before the drug could be put on the market.<sup>29</sup> The statute was enacted in the wake of another catastrophe where a Tennessee drug company marketed Elixir Sulfanilamide, a product chemically similar to antifreeze that killed over one hundred people.<sup>30</sup> However, the FDCA had a major flaw: if the FDA did not act on an application within a certain time period, it would automatically become approved, and therefore the requirement of proving safety did not serve as a sufficient gatekeeper to keep unsafe medicines off the market.<sup>31</sup>

The United States Congress was spurred to address this problem in the wake of the devastation caused by thalidomide. It enacted the Kefauver Harris Amendments to the FDCA, which required drug manufacturers to prove the efficacy and safety of a product before the FDA would approve it.<sup>32</sup> The Amendments specified that evidence of effectiveness must be based on “adequate and well-controlled clinical studies conducted by qualified experts.”<sup>33</sup> Further, they corrected the gap in the FDCA, giving the FDA only 180 days to approve a new drug

24. Katrin Weigmann, *The Ethics of Global Clinical Trials*, 16 EMBO REFS. 566, 566 (2015).

25. Bara Fintel et al., *The Thalidomide Tragedy: Lessons for Drug Safety and Regulation*, HELIX MAG. (July 28, 2009), <https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation> [<https://perma.cc/FT8Z-L2HZ>] (archived Aug. 25, 2018).

26. *Id.*

27. *Id.*

28. *Id.*

29. Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG., Jan.–Feb. 2006, <https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm2017809.htm> [<https://perma.cc/RPQ8-BFC4>] (archived Aug. 26, 2018).

30. *Id.*

31. *See id.* (explaining that the Act’s automatic approval mechanism was not effective in keeping unsafe drugs off the market).

32. *Id.*

33. *Kefauver-Harris Amendments Revolutionized Drug Development*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm322856.htm> (last updated Sept. 10, 2018) [<https://perma.cc/ND35-ZAF5>] (archived Aug. 26, 2018).

application, at which point the application would be considered denied.<sup>34</sup> The legislative bodies of the European Union (EU) and the United Kingdom (UK), among others, also enacted statutes overseeing clinical trials in the wake of the thalidomide scandal.<sup>35</sup>

It is important to regulate the actual clinical trials for ethical reasons as well. The greatest illustrator of this need is a forty-year study conducted by the United States Public Health Service that began in 1932, titled the “Tuskegee Study of Untreated Syphilis in the Negro Male.”<sup>36</sup> Researchers told the six hundred subjects—all poor, black men from rural Alabama—that they were being treated for “bad blood,” a term used at the time to describe ailments such as anemia or fatigue.<sup>37</sup> In reality, the government planned to observe the effects of syphilis and study the body after it succumbed to the disease.<sup>38</sup> Despite promises from the researchers, the patients never received the necessary treatment, even after scientists discovered penicillin could effectively combat syphilis in 1947.<sup>39</sup>

In the wake of the Tuskegee study, the United States enacted the National Research Act, which requires researchers to obtain voluntary consent from all persons taking part in studies or clinical trials and provides for oversight of any study using human subjects.<sup>40</sup> Internationally, the World Medical Association put forth the Declaration of Helsinki as a statement of ethical principles for conducting medical research with human patients.<sup>41</sup> These actions represent an international consensus that extensive regulation of clinical trials and drug development is necessary given the ethical, health, and safety concerns inherent in the process.

But everything costs money, and tight regulation makes drug development an extremely expensive industry. In the United States, a single clinical trial may cost anywhere from \$1 million to \$53 million.<sup>42</sup> The entire drug development process may run a pharmaceutical

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34. *Id.*

35. See Medicines Act 1968, ch. 67 (UK); Council Directive 65/65/EEC on the Approximation of Provisions Laid Down by Law, Regulation or Administrative Action Relating to Proprietary Medicinal Products, 1965 O.J. SPEC. ED. 022.

36. *U.S. Public Health Service Syphilis Study at Tuskegee: The Tuskegee Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/tuskegee/timeline.htm> (last visited Feb. 28, 2018) [<https://perma.cc/92T7-53AL>] (archived Aug. 26, 2018).

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. Sandra L. Alfano, *Conducting Research with Human Subjects in International Settings: Ethical Considerations*, 86 *YALE J. BIOLOGY & MED.* 315, 318 (2013).

42. Aylin Sertkaya et al., *Key Cost Drivers of Pharmaceutical Clinical Trials in the United States*, 13 *CLINICAL TRIALS* 117, 117 (2016).

company between \$650 million and \$2.7 billion.<sup>43</sup> The increasing cost of clinical research worldwide has serious implications. On the whole, the pharmaceutical industry has become more risk averse and, therefore, less willing to develop novel compounds or specialized drugs with smaller potential markets.<sup>44</sup> Clinical research facilities are similarly wary, carefully selecting the types of clinical trials they will take on in order to avoid putting the center in a deficit.<sup>45</sup> The pharmaceutical industry is therefore constantly looking for ways to combat the effects of rising costs and incentivize continued innovation.<sup>46</sup>

One way to manage the financial burden of the drug development process is to relocate clinical trials to developing countries, where the price of renting research facilities, hiring medical staff, and recruiting test subjects is significantly lower.<sup>47</sup> The ability to move clinical trials overseas is facilitated by the fact that the pharmaceutical industry, like much of the world, has become increasingly globalized in the last few decades.<sup>48</sup> Another way to ease the burden is to offer protection to data generated by originator pharmaceutical companies for a set period of time.<sup>49</sup> This prevents other companies from profiting from data they did not originally produce, at least for a certain amount of time, giving the originator company an opportunity to recoup costs without significant competition.

However, the decreased up-front financial burden of conducting clinical trials in lower-cost countries is often offset by an increased regulatory burden.<sup>50</sup> To maximize profits, multinational drug companies want to market their products in as many countries as

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43. Harris, *supra* note 5 (explaining that the pharmaceutical industry often cites much higher figures than those put forth by studies conducted by consumer groups or physicians).

44. AYLIN SERTKAYA ET AL., EASTERN RESEARCH GRP., EXAMINATION OF CLINICAL TRIAL COSTS AND BARRIERS FOR DRUG DEVELOPMENT 1–2 (July 25, 2014), <https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development> [<https://perma.cc/NFA2-XN7J>] (archived Sept. 15, 2018), [hereinafter EASTERN RESEARCH GROUP].

45. *Id.*

46. See, e.g., TODD D. CLARK, THE CASE FOR GLOBALIZATION: ETHICAL AND BUSINESS CONSIDERATIONS IN CLINICAL RESEARCH 3–5 (July 21, 2009), [https://www.acrohealth.org/wp-content/uploads/2014/09/Case-for-Globalization\\_FINAL.pdf](https://www.acrohealth.org/wp-content/uploads/2014/09/Case-for-Globalization_FINAL.pdf) [<https://perma.cc/R3U7-S6QR>] (archived Sept. 18, 2018) (advocating for clinical trials in emerging countries as a way to reduce costs while continuing to innovate).

47. See Paul R. DeMuro & John E. Steiner, Overview of Privacy Requirements and Compliance Issues in International Clinical Trials, Presentation at Health Care Compliance Association Research Compliance Conference (Oct. 18–20, 2009), [https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference\\_Handouts/Research%20Compliance%20Conf/2009/203H1.pdf](https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Research%20Compliance%20Conf/2009/203H1.pdf) [<https://perma.cc/8Y93-3S2Q>] (archived Sept. 15, 2018) [hereinafter HCCA Presentation].

48. See Seth W. Glickman et al., *Ethical and Scientific Implications of the Globalization of Clinical Research*, 360 NEW ENG. J. MED. 816, 816 (2009).

49. See Reichman, *supra* note 5, at 4. For an in-depth discussion of the different methods of clinical data protection, see *infra* Part III.

50. See Reichman, *supra* note 5, at 2.



possible. However, there is no widespread global harmonization of requirements for conducting clinical trials, collecting and reporting data, or protecting that data once it is generated.<sup>51</sup> Because of this, countries often have extensive review mechanisms to ensure clinical trials conducted in foreign countries comply with all the necessary requirements of the home country before approving a drug.<sup>52</sup> There are also problems that arise from reconciling different methods of clinical data protection, which can hinder the process of marketing a drug when regulations between countries do not align. These delays and difficulties largely counteract the financial benefits of globalization of clinical trials.

Incentivizing innovation in the pharmaceutical industry is extremely important. Given the high cost of drug development, many pharmaceutical companies choose not to focus on developing medicines that treat diseases that affect only a small portion of the population and therefore have small prospective markets.<sup>53</sup> Even if such drugs are discovered, they are often not tested because the low potential sales cannot justify the cost of development.<sup>54</sup> But just because a drug may not make a large profit does not mean the disease at issue does not deserve to be treated.

However, the need to promote development of novel drugs and reward pharmaceutical companies for engaging in research is counterbalanced by ethical and public health concerns stemming from overprotection. If clinical data is afforded too much protection, it is extremely difficult for generic versions of medications to make it to market, which means access to affordable drugs is significantly hindered.<sup>55</sup> Prohibiting generic manufacturers from relying on clinical data from the originator company may also lead to unnecessary duplication of preclinical and clinical research; this raises serious questions about the ethics of needlessly subjecting people and animals to trials regarding products that may have significant side effects.<sup>56</sup> Additionally, because pharmaceutical companies are, understandably, profit-motivated corporations, protecting clinical data more than is truly necessary to incentivize innovation does not lead to cost savings for consumers; in fact, it may actually lead to companies that hold a monopoly on a particular market sector continually inflating prices due

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51. See Kassa Ayalew, FDA Perspective on International Clinical Trials, Presentation (Dec. 12, 2013), <https://www.fda.gov/downloads/training/clinicalinvestigatortrainingcourse/ucm378499.pdf> [<https://perma.cc/BSS4-6R4W>] (archived Oct. 11, 2018).

52. Glickman, *supra* note 48, at 817.

53. G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L L. & BUS. 6, 11 (2003).

54. *Id.* at 9.

55. Lisa Diependaele et al., *Raising the Barriers to Access to Medicines in the Developing World—The Relentless Push for Data Exclusivity*, 17 DEVELOPING WORLD BIOETHICS 11, 12 (2017).

56. *See id.* at 13.

to lack of competition.<sup>57</sup> There is also a concern that many of these public health issues disproportionately affect poorer, less industrialized nations, who may not have equal bargaining power with which to negotiate international standards for clinical data protection.<sup>58</sup>

To balance these competing, valid considerations, clinical data protection must be standardized globally so as not to undermine its goals of incentivizing innovation and decreasing costs for pharmaceutical companies. However, the method of protection must also be more flexible, and take into consideration exactly what amount of safeguarding of data is necessary to achieve innovation while still allowing the policy goals of economic and social development in less industrialized countries, and public health considerations of access to affordable medication.

Part II of this Note presents a brief explanation of why clinical data protection is an issue worth exploring, points out the recent trend towards globalization in the pharmaceutical industry, and explains why that trend has created an urgent need to harmonize how countries protect clinical data generated within their borders. Part III explores the different methods and instruments currently used to protect clinical data in various countries. Part IV delves into the benefits and drawbacks of comprehensive protection of clinical data, leading into Part V, which proposes a hybrid scheme that combines a set period of data exclusivity with a period of cost sharing in order for generic companies to access such data.

