Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Clinical Drug Data Consistent with International Norms

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Introduction

Should doctors, patients, and policymakers have complete information about new drugs? Complete transparency may seem like the obvious answer. But the reality is that available information is often *incomplete*. In particular, although companies must submit extensive tests from clinical trials on new drugs to a regulatory agency such as the Food and Drug Administration (FDA) to obtain marketing approval, that information is generally considered confidential to the company and protected by intellec-

tual property rights that the government often helps protect.[1] In an information vacuum, companies can selectively provide information in advertising and even scientific papers for years while patient health and safety is unnecessarily compromised.[2] Recently, some flawed scientific papers published in premier medical journals concerning COVID-19 cures were retracted after independent scientists noticed anomalies which revealed that the authors had no access to the underlying proprietary data, such that the conclusions could not be replicated.[3] The fact that these authors did not have access to key data may seem unusual; however, it mirrors the reality for most approved drugs where the FDA, but not the general public or even sometimes authors of scientific papers, possess the complete data. Although the COVID spotlight helped illuminate problems with the published articles, that is not the norm.

Although policymakers and some domestic regulatory authorities recognize the need for greater public access to underlying clinical data, such disclosure may be complicated by international agreements regarding intellectual property.[4] Notably, although the European Union (EU) and Canada have recently required more public transparency of clinical data supporting reviewed drug applications,[5] their ability to increase trans-

1. *See, e.g.*, Public Information, 39 Fed. Reg. 44602, 44612, 44633 (Dec. 24, 1974) (to be codified at 21 C.F.R. pts. 1, 2, 4, 8, 10, 90, 121, 135, 146, 312, 314, 431, 601, 720, 730) (noting FDA position that safety and effectiveness data for new drugs "fall within the trade secrets exemption and thus are not available for public disclosure . . . even if disclosure . . . would be in the public interest, in order to protect the public health, and even if the Commissioner wishes as a matter of discretion to release such material" because disclosure "cannot lawfully be taken."); *see also* 21 U.S.C. § 331(j) (2018) (barring revealing information from a new drug application); 21 C.F.R. § 20.61(c) (2019) (trade secret and commercial info submitted to FDA stated as "not available for public disclosure"); 21 C.F.R. § 20.82(b)(1) (2019) (noting no discretion to disclose info submitted to FDA). Other countries have similar approaches. *E.g.*, Case T-73/13R, Order of the President of the General Court of 25 April 2013 – InterMune [U.K.] and Others v. EMA, ECLI:EU:T:2013:222, Preamble (noting traditional approach of EU).

2. *See infra* Part II.B.1.

3. *E.g.*, Heidi Ledford & Richard Van Noorden, *High Profile Coronavirus Retractions Raise Concerns about Data Oversight,* 582 NATURE 160, 160 (2020); Sharon Begley, *After Retractions of Two Covid-19 Papers, Scientists Ask What Went Wrong,* STAT (June 8, 2020), https://www.statnews.com/2020/06/08/covid19-paper-retractions-nejm-lancet-peer-review/ [https://perma.cc/XLH6-YVCQ].

4. *E.g.*, NATIONAL ACADEMIES OF MEDICINE (NAM), SHARING CLINICAL TRIAL DATA: MAXIMIZING BENEFITS, MINIMIZING THE RISKS 68–69 (2015) [hereinafter NAM REPORT]; REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 37 (2016) [hereinafter U.N. HIGH LEVEL PANEL]; Joshua M. Sharfstein et al., *Blueprint for Transparency at the US Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products*, 45 S2 J. L. MED. & ETHICS 7, 18 (2017); TRANSPARENCY INT'L, CLINICAL TRIAL TRANSPARENCY: A GUIDE FOR POLICY MAKERS 3–5, 16–17 (2017).

5. *E.g.*, Commission Regulation 536/2014, arts. 1, 81, 2014 O.J. (L 158) 1, 11, 48 (EU) (requiring all clinical trials conducted in the European Union to be made available to the public through a publicly available database, although with the possibility for some commercially confidential information to be withheld); European Medicines Agency [EMA], *European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*, Policy/0070, EMA/144064/2019 (Mar. 21, 2019),

parency efforts, or even to maintain current ones, could be considered in violation of the Trade Related Agreement on Intellectual Property (TRIPS) that applies to all members of the World Trade Organization (WTO).[6] Any WTO member, such as the United States (U.S.), could raise a TRIPS violation and seek a WTO panel to adjudicate the issue—and potentially require a change in domestic law.[7] Although no country has signaled intent to do so yet, U.S. pharmaceutical companies have repeatedly noted an alleged TRIPS violation.[8] Moreover, even if there is not a formal WTO challenge, the United States could pressure other countries to modify their laws by listing them in its annual Special 301 report.[9]

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superseding Policy/0070, EMA/240810/2013 (Oct. 2, 2014) [hereinafter EMA Policy 70]; EMA, *European Medicines Agency Policy on Access to Documents (Related to Medicinal Products and Veterinary Use)*, Policy/0043, EMA/110196/2006 (Dec. 1, 2010) [hereinafter EMA Policy 43]; *Public Release of Clinical Data: Guidance Document*, HEALTH CAN., (Mar. 12, 2019) [hereinafter Canada 2019 Guidance]. However, the EMA policy stopped publishing new data after 2018 due to logistical issues related to the EMA move from London to Amsterdam because of Brexit. *E.g.*, *Clinical Data Publication*, EUR. MEDICINES AGENCY [EMA], https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication [https://perma.cc/87AY-KA9W] (last visited Feb. 22, 2022).

6. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

7. A WTO panel may rule that a domestic law is inconsistent with a member's obligations and recommend that the offending measure is removed. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU]; WTO, Legal Effect of Panel and Appellate Body Reports and DSB Recommendations and Rulings, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c7s1p1_e.htm [https://perma.cc/SR42-NTTK] (last visited Feb. 22, 2022); *see also* Ed Lee, *Measuring TRIPS Compliance and Defiance: The WTO Compliance Scorecard*, 18 J. IP L. 401, 408 (2011) (noting that Dispute Settlement Understanding (DSU) does not require compensation or penalties for past violations, and instead seeks to change the offending law). The WTO does not have authority to require countries to actually change its laws, though failure to comply can lead to retaliatory trade sanctions (suspending usual WTO requirements) by another country as a mechanism to encourage a change. DSU, *supra* note 7, arts. 3.7, 22.1; *see also* WTO, Evaluation of the WTO Dispute Settlement System: Results to Date, 12.3 Strengths and Weaknesses (noting that in the majority of cases the suspension of obligations results in implementation), https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c12s3p1_e.htm [https://perma.cc/65MX-UL2M] (last visited Feb. 22, 2022); Lee, *supra* note 7, at 411–12 (noting that of the seven disputes in the first fifteen years of disputes involving TRIPS, all countries brought their laws into compliance except for two involving the United States).

8. *E.g.*, PHARMA. RSCH. & MFRS. AM. [PhRMA], SPECIAL 301 SUBMISSION 49–51 (2019) (alleging that amendments to Canadian laws violate TRIPS article 39(3) by permitting disclosure of clinical trial data). *See also* BIO, Response to Australia Pharmaceutical Reports Draft Report 7–8 (2013) (noting concern that a recommendation to make data exclusivity available in exchange for publication of clinical trial data would violate TRIPS article 39(3)); Letter from Tim Bennett, Director-General, Amb. Stuart E. Eizenstat, U.S. Board Chair, Amb. Hugo Paemen, EU Board Chair, PhRMA, to Douglas Bell, Chair, Trade Policy Staff Committee 12 (2013) (suggesting that EMA practice is inconsistent with TRIPS).

9. The Special 301 report lists countries with perceived inadequate or ineffective levels of intellectual property protection. 19 U.S.C. § 2242(a). Although companies often refer to violations of international agreements, this is not strictly required by the

This Article aims to promote policy recommendations to disclose clinical data by providing the first comprehensive analysis of how domestic laws permitting public disclosure of clinical data are consistent with TRIPS article 39(3).[10] This notably complicated and long-contested provision focuses on requiring nations that review clinical data before approving drugs for sale to protect the data from "unfair commercial use."[11] Some, but not all, believe that this requires countries to provide "data exclusivity,"[12] which the pharmaceutical industry considers a valuable type of intellectual property.[13] Data exclusivity[14] often complements trade secret

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statute. *See* 19 U.S.C. § 2242(d)(4) (noting that a country may be determined to deny adequate protection of IP "notwithstanding the fact that the country may be in compliance" with international agreements). Although this process has been criticized as arguably inconsistent with the WTO, it currently remains a practical reality for countries subject to the list. *E.g.*, Suzanne Zhou, *Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options Under the WTO Agreements*, 19 J. INT'L ECON. L. 51 (2016); Sean Flynn, *How listing Ukraine as a Priority Foreign Country In Special 301 Violates the World Trade Organization Agreements*, INFOJUSTICE (May 13, 2013), http://infojustice.org/archives/29556 [https://perma.cc/JH9L-8CJZ].

10. TRIPS, *supra* note 6, art. 39(3). The full text of Article 39(3) is as follows:

> 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.

11. *Id.*; *see also* Rosario Cartagena & Amir Attaran, *A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened?*, 17 HEALTH L. J. 269, 275 (2009) (noting this provision is one of the most contentious provisions in TRIPS). Indeed, even after TRIPS, the scope of protection for undisclosed data remains controversial. *E.g.*, Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46 FL. ST. L. REV. 641, 644 (2019) [hereinafter Yu, *Data Exclusivities*].

12. *E.g.*, U.S. TRADE REPRESENTATIVE [USTR], SPECIAL 301 REPORT 13 (1997) (alleging Denmark failed to comply with TRIPS for not providing exclusive test data protection); USTR, SPECIAL 301 REPORT 11 (1996) (alleging Australia failed to comply with TRIPS for not providing data exclusivity); Communication from the European Communities and their Member States, IP/C/W/280, at 4 (June 12, 2001) (WTO) (preventing reliance on data as the "most effective method" of protecting data from unfair commercial use) [hereinafter Communication from the European Communities, IP/C/W/280]. However, not all agree. *E.g.*, Proposal by the African Group et al., IP/C/W/312, para 7 (Oct. 4, 2001) (WTO) (asserting "nothing in the TRIPS agreement shall prevent members from establishing . . . marketing approval procedures for generic medicines . . . based on marketing approvals granted earlier for equivalent products."); Lisa Diependael et al., *Raising the Barriers to Access Medicines in the Developing World - The Relentless Push for Data Exclusivity*, 17 DEVELOPING WORLD BIOETHICS 11, 13 (2017) (noting that although some argue TRIPS imposes the first international requirement of data exclusivity, no such right is provided). Indeed, a number of middle-income countries do not provide data exclusivity today, and those that do often are required to do so because of agreements with the United States and EU. *E.g.*, Pascale Boulet et al., *Data Exclusivity in the European Union: A Briefing Document*, MEDICINES L. & POL'Y 1, 3 (June 2019).

13. *E.g.,* PHRMA, SPECIAL 301 SUBMISSION 32–33 (2020) (describing data exclusivity as an important complement to patents that is not universally provided); *see also* IFPMA, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY (2000) (asserting need for data exclusivity and arguing it is required by TRIPS).

protection[15] of data that is submitted to the government regulators, but otherwise kept secret from others.[16]

Regardless of whether TRIPS requires countries to provide data exclusivity, TRIPS also imposes an additional, under-studied obligation on countries to not disclose this data unless one of two exceptions exists. One exception permits disclosure if the data is protected from the disputed term "unfair commercial use," whereas the other ambiguously refers to disclosure to "protect the public."[17] Policymakers thus far have generally ignored these key public policy exceptions,[18] and scholars have not devoted substantial consideration to these exceptions either.[19] This Article aims to correct this by providing the first comprehensive analysis of these exceptions.

The international implications of publishing clinical data provide an opportunity to reconsider international and domestic laws. The need to evaluate whether domestic disclosure laws comply with TRIPS provides a concrete example of the dangers of increasing IP protection in international agreements, which has generally been the norm.[20] It underscores the need

14. Data exclusivity helps protect the company that obtains regulatory approval of a new drug from immediate competition from generics in countries that provide this right. *See infra* Part I.A.

15. A trade secret can be any information that is economically valuable from not being known and exists so long as its owner keeps it reasonably secret. *E.g.*, UNIFORM TRADE SECRETS ACT § 1 (UNIF. L. COMM'N 1996) [hereinafter UTSA].

16. *E.g.*, sources cited *supra* note 1 (noting information is generally confidential).

17. TRIPS, *supra* note 6, art. 39(3).

18. *See generally* TRANSPARENCY INT'L, CLINICAL TRIAL TRANSPARENCY: A GUIDE FOR POLICY MAKERS *passim* (2017) (explaining how to promote optimal clinical trial transparency, but with no mention of any international constraints); CRIT, PROMOTING TRANSPARENCY IN CLINICAL RESEARCH: WHY AND HOW *passim* (2017) (explaining clinical trial transparency goals without mention of international constraints). The lack of discussion of international constraints could be a function of the fact that health policymakers are not necessarily familiar with IP, let alone international IP constraints.

19. Initially, most discussion focused on basic data exclusivity obligations since no nations were contemplating disclosure of clinical trial data in the immediate years after TRIPS was concluded, whereas data exclusivity was strongly advocated by the pharmaceutical industry. *E.g.*, Aaron Xavier Fellmeth, *Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law*, 45 HARV. INT'L L. J. 443, 449–68 (2004) (analyzing exceptions briefly, but primarily focusing on basic data exclusivity obligation). However, even some recent articles written after EMA began disclosing clinical trial information provide inadequate analysis. *E.g.*, Gabriele Spina Ali, *TRIPS and Disclosure of Clinical Information: An Intellectual Property Perspective on Data Sharing*, 20 J. WORLD INTELL. PROP. 24, 32–39 (2018) (stating that detailed analysis is beyond its scope and providing conclusions inconsistent with proper interpretation of international agreements, including using US law to interpret); Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trial Transparency*, 38 AM. J. L. & MED. 63, 87 (2012) (noting that the exception for disclosures is understudied). Although there is one article that aims to address these exceptions and potential application to the EMA law, it notably does not come to any definitive conclusion. Daria Kim, *Enabling Access to Clinical Trial Data: When is Unfair Use Fair?*, 14 CHICAGO-KENT J. INTELL. PROP. 521, 551 (2015) (noting policy of publishing data raises a TRIPS issue, but ultimately concluding that it is ambiguous without evaluation, let alone application of the exceptions to disclosure).

20. *E.g.*, Susan Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*, PJIP RESEARCH PAPER NO. 15. AM. U. C. L. 1

for more caution in creating new international norms that may limit domestic regulatory authority when needed to protect public health. Accordingly, this Article argues that countries should thoughtfully consider international obligations. In addition, this Article also argues that the United States should revisit its domestic laws concerning clinical data.

This Article proceeds in four parts. Part I provides key background. Part I.A explains how drugs are approved and how clinical data is used in that context for approval of both new and generic drugs. Part I.B then explains that without public knowledge of clinical data, there is an information asymmetry that can result in public health problems, including unnecessary public health risk and wasted resources.