## II. DEFINING CLINICAL DATA AND EXPLORING THE INCREASING NEED FOR HARMONIZED CLINICAL DATA PROTECTION

Clinical trial data encompasses any information generated during the preclinical and clinical testing processes.<sup>59</sup> The United States requires extensive data from applicants in order to demonstrate to the FDA that the benefits of a drug outweigh its possible side effects.<sup>60</sup> This requirement applies even if the compound was previously approved by another country's government.<sup>61</sup> Other developed countries, such as Japan and most of the members of the EU, mandate similar amounts of data in order to achieve drug approval.<sup>62</sup>

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57. See Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States*, 316 JAMA 858, 863 (2016) (noting that the justifications for high drug prices in the United States have weak foundations).

58. Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Org., Address at the WHO-WIPO-WTO Technical Symposium on Sustainable Development Goals (Feb. 26, 2018), <http://www.who.int/dg/speeches/2018/technical-symposium-sdgs/en/> [<https://perma.cc/QDD8-99J8>] (archived Sept. 15, 2018).

59. Skillington & Solovy, *supra* note 53, at 6.

60. *Id.*; see also *infra* Part II.

61. Skillington & Solovy, *supra* note 53, at 6.

62. *Id.*

Given that consumers in developed countries constitute the majority of potential revenue for pharmaceutical companies, it makes sense that most drug developers, regardless of where they are located, generate massive amounts of clinical data with the goal of eventually marketing their products in the United States and the EU.<sup>63</sup> Pharmaceutical companies spend a great deal of money to produce this data: in the United States, clinical trials can cost anywhere from \$1 million to \$53 million, and drug developers must conduct several clinical trials before a drug may be marketed.<sup>64</sup> In order to encourage investment in generating clinical data and make it easier to recover the heavy costs of drug development, data from preclinical and clinical research are often protected from potential producers of generic versions of the drug for a set amount of time, allowing the originator company to ensure it will recover its expenses.<sup>65</sup>

Another way of managing the financial burden of the drug development process is to relocate clinical trials to developing countries, where costs are significantly lower.<sup>66</sup> Most large pharmaceutical companies today have research facilities in multiple countries—of the 171 companies that developed new molecular entities approved by the FDA between 1992 and 2004, approximately 60 percent were designated as “multinational,” meaning they had research facilities in more than two countries.<sup>67</sup> Many of these multinational companies conduct their preclinical and clinical testing in a single country, but use the data generated from those trials to obtain regulatory approval in multiple countries, thus allowing them to market a drug internationally without duplicating testing.<sup>68</sup> This is partially because of the cost savings, and partially because of the ethical issues that arise from unnecessarily exposing animals and humans to repeated testing for the same drug.<sup>69</sup>

As more trials cross borders, international clinical data protections have become an increasingly important issue.<sup>70</sup> Of the over 286,000 clinical trials currently under the supervision of the FDA, more than half are conducted at least partially outside of the United States.<sup>71</sup> In 2009, it was estimated that over half of the studies

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63. *See id.*

64. Sertkaya, *supra* note 42, at 117.

65. Reichman, *supra* note 5, at 4. *See also infra* Part III for a more detailed explanation of the different methods of clinical data protection.

66. *See* HCCA Presentation, *supra* note 47.

67. Salomeh Keyhani et al., *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075, 1076–77 (2010).

68. Daria Kim, *Protecting Trade Secrets Under International Investment Law: What Secrets Investors Should Not Tell States*, 15 J. MARSHALL REV. INTELL. PROP. L. 228, 235 (2016).

69. *Id.* at 235 n.42.

70. *See* HCCA Presentation, *supra* note 47.

71. Nat'l Inst. of Health, *Trends, Charts, and Maps*, CLINICAL TRIALS, <https://clinicaltrials.gov/ct2/resources/trends#wrapper> (last visited Feb. 28, 2018) [<https://perma.cc/WCE8-MVP9>] (archived Aug. 26, 2018). Numbers are accurate as of time of publication. *Id.*

submitted to the FDA contained at least some data generated in a foreign country.<sup>72</sup>

The move abroad has been exacerbated as pharmaceutical companies based in developed countries have realized that it is not feasible to keep up with the current pace of medical research without lowering costs and expanding the pool of potential clinical trial subjects.<sup>73</sup> Pharmaceutical companies believe it is not possible to continue to be profitable conducting expensive trials in developed countries that contain only 15 percent of the world's population.<sup>74</sup> The entire business in general is costly and high risk, with only 10 to 20 percent of drugs that make it to clinical trials ultimately receiving FDA approval.<sup>75</sup> While at one point running a clinical trial in a western European country was significantly less expensive than conducting trials in the United States, this is no longer the case, which has prompted drug development firms to look for new locales for their clinical research.<sup>76</sup> Conducting clinical trials in developing countries such as Estonia, Hungary, and Poland not only keeps costs down, but also increases availability of treatment-naïve patients—those patients who have never undergone treatment for a particular illness.<sup>77</sup> Such populations are attractive subjects because they have not built up any resistance to the medications being tested.<sup>78</sup> Meanwhile, these countries often still provide access to high-quality investigational sites and large, specialized hospitals.<sup>79</sup>

Some of the biggest cost drivers in pharmaceutical research include data management; patient recruitment and retention; physician and administrative staff salary; site recruitment, retention, and monitoring; and general overhead costs.<sup>80</sup> Unsurprisingly, most of these factors are significantly more expensive in western Europe and the United States than they are elsewhere.<sup>81</sup>

Difficulties with patient recruitment and retention, which have become common in the United States and western Europe, can cause costly delays in clinical trials.<sup>82</sup> In 2000, time costs accounted for approximately half of the overall cost of developing a new drug, so it is understandable that pharmaceutical companies are constantly seeking

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72. CLARK, *supra* note 46, at 7.

73. *See id.*

74. *See id.* at 8.

75. HCCA Presentation, *supra* note 47.

76. *Id.*

77. *Id.*; *see also* Elizabeth Boskey, *What Does it Mean to be Treatment Naïve?*, VERYWELL (June 28, 2017), <https://www.verywell.com/treatment-naive-3132655> [<https://perma.cc/T5ZL-2H36>] (archived Aug. 26, 2018) (giving a more in-depth analysis of the significance of treatment-naïve patients).

78. Boskey, *supra* note 77.

79. *See* HCCA Presentation, *supra* note 47.

80. EASTERN RESEARCH GROUP, *supra* note 44, at 3-6 to 3-7.

81. *Id.* at 4-25 (explaining how cost has driven many drug sponsors to move the bulk of their research overseas).

82. *Id.*

ways to reduce the timeline of clinical trials.<sup>83</sup> Eastern Europe and Asia have an advantage in patient recruitment because countries such as India, China, and Russia have large populations.<sup>84</sup> Clinical trials have extensive eligibility requirements that rule out a large portion of potential subjects, so a larger pool means it is significantly easier to fill a trial.<sup>85</sup> This is especially true when looking for participants in Phase II clinical trials and beyond, which require numerous people with a specific disease.<sup>86</sup> One study indicates that recruitment in such populous, less-developed countries could be accomplished in about half the time it would take to recruit in the western world.<sup>87</sup> This could lead to clinical trials costing 50–60 percent of what they would cost if they were performed in the United States or other developed countries.<sup>88</sup> Additionally—and controversially—patients in developing countries are commonly treatment-naïve, due to poverty or inability to access medications.<sup>89</sup> On a more general level, poverty may mean the population is more willing to participate in a clinical trial due to a pressing need for some source of income, or because it is the only way to receive adequate medical care.<sup>90</sup>

Physicians and administrative staff are also more expensive in the United States and western Europe than in countries with lower average incomes.<sup>91</sup> Further, there are more available sites for clinical trials in large countries such as India and China, decreasing the time and effort it takes to locate an appropriate facility.<sup>92</sup> Once a site is found, the cost of retaining it and paying for accompanying overhead costs is often lower in less developed countries.<sup>93</sup>

There are many benefits to clinical trials being conducted within a country's borders, such as income for its citizens, profit for its government, and increased technological knowledge through technology transfer.<sup>94</sup> As such, several countries without a large

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83. Glickman, *supra* note 48, at 816–17. Time costs are calculated as the difference between the out-of-pocket cost of drug development and the fully capitalized cost of developing the same drug, which accounts for fixed expenses that accrue over time such as research facilities and employee salaries and benefits. For an explanation of how these costs are calculated, see Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166–68 (2003).

84. See EASTERN RESEARCH GROUP, *supra* note 44, at 4–25.

85. *Id.*

86. See *Drug Development Process*, *supra* note 9.

87. EASTERN RESEARCH GROUP, *supra* note 44, at 4–25.

88. Dinesh C. Sharma, *India Pressured to Relax Rules on Clinical Trials*, 363 LANCET 1528, 1528 (2004).

89. Glickman, *supra* note 48, at 819.

90. *Id.* at 818 (noting that in some places, compensation for participating in a clinical trial may be greater than the average patient's yearly wages).

91. See EASTERN RESEARCH GROUP, *supra* note 44, at 4–25.

92. *Id.*

93. *Id.*

94. See Matthew Howes, *Attractiveness of conducting clinical trials outside the U.S.*, CENTER WATCH (July 24, 2017), <https://www.centerwatch.com/news-online/2017/07/24/attractiveness-conducting-clinical-trials-outside-u-s/> [<https://perma.cc/TA89-MSV5>] (archived Aug. 26, 2018).

market share in the pharmaceutical industry have begun to offer incentives to drug companies.<sup>95</sup> India offers a 200 percent tax deduction for all research and development done in the country.<sup>96</sup> Australia has a tax-incentive program that makes clinical trials up to 60 percent more cost effective, and also boasts a government-sponsored cash rebate for research and development.<sup>97</sup> Singapore allows pharmaceutical companies access to numerous high-tech research institutes that the government has invested significant capital to build.<sup>98</sup> These incentives have visibly impacted the location of clinical trials: for clinical trials sponsored by the twenty largest US-based pharmaceutical companies, the number of non-US countries serving as trial sites more than doubled between 1997 and 2007.<sup>99</sup>

Despite the benefits of conducting pharmaceutical research in developing countries with large populations, if regulations between the pharmaceutical company's home country and the country in which the research is conducted do not align, the goal of decreasing costs is undermined. Conflicting regulations often lead to difficulties in compliance during clinical trials, which in turn can lengthen the duration of clinical trials, negating one of the main benefits of performing clinical trials offshore.<sup>100</sup> After the trials are completed, there may be additional delays in getting the results accepted by the pharmaceutical company's home country.<sup>101</sup> Individual countries often have extensive review mechanisms to ensure that clinical trials conducted in foreign countries comply with all the necessary requirements of the home country before approving a drug.<sup>102</sup> In the United States, the FDA reviews all clinical trials conducted in a foreign country to ensure they adhere to certain FDA regulations before accepting the data.<sup>103</sup>

This review is especially necessary because poorer, developing countries feel significant pressure to relax rules on clinical trials

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95. *Id.*

96. *Id.*

97. *Id.*

98. SAUWAKON RATANAWIJITRASIN, DRUG REGULATION AND INCENTIVES FOR INNOVATION: THE CASE OF ASEAN 18 (2009).

99. Glickman, *supra* note 48, at 816.

100. See EASTERN RESEARCH GROUP, *supra* note 44, at 4-11.

101. See Glickman, *supra* note 48, at 821 (noting that delays result from the home country regulatory agency's lack of information about important aspects of clinical trials conducted outside of the home country).

102. Greg Minisman et al., *Implementing Clinical Trials on an International Platform: Challenges and Perspectives*, 13 J. NEUROLOGICAL SCI. 1, 2 (2012).

103. See generally U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF: FDA ACCEPTANCE OF FOREIGN CLINICAL STUDIES NOT CONDUCTED UNDER AN IND (2012), <https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm294729.pdf> [<https://perma.cc/63PT-WDLA>] (archived Sept. 15, 2018); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ACCEPTANCE OF FOREIGN CLINICAL STUDIES (2001), <https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm124939.pdf> [<https://perma.cc/7GMA-75PB>] (archived Sept. 15, 2018).

conducted within their borders in order to draw in more business.<sup>104</sup> India is an illustration of this: in 2004, the Indian pharmaceutical industry actively lobbied the government to decrease regulations surrounding clinical trials because the industry wanted capital-rich European and North American pharmaceutical companies to place their trials in India.<sup>105</sup> This practice not only raises ethical concerns, but also makes review in the home country even more essential to ensure the data generated meets the standards required for approval.<sup>106</sup>

Then there are difficulties that arise from different methods of clinical data protection, which can hinder the process of marketing a drug when regulations between countries do not align. Different countries choose to provide such protection through different instruments, such as statutes, data-sharing agreements between countries, free trade agreements, and treaties; many countries use some combination of these types of data protection, which makes the regulatory landscape even more difficult to navigate. Additionally, these instruments may use different methods of protecting clinical data, either through patent law, trade secret protection, or data and marketing exclusivity.<sup>107</sup> As previously detailed, these processes are long and costly, often causing delays in profitability for pharmaceutical companies and diminishing the benefits of outsourcing clinical trials to foreign countries.<sup>108</sup>

In response to increased globalization and its attendant problems, governments have moved towards more harmonized rules regarding how clinical trials should be conducted, what data should be collected, and how the data should be analyzed and reported.<sup>109</sup> For example, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings the regulatory authorities of several countries together with members of the pharmaceutical industry itself, and promulgates the ICH Guidelines in the areas of quality, safety, and efficacy with which all members must comply.<sup>110</sup> The ICH also sets international quality standards in

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104. See Matthew Anderson, *FDA Abandons Declaration of Helsinki for International Clinical Trials*, THE SOC. MED. PORTAL (June 1, 2008), <http://www.socialmedicine.org/2008/06/01/ethics/fda-abandons-declaration-of-helsinki-for-international-clinical-trials/> [<https://perma.cc/F9W9-YUHL>] (archived Aug. 26, 2018).

105. Sharma, *supra* note 88.

106. See *id.*

107. See WILLIAM CHRISTIAN ET AL., *CITIZENS AGAINST GOVERNMENT WASTE, THE TRANS-PACIFIC PARTNERSHIP TRADE AGREEMENT AND INTELLECTUAL PROPERTY 4* (Nov. 2015), <https://www.cagw.org/sites/default/files/users/user98/TPPA%20and%20IP%20Issue%20Brief%20Web%20Edition.pdf> [<https://perma.cc/BJ24-K4NR>] (archived Sept. 15, 2018); Rebecca Choi, *Increasing Transparency of Clinical Trial Data in the United States and the European Union*, 14 WASH. U. GLOBAL STUD. L. REV. 521, 523 (2015); Tom C. W. Lin, *Executive Trade Secrets*, 87 NOTRE DAME L. REV. 911, 912 (2012).

108. See *supra* Part II.

109. See HCCA Presentation, *supra* note 47.

110. *Mission*, INT'L CONF. ON HARMONISATION, <http://www.ich.org/about/mission>.

the form of Good Clinical Practices (GCP), which regulate the investigators, the trial sponsors, and the clinical trial protocols.<sup>111</sup>

While these efforts move clinical data protection towards globalization, and are therefore helpful in lessening the regulatory burden on clinical trials conducted outside of the home country, there are still problems to be solved. Not all countries are party to the ICH Guidelines and the GCPs—major players in the pharmaceutical industry, such as China and India, are not members, and no developing countries have adopted the guidelines—and therefore their effectiveness is somewhat lessened.<sup>112</sup> Even in member countries, the Guidelines and GCPs may merely supplement existing regulations, meaning that there is not true harmonization.<sup>113</sup> Most significantly, how clinical trial data is protected and shared has not yet been made uniform on a global scale.

### III. THE CURRENT STATE OF CLINICAL DATA PROTECTION

As detailed in Part II, there must be some way to ease the heavy burden of paying to get a drug to market, or else the incentive to innovate will continue to be undermined as costs rise.<sup>114</sup> The most common solution to this problem is to offer certain protections to data generated by originator pharmaceutical companies for a set period of time.<sup>115</sup> This prevents other companies from profiting from data for which they did not shoulder the financial burden of initial drug development—at least for a certain amount of time—and gives the originator company an opportunity to recoup costs without significant competition.

As stated above, countries can choose whether to provide protection through statutes that apply to all research conducted within a country's borders, data-sharing agreements between two countries, free trade agreements, large-scale international treaties, or a

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html (last visited Oct. 11, 2018) [<https://perma.cc/Z9A5-FPAP>] (archived Aug. 26, 2018). Regulatory members of the ICH include the United States, the EU, Japan, Canada, Switzerland, Brazil, Singapore, and the Republic of Korea. *Members and Observers*, INT'L CONF. ON HARMONISATION, <http://www.ich.org/about/members-observers.html> (last visited Aug. 26, 2018) [<https://perma.cc/3VD5-6ZLM>] (archived Aug. 26, 2018). Industry members include the European Federation of Pharmaceutical Industries and Associations, Japan Pharmaceutical Manufacturers Association, Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, International Generic and Biosimilar Medicines Association, and World Self-Medication Industry. *Id.*

111. See generally INT'L CONF. ON HARMONISATION, ICH HARMONISED TRIPARTITE GUIDELINES: GUIDELINE FOR GOOD CLINICAL PRACTICE (June 10, 1996), [https://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R1\\_Guideline.pdf](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf) [<https://perma.cc/3B5Y-7SBL>] (archived Sept. 1, 2018) [hereinafter ICH GUIDELINES].

112. *Members and Observers*, *supra* note 110.

113. See generally ICH GUIDELINES, *supra* note 111.

114. See *supra* Part II.

115. Reichman, *supra* note 5, at 25–28.



combination of mechanisms. Some of these instruments offer protection through patent law.<sup>116</sup> Others classify the clinical data as a trade secret that must be protected.<sup>117</sup> Still others grant protection through data and marketing exclusivity provided separately from patent protections.<sup>118</sup>

Complicating matters even further is that many countries use these types of data protection in combination. As an example, the United States, in addition to being a party to the United States-Mexico-Canada Agreement (USMCA)<sup>119</sup> and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),<sup>120</sup> also has many federal statutes and regulations regarding data protection.<sup>121</sup> Utilizing multiple data protection methods not only undermines the harmonization efforts of the larger, multinational instruments, but also contributes to the regulatory burden and costly delay for pharmaceutical companies.

### A. General Methods of Clinical Data Protection

Regardless of the instrument used to provide protection to clinical trial data, there must always be some method of protecting the data. The most common means of protection are various areas of intellectual property law, including patents, trade secrets (internationally known as “undisclosed data” or “undisclosed information”<sup>122</sup>) and offering data and market exclusivity. For the purpose of ease, these different mechanisms will be explained by examining processes in the United States—the protections are generally the same internationally, but some of the nuances may differ.

Utility patents may be granted to any new and useful process, machine, article of manufacture, or composition of matter.<sup>123</sup> A patent

116. See Choi, *supra* note 107, at 523.

117. See *id.* at 522–23; Lin, *supra* note 107, at 941.

118. CHRISTIAN, *supra* note 107, at 3–4.

119. *United States-Mexico-Canada Agreement Text*, OFFICE OF THE U.S. TRADE REP., <https://perma.cc/M3YZ-974N> (last visited Oct. 11, 2018) [<https://perma.cc/S5BV-83RD>] (archived Oct. 11, 2018) [hereinafter USMCA]. This agreement replaces the North American Free Trade Agreement (NAFTA). *North American Free Trade Agreement (NAFTA)*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <https://ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta> (last visited Feb. 28, 2018) [<https://perma.cc/2HD4-GNTJ>] (archived Aug. 26, 2018) [hereinafter USTR NAFTA]. For more information on NAFTA and the transition to USMCA, see *infra* Part III.D.

120. Agreement on Trade-Related Aspects of Intellectual Property, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

121. Examples include the Hatch-Waxman Act and the Orphan Drug Act, discussed in Part III.

122. TRIPS Agreement, *supra* note 120, art. 39.

123. *General information concerning patents*, U.S. PATENT & TRADEMARK OFFICE (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents> [<https://perma.cc/KV9G-A6J9>] (archived Aug. 26, 2018) [hereinafter USPTO General Information].

may be applied for and issued at any time as long as the requirements are met, regardless of a drug's approval status.<sup>124</sup> Patents generally grant the holder the right to exclude others from making, using, selling, or importing the patented drug.<sup>125</sup> This means a patent holder could prevent a generic company from putting the same pharmaceutical on the market, even if the generic manufacturer generated its own data rather than relying on the originator company's data.<sup>126</sup>

While patent protection is very comprehensive, there are also drawbacks. Most importantly, patents only protect the product itself, not the data generated in testing the product.<sup>127</sup> This means that while patents may keep a competitor from directly copying a chemical compound's structure, or the method of producing the drug, they do not offer any shield to the actual data, and are therefore an incomplete way of addressing the problems associated with clinical data disclosure. Additionally, once granted, patents only endure for a set amount of time; in the United States, the patent term is twenty years from the date the patent application was filed.<sup>128</sup> Given the long period of development before regulatory approval and sale, the average medication in the United States loses over six years of its patent life before it makes it to market.<sup>129</sup> In the international context, patent protections generally only exist within the country that granted the patent, which creates issues given the globalization of the drug development process.<sup>130</sup> This is exacerbated by the fact that developing countries historically have not recognized intellectual property rights and have only provided weak protection when intellectual property rights do exist.<sup>131</sup>

Trade secrets consist of certain information—a formula, pattern, complication, device, method, process, or design—not generally known by outsiders through which a business can obtain an advantage over competitors.<sup>132</sup> The categories of information that can be considered

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124. *Id.*

125. Wael Armouti, *Test Data Protection: Different Approaches and Implementation in Pharmaceuticals*, 20 MARQ. INTELL. PROP. L. REV. 267, 278 (2016).

126. *See id.*

127. USPTO General Information, *supra* note 123.

128. *Id.*

129. Francis H. Spiegel, Jr., *The Economics of Pharmaceutical Research and Development: An Industry Perspective*, in *THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY* 181 (1991).

130. USPTO General Information, *supra* note 123.

131. Charles Vorndran, *Biotechnology and Intellectual Property Protection from U.S. Law Through NAFTA*, 3 L. & BUS. REV. AMERICAS 103, 126 (1997).