Part II focuses on the need, as well as challenges, for providing greater clinical trial transparency to address the problems noted. This Part explains how disclosing clinical trial reports is important for the optimal transparency advocated by policymakers, which includes aspects of transparency many nations already recognize. For example, many nations require clinical trials be registered before they start and that completed trials provide summary results to avoid manipulation of data and evidence distortion. Part II.B shows why most objections to disclosure of clinical trial reports are unfounded and that TRIPS allegations have been inadequately addressed thus far.

Part III then turns to international obligations that most countries have as members of the WTO. Part III.A explains how TRIPS should be properly interpreted. Part III.B then explains the two obligations of member states under TRIPS article 39 concerning data submitted to regulatory authorities to seek approval to sell drugs. This Section briefly explains the basic obligation that data be protected from "unfair competition" and then explains how this duty is different from the separate obligation that the data generally be protected from disclosure. The two different exceptions to the general duty to prevent the data from disclosure are each explained. Finally, this Part concludes with an explanation of how domestic disclosure of clinical data can comply with TRIPS.

Part IV addresses policy implications. Part IV.A argues that the need to evaluate TRIPS with respect to clinical data disclosure underscores that nations should more cautiously consider international IP norms in the future. This Section also argues international norms beyond IP should be reconsidered to similarly avoid unduly limiting domestic discretion. Part IV.B then turns to suggestions for modification of U.S. law to promote more disclosure of clinical data.

I. Background

This Part provides pertinent information to understand the need for disclosure of clinical trial data. It explains the role of clinical trial data

(2010), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1016&context=research [https://perma.cc/568X-LQA8].

during domestic regulatory agencies' drug approval. Then it explains why the public needs this data to prevent information asymmetry.

A. Domestic Regulatory Approval and the Role of Clinical Data

Generally, before a drug can be legally sold, a domestic regulatory agency, such as the FDA, must be satisfied that the drug is safe and effective for its intended purpose, such as to treat acid reflux, or to treat depression.[21] Approved drugs will then be labeled with approved indication(s), together with any relevant restrictions, such as, *not for children under a certain age, individuals taking certain other medications*, etc. However, even though a drug is approved only for a specific use, once so-approved, doctors can prescribe drugs for *any* use based on their clinical judgment.[22]

To evaluate whether a drug is safe and effective, a domestic regulatory agency evaluates information provided by the company seeking drug approval. A company typically provides substantial data from multiple phases of human clinical testing in volunteers;[23] this can easily involve thousands of pages of data concerning hundreds or thousands of patients, as well as statistical analysis and other information.[24] The clinical data a company creates is arguably a trade secret because it has value from not being known to others.[25] Moreover, governments traditionally have agreed and have not released this information.[26]

Although the same standard of safety and efficacy applies to original brand name as well as generic drugs, there is a shortened regulatory pathway for approval of generic drugs. Most countries permit proposed manufacturers of a generic drug to obtain approval based on a limited clinical showing that their proposed drug has the same active ingredient that is bioequivalent (and thus expected to have the same effect)[27] as the originator drug that was approved based on the more extensive data just dis-

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21. 21 U.S.C. § 355(d)(5)(iv) (2018). Most countries have their own regulatory agencies; though, in the EU, the European Medicines Agency (EMA) effectively functions as the regulatory agency for all EU member states.

22. *See* Buckman Co. v. Plaintiffs' Legal Comm'n 531 U.S. 341, 351 (2001) (explaining that "off-label" usage for some other purpose is necessary for FDA's mission). Regulating authorities generally have no power to regulate the practice of medicine. *E.g.*, 21 U.S.C. § 396 (2012) (noting FDA authority is over drug approval, not the practice of medicine). However, insurers as well as health technology assessment may also play a role in impacting how drugs are used. *See, e.g.*, Tim Wilsdon, Eva Fiz, & Artes Haderi, *A Comparative Analysis of the Role and Impact of Health Technology Assessments*, CHARLES RIVER ASS'N (2013) (noting impact of HTA guidelines on clinical decisions); *Coverage of Drugs and Biologicals for Label and Off-Label Uses*, UNITED HEALTHCARE (Oct. 13, 2021), https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-guidelines/c/coverage-drugs-biologicals-label-off-label-uses.pdf [https://perma.cc/C3GW-SZQZ] (explaining coverage).

23. 21 C.F.R. § 312.21 (2019).

24. *Id.* § 314.50 (stating content of new drug application).

25. *E.g.*, IFPMA, *supra* note 13, at 2.

26. *See* sources cited, *supra* note 1.

27. When a drug is bioequivalent based on its absorption in the blood, it is assumed that it will likely provide the same therapeutic effect. *E.g.*, Shein-Chung Chow, *Bioequivalence in Drug Development*, 6 WILEY INTERDISC. REV. COMPUTER STAT. 304 (2014).

cussed.[28] For a proposed generic that is bioequivalent to the previously approved drug, the regulatory authority infers that the proposed generic is in fact safe and effective based on the prior clinical data of the approved drug that the regulatory authority possesses. In other words, whereas the first company had to have direct evidence that its drug is safe and effective, the generic manufacturer can get approved by relying on that prior evidence in conjunction with the simpler task of establishing bioequivalence.

In countries that recognize "data exclusivity,"[29] the generic company cannot be approved based on reliance of this data until after the term of data exclusivity ends, which can last for five or ten years from approval of the originator drug.[30] However, even after data exclusivity ends, such that another company can rely on the data for approval of a generic drug, this second company generally has no physical access to the previously submitted clinical data. This is because regulatory agencies permit the second company to simply rely on the existence of the data they possess.

The origins of data exclusivity are inherently tied to introduction of the abbreviated approval process for generic drugs.[31] Before this process was introduced, generic companies needed to create their own clinical studies that directly proved the safety and efficacy of their proposed drug because the earlier clinical data was considered an infinite trade secret. Few companies incurred this expense—even for drugs whose patents had expired.[32] This is not surprising since the proposed manufacturer of a generic drug has no possibility of obtaining patent protection for what is a copy of a known drug and, thus, no way to recover the costs of expensive

28. *E.g.*, 21 U.S.C. § 355(j) (2018); Canadian Food and Drug Regulations § C.08.002.1; EU Directive, 2001/83, art. 10 (2001).

29. IFPMA, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 4 (2000) (noting most developed countries provide this protection); *see also* IPFMA, DATA EXCLUSIVITY: ENCOURAGING DEVELOPMENT OF NEW MEDICINES 6–79 (2011) (noting over forty countries plus the EU as of 2011). The US, followed soon after by the EU, adopted data exclusivity in the mid 1980s. CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY 260–61 (2011). In addition, after disputes concerning whether TRIPS article 39 required data exclusivity, over thirty free trade agreements (FTAs) now require it. *E.g.*, Gabriele Spina Ali, *Sweetening a Bitter Pill: Of Drug Prices, Drug Delays and Data Exclusivity*, 12 ASIA PAC. J. HEALTH L. & ETHICS 11 (2019); *see also* Pascale Boulet et al., *supra* note 12, at 8 (noting that of the sixteen middle-income countries that provide data exclusivity, they are due to FTAs). This is despite concerns by some public health advocates. *E.g.*, *Data Exclusivity in International Trade Agreements: What Consequences for Access to Medicines?*, MSF (May 2004), https://www.citizen.org/wp-content/uploads/dataexclusivitymay04.pdf [https://perma.cc/32A3-6QMR].

30. 21 U.S.C. § 355 (2018) (five-year period of data exclusivity); Directive 2004/27/EC, O.J. (L 136) 34–57 (EC) (ten-year period of data exclusivity). Data exclusivity need not be enforced by the originator company that benefits from it since the government itself enforces the period by declining to permit generic companies to rely on the data during the period of exclusivity. *E.g.*, CYNTHIA HO, *supra* note 29, at 256–57.

31. Both of these elements were introduced in the US as part of the Hatch-Waxman Act. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified as 21 U.S.C. § 355).

32. For example, between 1962 and 1984, there were 150 drugs whose patents had expired, but for which there were no generics. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L. J. 187, 187 (1999).

clinical tests.[33]

B. The Need for Clinical Data Beyond Regulatory Authorities

This Section explains why clinical data needs to be disclosed to the public to optimally promote public health and judicious use of resources. This Section first explains the information asymmetry that traditionally exists with prescription drugs. This illustrates problems that could have been avoided if clinical data were available to the public.

1. Information Asymmetry with Prescription Drugs

The market for prescription drugs is unique. In other markets, consumers can more easily compare competing products and obtain independent reviews immediately after a product enters the market.[34] However, with new prescription drugs, only the self-interested company has the complete information essential to how the product works, including its efficacy, or lack thereof. Advertisement is the primary source of public information. Not surprisingly, corporate marketing touts positive claims,[35] which sometimes are later revealed to have no factual basis.[36] Before independent scientists can discover and disclose issues, companies are often remarkably successful at driving demand for expensive new drugs that are not superior to existing drugs.[37] Not only do companies use effective advertising techniques to selectively tout positive information that may not have factual support, but they also may even pressure those interested in revealing information contrary to their marketing claims.[38]

33. Patent protection is only available for inventions that are new. 35 U.S.C. §§ 101–02 (2018).

34. For many products there are independent reviews, or else consumers can test products themselves. This is true even when the product may involve a trade secret. For example, although the algorithms underlying search engines such as Google and Bing are trade secrets, consumers can assess these themselves—and without any danger to their own health or safety.

35. Moreover, companies may specifically instruct their sales representatives to not disclose relevant information. *E.g.*, Shannon Hall & Jeanne Lenzer, *The Problem with Medicine: We Don't Know if Most of it Works*, DISCOVER (Feb. 10, 2011), https://www.discovermagazine.com/health/the-problem-with-medicine-we-dont-know-if-most-of-it-works [https://perma.cc/Y8TF-RYPA].

36. CARL ELLIOTT, WHITE COAT, BLACK HAT: ADVENTURES ON THE DARK SIDE OF MEDICINE 103 (2010) (claiming that naproxen protected the heart, rather than that another drug, Vioxx, caused more heart attacks than naproxen); Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 223 (2009).

37. *E.g.*, Roberto Cardarelli et al., *A Cross-Sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and Their Underlying Studies: Is What They Tell Us Important and True*?, BMC FAM. PRAC., Mar. 2006, at 1, 2 (noting marketing success for new calcium channel blockers that were not superior to older drugs); Hall & Lenzer, *supra* note 35.

38. *E.g.*, ELLIOTT, *supra* note 36, at 103–04 (noting Merck's attempt to discredit an academic doctor that raised concerns, including trying to threaten withdrawal of funding to researcher's university); Gardiner Harris, *Research Ties Diabetes Drug to Heart Woes*, N.Y. TIMES (Feb. 19, 2010), https://www.nytimes.com/2010/02/20/health/policy/20avandia.html [https://perma.cc/YB9T-3CBF] (noting attempt to intimidate doctors).

Accordingly, doctors may prescribe new drugs primarily based on inaccurate promotional claims.

Although there are some studies of new drugs published in scientific journals, these do not reflect the full scope of information, and there are no laws requiring companies to publish anything related to marketed drugs.[39] Studies find that up to half of clinical trials submitted to the FDA are completely unavailable to the public.[40] Notably, clinical trials that were important to regulatory approval and that are clinically relevant are not always disclosed.[41] Even when data appears in published articles, it may provide a misleading picture since companies that publish articles have an interest in selectively including positive results; indeed, they are four times as likely to publish positive results.[42] For example, a study of a dozen approved antidepressant drugs found that, although the FDA had evidence that nearly half of the trials did *not* have a positive outcome, the published literature showed that the vast majority—forty-nine out of fifty-two studies—had a positive outcome.[43] In addition, many side effects noted in clinical trials are not reported in publications, and even among adverse events that are published, they are often not fully reported, or even distorted to suggest that the results are positive.[44] Corporate self-interest is compounded by

39. Regulations determine what companies must include in applications seeking regulatory approval, but there are no laws requiring companies to publish any of the information submitted in privately published journals.

40. Jennifer E. Miller et al., *Clinical Trial Registration, Reporting, Publication and FDAAA Compliance: A Cross-Sectional Analysis and Ranking of New Drugs by the FDA in 2012*, 5 BRIT. MED. J. OPEN, 1, 4 (2015); Thomas J. Hwang et al., *Failure of Investigational Drugs in Late-Stage Clinical Development and Publication of Trial Results*, J. AM. MED. ASS'N INTERNAL MED. 1826, 1830 (2016).

41. James W. Smithy et al., *Publication of Pivotal Efficacy Trials for Novel Therapeutics Approved Between 2005 and 2011: A Cross-Sectional Study*, 174 J. AM. MED. ASS'N INTERNAL MED. 1518, 1519 (2014) (finding 14% of pivotal trials not published and noting that these are essential for clinical practice).

42. *E.g.*, Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BRIT. MED. J. 1167 (2003); Richard Smith, *Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PLOS MED. 0364, 0364 (2005).

43. Erick H. Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 256 (2008).

44. Su Golder et al., *Reporting of Adverse Events in Published and Unpublished Studies of Health Care Interventions: A Systematic Review*, 13 PLOS MED. 10, 14–15 (2016) (finding "serious concerns" about substantial amount of adverse event data); Richeek Pradhan & Sonal Singh, *Comparison of Data on Serious Adverse Events and Mortality in ClinicalTrials.gov, Corresponding Journal Articles, and FDA Medical Reviews: Cross-Sectional Analysis*, 41 DRUG SAFETY 849, 851 (2018) (finding 30% deviation in adverse effects between summary results and journal articles for fifteen trials); Eve Tang et al., *Comparison of Serious Adverse Events Posted at ClinicalTrials.gov and Published in Corresponding Journal Articles*, 13 BMC MED. 1, 5–6 (2015) (finding only 11% of journal articles providing a complete account of all serious adverse effects for a random sample of 300 trials and with 15% of publications having no reported serious adverse effects at all); Turner, *supra* note 43, at 254–55 (finding only 3 of 36 negative results were accurately published, most of the negative results were not published at all, and 11 were published with evidence distortions to improperly suggest that the results were positive).

the tendency of journals to publish articles with positive results.[45] Accordingly, even doctors who seek out independent information concerning new drugs will gain little information that differs from marketing. Worse yet, doctors may not be aware that the "independent" journal articles are inherently flawed.

In addition to a lack of independent information, there are often misconceptions that further complicate the scenario. Consumers as well as some doctors often incorrectly assume that the FDA only approves new drugs if they are an improvement.[46] However, the regulatory standards only require a company to provide "substantial evidence" that a drug is safe and effective for its intended effect compared to a placebo, i.e., no treatment at all.[47] Moreover, assessing whether a drug satisfies this standard may be hindered by legal constraints regarding the time available to review this data.[48] Given these circumstances, perhaps it is not surprising that drugs can be—and have been—approved in the face of equivocal results.[49]

A further problem is that, although independent scientists can theoretically replicate research to discover whether marketing claims are well-founded, this is a resource-intensive endeavor; there are likely too few scientists with both interest and resources to verify all results.[50] Moreover,

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45. *E.g.*, Fujian Song et al., *Why Are Medical and Health-Related Studies Not Being Published? A Systemic Review of Reasons Given by Investigators,* 9 PLoS One 1 (2014); Ana Mlinaric et al., *Dealing with the Positive Publication Bias: Why You Should Really Publish Your Negative Results,* 27 Biochemia Medica 1, 1 (2017).