132. *Trade Secret Policy*, U.S. PATENT & TRADEMARK OFFICE, <https://www.uspto.gov/patents-getting-started/international-protection/trade-secret-policy> (last visited Feb. 28, 2018) [<https://perma.cc/4ENX-SJJ7>] (archived Aug. 26, 2018) [hereinafter USPTO Trade Secrets]. It is important to note that trade secrets as such are not recognized on an international level. Internationally, the equivalent to a trade secret is “undisclosed information,” and is often defined using Article 39 of the TRIPS Agreement. Stephanie Zimmerman, *Secret's Out: The Ineffectiveness of Current Trade*

trade secrets are fairly broad, meaning that this protection is readily and easily available.<sup>133</sup> Trade secrets are protected without any procedural formalities, which means there is no registration or paperwork needed for clinical data to be considered a trade secret, and the protection can theoretically exist in perpetuity.<sup>134</sup> However, a trade-secret holder is only protected from unauthorized disclosure and use of the data, not from any independent discovery by another party or from disclosure by the holder.<sup>135</sup>

Protection through data and marketing exclusivity has become more common in recent years, especially given that it was designed intentionally to promote new drug innovation while still allowing public access to generic drugs.<sup>136</sup> This form of protection allows the original drug developer to enjoy a competition-free market by delaying or prohibiting approval of competitor drugs; in this way, it is often considered a subset of trade secret protection.<sup>137</sup> For data exclusivity purposes, it does not matter where the clinical testing was conducted—rather, it is the decision of the national regulatory agency, such as the FDA in the United States, whether to grant the originator company exclusive approval for a set period of time.<sup>138</sup> Typically, exclusivity will only attach upon approval of a drug that meets certain requirements.<sup>139</sup> A drug developer may hold patents on its product and still be eligible for exclusivity, and the terms of patent protection and exclusivity may or may not run concurrently.<sup>140</sup>

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*Secret Law Structure and Protection for Global Health*, 29 PENN ST. INT'L L. REV. 777, 783 (2011).

133. USPTO Trade Secrets, *supra* note 132.

134. *Id.*

135. *Id.*

136. *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., [https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#What\\_is\\_the\\_difference\\_between\\_patents\\_a](https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#What_is_the_difference_between_patents_a) (last visited Feb. 28, 2018) [<https://perma.cc/46FC-NLQZ>] (archived Aug. 26, 2018) [hereinafter FDA FAQ].

137. See Armouti, *supra* note 125, at 269; USPTO General Information, *supra* note 123.

138. See, e.g., TRIPS Agreement, *supra* note 120, art. 39.3 (“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.”); INT’L FED’N OF PHARM. MFRS. & ASS’NS, DATA EXCLUSIVITY: ENCOURAGING DEVELOPMENT OF NEW MEDICINES (July 2011), [https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA\\_2011\\_Data\\_Exclusivity\\_En\\_Web.pdf](https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_2011_Data_Exclusivity_En_Web.pdf) [<https://perma.cc/ADB2-M2JG>] (archived Oct. 11, 2018) (discussing the domestic laws of several states governing data exclusivity); INT’L FED’N OF PHARM. MFRS. & ASS’NS, ENCOURAGEMENT OF NEW CLINICAL DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 2 (2000), [http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity\\_2000.pdf](http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf) [<https://perma.cc/GM37-A5H3>] (archived Oct. 11, 2018).

139. USPTO General Information, *supra* note 123. These requirements may include: the product must be a new chemical entity; the data must be unpublished; generating the data involved considerable effort; and the data are submitted to get marketing approval. Armouti, *supra* note 125, at 279.

140. FDA FAQ, *supra* note 136.

### B. Single-Country Statutes, Regulations, and Guidelines

Like any other industry, one way the pharmaceutical industry is regulated is through statutes, administrative regulations, or guidelines enacted by a single country's government that apply only within that country. While they allow countries to regulate their own economies, instruments that only have effect in one country do not solve the problem of regulatory delay or confusion.

In the United States, the Hatch-Waxman Act provides for a five-year period of exclusive marketing rights in clinical trial data, starting from the date the compound is approved by the FDA, if the product contains an active ingredient not previously approved.<sup>141</sup> An originator company may also be eligible for an additional three years of protection if it can demonstrate a new indication for the same drug, or if it develops a new dosage form.<sup>142</sup> These protections are independent of patent rights.<sup>143</sup> After this period expires, competitors can rely on the data of the original company, provided they can demonstrate that the products are bioequivalent; alternatively, the would-be competitor can perform its own testing to obtain the necessary data during the period of protection.<sup>144</sup> The statute promotes innovation by offering protection for pharmaceutical companies working on drugs unlike anything currently on the market, while also recognizing a need to avoid unnecessary costs that result from duplicative testing.<sup>145</sup> The Council of the European Community also adopted a similar regulation that prohibits reliance on the data of the originator company for six years, or ten years if the product is considered to be a "high-technology medicinal product."<sup>146</sup> Further, fifteen EU member states have statutes providing for protection of clinical data in the same way, varying slightly in the term the protection endures.<sup>147</sup>

One advantage of statutes and regulations is that they can be designed to address a specific problem, and can be put into force with relative ease. One example is the Orphan Drug Act in the United States, which was enacted in response to the fact that, given the high cost of drug development, many pharmaceutical companies choose not to focus on developing medicines that treat diseases that affect only a small portion of the population and therefore have small potential markets.<sup>148</sup> This holds true even if the drug is targeting a well-known disease, such as ALS or Huntington's disease.<sup>149</sup> Even if such drugs are

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141. 21 U.S.C. § 355 (2012); Reichman, *supra* note 5, at 7.

142. John A. Vernon et al., *Exploration of Potential Economics of Follow-On Biologics and Implications for Data Exclusivity Periods for Biologics*, 16 B.U. J. SCI. & TECH. L. 55, 62 (2010).

143. *Id.*; Reichman, *supra* note 5, at 6.

144. Skillington & Solovy, *supra* note 53.

145. *Id.* at 10.

146. *Id.* at 11.

147. *Id.* at 11, 49.

148. *Id.* at 9–10.

149. *Id.* at 9.

discovered, they are often not tested because the low potential sales cannot justify the costs of the preclinical and clinical trials.<sup>150</sup> The normal protections afforded by patents are sometimes insufficient to promote testing of these so-called “orphan drugs.”<sup>151</sup> The Orphan Drug Act accordingly provides seven years of exclusive marketing rights for the originator company during which it can theoretically recoup its investment.<sup>152</sup>

### C. *The Trans-Pacific Partnership*

The Trans-Pacific Partnership (TPP) was first proposed by then-President Barack Obama in 2009 with the goal of bringing countries bordering the Pacific Ocean closer together to address issues with global trade.<sup>153</sup> The members would be twelve countries with a collective population of 800 million that are responsible for approximately 40 percent of world trade.<sup>154</sup> Under the TPP, data used in bringing biologic drugs to market would have been afforded five years’ protection—although the US pharmaceutical industry actually lobbied for the data to be protected for twelve years.<sup>155</sup> For nonbiologic pharmaceuticals, the agreement would have offered five to eight years of protection for undisclosed test data.<sup>156</sup> The parties believed this length of time would incentivize innovation while still allowing patient access to cheaper versions of the drugs after a reasonable amount of time.<sup>157</sup> The data protected would have included all clinical trial data relevant to a new medicine’s safety and efficacy.<sup>158</sup> In order to enforce these protections, the TPP would have required all signatory countries

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150. *Id.*

151. *Id.*

152. *Id.*

153. Kevin Granville, *What Is TPP? Behind the Trade Deal That Died*, N.Y. TIMES (Jan. 23, 2017), [https://www.nytimes.com/interactive/2016/business/tpp-explained-what-is-trans-pacific-partnership.html?\\_r=0](https://www.nytimes.com/interactive/2016/business/tpp-explained-what-is-trans-pacific-partnership.html?_r=0) [<https://perma.cc/6BNA-DFTU>] (archived Aug. 24, 2018); Dan Stanton, *TPP: Five years data protection for biologics in US-Asia trade deal*, BIOPHARMA REPORTER (Oct. 6, 2015), <https://www.biopharma-reporter.com/Article/2015/10/05/TPP-Five-years-data-protection-for-biologics-in-US-Asia-trade-deal> [<https://perma.cc/6HSU-VQ5T>] (archived Aug. 24, 2018).

154. *TPP: What is it and why does it matter?*, BBC (Jan. 23, 2017), <http://www.bbc.com/news/business-32498715> [<https://perma.cc/UN7G-P9LB>] (archived Aug. 24, 2018) [hereinafter BBC *TPP*]. The member countries were to be the United States, Canada, Mexico, Peru, Chile, Japan, Vietnam, Brunei, Malaysia, Singapore, Australia, and New Zealand. *Id.*

155. Stanton, *supra* note 153.

156. Carlos A. Primo Braga, *TPP: The New Gold Standard for Intellectual Property Protection in Trade Agreements?*, HUFFINGTON POST (Mar. 25, 2017, 10:35 PM), [https://www.huffingtonpost.com/eastwest-center/tpp-the-new-gold-standard\\_b\\_9544428.html](https://www.huffingtonpost.com/eastwest-center/tpp-the-new-gold-standard_b_9544428.html) [<https://perma.cc/SE64-ULK5>] (archived Aug. 24, 2018).

157. Stanton, *supra* note 153.

158. Yanbai Andrea Wang, *Will the Trans-Pacific Partnership hinder access to medicine?*, STANFORD LAW SCH. BLOGS (Nov. 19, 2015), <https://law.stanford.edu/2015/11/19/will-the-trans-pacific-partnership-hinder-access-to-medicine-part-i/> [<https://perma.cc/6HLC-VNNN>] (archived Aug. 24, 2018).

to conform their own domestic laws and policies to the terms of the TPP.<sup>159</sup> This agreement represented the most comprehensive protection of clinical data in history.

After five years of negotiations, all twelve parties signed the agreement in February 2016.<sup>160</sup> However, as of today, only two countries—Japan and New Zealand—have actually ratified the TPP.<sup>161</sup> In order to go into effect, the TPP must be ratified by at least six of the parties that together account for 85 percent or more of the member countries' economic output.<sup>162</sup>

The agreement seemed to be on life support during the 2016 US presidential election, when both candidates ran on the platform that the TPP was not a good deal for the United States, and that it either needed to be renegotiated or abandoned altogether.<sup>163</sup> Then-candidate Donald Trump rallied his supporters around the idea that international trade agreements would only lead to increased job outsourcing while limiting competition.<sup>164</sup> As to the data-protection component of the agreement, Trump and other critics feared that comprehensive data protection would raise prices for pharmaceuticals in developed countries by spreading higher standards for patent protections to other, less developed nations.<sup>165</sup>

Holding true to his campaign promise, President Trump signed a statement formally abandoning the deal on his first day in office.<sup>166</sup> This effectively killed the TPP, as the requirement that the ratifying nations make up at least 85 percent of the group's economic output likely cannot be satisfied without the United States.<sup>167</sup>

#### D. NAFTA: Do We Hafta?<sup>168</sup> (and Other Free Trade Agreements)

Free trade agreements arise when two or more countries negotiate and agree upon terms to regulate trade among them, including tariffs and duties on imports and exports.<sup>169</sup> NAFTA—which actually began

159. *Trans-Pacific Partnership Agreement*, ELEC. FRONTIER FOUND., <https://www.eff.org/issues/tpp> (last visited Feb. 28, 2018) [<https://perma.cc/QS6R-TVGF>] (archived Aug. 24, 2018).

160. BBC *TPP*, *supra* note 154.

161. Vernon Small, *Government ratifies TPP as Bill English heads to Japan for trade talks*, STUFF (May 11, 2017), <https://www.stuff.co.nz/business/92466121/government-ratifies-tpp-as-bill-english-heads-to-japan-for-trade-talks> [<https://perma.cc/CQ8Z-NPD6>] (archived Oct. 11, 2018).

162. BBC *TPP*, *supra* note 154.

163. Granville, *supra* note 153.

164. *Id.*

165. *Id.*

166. *Id.*

167. BBC *TPP*, *supra* note 154.

168. Creative title attributed to Susan Dobrof & John Sutter, *NAFTA: Do We Hafta?*, 53 OR. ST. B. BULL. 23 (1993).

169. Kimberly Amadeo, *Free Trade Agreement, Their Impact, Types, and Examples*, THE BALANCE (updated Oct. 11, 2018), <https://www.thebalance.com/free-trade-agreement-types-and-examples-3305897> [<https://perma.cc/5JES-TWQS>] (archived Oct. 11, 2018); *What Is the North American Free Trade Agreement?*, THE BALANCE

as a bilateral free trade agreement between Canada and the United States, and was later expanded to include Mexico in 1994—is the largest free trade agreement in the world.<sup>170</sup> This agreement essentially eliminated tariffs on products that were imported and exported between the member states.<sup>171</sup>

Under NAFTA, when clinical data is submitted to a member state's government in order to obtain regulatory approval for a new chemical entity, that data must be protected against disclosure "except where the disclosure is necessary to protect the public or unless steps are taken to ensure the data is protected against unfair commercial use."<sup>172</sup> Additionally, a pharmaceutical company attempting to produce a generic version of a drug cannot rely on preexisting test data for at least five years from the time of first market approval.<sup>173</sup> These protections run independently of patent protections.<sup>174</sup>

While these regulations may seem fairly uniform and straightforward, that is not necessarily the case. For example, the agreement does not define what constitutes "unfair commercial use," giving member countries the opportunity to interpret the agreement differently, leading to uncertainty as to how to comply with the requirement.<sup>175</sup> Additionally, NAFTA does not require its member states to have the exact same protection for clinical data.<sup>176</sup> Article 1702 of the agreement states that any party "may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement."<sup>177</sup> This means that any of the three members may have statutes, regulations, or other international agreements that require more stringent clinical data protection; this also clouds the regulatory landscape between these countries.<sup>178</sup>

In October 2018, following President Trump's threats to end the United States' participation in NAFTA, the parties reached an agreement on a revised North American trade deal, the United States-

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(updated Oct. 2, 2018), <https://www.thebalance.com/nafta-definition-north-american-free-trade-agreement-3306147> [<https://perma.cc/537H-DHWA>] (archived Aug. 24, 2018) [hereinafter *What is NAFTA?*].

170. Sungjoon Cho, *Defragmenting World Trade*, 27 NW. J. INT'L L. & BUS. 39, 51 (2006); *What is NAFTA?*, *supra* note 169.

171. USTR *NAFTA*, *supra* note 119.

172. North American Free Trade Agreement, Can.-U.S.-Mex., art. 1711.5, Dec. 17, 1992 [hereinafter *NAFTA*]; Reichman, *supra* note 5, at 15 n.60.

173. Reichman, *supra* note 5, at 13.

174. *Id.*

175. See *NAFTA*, *supra* note 172, art. 1711 (setting forth requirements for data protection without defining the term "unfair commercial use").

176. Raymundo Valdes & Maegan McCann, *Intellectual Property Provision in Regional Trade Agreements: Revision and Update* 13 (World Trade Org. Econ. Research and Statistics Div., Working Paper No. ERSD-2014-14, 2014).

177. *NAFTA*, *supra* note 172, art. 1702.

178. See Reichman, *supra* note 5, at 12 (discussing various forms of clinical data protection enacted in different countries).

Mexico-Canada Agreement (USMCA).<sup>179</sup> While the bulk of the changes centered around trade, there were some amendments to the clinical data protection regime.<sup>180</sup> For example, the new deal increases the period of exclusivity for biologic drugs from eight years to ten years.<sup>181</sup> However, many of the clinical data protection provisions remain the same under the new agreement, including using data exclusivity as the mechanism of protection, and retaining the five-year period of protection for nonbiologic drugs.<sup>182</sup> USMCA likely won't go into effect until 2020 after signature and ratification by the parties' legislatures.<sup>183</sup>

In general, free trade agreements provide great advantages to the originating pharmaceutical company, often for long periods of time.<sup>184</sup> This tends to benefit developed countries with the ability to sink significant resources into pharmaceutical research.<sup>185</sup> Even when the provisions of the agreement are the same as NAFTA's, the protections can be much more one-sided when one party has a significantly higher ability to produce pharmaceuticals than the other. For example, the US-Morocco free trade agreement has an "ever-greening" clause, which continually extends the patent protections for existing drugs if the originator company can demonstrate a "new use" for the drug.<sup>186</sup> This provision benefits the United States, where most of the drug companies are located, and ensures that Morocco does not have access to generic versions of drugs for a potentially unlimited period of time.<sup>187</sup> Another example is an agreement between the United States and Singapore that has essentially identical protections to NAFTA, but

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179. Heather Long, *U.S., Canada and Mexico just reached a sweeping new NAFTA deal. Here's what's in it.*, THE WASH. POST (Oct. 1, 2018), [https://www.washingtonpost.com/business/2018/10/01/us-canada-mexico-just-reached-sweeping-new-nafta-deal-heres-whats-it/?noredirect=on&utm\\_term=.7143fdc88ef5](https://www.washingtonpost.com/business/2018/10/01/us-canada-mexico-just-reached-sweeping-new-nafta-deal-heres-whats-it/?noredirect=on&utm_term=.7143fdc88ef5) [<https://perma.cc/QV3H-NQZA>] (archived Oct. 11, 2018).

180. *Id.*

181. *The USMCA: What Does it Mean for Patents and the Pharmaceutical Industry?*, GOWLING WLG (Oct. 5, 2018), [https://gowlingwlg.com/en/insights-resources/articles/2018/usmca-what-it-means-for-patents-and-pharmaceutical/#\\_ftnref10](https://gowlingwlg.com/en/insights-resources/articles/2018/usmca-what-it-means-for-patents-and-pharmaceutical/#_ftnref10) [<https://perma.cc/3L8Y-4VRU>] (archived Oct. 11, 2018).

182. USMCA, *supra* note 119. Article 20.F.13 provides "[i]f a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or similar product on the basis of that information; or the marketing approval granted to the person that submitted such information, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party." *Id.*

183. Long, *supra* note 179. Because USMCA is not currently in effect, and because the agreements are very similar with respect to clinical data protection, this Note will continue to refer to NAFTA as the free trade agreement currently in force in North America.

184. See generally Reichman, *supra* note 5 (discussing how free trade agreements can protect clinical trial results).

185. See Cho, *supra* note 170, at 61 (discussing how many poor countries have failed to profit from the multilateral trading system).

186. *Id.* at 74.

187. *Id.*



disproportionately benefits the United States due to its more significant presence in drug development.<sup>188</sup> This problem is not unique to the United States—the European Union Free Trade Association has attempted to force ten-year clinical data protection requirements on south African countries, although this provision was ultimately rejected by the African countries due to fears that it would put their access to life-saving medications at risk.<sup>189</sup>

#### E. *The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*

In the late 1980s, intellectual property was becoming an increasingly important factor in international trade.<sup>190</sup> Large players in this arena began to realize the need for more centralized regulation in order to correct potential imbalances in trade due to unequal intellectual property systems.<sup>191</sup> They sought to incorporate the principles of their individual statutes into a comprehensive international agreement.<sup>192</sup> Thus began the multilateral trade negotiations known as the Uruguay Round that spanned from 1986 to 1994 and ultimately culminated in TRIPS, as well as the creation of the World Trade Organization (WTO).<sup>193</sup>

Negotiations commenced with delegates from about twenty countries, and later expanded to include thirty countries.<sup>194</sup> Approximately half of the countries represented were large, industrialized nations with a significant presence in international trade, while the rest were developing countries.<sup>195</sup> In general, the developing countries advocated for more limited data protection, emphasizing the need for flexibility in order to continue economic and social development at home.<sup>196</sup> However, the industrialized countries'

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188. *Id.* at 55; see Brian Cimolic, *The Impact of Regional Trade Areas on International Intellectual Property Rights*, 48 IDEA 53, 58 (2007).

189. Cimolic, *supra* note 188, at 60–61.

190. *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (last visited Aug. 24, 2018) [<https://perma.cc/L9FN-UVNJ>] (archived Aug. 24, 2018).

191. Daniel J. Gervais, *The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 929, 939 (2002).

192. See Skillington & Solovy, *supra* note 53, at 12; Zimmerman, *supra* note 132, at 783.

193. *The Uruguay Round*, WORLD TRADE ORG., [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact5\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm) (last visited Feb. 28, 2018) [<https://perma.cc/6YQW-8725>] (archived Aug. 24, 2018).

194. Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 FORDHAM L. REV. 505, 507 (2005) [hereinafter Gervais *State of Play*].

195. *Id.*

196. *Id.* at 508. Specifically, a number of representatives proposed an alternative version of TRIPS to the one that ended up being adopted that reflected the policy values of public health and development. Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, and Uruguay initially put forth this alternate

desire for stringent protection of intellectual property, including clinical data, won in the end—TRIPS is the most comprehensive multinational agreement regarding intellectual property and is responsible for introducing intellectual property regulation into international trade.<sup>197</sup> In the end, the parties to the agreement were all 128 members of the newly-minted WTO.<sup>198</sup> Today, there are 164 members of the WTO, representing over 96 percent of global trade and global gross domestic product.<sup>199</sup>

Article 39 of the agreement protects both undisclosed data and data that has been submitted to the government or a government agency; the text is worth reproducing here in full.<sup>200</sup>

In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information: is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; has commercial value because it is secret; and has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.<sup>201</sup>

The foundation for the agreement's clinical data protection is found in Article 10bis of the Paris Convention, which requires all member states to provide "effective" protection against unfair competition.<sup>202</sup> In order to ensure adequate protection from unfair competition, parties to TRIPS must protect undisclosed test data or other proprietary clinical data against unfair commercial use or

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proposal, with Pakistan and Zimbabwe later endorsing the more relaxed iteration as well. *Id.* at 508 n.18.

197. See *id.* at 507; *Intellectual Property: Protection and Enforcement*, *supra* note 190.

198. *Accession in perspective*, WORLD TRADE ORG., [https://www.wto.org/english/thewto\\_e/acc\\_e/cbt\\_course\\_e/c1s1p1\\_e.htm](https://www.wto.org/english/thewto_e/acc_e/cbt_course_e/c1s1p1_e.htm) (last visited Feb. 28, 2018) [<https://perma.cc/3VD2-6CUV>] (archived Aug. 24, 2018).

199. *Id.* A comprehensive list of current WTO members can be found at *Members and Observers*, *supra* note 110.

200. TRIPS Agreement, *supra* note 120, art. 39.

201. *Id.*

202. Skillington & Solovy, *supra* note 53, at 13.

disclosure, unless necessary to protect the public.<sup>203</sup> “Unfair commercial use” is typically understood as use by a competitor that gives that competitor a way to shortcut research and development, although the term is not defined in TRIPS.<sup>204</sup> In practice, the law of the country in which the data is to be used typically provides the definition of unfair use.<sup>205</sup>

TRIPS also clarifies what type of data are afforded protection under the agreement by setting out five criteria: (1) the data were submitted as a condition for obtaining marketing approval for a product; (2) the product was a pharmaceutical product; (3) the product was a new chemical entity; (4) the data were disclosed at the time of submission; and (5) generation of the data required considerable effort.<sup>206</sup> This approach to clinical test data protection has the advantage of allowing generic products to reach the market quickly without unnecessary regeneration of data.<sup>207</sup> Additionally, implementing this approach is theoretically easy because there is no regulatory burden imposed on the government entity.<sup>208</sup>

However, even this comprehensive agreement left a good amount of room for interpretation and international variation. TRIPS must be implemented via statute in each member country, meaning that each party to the agreement can take its own approach on how to best protect data from unfair use, and how to enforce its provisions.<sup>209</sup> Some members have chosen to protect data by enjoining direct reliance on the data for a certain period of time; others grant originator companies exclusive marketing rights.<sup>210</sup> It leaves open the possibility of member states creating exclusions or exceptions to the intellectual property protections.<sup>211</sup> Additionally, TRIPS does not include any specific requirement for duration of protection against unfair commercial use, leaving that determination up to the discretion of each member state.<sup>212</sup> Further, there are several terms in the agreement left undefined—there is no clarification of what constitutes a “pharmaceutical product” or a “new chemical entity,” or what level of effort is “considerable.”<sup>213</sup>

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203. Jeffrey K. Francer & Natalie A. Turner, *Responsible Clinical Trial Data Sharing: Medical Advancement, Patient Privacy, and Incentives to Invest in Research*, 8 J. HEALTH & LIFE SCI. L. 63, 96 (Oct. 2014).