46. *See* Aaron S. Kesselheim et al., *Physicians' Knowledge About FDA Approval Standards and Perceptions of the "Breakthrough Therapy" Designation,* 315 J. Am. Med. Ass'n 1516, 1516 (2016). Although not part of drug approval standards, the government is cognizant of the need for evaluating comparative effectiveness of drugs. *E.g.*, Eugene C. Rich, *From Concept to Policy: 10 Years After the Call for a US Center for Comparative Effectiveness Information*, 6 J. Comp. Effectiveness Res. 9, 9 (2016).

47. 21 U.S.C. § 355(d)(5) (2018).

48. *E.g.*, 21 U.S.C. § 355(c)(1) (2018) (noting six-month default timeline to approve new drug application); Ctr. Drug Evaluation & Rsch., Manual of Policies and Procedures, MAPP 6020.3 Rev. 2, at 1, 2 (2013) (noting six-month goal for priority review applications versus ten-month goal for standard review applications).

49. For example, a FOIA request revealed that for six of the most widely prescribed antidepressants approved between 1987 and 1999, more than half of efficacy studies provided to the FDA showed no significant difference between the approved drug and placebo. Irving Kirsch et al., *The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration,* 5 Prevention & Treatment 1, 3 (July 2002).

50. *E.g.*, Daniel Engber, *Cancer Research is Broken*, Slate (Apr. 9, 2016), https://slate.com/technology/2016/04/biomedicine-facing-a-worse-replication-crisis-than-the-one-plaguing-psychology.html [https://perma.cc/K6PK-AMZ3] (noting that replication of cancer studies is generally done by industry since they have money and incentive, but they don't necessarily share their findings—although the Reproducibility Project, begun in 2013, has attempted to improve this issue). Moreover, there is a general reproducibility problem with scientific studies. *E.g.*, C. Glenn Begley & John P.A. Ioannidis, *Reproducibility in Science: Improving the Standard for Basic and Preclinical Research* 116 Am. Heart Ass'n: Circulation Rsch. 116, 116–17 (Jan. 2015); Tom Feilden, *Most Scientists 'Can't Replicate Studies By Their Peers,'* BBC News (Feb. 22, 2017), https://www.bbc.com/news/science-environment-39054778 [https://perma.cc/HCA5-JV22]. Furthermore, the patent law doctrine of enablement may hinder or even dissuade repro-

although some independent scientists have engaged in such inquiries and found flaws with marketed products,[51] doctors and patients are still influenced by marketing claims for years. Extensive marketing is often so influential that doctors are resistant to embracing knowledge revealed by independent scientists.[52] Moreover, doctors are generally not aware of this influence and assume that they are primarily influenced by independent information.[53]

Steps have been taken to improve the situation after increasing public pressure.[54] First, in 2005, major company trade groups that initially claimed public reporting of clinical trial results was unnecessary[55] agreed to self-disclose summary results, but not necessarily in a government-sponsored registry.[56] However, this voluntary system resulted in conclusions more favorable than those in published articles or FDA reviews.[57] Accordingly, regulations mandating greater transparency were considered neces-

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ducible data. Jacob S. Sherkow, *Patent Law's Reproducibility Paradox,* 66 DUKE L. J. 845, 846–47 (2017) (discussing misalignment of patent law doctrine incentives with clinical trials that result in quick patenting of often futile drugs, enhanced secrecy in clinical trials, and dissuading competitors from researching alternative uses that are unpatentable).

51. *E.g.*, CRIT, *supra* note 18, at 12–13 (noting independent researchers discovered that the drug Avandia treats increased risk of strokes and heart attacks caused by diabetes only after a lawsuit that required the manufacturer to make full data available); Dirk Eyding, *Reboxetine for Acute Treatment of Major Depression: Systematic Review and Meta-Analysis of Published and Unpublished Trials*, 341 BRIT. MED. J. 1, 1 (2010) (finding that Pfizer's antidepressant drug Edronex was ineffective and potentially harmful for several years, with prior data overestimating benefits and underestimating harm); Nancy Krieger et al., *Hormone Replacement Therapy, Cancer, Controversies, and Women's Health: Historical, Epidemiological, Biological, Clinical, and Advocacy Perspectives*, 59 J. EPIDEMIOLOGY & COMMUNITY HEALTH 740, 740 (2005) (noting that independent researchers discovered that drugs promoted to treat menopause and prevent heart disease in fact *increased* the risk of heart disease); *see also* John P.A. Ioannidis, *Contraindicated and Initially Stronger Effects in Highly Cited Clinical Research*, 294 J. AM. MED. ASS'N 218, 218 (2005) (finding that less than half of highly citied clinical research studies could be replicated and that nearly twenty-five percent were largely unchallenged).

52. *E.g.*, Cynthia M. Ho, *A Dangerous Concoction: Pharmaceutical Marketing, Cognitive Biases, and First Amendment Overprotection,* 94 IND. L.J. 773, 811–13 (2019).

53. *E.g.*, *id.* at 813–16.

54. *E.g.*, INST. OF MEDICINE, PREVENTING MEDICATION ERRORS 1–2 (2006) (noting support for greater transparency by public and private groups and the importance of 2014 publication guidelines by international Medical Journal Editors in spurring discussion amongst interest groups). This public pressure developed because of public health tragedies. *See infra* Part I.B.2.

55. *E.g.*, Barry Meier, *Contracts Keep Drug Research Out of Reach*, N.Y. TIMES (Nov. 29, 2004), https://www.nytimes.com/2004/11/29/business/contracts-keep-drug-research-out-of-reach.html [https://perma.cc/3XJQ-3XME].

56. Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases by EFPIA, IFPMA, JPMA and PhRMA (2005), *reprinted in* IOM, *supra* note 54, at 91, 93 (stating commitment to publish results of clinical trials other than "exploratory trials" for drugs approved for marketing in at least one country for trials initiated on or after July 1, 2005); *see also* Christine Galbraith Davik, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data,* 78 MISS. L. J. 705, 739 (2009) (noting that statement left open possibility of companies publishing information on their own websites with inconsistent rules).

57. Deborah Zarin, *Issues in the Registration of Clinical Trials*, 297 J. AM. MED. ASS'N 2112, 2118 (2007).

sary, and nations, including the United States, enacted laws requiring public disclosure of not only summary results but also initial methods.[58] However, there are issues with compliance,[59] and even when this summary information is provided, it still provides far less detail than the clinical data submitted to regulatory authorities.[60] One possible upside of the COVID pandemic is that it has encouraged unprecedented data sharing and transparency that could potentially apply more broadly.[61]

2. *Information Asymmetry Causes Public Health Problems*

This section demonstrates how the combination of publication biases and marketing manipulation without public access to full clinical data can result in unnecessary tragedies and wasted public resources.[62] A number of the examples in this section were discovered only after litigation revealed

58. 42 U.S.C. § 282(j)(3)(C) (2018); 42 C.F.R. § 11.42 (2016); Commission Guideline (EC) 2012/C302/03 of June 10, 2012, Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006. In addition, funding agencies may also require result reporting, regardless of whether otherwise required by law. *E.g.*, *NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information*, NIH (Sept. 16, 2016), https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html [https://perma.cc/93S3-PPP7].

59. For example, current reporting in the US is just under sixty percent. *Who's Sharing Their Clinical Trial Results?*, FDAAA TRIALSTRACKER (Mar. 26, 2019), http://fdaaa.trialstracker.net/?status%5B%5D=Overdue&status%5B%5D=Overdue-cancelled&status%5B%5D=reported-late [https://perma.cc/G6RD-NSUY]; Sile Lane, *AllTrials Report to the House of Commons Science and Technology Committee Inquiry Into Research Integrity: Clinical trial Transparency* (Oct. 19, 2019), https://www.alltrials.net/wp-content/uploads/2019/10/AllTrials-update-report-for-STC-2019-Oct-14.pdf [https://perma.cc/G6RD-NSUY]; Nicholas J. DeVito, *Compliance with Legal Requirement to Report Clinical Trial Results on ClinicalTrials.gov: A Cohort Study*, 395 LANCET 361, 361–69 (2020); Shraddha Chakradhar, *More Trial Results Are Being Posted to Public Database, but Data Quality Lacking, Report Finds,* STAT (Nov. 13, 2019), https://www.statnews.com/2019/11/13/more-results-published-clinical-trials-database-data-quality/ [https://perma.cc/F7Z2-QB3A]; Christopher Morten et al., *Lost Opportunities from FDA Inaction When Sponsors Fail to Report Clinical Trial Results*, STAT (Apr. 13 2020), https://www.statnews.com/2020/04/13/lost-opportunities-clinical-trial-results-unreported-lost-opportunities/ [https://perma.cc/L6P9-DXFR].

60. *E.g.*, Beate Wieseler et al., *Completeness of Reporting of Patient-Relevant Clinical Trial Outcomes: Comparison of Unpublished Clinical Study Reports with Publicly Available Data*, 10 PLOS MED e1001526, 3–8 (2013).

61. *E.g.*, C. Simone Fishburn & Steve Usdin, *Having Touched the Third Rail of Data Sharing in the Pandemic, Drug Developers Should Hold on Tight,* BIOCENTURY 13, 17–19 (Sept. 9, 2020). In addition, even though industry may resist sharing with academic or independent scientists, there are multiple platforms that promote sharing within the industry, though some of the data is limited to control arm only. *See id.* at 17–18.

62. Although this section focuses on information asymmetry primarily due to lack of disclosure of underlying clinical trials, there have been other issues with information asymmetry in terms of public health harms due to lack of trial registration. *E.g.*, TILL BRUCKNER & BETH ELLIS, CLINICAL TRIAL TRANSPARENCY: A KEY TO BETTER AND SAFER MEDICINES 3, 13–14 (2017) (noting that over 100,000 died because the results of a single trial on Remivox were hidden and also that academic articles exaggerated the benefits and understated harms of an antidepressant, Edronax, resulting in undue expense on a drug that was four times more expensive, yet not actually more effective).

the full scope of discrepancies. Accordingly, the situations discussed may not reflect the full scope of the problem.

One infamous example of the dangers of information asymmetry involves the unnecessary deaths from the drug Vioxx, which was approved in 1999 to treat arthritis and remained on the market until its manufacturer, Merck, removed it in 2004.[63] Merck knew that the drug was associated with cardiovascular risks yet went to great lengths to hide this. The studies that Merck submitted to the FDA included patients with *low* risk of cardiovascular disease and had no method to evaluate cardiovascular outcomes—even though Merck knew that this would be an issue.[64] Merck hid unfavorable data in academic papers,[65] a number of which were authored by company scientists, with external academic scientists later recruited to be primary authors.[66] Merck also engaged in disingenuous marketing that falsely asserted the drug was safe and intentionally hid negative data that was considered an "obstacle" to sales.[67] Data made available through litigation revealed that Merck's actions resulted in unnecessarily exposing the public to risks for several years before Merck withdrew the drug.[68] Some commentators noted that "if physicians and patients had had the facts, it would have taken an alchemist, not a marketing department, to turn this lemon into gold."[69]

A related example involves the improper marketing of the antidepressant Paxil. SmithKline Beecham, which later merged with Glaxo to become GlaxoSmithKline (GSK), obtained FDA approval to market Paxil in 1999 for depression in adults.[70] Glaxo sales representatives distributed a scien-

63. *Vioxx (Rofecoxib) Questions & Answers*, FDA (Sept. 30, 2004), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/vioxx-rofecoxib-questions-and-answers [https://perma.cc/EW6P-DSSC].

64. Harlan Krumholz, *What Have We Learnt from Vioxx?*, 334 BRIT. MED. J. 120, 120 (2007). A Merck sponsored study revealed a problem in 1996, but Merck softened the interpretation before it was published. *Id.*

65. *Id.* at 121–22; *see also* Gregory Curfman et al., *Expression of Concern: Bombardier et al., "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxin in Patients with Rheumatoid Arthritis," N. Eng. J. Med. 2000,* 355 NEW ENG. J. MED. 2813, 2813–14 (2005) (expressing concern that original study excluded data that made the ultimate conclusion incorrect as revealed in subsequent litigation).

66. *E.g.,* Joseph Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 J. AM. MED. ASS'N 1800, 1802–06 (2008).

67. *Risk and Responsibility: The Roles of FDA and Pharmaceutical Companies in Ensuring the Safety of Approved Drugs, like Vioxx: Hearing Before the Comm. on Gov't Reform*, 109th Cong. 2–3 (May 5, 2005) (Statement of Hon. Henry A. Waxman, Cong. Representative, Cal.) (Merck documents show aggressive marketing of Vioxx after studies indicated risk); *see also* Henry Waxman, *The Lessons of Vioxx - Drug Safety and Sales,* 325 NEW ENG. J. MED. 2578, 2577 (2005) (noting disparity between actual data versus marketing information).

68. Joseph Ross et al., *Pooled Analysis of Rofecoxib Placebo-Controlled Clinical Trial Data*, 169 ARCHIVES INTERN. MED. 1976, 1976 (2009).

69. Steven Woloshin & Lisa Schwartz, *Bringing the FDA's Information to Market*, 169 ARCHIVES INTERN. MED. 1985, 1985–87 (Nov. 23, 2009).

70. CENTER FOR DRUG EVALUATION AND RESEARCH, APPROVAL PACKAGE FOR APPLICATION NUMBER 020936 (Feb. 16, 1999), https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20-936_Paxil_Approv.pdf [https://perma.cc/7ZGL-ZNWB].

tific article "ghost-written" by Glaxo[71] that falsely stated that Paxil was "generally well tolerated and effective" to treat depression in adolescents.[72] In actuality, Glaxo knew that the drug was ineffective in young people and that it even caused suicidal thoughts.[73] The New York Attorney General prosecuted Paxil for this fraudulent behavior.[74] A settlement of that case resulted in clinical study reports being available to independent researchers.[75] Researchers then found that Paxil failed to show any efficacy for major depression in adolescents and was instead associated with harms contrary to the previous study published a decade earlier.[76] Notably, the earlier publication reported results based on limited data to mask poor results from the omitted data.[77]

Information asymmetries may have also exacerbated the opioid epidemic. For example, Purdue, the manufacturer of OxyContin, aggressively marketed its drug with sales representatives that mispresented abuse potential with misleading graphs, which ultimately led to a criminal charge.[78] Purdue's actions were especially egregious since it failed to dis-

71. Leemon B. McHenry & Jon N. Jureidini, *Industry-Sponsored Ghostwriting in Clinical Trial Reporting: A Case Study,* 15 ACCOUNTABILITY RES. 152, 152–55 (2015).

72. Martin B. Keller et al., *Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial,* 40 J. AM. ACAD. CHILD ADOLESCENT PSYCHIATRY 762, 768 (2001).

73. *E.g.*, Charles Piller, *Transparency on Trial,* 367 SCIENCE 240, 241–42 (2020).

74. Gardiner Harris, *New York State Official Sues Drug Maker over Test Data*, N.Y. TIMES (June 3, 2004), https://www.nytimes.com/2004/06/03/business/new-york-state-official-sues-drug-maker-over-test-data.html [https://perma.cc/UGD7-54Y2]; David Teather & Sarah Boseley, *Glaxo Faces Drug Fraud Lawsuit*, GUARDIAN (June 3, 2004), https://www.theguardian.com/business/2004/jun/03/mentalhealth.medicineandhealth [https://perma.cc/22DM-KZRZ]; *see also* Press Release, Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report [https://perma.cc/Y6HX-UMC9] (settling criminal and civil charges relating to the same issues with Paxil, as well as Wellbutrin).

75. State of New York v. GlaxoSmithKline, LLC, Civil Action No. 04-V-5304 MGC, Consent Order and Judgment, ¶ 8 (2004) (requiring clinical studies for Paxil).

76. The clinical study reports initially made available were incomplete even though they constituted 6,000 pages, such that researchers had to contact GSK to request de-identified individual case report forms. Peter Doshi, *Putting GlaxoSmithKline to the Test Over Paroxetine*, 347 BRIT. MED. J. 15, 15–17 (2013). GSK eventually agreed to make 77,000 additional pages of de-identified data available through a website, although only to users approved by GSK. BRUCKNER & ELLIS, *supra* note 62, at 17.

77. Joanna Le Noury et al., *Restoring Study 329: Efficacy and Harms of Paroxetine and Imipramine in Treatment of Major Depression in Adolescence,* 351 BRIT. MED. J. h4320 (2015); *see also* Mark Terry, *Re-Analysis of GlaxoSmithKline's Seroxat/Paxil Antidepressant Data Shows Lack of Transparency*, BIOSPACE (Sept. 17, 2015), https://www.biospace.com/article/re-analysis-of-glaxosmithkline-s-seroxat-paxil-antidepressant-data-shows-lack-of-transparency-/ [https://perma.cc/66LD-HCCL] (explaining study was part of BMJ initiative to encourage companies to publish or correct misreported or abandoned trials).

78. Shraddha Chakradhar & Casey Ross, *The History of OxyContin, Told Through Unsealed Purdue Documents,* STAT (Dec, 3, 2019), https://www.statnews.com/2019/12/03/oxycontin-history-told-through-purdue-pharma-documents/ [https://perma.cc/LHL4-M2EF]; David Armstrong, *Secret Trove Reveals Bold 'Crusade' to Make OxyContin a Blockbuster,* STAT (Sept. 22, 2016), https://www.statnews.com/2016/09/22/abbott-oxy

close a study. Moreover, after the FDA approved a reformulated version of OxyContin that was expected to discourage abuse, publicly available studies funded by Purdue presented a more positive picture than an independent FDA investigation.[79]

Sometimes lack of transparency regarding underlying clinical studies does not cause direct public health harms, but may nonetheless waste public resources, as illustrated by issues involving Tamiflu where policymakers had inadequate information from published articles alone.[80] The antiviral drug Tamiflu was heralded by many presumably objective entities, including HHS, CDC, and the European Medicines Agency (EMA), to reduce complications from the flu pandemic; Tamiflu was allegedly able to reduce flu-related hospitalization based on a "meta-analysis" article that analyzed ten clinical trials conducted by the manufacturer.[81] Notably, the FDA, in evaluating these same trials, concluded that Tamiflu was not effective in reducing complications and required the drug's label to explicitly say so.[82] Despite rules barring marketing for unapproved uses, Tamiflu's manufacturer, Roche, asserted that its drug reduced hospital admissions by 61% in patients based on the meta-analysis.[83] Although the FDA did cite Roche for violating these rules,[84] Tamiflu was stockpiled by several governments in the wake of concern over avian and pandemic influenza.[85] Even an initial review by the independent research group Cochrane Collaboration

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contin-crusade/ [https://perma.cc/J5B6-EWGN]; *see also* Fred Schulte, *How Rival Opioid Makers Sought to Cash in on Alarm Over OxyContin's Dangers*, KAISER HEALTH NEWS (Aug. 2, 2018), https://khn.org/news/how-rival-opioid-makers-sought-to-cash-in-on-alarm-over-oxycontins-dangers/ [https://perma.cc/78VA-H2QD] (noting marketing by Purdue and competitor Janssen); Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused,* N.Y. TIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html [https://perma.cc/78VA-H2QD] (noting Purdue failed to tell the FDA about a study that indicated its related long-acting opioid MS Contin was being abused by drug users, contrary to Purdue's claim that the long-acting drug would reduce its appeal with drug abusers).

79. *E.g.*, *Revamped OxyContin Was Supposed to Reduce Abuse, But Has It?*, STAT (July 19, 2019), https://www.statnews.com/2019/07/22/revamped-oxycontin-was-supposed-to-reduce-abuse-but-has-it/ [https://perma.cc/L7LR-7M3Y].

80. Katie Thomas, *Breaking the Seal on Drug Research*, NY TIMES (June 29, 2013), https://www.nytimes.com/2013/06/30/business/breaking-the-seal-on-drug-research.html [https://perma.cc/H5PS-FNHF].

81. Peter Doshi et al., *The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience*, 9 PLOS MED. 1, 1 (2012) [hereinafter Doshi et al., *The Imperative to Share*].

82. Hoffmann-La Roche, Product Label, Tamiflu (oseltamivir phosphate) (2011).

83. Shannon Brownlee & Jeanne Lenzer, *The Truth about Tamiflu*, ATLANTIC (2009), https://www.theatlantic.com/magazine/archive/2009/12/the-truth-about-tamiflu/307801/ [https://perma.cc/AQ4T-Z8M6]; *see also* Laurent Kaiser et al., *Impact of Oseltamivir Treatment on Influenza-Related Respiratory Tract Complications and Hospitalizations*, 163 ARCH. INTERNAL MED. 1667 (2003) (the metastudy).

84. Food & Drug Admin. [FDA], NDA 21-087/S-042, Tamiflu (oseltamivir phosphate), NDA 21-087, MACMIS ID#8675 (Apr. 14, 2012).

85. *E.g.*, Shannon Brownlee & Leanne Lenzer, *The Truth about Tamiflu,* ATLANTIC (2009), https://www.theatlantic.com/magazine/archive/2009/12/the-truth-about-tamiflu/307801/ [https://perma.cc/2S29-FKTE]; Kate Kelland, *Stockpiles of Roche Tamiflu Drug Are Waste of Money, Review Finds,* Reuters (Apr. 10, 2014), https://www.reuters.com/article/us-roche-hldg-novartis-search/stockpiles-of-roche-tamiflu-

(Cochrane) suggested that Tamiflu reduces complications—based on the same meta-analysis article.[86] Only after a Japanese doctor posted an online comment that Cochrane's recommendation was based on conclusions from the industry-funded summary of trials did Cochrane dig deeper for the actual underlying clinical data.[87] Cochrane was unable to obtain any information from authors of the meta-study, one of whom claimed he had not seen any trial data and instead relied solely on Roche summaries.[88] Cochrane approached Roche for data on the underlying clinical trials, but could not obtain it without signing a confidentiality agreement that would prevent publication of any results, or even acknowledgement that the agreement existed.[89] So, Cochrane published a new conclusion in 2009 that Tamiflu did *not* reduce complications from flu in the British Medical Journal.[90] That journal also did its own investigation that revealed that some of the published articles on Tamiflu were written by "ghost writers" of Roche who had been pressured to write positive messages.[91]

After these publications, Roche finally revealed portions of clinical study reports,[92] but only after multiple instances where Roche expressed great reluctance or outright refusal to share even this limited data, citing reasons that changed over time.[93] However, what Roche ultimately released was only a fraction of the data. This was revealed in 2011, when the EMA provided 22,000 pages of reports to Cochrane in response to a Freedom of Information request, which was over seven times as much data as Roche previously released.[94] Once the clinical data was disclosed, researchers found that there were definitely reporting biases and even fun-

drug-are-waste-of-money-review-finds-idUSBREA390EJ20140410 [https://perma.cc/6P6F-VY6Q].

86. Tom Jefferson et al., *Neuraminidase Inhibitors for Preventing and Treating Influenza in Healthy Adults*, 3 COCHRANE DATABASE SYSTEMIC R??. (Apr. 20, 2005), *cited in* Tom Jefferson et al., *Neuraminidase Inhibitors for Influenza: A Systematic Review and Meta-Analysis of Regulatory and Mortality Data*, 339 BRIT. MED. J. 1 (2009).

87. The doctor had come to question its efficacy in his practice and pointed out that only two of the ten clinical trials were fully published, such that he wondered how researchers could be certain Tamiflu reduced flu complications. *E.g.*, Kamran Abassi, *The Missing Data That Cost $20 Bn*, 348 BRIT. MED. J g2695 (2004), https://www.bmj.com/content/bmj/348/bmj.g2695.full.pdf [https://perma.cc/2ER3-DV9G].

88. Thomas, *supra* note 80; Ben Goldacre, *What the Tamiflu Saga Tells Us About Drug Trials and Big Pharma*, THE GUARDIAN (Apr. 10, 2014, 2:00 AM), https://www.theguardian.com/business/2014/apr/10/tamiflu-saga-drug-trials-big-pharma [https://perma.cc/JP5C-RZ9S].

89. Goldacre, *supra* note 88.

90. Jefferson et al., *supra* note 86.

91. Debra Cohen, *Complications: Tracking Down the Data on Oseltamivir,* 339 BRIT. MED. J. 1342 (2009); *see also* Martin Enserink, *After Struggle with Roche, Panel Casts Doubt on Tamiflu*, SCIENCE (Dec. 9, 2009), https://www.sciencemag.org/news/2009/12/after-struggle-roche-panel-casts-doubt-tamiflu [https://perma.cc/H6J9-6F7G].

92. Doshi et al., *Imperative to Share*, *supra* note 81, at 2 (noting disclosure of 3,000 pages)

93. *Id.* at 4–5, Tables 2–3 (displaying extensive list of Roches' stated reasons for reluctance or refusal to share data).

94. *Id.* at 2.

damental problems in the trial design. For example, none of the published articles noted serious adverse events, but the clinical study reports showed ten serious adverse events.[95] In addition, in assessing whether patients had pneumonia, the study relied only on patient self-reporting, with no actual diagnostic test.[96] Also, in trials that were described as double-blinded—where neither doctor nor patient should be able to tell if they are getting the drug at issue or a placebo—the placebo and active pills were different colors.[97]

Another example of wasted resources involved Genentech's drug, Tarceva, to treat cancer. The company knew that the drug only helped patients with a specific gene mutation yet marketed it broadly; the drug was ineffective for 90% of patients to which it was prescribed.[98]

The FDA later requested a post-market study that revealed this issue, and Genentech was eventually forced to reimburse the government for unnecessary costs to Medicare and Medicaid.[99] However, this reimbursement did not cover patients with private insurance for a drug marketed at nearly $8,000/month.[100] Moreover, this may indicate a broader problem for cancer drugs that are often no more effective than older ones.[101]

3. *The Need and Benefit of Reducing Information Asymmetry Through Clinical Data*

One example highlights the benefits of transparency, as well as why more flexible rules regarding transparency are important even with older drugs. After a patient asked Canadian doctor Nav Persaud about Diclectin, a widely prescribed drug to treat nausea during pregnancy approved by Canada in the early 1980s, the doctor sought more information from Canadian regulators.[102] Dr. Persaud sought information in 2011 under

95. Tom Jefferson et al., *Ensuring Safe and Effective Drugs: Who Can Do What It Takes?*, 342 BRIT. MED. J. 148, 149 (2011).

96. Tom Jefferson et al., *Oseltamivir For Influenza In Adults and Children: Systematic Review of Clinical Study Reports and Summary of Regulatory Comments*, 348 BRIT. MED. J. g2545, at 17 (2014).

97. Goldacre, *supra* note 88.

98. *E.g.*, Melody Peterson, *This $7,800-a-Month Cancer Drug Caused Rashes and Rarely Worked. Now Trump Could Make FDA Approvals Even Easier*, L.A. TIMES (Feb. 3, 2017), https://www.latimes.com/business/la-fi-fda-tarceva-approval-20170204-html-story.html [https://perma.cc/24J5-WAPT]; Ed Silverman, *Drug Makers Pay $67 million for Misleading Docs About Cancer Drug Survival Data,* STAT (June 6, 2016), https://www.statnews.com/pharmalot/2016/06/06/drug-makers-pay-67m-misleading-docs-cancer-drug-survival-data/ [https://perma.cc/X8TJ-25NW].

99. Press Release, Dep't of Justice, Pharmaceutical Companies to Pay $67 Million to Resolve False Claims Act Allegations Relating to Tarceva (June 6, 2016).

100. *See, e.g.*, *id.*; Peterson, *supra* note 98.

101. *See* Tito Fojo et al., *Unintended Consequences of Expensive Cancer Therapeutics*, 140 J. AM. MED. ASS'N OTOLARYNGOLOGY HEAD NECK SURGERY 1225, 1228–32 (2014) (noting that companies have an incentive to develop and market expensive cancer that may not be of much utility given that Medicare is required to pay for all cancer treatments regardless of actual benefit).

102. David Bruser et al., *Toronto Doctor Asks Health Canada About Pregnancy Drug, Gets 212 Pages of Censored Information*, THE STAR (Apr. 24, 2015), https://www.thestar.com/news/canada/2015/04/24/toronto-doctor-asks-health-canada-about-

Canada's Access to Information Act[103] and, after more than a year, obtained information, but the majority of pages provided were redacted as allegedly confidential, including information on adverse events.[104] Only after Canada revised its laws in 2014 to permit disclosure of clinical data to certain individuals without notifying the owner of the data[105] was Persaud able to obtain more information. This information ultimately revealed that, although Diclectin had been the recommended standard of care, that recommendation was based on a flawed 1997 study that overstated the benefits of the drug; it was no better than vitamin B6 alone.[106] Although the drug did not endanger patients, because doctors were misinformed about its lack of efficacy, patients and providers had wasted money on this drug. However, for years, Dr. Korean, a co-author of the study and paid consultant to the company, had been successfully promoting the drug.[107] Although no patients suffered after Persaud's public revelation, some professional societies continued to defend the corporate position.[108] However, one group of Canadian doctors published a correction criticizing its own earlier public recommendation.[109] This suggests that not only is disclosure of underlying clinical data important, but that earlier disclosure

pregnancy-drug-gets-212-pages-of-censored-information.html [https://perma.cc/ZFL6-5CTD]; Kelly Crowe, *Health Canada Requires Doctor to Sign Confidentiality Agreement to See Drug Data*, CBC (Oct. 14, 2015), https://www.cbc.ca/news/health/health-canada-drug-confidentiality-data-1.3269107 [https://perma.cc/VTC9-LM6C].