204. *See id.* at 97.

205. Armouti, *supra* note 125, at 269.

206. TRIPS Agreement, *supra* note 120, art. 39.

207. *See* Armouti, *supra* note 125, at 270.

208. *See id.*

209. Skillington & Solovy, *supra* note 53, at 31.

210. *Id.*

211. *Intellectual Property: Protection and Enforcement*, *supra* note 190.

212. Skillington & Solovy, *supra* note 53, at 31.

213. *See generally id.* (noting that the agreement does not specify how protections should be provided).

#### IV. THE BENEFITS AND DRAWBACKS OF COMPREHENSIVE CLINICAL DATA PROTECTION

It is clear that discord in methods and comprehensiveness in clinical data protection causes regulatory delays, increases costs, and leads to unnecessary confusion and duplication of research.<sup>214</sup> The demand for broad, global reform to standardize how clinical data is regulated only continues to grow more insistent, especially considering the potentially life-saving effects of some medications. What is less clear is exactly what level of protection such broad reform should espouse. Answering this question requires balancing the desire to protect the pharmaceutical industry, reward development of drugs that treat rare diseases, and encourage research of novel compounds against the need to increase access to necessary drugs and keep costs affordable for consumers.

In the absence of any clinical data protection, it is likely that innovation in the pharmaceutical industry would be significantly dampened. Prohibiting competitors from relying on data generated by other companies spurs development and testing of new active ingredients because it allows the originator company time to recoup the costs of developing an innovative drug.<sup>215</sup> Therefore, there must be some economic incentives for companies to engage in this risky business.

Countries with strong protections for clinical data also contribute significantly to research and development in the pharmaceutical industry. For example, the United States—which has extensive patent protections and is a party to several bilateral and multinational agreements regarding clinical data protection—produced over half of the world's novel drugs in the early 2000s.<sup>216</sup> This may be due to a potential relationship between spending on research and development, financial returns, and the length of market exclusivity for a given product.<sup>217</sup>

However, there is fundamental disagreement as to how much protection, if any, is necessary to protect the pharmaceutical industry and ensure that new, innovative medications continue to be developed. It is unclear exactly how long it takes a drug company to recover the costs of drug development. One study suggests that due to high costs and the fact that only approximately 12 percent of drugs ever turn a profit, new biologics require seventeen years of protection, while small molecule drugs should receive between eleven and thirteen years.<sup>218</sup>

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214. See *supra* Parts II & III.

215. See generally Skillington & Solovy, *supra* note 53 (discussing the potential injustice an originator may face if a competitor relied on its data before it had the chance to recoup the resources it expended to develop the data).

216. PHARM. RESEARCH & MFRS. OF AM., SPECIAL 301 SUBMISSION 4 (2014), <http://phrma-docs.phrma.org/sites/default/files/pdf/2014-special-301-submission.pdf> [<https://perma.cc/GT6K-DS6M>] (archived Sept. 15, 2018).

217. Vernon, *supra* note 142, at 13.

218. See *id.* at 16.

Conversely, Doctor Aaron Kesselheim points out that much of the “important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health.”<sup>219</sup> He also argues that the pharmaceutical industry is not nearly as vulnerable as it makes itself out to be—in reality, biotechnology companies often have some of the highest revenues of any in the global economy,<sup>220</sup> and the largest pharmaceutical companies consistently see profit margins between 15 and 20 percent.<sup>221</sup> To support his argument, Kesselheim cites a Hepatitis C drug called Sovaldi, which recouped almost all its development costs during its first year on the market, raking in sales of over \$10 billion.<sup>222</sup>

Some experts argue that high drug prices are actually exacerbated by market exclusivity and other methods of clinical data protection.<sup>223</sup> Although consumer pharmaceutical spending has grown approximately 30 percent in recent years, the number of drug units sold has remained essentially the same—this means that pharmaceutical companies are continuing to raise prices to combat stagnant sales.<sup>224</sup> During exclusivity periods, there is unlikely to be competition from a generic version of the drug. There may be another brand-name manufacturer that developed a similar treatment using its own data; however, either because physicians often do not consider drug prices when deciding to prescribe a certain drug, or because of quasi-collusion among brand-name pharmaceutical developers, this competition often does not significantly lower costs to consumers.<sup>225</sup> A specific example of this is Amgen’s rheumatoid arthritis drug, Enbrel. The company received a significant patent extension, and a competitor drug made by Pfizer was approved. Although this theoretically should have decreased the cost of the drug for consumers, the average price of Enbrel actually increased almost 10 percent the following year.<sup>226</sup> This trend is amplified in countries like the United States that do not

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219. Kesselheim, *supra* note 57, at 863.

220. *See id.* (“The biotechnology and pharmaceutical sectors have for years been among the very best-performing sectors in the US economy.”).

221. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 18 (2017).

222. Kesselheim, *supra* note 57, at 864 (citing Andrew Pollack, *Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to \$10.3 Billion*, N.Y. TIMES (Feb. 3, 2015), <https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html> [<https://perma.cc/56YA-4KUR>] (archived Sept. 9, 2018)).

223. *See id.* at 858.

224. Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 5 (Hutchins Ctr. on Fiscal & Monetary Policy at Brookings, Working Paper No. 30, 2017).

225. *See Kesselheim, supra* note 57, at 861.

226. Stewart Lyman, *Would Longer Drug Patents Really Lead to Lower Drug Prices?*, XCONOMY (Sept. 5, 2012), [https://www.xconomy.com/seattle/2012/09/05/would-longer-drug-patents-really-lead-to-lower-drug-prices/?single\\_page=true](https://www.xconomy.com/seattle/2012/09/05/would-longer-drug-patents-really-lead-to-lower-drug-prices/?single_page=true) [<https://perma.cc/4DQL-777V>] (archived Aug. 25, 2018).

directly regulate the cost of pharmaceutical products, even as a condition for extended patent protection.<sup>227</sup> In fact, prices for the most common brand-name drugs in the United States increased 164 percent between 2008 and 2015.<sup>228</sup> Additionally, the ability of pharmaceutical companies to set prices often leads to low- and middle-income countries paying more for drugs than high-income countries with larger markets due to a lack of bargaining power.<sup>229</sup>

Comprehensive clinical data protection may also be an effective way to incentivize companies to develop drugs for rare diseases with smaller markets.<sup>230</sup> Incentives are necessary because studies have shown that larger market size and larger potential profit have a positive correlation with innovation; in the absence of these factors, innovation may be dampened.<sup>231</sup> This problem not only affects drugs targeting less common diseases, but also reflects the fact that pharmaceuticals are becoming increasingly specialized—for example, while in the past a company would develop a drug to treat cancer generally, advances in medical knowledge and technology have made it possible to focus on a specific treatment for one type of cancer.<sup>232</sup> The market for the product is therefore artificially narrowed, decreasing the potential sales and increasing the burden on the developer to recover the costs. Without sufficient data protection, pharmaceutical companies are often hesitant to take the risk of investing in developing such drugs without a guarantee of at least making their money back, if not turning a profit.<sup>233</sup> When they do focus on rare conditions, the prices of the products are often among the most expensive on the market, sometimes exceeding \$250,000 per patient per year.<sup>234</sup> Similarly, strong protection provides a reason for pharmaceutical companies based in the western world to develop products that benefit people mainly in developing countries, such as drugs targeting malaria and other tropical diseases.<sup>235</sup>

Another consideration is the effect of data protection on the generic-drug market. Too much data protection makes it very difficult for a generic version of a drug to make it to market.<sup>236</sup> Generic producers must prove not only safety and efficacy of their drug, but also need to demonstrate that it is essentially an identical copy of the

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227. Morton & Boller, *supra* note 224, at 1.

228. Kesselheim, *supra* note 57, at 860.

229. Ghebreyesus, *supra* note 58.

230. See Skillington & Solovy, *supra* note 53, at 10–11.

231. Richard Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, HEALTH AFFAIRS (Nov. 13, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171113.880918/full/> [<https://perma.cc/46GL-5JAX>] (archived Sept. 15, 2018).

232. Skillington & Solovy, *supra* note 53, at 14.

233. *See id.*

234. Kesselheim, *supra* note 57, at 860.

235. Skillington & Solovy, *supra* note 53, at 13.

236. See Joanne Nicholas, *Outsourcing Clinical Trials*, 104 J. NAT'L CANCER INST. 1043, 1045 (2012).

non-generic drug before it will be approved for sale.<sup>237</sup> This requires largely the same drug development process as is required of the originator pharmaceutical company.<sup>238</sup> When the originator company is allowed to protect the results of its trials as a trade secret or pursuant to a patent, it forces potential generic producers to duplicate the same efforts, expending precious money and resources to produce the same data.<sup>239</sup> Further, any errors committed by the originator company during the drug development process are likely to be reproduced, as opposed to avoided, including errors which led to highly detrimental side effects in trial subjects.<sup>240</sup>

In order to avoid these issues, would-be generic producers typically wait until clinical trial data is no longer protected, at which point they can rely on the originator data and prove equivalence without unnecessary duplication.<sup>241</sup> In terms of consumer access, the ability of generics to make it to market makes a world of difference—for example, AstraZeneca's cholesterol-controlling drug Crestor initially sold for approximately \$200 for a month's supply; when the FDA approved generic versions of the drug, the price dropped to \$20 for the same number of pills.<sup>242</sup>

There are also numerous ethical issues surrounding stringent clinical data protection. Some academics believe that closely holding clinical data puts too high a social cost on poor, developing countries by forcing them to pay exorbitantly high prices for non-generic versions of drugs.<sup>243</sup> According to the World Health Organization (WHO), approximately one-third of the world population does not have access to necessary medications.<sup>244</sup> Even when data protection instruments do allow for marketing of generic drugs, people in poorer countries still end up purchasing the name-brand medicine, often because their country does not have the capacity to develop the generic version.<sup>245</sup> If these populations do have access to generic drugs, it is because they have paid to import them from other countries, and consumers are often still not able to afford them, given that up to 90 percent of people in the developing world must purchase medicines entirely out of pocket.<sup>246</sup>

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237. *Id.*

238. *See id.*

239. *See id.*

240. *See id.*

241. *See* Diependaele, *supra* note 55.

242. Teresa Carr, *How the FDA Plans to Lower Your Drug Costs*, CONSUMER REPORTS (July 18, 2017), <https://www.consumerreports.org/drug-prices/how-new-fda-proposals-to-lower-drug-costs-will-affect-you/> [<https://perma.cc/XUY8-H9DS>] (archived Aug. 25, 2018).

243. *See, e.g.*, Cho, *supra* note 170; Choi, *supra* note 107; Reichman, *supra* note 5, at 4.

244. WORLD HEALTH ORG., *THE WORLD MEDICINES SITUATION* 61 (2004). What's more, developing countries often spend up to 60 percent of health care budgets on medicines. *Id.* at 45.

245. Cho, *supra* note 170, at 73.

246. *Id.*; Ghebreyesus, *supra* note 58.