103. Access to Information Act, R.S.C. 1985, c. A-1, § 20(6) (Can.).

104. Bruser et al., *supra* note 102.

105. Protecting Canadians from Unsafe Drugs Act, S.C. 2014, c.24, § 21.1(3)(c). However, the data may be subject to a confidentiality agreement, even though the results of the study are to be made publicly available. Health Canada, Guidance Document - Disclosure of Confidential Business Information under Paragraph 21.1(3)(c) of the Food and Drug Act, ¶¶ 6, 9 (2017, rev., 2019) [hereinafter Canada Guidance ¶ 21.1(3)(c)]. Canada did in fact impose this requirement on Persaud. *E.g.*, Kelly Crowe, *Morning Sickness Drug Diclectin Doesn't Work, Confidential Industry Documents Reviewed By Doctor Show*, CBC News (Jan. 17, 2018), https://www.cbc.ca/news/health/diclectin-pregnancy-nausea-vomiting-persaud-duchesnay-confidential-industry-documents-health-canada-1.4491300 [https://perma.cc/5XHC-DP6S].

106. Jessica Chin et al., *Re-Analysis of Safety Data Supporting Dosylamine Use For Nausea and Vomiting of Pregnancy*, 31 Am. J. Perinatology 701, 701–02 (2013); Nivandra Persaud, *Should Doxylamine Be Used For Nausea and Vomiting During Pregnancy?*, 36 J. Obstetrics & Gynecology Canada 343, 346 (2014); *see also* Nivandra Persaud, *Doxylamine-Pyridoxine For Nausea and Vomiting of Pregnancy Randomized Placebo Controlled Trial: Prespecified Analyses and Reanalysis*, 13 PLoS One e0189978, 1–19 (Jan. 17, 2018) (finding no benefit after reviewing patient level data from Canada as well as some information from the United States).

107. Anne Kingston, *What You Don't Know About a Leading Morning Sickness Drug*, MacLeans (Oct. 23, 2015), https://www.macleans.ca/society/health/what-you-dont-know-about-a-leading-morning-sickness-drug/ [https://perma.cc/2FHV-AM89]. The efforts were highly effective as underscored by the fact that in 1989 less than 3% took the drug, whereas in 2015 half of pregnant women took the drug. *Id.*

108. *Id.*

109. Barbara Mantel, *Canada's Decision to Make Public More Clinical Trial Data Puts Pressure on FDA*, NPR (Oct. 11, 2019), https://www.npr.org/sections/health-shots/2019/10/11/769348119/canadas-decision-to-make-public-more-clinical-trial-data-puts-pressure-on-fda [https://perma.cc/HYV2-PXFC].

may be especially important.[110]

Increased transparency regarding clinical data may be especially important now. In recent years, there is an increasing number of drugs approved through accelerated pathways,[111] such that new drugs today may be approved based on preliminary evidence that does not definitively establish whether the drug is even effective for its intended purpose.[112] Indeed, some studies suggest that drugs approved under expedited conditions are more likely to be ineffective or even require post-market warnings.[113] In addition, clinical data may be important to development of biosimilars, which are highly complex drugs made of biological processes. In particular, the original drugs to which the biosimilar is comparable often are made with undisclosed trade secrets,[114] such that public disclosure of clinical data, which includes methods of drug manufacture, may be especially important for companies to develop cheaper versions.[115] Cheaper versions

110. Cynthia Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation,* 51 SAN DIEGO L. REV. 419, 438–42 [hereinafter Ho, *Drugged Out*] (noting individuals are reluctant to change established views, even in the face of contrary evidence).

111. Aaron Kesselheim, *Trends in Utilization of FDA Expedited Drug Development and Approval Programs, 1987-2014*, 351 BRIT. MED. J. 1 (2015) (noting statistically significant increase in drugs qualifying for expedited review). In the United States, there are multiple pathways that permit expedited approval of drugs, some of which lower the evidentiary standard. *See, e.g.*, Janet Woodcock, *Expediting Drug Development for Serious Illness: Trade-offs between Patient Access and Certainty*, 15 CLINICAL TRIALS 219, 230–31 (2018); *see also* Farrah Raja, *Evidentiary Standards for Drug Approvals in the 21st Century Cures Act*, 18 N.C. J. L. & TECH. 409, 418–21 (2017) (providing overview of approval processes and noting that drugs approved through these pathways have increased over time).

112. *E.g.*, Nicholas Downing et al., *Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents, 2005-2012,* 311 J. AM. MED. ASS'N 368, 373–74 (2014) (finding wide range of evidence supporting FDA approvals, with reliance on surrogate outcomes used as the exclusive basis in nearly half of the approved indications); *see also* Tracy Rupp & Dianne Zuckerman, *Quality of Life, Overall Survival and Costs of Cancer Drugs Approved Based on Surrogate Endpoints,* 177 J. AM. MED. ASS'N INTERNAL MED. 276, 276 (2017) (noting many expensive cancer drugs approved based on surrogate data such as tumor shrinkage did not result in any extension of survival time); Joseph Wallach et al., *FDA's Expedited Approval Programs: Evidentiary Standards, Regulatory Trade-offs and Potential Improvements*, 3 CLINICAL TRIALS 219, 223–24 (2018) (noting problems with surrogate markers).

113. *See, e.g.*, Jonathan Darrow et al., *The FDA Breakthrough Drug Designation - Four Years of Experience*, 378 NEW ENG. J. MED. 1444, 1448–50 (2018) (finding many drugs approved as breakthroughs are unlikely to provide substantial improvement); Wallach et al., *supra* note 112, at 225 (noting more post market safety actions for drugs approved in an expedited manner); *see also* Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production: Past and Future*, 102 MINN. L. REV. 2357, 2380–81 (2018) (explaining studies show drugs approved based on surrogates may not be effective and that more rigorous post approval studies are needed).

114. *E.g.*, W. Nicholson Price & Arti Rai, *Manufacturing Barriers to Biologics Competition and Innovation,* 101 IOWA L. REV. 1023, 1028 (2016); W. Nicholson Price, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1797–98 (2016); Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J. L. MED. & ETHICS 54, 58–61 (2019).

115. *E.g.*, Yaniv Heled, *Follow-On Biologics Are Set Up to Fail*, U. Ill. L. Rev. 113, 121 (2018); Heled, *The Case for Disclosure of Biologics Manufacturing Information*, *supra* note 114, at 58–64 (arguing that there is precedent for making data available and suggesting different ways to make the data available). Of course, if clinical data are disclosed, the

of these complex drugs are especially important because they are incredibly expensive—although they are a mere two percent of U.S. prescriptions, they constitute almost forty percent of U.S. prescription drug costs.[116]

II. Clinical Trial Transparency

Although the above public health problems easily illustrate the need for more transparency with clinical data, an important question is what transparency should entail. This Part first explains optimal clinical trial transparency. Then, it explains why most challenges to disclosure of clinical study reports are easily addressed.

A. Clinical Data as Part of Optimal Clinical Trial Transparency

Advocates of clinical trial transparency recommend three separate, yet complementary, requirements to ensure clinical trials are complete, scientifically sound, and publicly available in an efficient and accessible manner.[117] In particular, the requirements include:

> (i) prospective clinical trial registration in an online database of each trial (to avoid later outcome switching, such as what happened with antidepressant Paxil[118]),
> (ii) publication of summary results in the database promptly after clinical trials (to avoid time delays of journal publication and also provide uniform format of information that is not behind a publication paywall),
> (iii) disclosure of the underlying clinical study reports (CSR), i.e., the documents submitted to regulatory agencies that include trial methods and data.[119]

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critical know-how concerning how the original biologic was made could be considered proprietary and redacted, such that even countries permitting disclosure of clinical data may still not fully assist with development of biosimilars.

116. IQVIA INSTITUTE, BIOSIMILAR MARKET IN THE US 3 (2020); Avik Roy, *Biologic Medicines: The Biggest Driver of Rising Drug Prices*, FORBES (Mar. 8, 2019), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=5c94ece718b0 [https://perma.cc/5P7S-L5JK].

117. *E.g.*, Deborah Zarin & Tony Tse, *Sharing Individual Participant Data Within the Context of the Trial Reporting System,* 13 PLOS MED. e1001946, 1, 4 (Jan. 19, 2016); *see also* World Med. Ass'n, Declaration of Helsinki, *Ethical Principles For Medical Research Involving Human Subjects*, ¶¶ 35–36 (July 9, 2018) (recommending prospective trial registration and publication of summary results, but not mandating disclosure of all documents submitted to regulatory agencies). Full transparency may be particularly important considering that clinical trials not only may not be reproducible, but also often fail to enroll diverse subjects. *See, e.g.*, STAT, REPRESENTATION AND DIVERSITY IN CLINICAL TRIALS *passim* (2020) (noting that women, blacks, and older subjects are all poorly represented).

118. If the first clinical trial of the antidepressant Paxil had been prospectively registered to indicate the study objectives, it would have been impossible to publish articles with different outcomes than originally planned. *See* Le Noury et al., *supra* note 77 and accompanying text; *see also* BRUCKNER & ELLIS, *supra* note 62, at 4 (noting the importance of pre-registration to enable a doctor to realize the existence of a completed clinical trial so that he could pursue its publication when its sponsor had failed to do so for several years).

119. *E.g.*, BRUCKNER & ELLIS, *supra* note 62, at 2; ALLTRIALS, ALL TRIALS REGISTERED AND REPORTED 1 (2013); CRIT, *supra* note 18, at 18. In addition, prospective registration

Although companies at one point contested all requirements, most are not currently at issue. The public health scandals discussed in Part I resulted in broad attention and scrutiny[120] that eventually resulted in the United States enacting legislation in 2007 to require prospective registration of later-stage clinical trials[121] and publication of summary results in a public register.[122] Thereafter, the EU imposed registration requirements.[123] By 2008, there was broad international support for prospective registration, as well as publication of results, by the World Health Organization (WHO).[124] In addition, other countries also now have this requirement.[125] So, although the first two requirements were once vigorously contested,[126] those objections are now moot,[127] though compliance with

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should include metadata regarding trial protocols and statistical analysis plans. *See, e.g.*, CRIT, *supra* note 18, at 7.

120. *E.g.*, *Publication and Disclosure Issues in Antidepressant Pediatric Clinical Trials: Hearing Before the H. Comm. on Energy and Commerce*, 108th Cong. 26 (2004); *FDA, Merck and Vioxx: Putting Patient Safety First; Hearing before the S Comm on Finance*, 108th Cong. (2004); *see also* Sharon Jacobs, *Crises, Congress and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States*, 64 FOOD & DRUG L.J. 599, 615 (noting that there were almost 10,000 articles on Vioxx in 2004 alone).

121. 42 U.S.C. § 282(j)(2)(C)(ii) (2018) (requiring new clinical trials beyond phase I to submit the trial information to a registry no later than 21 days after first patient is enrolled); 42 C.F.R. § 11.24(a) (2016) (requiring submission of clinical trial registration); *see also* Seife v. U.S. Dep't of Health & Human Servs., 440 F. Supp. 3d 254 (S.D.N.Y. 2020) (noting that the Act sought to increase publicly available information to "help patients, providers and researchers learn new information and make more informed healthcare decisions"); Jacobs, *supra* note 120, at 616 (noting Vioxx scandals as important to prompting legislation). This legislation was able to be passed unlike prior attempts because the clinical trial requirements were combined with other industry desired legislation such as funding to promote expedited approvals. *E.g.*, Davik, *supra* note 56, at 740. However, for prior proposals, see Fair Access to Clinical Trials Act, HR 3196, 109th Cong. (2005); Fair Access to Clinical Trials Act, S. 470, 109th Cong. (2005), Fair Access to Clinical Trials Act, S. 467, 110th Cong. (2007); Enhancing Drug Safety and Innovation Act, S. 3807, 109th Cong. (2006); Enhancing Drug Safety and Innovation Act, S. 3807, 110th Cong. (2007).

122. 42 U.S.C. § 282(j)(3)(B) (2018).

123. Communication from the Commission Regarding the Guideline on the Data Fields Contained in the Clinical Trials Database Provided for in Article 11 of Directive 2001/20/EC to be Included in the Database on Medicinal Products Provided for in Article 57 of the Regulation (EC) No. 726/2004, 2008 O.J. (C 168) 3.

124. Davina Ghersi et al., *Reporting the Findings of Clinical Trials: A Discussion Paper*, 86 BULL. WORLD HEALTH ORG. 492, 492 (2008); *see also* World Med. Ass'n, Declaration of Helsinki, *supra* note 117, ¶¶ 19, 30 (2008) (noting researchers not only prospectively register every clinical trial, but also that researchers have a duty to make research results publicly available).

125. Lemmens & Telfer, *supra* note 19, at 72 (noting that Brazil, Argentina, India, and Japan all require mandatory registration).

126. *E.g.*, Laurence Hirsh, *Randomized Clinical Trials: What Gets Published and When?*, 170 CAN. MED. ASS'N J. 481, 482 (2004) (providing Merck view that existence of studies cannot be disclosed to protect IP despite acknowledging the existence of publication bias); Barry Meier, *Contracts Keep Drug Research out of Reach*, N.Y. TIMES (Nov. 29, 2004), https://www.nytimes.com/2004/11/29/business/contracts-keep-drug-research-out-of-reach.html [https://perma.cc/JA6Z-8642] (noting industry saw no need for reporting requirement to address revealed undisclosed antidepressant studies).

127. Even before the U.S. legislation, industry agreed to release summary results, albeit based on its own rules. Joint position on the Disclosure of Clinical Trial Informa-

these requirements remains challenging.[128] The third requirement of disclosing clinical study reports, however, remains an issue. Although the EMA and Canada have taken steps to disclose some of these reports, companies argue this is improper.[129] Nonetheless, clinical study reports are essential to doctors, insurers, and policymakers alike with an interest in evidence-based medicine.[130]

To better understand industry objections to disclosure of clinical study reports (CSRs), it is important to consider what they include. CSRs are lengthy documents in a standardized form that provide substantial detail concerning design, conduct, analysis, and outcomes of a trial.[131] The CSRs include the original objectives of the study and the basis by which some patients were excluded, as well as side effects experienced by patients. All this information is provided in substantially more detail than in public sources (such as summary reports online or scientific publications).[132] For example, one study found that CSRs provide twice as much information on patient outcomes than all publicly available sources combined.[133]

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tion via Clinical Trial Registries and Databases, *supra* note 56. This was likely prompted not only by the noted scandals, but also the fact that a number of major medical journals announced that prospective registration would be required for publication. *See* Catherine DeAngelis et al., *Clinical Trial Registration: A Statement from the International Committee of Med Journal Editors*, 141(6) ANNALS INTERNAL MED. 477 (2004).

128. *See* FDAAA TRIALSTRACKER, *supra* note 59 (noting compliance issues). This may be a particular problem with Covid-19 treatments since nearly two-thirds of current clinical trials are being conducted by entities that have previously failed to comply with the requirement to provide summary results of completed trials. *E.g.*, Ed Silverman, *Some Covid-19 Trial Sponsors Never Posted Other Study Results in an EU Database. Will They Hide the Data Again?*, STAT (June 17, 2020), https://www.statnews.com/pharmalot/2020/06/17/covid19-coronavirus-clinical-trials-transparency/ [https://perma.cc/3XUX-UC6J].

129. *E.g.*, Case T-73/13 R, InterMune U.K. et al. v. EMA, ¶¶ 1, 3–16 (Apr. 25, 2013) (noting challenge to EMA decision granting competitor Boehringer access to documents from marketing application of Esbriet) [hereinafter Case T-73/13R, InterMune]; Abbvie, Case T-44/13 R, ¶¶ 20–24 (Apr. 25, 2013) (noting challenge to EMA decision to grant access to documents from AbbVie's application for approval of Humira to treat Crohn's disease to a University student); *see also* Eur. Fed'n Pharma. Indus. Ass'ns [EFPIA], *Overview of Comments received on 'Publication and Access to Clinical-Trial Data' (EMA/342115/2014)*, 38 (2014) (EFPIA comments); EFPIA, EXECUTIVE SUMMARY: EFPIA SUBMISSION OF COMMENTS ON POLICY 0070 ON PUBLICATION AND ACCESS TO CLINICAL TRIAL DATA 2 (2013) [hereinafter EFPIA 2013 SUMMARY].

130. TRANSPARENCY INT'L, *supra* note 4, at 3.

131. Food and Drug Administration [FDA], *International Conference on Harmonisation: Guideline on Structure and Content of Clinical Study Reports*, 61 Fed. Reg. 37, 320 (July 17, 1996).

132. Barbara Mintzes, *Clinical Trial Transparency: Many Gains but Access to Evidence for New Medicines Remains Imperfect,* BRIT. MED. BULL. 1, 3 (2015).

133. Wieseler et al., *supra* note 60, at 1 (finding that clinical study reports provided complete information of 86% of patient relevant outcomes versus only 39% from publicly available sources regarding clinical study reports voluntarily provided by companies to the main Germany health assessment agency for drugs approved by 2011); *see also* Peter Doshi & Tom Jefferson, *Clinical Study Reports of Randomised Controlled Trials: An Exploratory Review of Previously Confidential Industry Reports*, 3 BRIT. MED. J. OPEN e002496, 1 (2013) (discussing CSR as most complete source of information).

CSRs are essential to combat information asymmetry and optimize medical treatment. Companies do not always disclose summary information to the public even when required by law, and even when they do disclose information, it may not be accurate.[134] The detail inherent in CSRs is helpful for doctors to make clinical decisions based on accurate information. In addition, CSRs can enable independent scientists to expeditiously assess the accuracy, reliability, and validity of results, rather than engage in time-consuming replication of studies. This independent review can help to counter misleading marketing information. Moreover, CSRs can be especially beneficial in evaluating comparative effectiveness of drugs within a class (i.e., all SSRI antidepressants) which can only be properly done with access to complete data.[135] Given all the rich detail provided in a CSR that is not available from other sources, researchers and public health advocates have often argued that this information should be available.[136]

The most controversial type of clinical data involves individual patient data (IPD), which includes case report forms for all metrics taken concerning individual patients. Some data may be included in the CSR, but typically not the data for each patient.[137] IPD will list every adverse event for individual patients and permit subsequent investigators the ability to see if the categorization of the adverse event was improper—as in the case of Paxil.[138] Individual patient data in conjunction with the CSR can provide the most accurate review of the original study.[139] Moreover, IPD from different studies may be combined to yield new information including comparative effectiveness analysis,[140] the impact of a drug on different subpopulations than originally studied groups,[141] alternative uses of existing treatments, more effective treatments, as well as form the basis of

134. *See infra* Part I.B.1.

135. *E.g.*, Wieseler, *supra* note 60, at 9.

136. *E.g.*, *id.* at 11; ALLTRIALS, *supra* note 119, at 4.

137. *E.g.*, Eur. Medicines Agency [EMA], *External Guidance on the Implementation of European Medicines Agency Policy on the Publication of Clinical Data for Medicinal Products for Human Use*, 90915/2016, at 86 (2016) (noting individual case report forms are not published).

138. TRANSPARENCY INT'L, *supra* note 18, at 23; Zarin & Tse, *supra* note 117, at 5.

139. *E.g.*, Zarin & Tse, *supra* note 117, at 3 (noting value of IPD with other requirements); Deborah Zarin, *Participant Level Data and the New Frontier of Clinical Trial Transparency*, 369 NEW ENG. J. MED. 468, 468 (2013) (noting information is lost between transformation of participant level data to summary results). Sometimes even without the CSR, researchers can make important findings based on summary data in conjunction with IPD. *E.g.*, Joshua Wallach et al., *Updating Insights into Rosiglitazone and Cardiovascular Risk through Shared Data,* 368 BRIT. MED. J. 17078 (2020) (establishing that prior blockbuster drug Avandia is associated with cardiovascular risk).

140. Hans-Georg Eichler et al., *Access to Patient Level Trial Data - A Boon to Drug Developers,* 369 NEW ENG. J. MED. 1577, 1577–78 (2013).

141. The WorldWide Antimalarial Resistance Network (WWARN) DP Study Group, *The Effect of Dosing Regimens on the Antimalarial Efficacy: A Pooled Analysis of Individual Patient Data*, 10 PLOS MED. E1001564 (2013) (finding best dosage of malaria treatment for young even without the existence of any single study devoted to this).

exploratory research that could lead to new discoveries.[142] Accordingly, some have advocated that de-identified IPD be shared.[143] However, there is no current consensus on sharing this data given privacy concerns if individuals could be identified, as well as substantial burdens to protect individual information.[144] Although the EMA has signaled that it intends to eventually disclose this information for recently approved drugs, Canada has decided not to do so.[145]

An alternative to government mandated disclosure is voluntary disclosure by companies. In fact, despite early opposition to registration and disclosure, the trade group Pharmaceutical Research and Manufacturers of America (PhRMA) has, since 2013, embraced principles for data sharing for CSR as well as individual patient data for approved drugs in the United States and Europe if approved by individual companies.[146] A number of

142. Eichler et al., *supra* note 140, at 1578; *see also* Jayne F. Tierney et al., *How Individual Participant Data Meta-Analyses Have Influenced Trial Design, Conduct and Analysis,* 68 J. CLINICAL EPIDEMIOLOGY 1325 (2015) (discussing value of meta-analysis using IPD).

143. *E.g.*, BRUCKNER & ELLIS, *supra* note 62, at 1; *see also* Kayvon Modjarrad, *Developing Global Norms for Sharing Data and Results During Public Health Emergencies,* 13 PLOS MED. 1, 4 (2016) (recommending that in an emergency, there is special justification to make this data available). Since January 2013, The British Medical Journal requires as a condition of publication that authors of drug studies agree to make this data available on reasonable request. *Open Data*, BRITISH MEDICAL JOURNAL, https://www.bmj.com/open-data [https://perma.cc/T8SK-MAJK] (last visited Feb. 22, 2022); Fiona Godlee & Tricia Groves, *The New BMJ Policy on Sharing Data from Drug and Device Trials*, 345 BRIT. MED. J. e7888 (2012). ICMJ abandoned a 2016 proposal to make IDP sharing compulsory in light of controversy, including concerns that patients might still be able to be identified despite de-identification efforts; instead, authors are to provide a data sharing plan, including if IPD will be shared that might be considered when manuscripts are evaluated. Darren Taichman et al., *Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors,* 95 BULL. WORLD HEALTH ORG. 482, 482 (2017).

144. E.g., NAM REPORT, *supra* note 4, at 98 (concluding that in most cases, sharing raw data from individual participants would be "overly burdensome and impractical," and not generally necessary for most secondary analysis); ALLTRIALS, *supra* note 119, at 6–7 (not currently recommending this, although recognizing significant consideration of the issue).

145. EMA Policy 70, *supra* note 5, at 4.2.4 (noting disclosure of this data is planned in the next phase); Canada 2019 Guidance, *supra* note 5, at 3.2 (noting because individual patient data includes extensive personal information, extensive modification is required to anonymize the information that would consume resources and "significantly reduces the research value").

146. PHRMA, PRINCIPLES FOR RESPONSIBLE CLINICAL TRIAL DATA SHARING 1–2 (2013); EFPIA 2013 SUMMARY, *supra* note 129. GSK, the company previously sued for fraud, will consider academic research requests for anonymized individual patient data. GLAXOSMITHKLINE [GSK], GSK PUBLIC POLICY POSITIONS: PUBLIC DISCLOSURE OF CLINICAL RESEARCH 2 (2019), https://www.gsk.com/media/2946/disclosure-of-clinical-trial-information-policy.pdf [https://perma.cc/VP64-GUD6]; Perry Nisen & Frank Rockhold, *Access to Patient-Level Data From Glaxosmithkline Clinical* Trials, 369 NEW ENG. J. MED 475, *passim* (2013) (explaining GSK sharing since 2013); *see also* Deborah Zarin, *Participant Level Data and the New Frontier of Trial Transparency,* 369 NEW ENG. J. MED. 468, 468 (2013) (discussing GSK's limited approach to sharing with qualified researchers, as well as a more open policy to participant level data). Johnson & Johnson began to do so in 2014. Kevin Outterson, *Clinical Trial Transparency–Antidote to Weaker Off-Label Promotion Rules?*, 371 NEW ENG. J MED 1, 2 (2014). Bristol-Meyer Squibb trial data exists through partnership with Duke, whereas data from Johnson & Johnson and Medtronic

companies have made data available, although what is shared, as well as the manner of data sharing (including even the process for evaluating requests), differs.[147] A 2017 audit of actual data shared revealed high variability.[148] Although voluntary disclosures by companies are not uniform, they can nonetheless yield valuable information, and, since 2012, roughly a half dozen platforms permit sharing of some data with academic researchers for approved projects.[149] For example, using IPD from GlaxoSmithKline (GSK), researchers were able to clarify uncertainties concerning a drug traditionally used to treat type 2 diabetes that had previously been subject to conflicting findings concerning whether it increases risk of heart attacks almost two years after approval.[150] Nonetheless, since there is no standardized format for how voluntary data are shared, the utility of material potentially disclosed to independent researchers is unlikely to be use-

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are available in conjunction with university-based platforms such as the Yale University Open Data Access Project. *E.g.*, Pranammya Dey et al., *Data Sharing and Cardiology: Platforms and Possibilities,* 70 J. Am. College Cardiology 3018, 3021 (2017); J. Ross et al., *Overview and Experience of the YODA Project with Clinical Trial Data Sharing After 5 Years*, 5 Sci. Data 180268, *passim* (2018); Harlan Krumholz, *The Yale Open Data Access (YODA) Project–A Mechanism for Data Sharing,* 375 New Eng. J Med 403, *passim* (2016).

147. *E.g.* Daniel L. Shaw & Joseph S. Ross, [*U.S.*] *Federal Government Efforts to Improve Clinical Trial Transparency with Expanded Trial Registries and Open Data Sharing,* 17 Am. Med. Ass'n J. 1152, 1155 (2015) (noting differences in scope and access to data, with some having cumbersome data use agreements); Harlan Krumholz et al., *Sea Change in open science and Data Sharing: Leadership by Industry*, 7 Circ. Cardiovascular Quality Outcomes 499, 500-03 (2014) (detailing different data sharing procedures of top twelve pharmaceutical companies). Sometimes self-interested companies may decide whether to give permission whereas other times there is an independent review board that makes the decision. *E.g.*, Michael J. Pencina et al., *Supporting Open Access to clinical trial data for researchers: The Duke Clinical Research Institute-Bristol-Myers Squibb Supporting Open Access to Researchers Initiative,* 172 Am. Heart J. 64, 64 (2016) (noting individual company total discretion versus independent review committees led by academic centers, or multi-sponsor collaborations for reviewing data requests).

148. Ben Goldacre, *Pharmaceutical companies' policies on access to trial data, results and methods: audit study*, 358 Brit. Med. J 1, 4–5 (2017). Although industry groups issued a public statement that they were committed to registering all clinical trials, this study indicates almost thirty percent did not, despite this being the most minimal level of transparency. *Id.*at 5; *see also* EFPIA/PHARMA, Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009, rev. 2018). In addition, some company disclosure policies did not match the 2013 industry position, although that position was admittedly not binding. Goldacre, *supra* note 88, at 88.

149. *E.g.*, Fishburn & Usdin, *supra* note 61, at 17–18. However, the utility of these may be limited not only by the fact that approval is required, but that many do not permit downloadable data or only provide limited access to the control arm but not to the treatment arm. *Id.*

150. Joshua D. Wallach et al., *Updating Insights Into Rosiglitazone and Cardiovascular Risk Through Shared Data: Individual Patient and Summary Level Meta-Analyses,* 368 Brit. Med. J. 1, 11 (2020). After considering the IPD, independent researchers conclusively found an increased risk and also that the IPD provided higher risks of heart attacks than analysis based on clinical summary reports. *Id.* at 12; *see also* Sayuri Gavaskar, *Yale study Adds to Evidence of Diabetes Drug Link to Heart Problems*, Yale Sch. Med. (Feb. 11, 2020), https://medicine.yale.edu/news-article/22570/ [https://perma.cc/C7ST-V6GL] (news release concerning study).

ful since it minimizes the ability to truly compare information.[151] Moreover, another issue is that, since disclosure is voluntary by self-interested companies, disclosure likely will not be granted with the goal of maximizing public interests.

B. Intellectual Property and Innovation Issues with Disclosure of Clinical Study Reports

Although the EMA and Canada have taken the lead in making clinical study reports available prospectively for newer drugs, whether this disclosure continues and expands requires consideration of intellectual property issues which the industry consistently raises. This Section addresses domestic and international objections that have been raised thus far. Although the industry has not always been consistent or coherent in its objections,[152] this Section will refute their most plausible claims.[153] This Section first explains why disclosure will not limit IP rights or innovation or unduly benefit competitors. Then, this Section ends with a discussion of alleged violations of TRIPS discussed by domestic courts to highlight that these issues have thus far not been fully or properly analyzed.

1. Disclosure Does Not Unduly Limit IP Rights or Innovation or Benefit Competitors

There are several types of IP rights that have been asserted to be potentially compromised by disclosure of clinical data: trade secrets, data exclu-

151. *See* Mohamed Shahin et al., *Open Data Revolution in Clinical Research: Opportunities and Challenges*, 13 CLINICAL TRANSLATION SCI. 665, 672 (2020) (noting that non-standardized data collection could result in trial design and other study complexities being missed and result in incorrect evaluation of data that undermines the goals of data sharing).

152. Companies often have shifting reasons for lack of disclosure. *E.g.*, Peter Doshi et al., *The Imperative to Share Clinical Study Reports*, 9 PLOS MED. e1001201, 4–5 (2012) (noting shifting objections of Roche, the manufacturer of Tamiflu, against disclosure of CSRs with shifting and unfounded reasons such as the claim asserted that published articles provided adequate information—even though it was well-known at that time that published articles do not provide complete or even accurate data); *see also* Peter Doshi, *Putting GSK to the Test Over Paroxetine*, 347 BRIT. MED. J. 15, 16 (2013) (GSK asserted that there is no need to disclose CSRs to researchers since it is provided to regulatory authorities, rather than assert that it was confidential information).

153. Some weak industry claims include that disclosure would undermine trust in regulatory approval, be of little value, and result in inappropriate analyses, and compromise patient privacy. *E.g.*, EFPIA 2013 Summary, *supra* note 129. The claim that disclosure of data will undermine trust in regulatory authority is nonsensical in light of the fact that many nations have legal mechanisms permitting disclosure of information. *E.g.*, 5 U.S.C. § 552 (2018) (providing US agencies should generally make information publicly available); Access to Information Act, R.S.C. 1985, c. A-1, ¶¶ 4(1), 20(1) (providing right to obtain information within possession of government agencies) [hereinafter Access to Information Act]; Regulation No. 1049/2001 of the EU Parliament and of the Council, L 145/43 art. 4(2) (providing right to obtain information from EU agencies). Also, the claims that the info would be of little value or result in inappropriate analysis are completely undermined by the unnecessary public health tragedies that have resulted from lack of disclosure.

sivity, and patent protection. However, as will be explained, there is no inherent conflict.