Concerns about access to medication are exemplified by the HIV/AIDS crisis that especially affected poor, developing countries.<sup>247</sup> Even after medications to treat the disease were approved in high-income countries, they were still unavailable in the countries that needed them most. In response to this problem, the WTO amended TRIPS to add Article 31bis, which allowed signatories to issue “compulsory licenses” requiring pharmaceutical companies to manufacture and send drugs to developing countries that could not produce the drugs themselves in emergent situations.<sup>248</sup> Although the amendment was enacted to address the AIDS crisis, the issuance of compulsory licenses is not limited to any specific disease.<sup>249</sup> That the WTO went as far as to amend TRIPS to increase flexibility demonstrates a recent international trend towards decreasing the level of protection as a general matter.

The drawbacks of clinical data protection coupled with the concerns of developing countries have led to increased demand for public transparency of clinical trial data.<sup>250</sup> Some of the loudest voices calling for relaxed protection for clinical data are developed countries, which are disproportionately disadvantaged by tight regulation of proprietary data. Although TRIPS and its stringent protections seem to represent an international consensus about the proper level of data protection, the history of the agreement casts doubt on this assertion. Because TRIPS was negotiated as part of a larger agreement that established the WTO, some members adopted it as part of a package where they got concessions in other areas; this means the signatories did not all necessarily agree on TRIPS’ data protection provisions.<sup>251</sup>

Certain developing countries have advocated for a more flexible reading of TRIPS that takes into account public health concerns and developmental objectives. Their position was eventually backed by large, powerful organizations such as the UN Development Programme, the World Bank, and the UK Secretary of State for International Development.<sup>252</sup> In the early 2000s, WHO started to encourage such a flexible reading through the Doha Declaration, which emphasizes the gravity of supporting developing countries’ public health needs, promoting access to necessary medications, and incentivizing development of new compounds.<sup>253</sup> The Doha Declaration also reminded countries of their broad discretion to issue compulsory

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247. Daniel Gervais, *TRIPS and Development*, in THE SAGE HANDBOOK OF INTELLECTUAL PROPERTY 95, 100 (2014) [hereinafter SAGE HANDBOOK].

248. TRIPS Agreement, *supra* note 120, art. 31bis; SAGE HANDBOOK, *supra* note 247, at 100.

249. See SAGE HANDBOOK, *supra* note 247, at 100.

250. See Choi, *supra* note 107, at 251.

251. See Gervais *State of Play*, *supra* note 194, at 507–09.

252. Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 319 (2008).

253. SAGE HANDBOOK, *supra* note 247; Zimmerman, *supra* note 132, at 804; World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).



licenses.<sup>254</sup> Today, WHO is vocal about the need to avoid “bad” trade agreements that prevent access to innovative technologies and affordable medication for vulnerable populations—that “patients must always come before patents.”<sup>255</sup>

The most dramatic of these demands for transparency in recent years is the Declaration of Helsinki, originally adopted in 1964 and amended in 2000, calling for complete disclosure of all clinical trial data in response to perceived human rights violations perpetrated by clinical trial sponsors.<sup>256</sup> Some scholars have even asserted that clinical data should be considered a public good available to all because the funds for clinical trials are supplied by pharmaceutical companies who receive large public subsidies.<sup>257</sup> Pharmaceutical companies, it is argued, must be held accountable for the quality of their research, and requiring disclosure of clinical trial data would increase such accountability to consumers.<sup>258</sup> Complete disclosure would “promote research integrity, medical knowledge, and public health.”<sup>259</sup> Additionally, if clinical data were considered a public good, it would be freely available, not only to the FDA, but also to physicians, medical schools, insurers, scholars, patients, and other research institutions, all of whom could put the data to productive use.<sup>260</sup>

## V. SOLUTION

While the current instruments to protect clinical data all have certain benefits, it is also clear that none are perfect solutions to the problem. Currently, there is not one comprehensive data protection instrument that successfully balances the need to incentivize pharmaceutical companies to innovate with the ethical duties to provide affordable medical treatment to all people for all diseases, if

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254. Baker, *supra* note 252, at 320.

255. Ghebreyesus, *supra* note 58.

256. World Med. Ass'n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, ¶ 36, (June 1964), <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [ <https://perma.cc/Y4W4-WT48>] (archived Oct. 11, 2018) (“Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports.”); see Choi, *supra* note 107, at 521–22; Anushya Vijayanathan, *The Importance of Good Clinical Practice Guidelines and Its Role in Clinical Trials*, 4 BIOMEDICAL IMAGING INTERVENTION J. 1, 1 (2008). Note that when these articles advocate for complete transparency of clinical trial data, they are truly asking for disclosure of Clinical Study Reports, which summarize clinical trials, describe the methods, and analyze some of the data. This is not the same as advocating for complete abandonment of protection through patents, trade secrets, or market exclusivity, but rather is an alternative view on how results of clinical trials should be treated. Marc A. Rodwin & John D. Abramson, *Clinical Trial Data as a Public Good*, 308 JAMA 871, 872 (2012).

257. Rodwin & Abramson, *supra* note 256, at 872.

258. See Choi, *supra* note 107, at 523.

259. Rodwin & Abramson, *supra* note 256, at 871.

260. *Id.*

possible. Additionally, while there has been an overall move toward global harmonization of data protection, there are still countless instruments governing clinical data transparency internationally. Even under a single instrument, member states are often allowed significant leeway in interpreting data protection requirements, undermining the goal of harmonization. As detailed in Part II, the need for such harmonization only continues to grow more pressing.

To ensure that all countries involved in pharmaceutical development reap the benefits of clinical data protection, some type of standardized global regime is necessary. What is less clear is whether that regime should be one of extreme protection, extreme transparency, or somewhere in the middle. In the end, the calculus boils down to weighing the ethical and economic ramifications of comprehensive clinical data protection against the ethical and economic ramifications of allowing greater transparency and access to clinical data. This is a complicated calculation because it essentially involves balancing trade law, which is largely pragmatic and profit focused, with human rights law, which is often more theoretical.<sup>261</sup>

However, given that major pharmaceutical companies are actually seeing profits significantly larger than those of most other industries and the lack of clarity about the actual length of time it takes to recoup drug development costs, the concerns of the drug development industry appear to be outweighed by ethical concerns about access to affordable medications and the need to foster development in poorer countries. Knowledge is a “nonrival” industry—there is no way to exhaust it, even if multiple people use it.<sup>262</sup> Because of this, the goal of clinical data protection should be to maximize access to knowledge in order to benefit global public health at the lowest cost possible.<sup>263</sup> The pharmaceutical industry is powerful and has convinced the world it needs more protection than it actually does. As such, the true solution to the problem is to find a way to scale back the level of clinical data protection as a general matter, while attempting to harmonize protection on a global scale.

#### *A. Data Exclusivity as the Gold Standard for Clinical Data Protection*

The first issue is which intellectual property tool is the most appropriate to protect clinical data, regardless of the level of protection. There are several drawbacks to patents in the context of incentivizing drug development that make them ill-suited to protect clinical data. First, patents only protect the particular product, not necessarily the data used to generate that product, meaning they are not a good fit for

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261. Daniel J. Gervais, *Intellectual Property and Human Rights: Learning to Live Together*, in *INTELLECTUAL PROPERTY AND HUMAN RIGHTS* 1, 7 (2008).

262. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 *YALE J. HEALTH POL'Y L. & ETHICS* 193, 199 (2005).

263. *Id.* at 217.

ensuring generic manufacturers do not free ride on the originator company's data.<sup>264</sup> The patent system is also relatively inefficient, both in terms of time and cost. An originator company must take affirmative steps to receive patent protections—namely, it must expend the effort to file a patent application, and the regulatory agency must consider the application and ultimately grant or deny the patent.<sup>265</sup> Additionally, enforcement of patent rights often requires seeking relief from a court after the patent holder's rights have been violated, which can be costly.<sup>266</sup>

Instead, the most fitting form of protection is data exclusivity, which was designed to promote new drug innovation while still allowing public access to generic drugs.<sup>267</sup> Data exclusivity therefore offers a good deal of flexibility, which is important if we believe that perhaps blanket, uniform clinical data protection does not properly address the complexities of the pharmaceutical industry. Implementing a system based in data exclusivity would be made easier by the fact that most industrialized countries already frequently use data exclusivity to a certain extent: Japan, Australia, the EU, and the United States all have some data exclusivity laws in place currently.<sup>268</sup>

Further, the system of enforcement is generally efficient. Because data exclusivity results from inaction of a government agency—that is, the regulatory agency is prohibited from granting approval for generic versions of drugs for a specified amount of time—it is relatively easy to administer.<sup>269</sup> The beneficiary of the exclusivity does not have to take any affirmative action to receive the protections.<sup>270</sup> What's more, unlike patents, which are litigated constantly, government inaction such as is found in data exclusivity is much more difficult to challenge.<sup>271</sup> This means the costs of administering such a system are significantly lower than a patent-based system.<sup>272</sup>

In order to properly accommodate the competing interests, the ideal system of protection would be based solely on data exclusivity, and would override individual countries' patent and trade-secret laws in this particular arena. Because these intellectual property tools are currently allowed to coexist when it comes to data protection, the ultimate goal of having less protection as a general matter is undermined if a product is also protected by another mechanism.

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264. See *supra* Part III.A.

265. See Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419, 451 (2012).

266. *Id.* at 431.

267. FDA FAQ, *supra* note 136.

268. Robert Weissman, *Public Health-Friendly Options for Protecting Pharmaceutical Registration Data*, 1 INT'L J. INTELL. PROP. MGMT. 1, 2 (2006).

269. See Heled, *supra* note 265, at 432.

270. See *id.* at 455.

271. See *id.*

272. *Id.*

However, accomplishing this feat on a global scale is likely not possible, and it is beyond the scope of this Note to explore in further detail.

### B. A Hybrid Approach: Pro Rata Data Exclusivity and Cost Sharing

The next problem to solve is what level of protection should be adopted on an international scale. Addressing this issue is not simple, but it is clear that the answer does not lie in merely offering protection for a set period of time, as is common today—as one scholar noted, a “one size fits all” approach is rarely workable in all situations.<sup>273</sup> Rather, the calculus needs to account for the effort and money actually expended by a pharmaceutical company to produce the data. Only then does clinical data protection come close to allowing companies to recover necessary costs without unduly deterring competition and burdening less developed countries disproportionately.

As such, this Note proposes a two-part, hybrid scheme to protect clinical data. First, the originator company receives one year of traditional data exclusivity after obtaining marketing approval, during which no generic manufacturer may rely on the originator’s data. After the year is up, a cost-sharing system takes over, allowing generic competitors to rely on the originator’s data for a price proportionate to the actual cost of generating the data.<sup>274</sup> The cost-sharing system endures for an additional four years, at which point the data become publicly available to anyone.

The first stage functions much as data exclusivity currently functions under TRIPS and other similar agreements. The beneficiary of the exclusivity does not need to take any affirmative action in order to receive protection. Rather, exclusivity attaches automatically, with each country’s regulatory agency prohibited from giving approval to a competitor drug that relies on the originator data for a period of one year. The benefits of this are twofold—first, it is a system with which developed countries are already familiar, and to which they are partial. Second, providing a standard, nonnegotiable period of protection would assure pharmaceutical companies that they would have at least a year to recoup costs without significant competition on the market. Given that most pharmaceutical companies are located in powerful, industrialized nations, it is important to have them on board to implement any new global scheme.