Trade secret protection is a claim that has often been raised against disclosure of clinical trial data. Companies,[154] as well as domestic regulatory authorities, have asserted that the *entirety* of clinical study reports constitute trade secrets that cannot be disclosed.[155] However, a trade secret must be information that is confidential and retains commercial value from not being generally known.[156] Accordingly, as courts and commentators have properly noted, the entirety of clinical study reports is not a trade secret.[157] This is because CSRs often contain information revealed through other means such as through public presentations. In addition, CSRs provide data based on standard tests and protocols that would be known in the industry and applicable to any drug.[158] Even if there might be a trade secret process used, that could be redacted and would not justify considering the entirety of the document confidential. Overly broad claims that the entirety of CSRs constitute trade secrets should not have much weight given prior rejections by domestic courts and regulators.[159] Notably, after an EU regulation declared that CSRs would not be entirely confidential once regulatory approval was granted,[160] AbbVie abandoned its prior legal challenge to block the EMA from disclosing the CSRs to its

154. Case T-44/13, EMA v. AbbVie, Ltd., Order of the Vice-President of the Court, ECLI:EU:C:2013:794, ¶¶ 18, 28, (Nov. 28, 2013) [hereinafter Case T-44/13, AbbVie, Order]; *see also* EFPIA comments to EMA on Publication and Access to Clinical-Trial Data, EMA/24090/2013 (stakeholder 5) at 38 (2013), https://www.ema.europa.eu/en/documents/comments/overview-comments-received-publication-access-clinical-trial-data-ema/240810/2013-stakeholder-01-88_en.pdf [https://perma.cc/MZ4L-2HNZ] (asserting improper interpretation of a judicial decision granting it interim relief from EMA disclosure based on the need for delicate assessments not appropriate to interim relief given lack of case law).

155. See sources cited *supra* note 1; Davik, *supra* note 56, n. 273–77.

156. *E.g.* UTSA, *supra* note 15, § 1.

157. *E.g.*, Case T-44/13, AbbVie *supra* note 154, ¶¶ 62–63; Case T-73/13R, InterMune, *supra* note 129, ¶¶ 48–49; Case C-175/18P, PTC Therapeutics Int'l, Ltd. v. EMA, Judgment of the General Court, ¶ 53 (Feb. 5, 2018), *aff'd* EU Court of Justice (Fourth Chamber), ECLI:EU:C:2020:23, ¶ 83 (Jan. 22, 2020), https://curia.europa.eu/juris/document/document.jsf?text=&docid=222502&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=2162833 [hereinafter Case C-175/18P, PTC].

158. Peter Gotzsche & Anders Jorgensen, *Opening Up Data at the European Medicines Agency*, 342 BRIT. MED. J. 1, 2 (2011); Decision of the European Ombudsman closing his inquiry into complaint 2560/2007 against the European Medicines Agency [EMA], 2560/2007/BEH, ¶ 78 (Nov. 24, 2010) [hereinafter Decision of the European Ombudsman].

159. Case C-175/18P, PTC, *supra* note 157, ¶¶ 81–83; AIDS Healthcare Foundation v. F.D.A., No. CV 11-07925 MMM (JEMx), 2014 WL 10983763, Order Re: Defendant's Motion for Summary Judgment (C.D. Cal. Feb. 13, 2014) (finding that FDA failed to show safety and efficacy record were confidential and thus ordering FDA to provide unredacted copies to the FOIA requester); Public Citizen Health Research Group v. F.D.A. et al., 704 F.2d 1280, 1290, n. 28 (D.C. Cir. 1983) (noting that not all information in clinical data submitted to FDA submitted constitutes commercially confidential information immune from FOIA requests).

160. Commission Regulation 536/2014, *supra* note 5, ¶ 68.

Humira drug to researchers.[161] AbbVie also stopped asserting that the *entirety* of CSRs should be confidential.[162] Indeed, even before this time, the industry may have realized that claiming the entirety of CSRs as confidential was untenable since a 2013 industry document states that CSRs *may* contain commercially sensitive information.[163] Accordingly, despite previous complaints from the industry, it seems appropriate to consider CSRs for approved drugs not to be presumptively confidential since they are not entirely comprised of trade secret information.[164]

Allegations that disclosure of a portion of a CSR would compromise a trade secret and/or give an undue advantage to competitors are also generally unjustified. Although companies have repeatedly asserted that CSRs will provide a short-cut to competitors that want to develop similar drugs, courts have rejected such claims since they are typically made without any support.[165] CSRs typically do not contain any information on the actual medical product, but instead focus on clinical observations from using the product.[166] Indeed, a U.S. court has rejected a claim that a competitor could use information in a disclosed CSR to more rapidly support its own new drug application as overly conclusory.[167]

Disclosure of CSRs is often suggested to undermine data exclusivity, which is a slightly complicated issue since the claim about undermining data exclusivity often relates to a different jurisdiction than the one that discloses the data. As a reminder, in the many countries that recognize this protection, during the duration of data exclusivity, a second company is barred from relying on the submitted data to obtain speedy approval of a generic version. The concern with disclosure of CSRs is that if the EMA discloses CSRs of a company such as Pfizer, this might compromise the company's ability to obtain data exclusivity in another country to the

161. Press Release, EMA, EMA Confirms Withdrawal of Two Court Cases Concerning Access to Clinical Data (Apr. 3, 2014), https://www.ema.europa.eu/en/news/ema-confirms-withdrawal-two-court-cases-concerning-access-clinical-trial-data [https://perma.cc/3TMW-SRVL].

162. European Ombudsman, Case OI/3/2014/FOR, *Decision on Own-Initiative Inquiry* Oi/3/2014/FOR *Concerning the Partial Refusal of the European Medicines Agency to Give Public Access to Studies Related to the Approval of a Medicinal Product*, Report, ¶ 17 (June 9, 2006), https://www.ombudsman.europa.eu/mt/decision/en/68107 [https://perma.cc/R89S-XTQY].

163. EFPIA 2013 SUMMARY, *supra* note 129, at 2.

164. This would also seem consistent with research ethics in the Belmont Report that emphasize the principle of beneficence. *See* THE NAT'L COMM'N FOR THE PROTECTION OF HUM. SUBJECTS, BELMONT REPORT 5 (1979).

165. *E.g.*, Case C-175/18P, PTC, *supra* note 157, ¶ 101; Case T-44/13, AbbVie, *supra* note 154, ¶ 60; Gov't Accountability Project [GAO] v. U.S. Dep't of Health & Human Servs. [HHS], 691 F Supp.2d 170, 178–79 (D.D.C. 2010); *see also* Decision of the European Ombudsman, *supra* note 158, ¶ 49 (asserting that disclosure of CSR would be used by competitors to develop competitive products).

166. *E.g.*, Decision of European Ombudsman, *supra* note 158, ¶ 81 (noting that CSRs at issue contain no information on composition of drug such that it couldn't be used by competitors seeking to gain advantage in creating similar product); Case C-175/18P, PTC, *supra* note 157, ¶ 101 (finding CSR at issue had no information on the composition or manufacturing given that EMA had redacted such information).

167. GAO v. HHS, *supra* note 165, at 178–79.

extent that data exclusivity is only granted to confidential information.[168] There are multiple problems with this claim. First, data exclusivity often expires before patent protection, such that a company that "only" has patent protection still has substantial market power against competitors.[169] In other words, even if a competitor could theoretically get regulatory approval for a generic drug more quickly due to loss of data exclusivity, it could not make the drug without infringing a patent that covers the drug.[170] Also, countries sympathetic to industry concerns can modify data exclusivity laws to provide exclusivity if disclosure was from another regulatory agency. However, considering that there are serious concerns about over-protection of drugs that results in high costs to society, whether this approach is good policy is questionable.[171]

Any potential loss of data exclusivity does not necessarily result in corollary benefit to competitors. Although some have suggested that a competitor could use published data to obtain regulatory protection, i.e., passing off the data as its own, this is likely a theoretical problem. First, even if the competitor obtained regulatory approval, it would likely still be barred from making and selling the drug by patent laws. In addition, a number of jurisdictions permit marketing approval of a drug already approved in another country without any clinical data.[172] Even if clinical data were required for marketing approval, since most authorities are disclosing data only with redactions and watermarks, it would seem impossible for a competitor to use another's data as its own.[173] Domestic

168. AUSTL. PHARMA. PATENTS REV. 8.9 (2013) (noting that publication of clinical data could bar data exclusivity in a different country if publication was not adequately coordinated on an international level).

169. *E.g.*, ICTSD-UNCTAD, DIALOGUE ON ENSURING POLICY OPTIONS FOR AFFORDABLE ACCESS TO ESSENTIAL MEDICINES (2004).

170. *See* 35 U.S.C. § 271(a) (2018).

171. *E.g.*, IMAK, OVERPATENTED, OVERPRICED 1, 11 (2018), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf [https://perma.cc/K3AP-LEM8]; Aaron S. Kessleheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J AM. MED. ASS'N 858, 858 (2016). This is especially true since some have suggested that data exclusivity laws may fail to incentivize companies to promptly seek regulatory approval in poorer countries, thus resulting in poorer countries paying more for drugs long after they are available as low-cost generics in other countries. Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkag*e, 34 AM. J. L. & MED 303, 310 (2008).

172. *E.g.*, *Final Advice to the European Medicines Agency from the Clinical Trial Advisory Group on Legal Aspects*, CLINICAL TRIAL ADVISORY GROUP (CTAG5) 1, 3 (Apr. 30, 2013) [hereinafter Final Advice to the EMA]; Amy Kapczynski, *The Interaction Between Open Trial Data and Drug Regulation in Selected Developing Countries*, *commissioned by* NAT'L ACADEMY MEDICINES COMM. ON STRATEGIES FOR RESPONSIBLE SHARING OF CLINICAL TRIAL DATA 1, 3-8 (2014), https://law.yale.edu/sites/default/files/area/center/ghjp/documents/kapczynski_interaction_between_open_data_report_for_nam_.pdf [https://perma.cc/HTP8-VAKZ] (noting that emerging markets like India and China permit approval of regulatory applications without full clinical data, such that disclosure of CSR is not relevant).

173. This is true for recently approved drugs, but there is a possibility that some unredacted data could be disclosed under Canadian laws and without watermarks. *See infra* Part III.B.1.

regulatory agencies could also seek to minimize concerns by either international coordination[174] or mechanisms to prevent resubmission of data,[175] and/or penalties that could include a bar to subsequent regulatory approval.[176]

Some allege that disclosure of CSRs will undermine patent protection, although this is among the weakest of the IP claims. Notably, some have asserted that disclosure of CSRs would make information in the CSRs publicly available such that a patent could not thereafter be submitted for any information disclosed therein since it would violate the "newness" (or "novelty") requirement.[177] However, this is unlikely since companies seek patent protection long before clinical trials even start.[178] Even in the unusual situation that a new drug composition or new use of a drug was discovered in the process of the clinical trials—given that clinical trials take years and CSRs are not disclosed until after the trials are completed and after completion of regulatory approval—there would still be plenty of time for companies to seek patent protection. In addition, new uses can be protected by data exclusivity in some countries.[179] Moreover, scholars and policymakers are actually concerned that companies are too easily patenting new uses of known compounds to extend patent terms.[180] So, there is no fundamental patent problem with disclosure of CSRs.

In addition, claims relating to inadequate protection of any type of IP often assert that inadequate IP protection impedes innovation. Such claims are often raised without any support.[181] Empirical studies have yet to provide any basis for this claim that has been made in other contexts; although the industry repeatedly asserts that IP rights are essential for

174. AUSTL. PHARMA. PATENTS REV., *supra* note 168, at 8.9, Recommendation 8.1.

175. Agreements can provide contractual restrictions and regulators can provide restrictions on disclosed data (i.e., watermarks and/or technologically limit download capacities). Sean A. Coady et al., *Use of the National Heart, Lung and Blood Institute Data Repository*, 376 NEW ENG. J. MED. 1849 (2017); Joseph S. Ross et al., *Overview and Experience of the Yoda Project with Clinical Data Sharing After 5 Years*, 5 SCI. DATA 180267 (2018).

176. *E.g.*, Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs*, 109 CALIF. L. REV. 493 (Apr. 2021).

177. *E.g.*, Final Advice to the EMA, *supra* note 172, l. 311–21 (2013).

178. Decision of the European Ombudsman, *supra* note 158, ¶¶ 77–79; *see also* 35 U.S.C. § 102(a)–(b) (2018) (stating that public knowledge bars patentability).

179. 21 U.S.C. §§ 355(c)(3)(E)(iii)–(v), (j)(5)(F)(iii)–(iv) (2018); 21 C.F.R. § 314.108 (2016).

180. *E.g.*, AUSTL. PHARMA. PATENTS REV., *supra* note 168, § 6, at 105–09 (noting that new uses can be part of a corporate strategy of "evergreening"); EUR. COMM'N, PHARMA. SECTOR INQUIRY (2009) (noting concern that new use patents are improperly used to stifle competition); Scott Hempel & Bhaven N. Sampat, *Evergreening, Patent Challenges and Effective Market Life in Pharmaceuticals,* 31 J. HEALTH ECON. 327, 327–28 (2012); Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications and the FDA*, 4 IOWA L. REV. 1129 (2019); *see also* Amy Kapczysnski et al., *Polymorphs and ProDrugs and Salts (Oh My!): An Empirical Analysis of Secondary Patents*, 7 PLOS e49470 (2012) (empirically evaluating patent strategies that include new uses).

181. *E.g.*, EFPIA 2013 SUMMARY, *supra* note 129, at 2 (noting that proposed disclosure of CSR is a "threat to research and innovative medicine development").

innovation, studies show that more IP protection correlates with greater use of these rights but not necessarily more innovation.[182] In the specific context of disclosing data, it should be noted that companies have not ceased developing drugs or seeking regulatory approval even where disclosure has been clearly mandated.[183] This is not surprising given that a change to U.S. law that permitted it to disclose data previously submitted for approval of agricultural products resulted in no reduction in subsequent requests for approval, despite similar claims from the agricultural industry that disclosure would reduce innovation.[184]

Companies may be concerned competitors can identify possible errors in data or inconsistencies that they can then use to their advantage.[185] However, even if this benefits a competitor, it importantly benefits the public interest in uncovering truth that would otherwise be hidden.[186] This is especially true given the myriad harms that lack of disclosure is known to have caused. So, public interest is furthered by disclosure and should be prioritized over corporate interest in maximizing sales through secrecy.