The second phase, cost sharing, requires a generic company to fairly compensate the originator company for the right to rely on its data. In order to accomplish “fair” compensation, the originator company must document its actual costs incurred to generate the data, and disclose those costs to the national regulatory agency. To best

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273. See Weissman, *supra* note 268, at 3.

274. While not currently used by any countries in the drug development arena, the cost-sharing approach has been advocated for by several scholars as a better way to advance public health goals while still promoting innovation. See, e.g., Armouti, *supra* note 125, at 271–75; Weissman, *supra* note 268, at 8–12.

facilitate the process, originator companies must provide these disclosures with their materials for initial market approval. In that way, any disputes over expenditures may be able to be resolved before the cost-sharing period begins, allowing efficient entry of generic products into the market.

Once the cost is disclosed and the cost-sharing period commences, any generic company wishing to rely on the originator data must pay a portion of that cost. The cost to share in the data depends on the size of the market the generic company plans to enter, and the number of generic competitors relying on the data.

To illustrate, assume a company obtains approval to market a drug.<sup>275</sup> It discloses that it spent \$100 million to generate the data needed to bring the drug to market. If a generic competitor wanted to rely on that data to market a drug in Saudi Arabia, which represents 1 percent of the global pharmaceutical market,<sup>276</sup> it must pay 1 percent of the originator company's costs spread out over the four-year cost-sharing period—\$1 million in total, or \$250,000 per year. Now assume the same generic company wanted to market the drug in China, a country that comprises 10 percent of the global market. The generic manufacturer would be responsible for paying 10 percent of the originator's costs, amounting to \$10 million in total, or \$2.5 million each year.

These costs would be defrayed both by additional generic competitors entering the market around the same time as the originator company, and by generic companies entering the market later in the four-year cost-sharing period. If a second generic manufacturer also enters the Saudi Arabian market relying on the originator company's data, the annual costs for both generic companies are cut in half, because there is another actor to share the costs. Additionally, generic companies are only responsible for the annual payments: if a generic manufacturer entered the Saudi Arabian market two years into the cost-sharing period, it would only have to pay \$500,000—for the remaining two years of the cost-sharing period at \$250,000 annually—rather than the \$1 million total fee.

In order to ensure that originator companies are not needlessly overcompensated, there are additional caps on how much the originator may recoup. This Note proposes that once the originator company has recovered fifteen times what it cost to develop the drug, the cost-sharing period ends, even if that occurs before the typical four-year term. A fifteen-fold return on investment is more than even the most successful pharmaceutical companies can boast currently—for example, in 2013, Pfizer, a large, US-based drug company, spent

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275. Credit for the following illustration goes to Robert Weissman. Weissman, *supra* note 268, at 8.

276. *Share of pharmaceutical revenue worldwide in 2017, by country*, STATISTA, <https://www.statista.com/statistics/784420/share-of-worldwide-pharma-revenue-by-country/> (last visited Aug. 25, 2018) [<https://perma.cc/8JBJ-2SQC>] (archived Aug. 25, 2018).

\$6.6 billion on research and development, while its total revenue was \$51.6 billion, less than an eight-fold return.<sup>277</sup> Such a cap would allow pharmaceutical companies to adequately compensate for research costs for products that did not make it to market.

This hybrid system may seem novel, but it is not wholly unheard of. The United States uses a combination of data exclusivity and cost sharing for approval of agricultural chemicals in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>278</sup> Under FIFRA, covered chemicals receive ten years of exclusivity, during which the underlying data may not be relied on by other parties who want to register the same chemical with the Environmental Protection Agency.<sup>279</sup> For the next ten years, generic competitors may rely on the originator's data for a fee.<sup>280</sup> This system has successfully been in place since 1975, and has generally run smoothly.<sup>281</sup>

This proposed hybrid scheme has several benefits and resolves many outstanding issues with clinical data protection. Currently, clinical data is often protected longer than is truly necessary to recover costs and incentivize innovation. Regardless of exactly how long it takes for a pharmaceutical company to begin to profit on a particular product, it is obvious that indiscriminately offering the same amount of protection to all clinical data necessarily means sometimes offering too much protection. By offering a set period of pure data exclusivity followed by a tailored cost-sharing system, originator companies are only compensated as much as they need to be.

Further, the burden of fairly compensating the originator is shared between multiple generic companies, eliminating monopolies and passing fewer costs to the consumer. The cost to generic manufacturers to rely on the originators' data is relatively modest when compared to the cost of developing a drug from start to finish, which can be as high as \$53 million.<sup>282</sup> Allowing generic companies affordable access to originator data after one year means generic drugs will make it to market much sooner and much more affordably than under the current system, increasing access to affordable and necessary medications in developing countries. And importantly, this scheme accomplishes all this with an easy-to-administer system through which the beneficiary need take no action other than properly disclosing its costs when applying for market approval.

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277. Richard Anderson, *Pharmaceutical industry gets high on fat profits*, BBC (Nov. 6, 2014), <https://www.bbc.com/news/business-28212223> [<https://perma.cc/25F9-8NQ7>] (archived Aug. 25, 2018).

278. Weissman, *supra* note 268, at 9.

279. *Id.*; *Pesticide Registration Manual: Chapter 10—Data Compensation Requirements*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements#FIFRA> (last visited Sept. 15, 2018) [<https://perma.cc/EJR7-ZSBP>] (archived Aug. 26, 2018).

280. Weissman, *supra* note 268, at 9.

281. *Id.*

282. Sertkaya, *supra* note 42.

Some may argue that this system would lead to bad incentives for pharmaceutical companies. Just like lawyers may be tempted to run up legal costs if they get paid by the hour, drug developers may see a benefit to delaying drug development or spending more money than necessary in order to receive higher compensation from generic competitors for their clinical data. However, under the cost-sharing scheme, there is no real incentive to artificially inflate costs, because the originator company can only recoup up to fifteen times what it spent. The one-year data exclusivity period might allow the originator to recover some of the artificially high costs, but not enough to encourage companies to intentionally spend more money. There is also the additional pressure of the economic market—if a company spends an exorbitant amount during drug development, it will need to charge more for its product to ensure it will recover its costs. The originator company cannot rely entirely on the cost-sharing mechanism, because there is no guarantee that any generic company will want to rely on its data. Should a competitor enter the market without having to rely on the originator's data, and the competitor is able to price its product more affordably, the free market will punish the higher-priced medicine.

Additionally, clinical data protection essentially only applies to products that are successful. There is significantly reduced need to shield data that stemmed from a product that was ultimately never approved. Because so few compounds actually make it to market, pharmaceutical companies would be playing a very dangerous game if they chose to artificially inflate costs of developing all their drugs in the hopes of longer protection for the data generated in creating the rare successful drug.

### *C. How Do We Get There?*

While it is beyond the scope of this Note to delve too deeply into the exact mechanism by which this system would be accomplished on a global level, it is worth at least noting the most likely options for implementation.

Currently, treaties are the most common method of accomplishing harmonization on a global scale. Large, international agreements allow all potential members to have a voice about the terms of the agreement. They also require parties to affirmatively express “consent to be bound,” or willingness to undertake and comply with all obligations set out by the treaty.<sup>283</sup> This not only creates a sense of ownership in the terms of the treaty, but it also leaves no room for ambiguity as to whether a country agrees to its contents.

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283. U.N., FACT SHEET #5: UNDERSTANDING INTERNATIONAL LAW (2008), [https://treaties.un.org/doc/source/events/2008/Press\\_kit/fact\\_sheet\\_5\\_english.pdf](https://treaties.un.org/doc/source/events/2008/Press_kit/fact_sheet_5_english.pdf) [<https://perma.cc/V2ST-R84B>] (archived Sept. 15, 2018).

However, treaties also have several drawbacks that make them unsuitable to the global clinical data protection context. First and most importantly, data exclusivity turns on a decision by the regulatory authority in the country in which the drug will be marketed, rather than on the laws of the country where the clinical trial was conducted. This decreases the force and effectiveness of an international treaty, because each country's regulatory authority must ultimately decide whether to implement the hybrid system. Second, the fact that all members of a treaty get to participate in negotiations often leads to watered-down terms in order to appease the largest number of actors.<sup>284</sup> Further, for a treaty to be effective, member nations must actually ratify and enforce it.<sup>285</sup>

Despite these downsides, it may be that the best way to accomplish implementation of the proposed solution is through amending the TRIPS agreement. Although the actual agreement in its current form does not reach the right balance of incentivizing innovation and allowing access to affordable medication, it is still a good place to start because it is linked to the WTO. There are already 164 members of the WTO, representing over 96 percent of global trade and global gross domestic product.<sup>286</sup> Should all 164 WTO members adopt the TRIPS amendment, achieving global harmonization through universal adoption of the hybrid system would be much closer to accomplished.

For many developing countries that are not already party to TRIPS, the relaxed data protection alone may be sufficient to spur becoming a member. In light of the recent call by developing countries for a more flexible reading of TRIPS, a standardized system of protection that is overall more permissive would likely seem preferable to the more stringent protections already in place. Further, the cost-sharing element of the hybrid system would probably not be a deterrent to developing countries because they are generally not home to either originator or generic pharmaceutical companies. While this proposal may raise the price of generic drugs, it would increase general availability of medicines and would expand innovation into less common or profitable diseases, allowing more access to necessary medications in developing nations.

The hybrid approach may even appease developed countries. Although the level of data protection would decrease as a general matter, offering a set period of data exclusivity would still assure originator pharmaceutical companies, which are largely based in industrialized nations, that they would at least have some time to recoup costs. The cost-sharing aspect would ensure that even if generic drugs were able to make it to market sooner, the originator company

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284. John O. McGinnis, *The Comparative Disadvantage of Customary International Law*, 30 HARV. J.L. & PUB. POL'Y 7, 9 (2007).

285. *Id.*

286. *Accession in perspective*, *supra* note 198; see also *Members and Observers*, *supra* note 110.



would still be fairly compensated. Additionally, developed nations may be enticed by the potential cost savings that would accompany a completely standardized regime.

For those countries that are not persuaded merely by the terms of the agreement, there are several possible mechanisms for incentivizing membership without unduly coercing potential signatories. For example, the agreement could contain a stipulation that all member countries will not conduct any clinical research within a country if the potential host country is not party to the agreement. This would likely convince nations where the cost of conducting clinical trials is still low, because they are currently benefitting from the influx of money and technology that accompanies such research. The agreement could also require all member states to impose severe market repercussions, such as high taxes, on all drugs manufactured by a pharmaceutical company based in a nonmember country. Such a provision would be highly influential to developed countries with a large presence in the pharmaceutical industry who may be more reluctant to accept decreased protection for clinical data.

## VI. CONCLUSION

Appropriately protecting clinical data is a complex problem that requires marrying very different areas of the law. Trade law, intellectual property law, international law, and human rights law have distinct goals that may seem hard, if not impossible, to reconcile. The current clinical data protection regime does not adequately address this issue—not only is there currently significant variation in the mechanisms and amount of clinical data protection internationally, undermining the goals of providing protection in the first place, there is also little consideration of normative and ethical concerns stemming from overprotection. In order to join all these disparate interests into one cohesive system, the “one size fits all” method of offering the same amount of clinical data protection regardless of the time or effort spent to produce the data must be abandoned. A hybrid system that combines a standard period of data exclusivity with a cost-sharing approach attempts to address the flaws in the current scheme by properly balancing the need to incentivize innovation with the need for access to medication. It capitalizes on the fact that knowledge is nonrival—that an unlimited number of people can benefit from it at the same time without it being depleted—while still adequately compensating those companies that expend resources to generate such knowledge.

Although such disparate philosophies may seem at odds, the hybrid system creates a global regime that truly is the best of both worlds.

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