Disclosure of clinical study reports may actually *improve* innovation and reduce costs. Disclosure may result in avoiding wasteful duplication of development of unsuccessful drug candidates. This is especially true because without CSRs, it is difficult to obtain information about ineffective drugs given the tendency for journals to only publish positive results.[187] In addition, broader disclosure on risks and benefits of drugs could promote socially desirable innovation. Currently, the majority of new drugs do not provide improvements; yet, due to substantial marketing in conjunction with an information vacuum, these new drugs are frequently used.[188] If the public had more information, companies would need to actually develop innovative drugs, rather than mediocre but heavily marketed products.

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182. *See* Ho, *Drugged Out*, *supra* note 110, at 472–75. Less protection through disclosure of CSR would seem unlikely to result in decreased innovation. Morten & Kapczynski, *supra* note 176.

183. Less protection through disclosure of CSRs would seem unlikely to result in decreased innovation. *See generally* Morten & Kapczynski, *supra* note 176.

184. Heled, *The Case for Disclosure of Biologics Manufacturing Information*, *supra* note 114, at 58–61. Moreover, there was a marked improvement in safety. *E.g.*, *id.*

185. *E.g.*, Final Advice to the EMA, *supra* note 172, at 3. Indeed, a number of the initial requests for disclosure of clinical data from the EMA were actually from corporations rather than independent scientists. Sergio Bonini, *Transparency and the European Medicines Agency-Sharing of Clinical Trial Data*, 371 NEW. ENG. J. MED. 2451, 2451 (2014).

186. This logic can also be seen in the fact that many countries permit competitors to challenge patents of other companies since these admittedly self-interested companies can help supplement the limited resources of patent examiners. *E.g.*, *Opposition Systems*, WORLD INTELL. PROP. ORG. [WIPO], https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html [https://perma.cc/QC8M-67AQ].

187. Gotzsche & Jorgensen, *supra* note 158, at 2–3.

188. *See* Ho, *Drugged Out, supra* note 110, at 457–65 (noting that although industry believes that drugs are innovative, that is based on selective views of the evidence).

2. TRIPS Issues Are More Challenging

Although there are strong policy reasons for making clinical study reports publicly available, domestic regulators can nonetheless be constrained by TRIPS. In particular, although there has not yet been a formal WTO challenge to domestic disclosure of clinical study reports, some domestic courts have wrestled with claims that such disclosures violate TRIPS.[189] The EMA itself previously argued that disclosure would violate TRIPS article 39(3) based on its assumption that the requirement to protect data submitted to it from unfair commercial use would be violated.[190] A 2010 Ombudsman opinion rejected this claim, correctly noting that TRIPS permits disclosures pursuant to two exceptions, including where necessary to protect the public or if steps are taken to ensure data are protected against unfair commercial use.[191] The EMA never explained why disclosure would result in unfair commercial use given that it was sought by independent scientists.[192] More recently, PTC Therapeutics argued that this provision means that CSRs are entitled to a general presumption of confidentiality,[193] which was rejected by the General Court that first addressed this issue, and affirmed by the EU Court of Justice.[194] The Court of Justice found the EMA adequately fulfilled its duty to protect the data from unfair commercial use through various mechanisms, including providing EU data exclusivity.[195]

Notably, none of these opinions considered how TRIPS should be properly interpreted as an international agreement. That is not entirely surprising since international laws are not the province of such courts and generally do not even directly apply to domestic actors. Nonetheless, it may be helpful to acknowledge that TRIPS issues raised thus far have been incompletely analyzed. Part III provides such an interpretation.

III. International Constraints—TRIPS

Although domestic courts have not provided a robust analysis of the key sentence of TRIPS article 39(3), it is nonetheless an important con-

189. Notably, TRIPS issues are sometimes raised with little explanation of the alleged violation by industry. *E.g.*, PHRMA SPECIAL 301 SUBMISSION 2019, at 50–51 (arguing that the 2014 amendments to Canadian food and drug laws as well as the 2019 regulation declaring clinical data to cease to be confidential for an approved drug violate TRIPS article 39 and expressing concern about a 2018 Canadian decision ordering clinical trial data be released without expressly stating whether this violates article 39(3)).

190. Decision of the European Ombudsman, ¶ 14 (noting that the EMA believed it must protect submitted data from disclosure except if access was necessary to protect the public although not discussing whether disclosure would be necessary to protect the public).

191. *Id.* ¶ 38.

192. *Id.* ¶ 67.

193. *See* Case C-175/18P, PTC, *supra* note 157.

194. *Id.* ¶¶ 61–65.

195. *Id.*, ¶ 71. *But see* Case C-175/18P, PTC v. EMA, Opinion of Advocate General, ECLI:EU:C:2019:709, ¶¶ 89–97 (Sept. 11, 2019), https://curia.europa.eu/juris/document/document.jsf?text=&docid=217636&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=2179387 (disagreeing with General Court).

straint on domestic laws that must be considered and properly analyzed.[196] This Part provides such an analysis. Section A first explains how to interpret TRIPS, then applies this interpretation to the two obligations under TRIPS article 39(3). After explaining how to properly interpret TRIPS article 39(3), Section B evaluates what domestic disclosure policies comply.

A. TRIPS

1. Article 39(3) Overview

TRIPS article 39(3) permits countries to disclose clinical data submitted to regulatory authorities; however, this ability is an exception to a general obligation. So, it makes sense to start by looking at the entirety of Article 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. *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.*[197]

This provision has two separate obligations, and each sentence provides a slightly different obligation. The first obligation (sentence one) is to protect undisclosed data submitted to governments for regulatory approval of drugs from undefined "unfair commercial use."[198] The second obligation (sentence two) is to protect this data from disclosure, subject to two exceptions (one of which refers once again to undefined "unfair commercial use").[199] In other words, sentence one focuses on government obligations to prevent individuals or companies from "unfair commercial use" *if* the government does not disclose the data whereas sentence two has two exceptions that permit a government to disclose data. Domestic laws that require publication of clinical data only address the obligation to protect data from disclosure—the italicized portion of TRIPS article 39(3), above. However, given that this refers to "unfair commercial use," which is also part of the first sentence, it is still important to define that part.

The key (italicized part) of article 39 provides two possible bases for a country to disclose data with some very broad language. First, disclosure is possible where "necessary to protect the public," without any definition of what would be "necessary" or what it means to "protect the public."

196. If a nation fails to comply with TRIPS, another WTO member country could bring an action challenging that lack of compliance, which could ultimately result in trade sanctions. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

197. TRIPS, *supra* note 6, art. 39(3) (emphasis added).

198. *Id.*

199. *Id.*

Second, disclosure is possible where "steps" are taken to "ensure" the data are protected against the undefined term "unfair commercial use." As will be explained, the pivotal term "unfair commercial use" is not defined in TRIPS. This lack of definition in conjunction with additional context support member states self-defining this term. As will be explained, the entirety of article 39 focuses on policing bad acts rather than providing exclusive rights, and other key context supports member states self-defining terms, especially in a way that helps promote a balance between IP owners and users.

2. TRIPS Interpretation

a. Interpretive Approach and Principles

All TRIPS provisions should be interpreted according to the Vienna Convention rules for interpreting international agreements.[200] In particular, TRIPS provisions are to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose."[201] In other words, a subsection of an article (e.g., article 39(3)) should be interpreted in light of the entire TRIPS article (e.g., article 39) as well as the objects and purposes of TRIPS. Importantly, amongst the different interpretative tools of "ordinary meaning, context, and overall object and precedence, there is none that takes precedence;"[202] as stated by one panel, there is one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order.[203]

The object and purpose of TRIPS are specifically articulated in TRIPS articles 7–8, which are titled "Objectives" and "Principles."[204] Secondary material, such as negotiating history and the circumstances of a treaty's conclusion, is only considered to confirm an interpretation achieved by the usual interpretation, or if the usual interpretation leads to an interpretation that is ambiguous or an absurd result.[205]

Of course, a key question is what constitutes the relevant context for interpreting a provision of TRIPS. The interpretative context includes not only other clauses of the same article at issue but also other key aspects of

200. DSU, *supra* note 7, art. 3(2).

201. Vienna Convention on the Law of Treaties art. 31, *opened for signature* May 23, 1969, 1144 U.N.T.S. 331 [hereinafter Vienna Convention].

202. HIROKE YAMANE, INTERPRETING TRIPS 196 (2011).

203. Panel Report, *United States—Sections 301-310 of the Trade Act of 1974*, ¶ 7.22, WTO Doc. WT/DS152/R (adopted Jan. 25, 2000) [hereinafter Section 301 Panel Report].

204. *Id.*; World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 ILM 746, ¶ 5(a) (2002) [hereinafter Doha Public Health Declaration]; Appellate Body Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, ¶ 6.658, WTO Doc. WT/DS435/AB/R (adopted June 9, 2020) [hereinafter Appellate Body Report (Australia)] (confirming that the Doha Public Health Declaration reflects applicable rules of interpretation, which require consideration of context, object, and purpose of TRIPS).

205. Vienna Convention, *supra* note 201, art. 32.

TRIPS, such as the overarching goals set forth in TRIPS articles 7–8 and the overall structure of the agreement. Notably, TRIPS binds countries to comply with minimal rather than uniform levels of protection.[206] For example, article 1 of TRIPS clearly states that "[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[207] Since this article states that members may optionally provide more than what TRIPS requires, it is clear that there can be variation in how members properly comply with TRIPS, with some members electing to provide more or less IP protection.[208] In addition, the entirety of TRIPS requires member states to provide minimum levels of IP rights as well as some enforcement measures. However, although a few key articles of TRIPS such as "Objectives" and "Principles" are relevant to interpretation of every article of the agreement, not every article therein is always pertinent. Particularly, since TRIPS provides rules regarding a range of IP rights, provisions relating to one right generally do not provide context for unrelated rights. So, for example, the articles on copyright law typically do not have any bearing on articles concerning patent law.

Moreover, subsequent agreements between the parties are also to be considered alongside this context.[209] The 2001 Doha Public Health Declaration that was uniformly adopted by all WTO members can be considered such an agreement.[210] The Declaration reaffirms the importance of using articles 7–8 for interpreting TRIPS.[211] The Declaration also emphasizes the importance of public health by stating that TRIPS "can and should be interpreted and implemented in a manner supportive of . . . public health" while consistent with the TRIPS agreement.[212] In other words, the Declara-

206. TRIPS, *supra* note 6, art. 1 ("[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"); *see also* CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 27 (2007) ("[the] TRIPS Agreement cannot be seen as a uniform law, but rather as a set of elements that IPR national laws must observe, thereby leaving members . . . significant room for interpreting and implement its provisions in accordance with the Members' policy objectives and legal systems.").

207. TRIPS, *supra* note 6, art. 1; *see also* CORREA, *supra* note 206, at 27.

208. CORREA, *supra* note 206, at 27.

209. Vienna Convention, *supra* note 201, art. 31(3)(a) (subsequent agreement).

210. Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, ¶ 7.208–7.220, WTO Doc. WT/DS435/R (adopted June 28, 2018); *see also* OWAIS H. SHAIKH, ACCESS TO MEDICINE VERSUS TEST DATA EXCLUSIVITY 57 (2016) (noting that the Declaration is "considered one of the very few documents as a subsequent agreement" of TRIPS); James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties,* 15 HARV. J.L. & TECH. 291, 300–03 (2002).

211. *See* Doha Public Health Declaration, supra note 204, art. 4.

212. *Id.* The entirety of this provision reads as follows:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Mem-

tion reaffirms the public health emphasis of article 8 as well as the need for balanced IP rights in article 7 of TRIPS.

There are also some additional interpretive guidelines. For example, all provisions are read to give meaning to all others harmoniously.[213] So, whole clauses or paragraphs should not be reduced to redundancy or inutility.[214] In addition, the principle *of in dubio mitius* suggests that interpretations should not impose an onerous obligation where the language is ambiguous.[215] Consistent with this principle, many commentators have noted that TRIPS has inherent flexibilities to the extent that a number of its obligations are undefined.[216] As will be discussed, such flexibilities definitely apply to TRIPS article 39.

b. Relevant Context and Its Application to Article 39

This section follows the Vienna interpretation principles in assessing the proper meaning of the key sentence of TRIPS article 39(3). So, while there is only one pivotal sentence relevant to domestic disclosure of clinical data, the entire context, which includes not only the entirety of article 39 but also the entirety of TRIPS, including its objectives and principles and the Doha Public Health Declaration, must be examined. This section begins with a brief introduction to the objectives and principles and then turns to article 39 overall and how it should be interpreted in light of this context.

i. Objects and Principles of TRIPS

Although it is easy to identify the object and principles of TRIPS, how to apply them is more elusive.[217] As multiple scholars have noted, although WTO panels and the Appellate Body have occasionally men-

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bers' right to protect public health and, in particular, to promote access to medicines for all.

213. Appellate Body Report, *Argentina—Safeguard Measures on Imports of Footwear*, ¶ 81, WTO Doc. WT/DS121/AB/R (adopted Dec. 14, 1999).

214. *E.g.*, Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, at 23 (adopted May 20, 1996). This principle is not necessarily part of the Vienna Convention rules but is recognized as naturally flowing with the method of interpretation provided in article 31 of the Vienna Convention. YAMANE, *supra* note 202, at 192.

215. *E.g.*, Appellate Body Report, *EC—Measures Concerning Meat and Meat Products*, WTO Doc. WT/DS26/29, ¶ 165, n. 154 (adopted Feb. 13, 1998).

216. *E.g.*, U.N. HIGH LEVEL PANEL, *supra* note 4, § 2.6; World Intell. Prop. Org. [WIPO] Comm. on Dev. & Intell. Prop. (CDIP), Fifth Session, *Patent related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, CDIP/5/4 (Apr. 26–30, 2010); CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES 70–97 (2009); Matthias Lamping et al., *Declaration on Patent Protection—Regulatory Sovereignty under TRIPS* 1 (Max Planck Inst. for Innovation & Competition, Rsch. Paper No. 14-19, 2014), https://www.mpg.de/8133454/Patent-Declaration1.pdf [https://perma.cc/AC9M-PN7E].

217. *E.g.*, Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement,* 46 HOUS. L. REV. 797, *passim* (2009) (discussing how to potentially interpret these two provisions and utilize them in various ways).

tioned these provisions, this has not yet resulted in definitive interpretation or application of articles 7–8.[218] A possible reason could be that these provisions not only reference contradictory goals but also each contain multiple goals that were essential to what developing countries proposed.[219] A brief examination of the details of articles 7–8 should help illustrate how these advocate competing goals.

Article 7 articulates several goals, but with an overall emphasis on balance. In particular, article 7 states,

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[220]

Since maximizing IP rights generally increases consumer costs and thus negatively impacts the economic welfare of IP users, this statement underscores that IP rights under TRIPS should not necessarily always be maximized since that would only benefit the owners of IP.[221] Although rights owners, such as pharmaceutical companies, might claim that innovation always benefits users in that they are creating valuable products that would not otherwise exist, the reference to social and economic welfare should be read to mean that IP rights should not be pursued without consideration to costs.[222] Also, article 7 explicitly refers to the fact that there should be a

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218. As one scholar noted, one WTO panel "avoided elaboration of the content and implications" of these provisions, despite specific references by the parties. CORREA, *supra* note 206, at 101–02 (discussing Canada's patent protection of pharmaceutical products); *see also* Denis Borges Barbosa et al., *Slouching Towards Development in Intellectual Property,* 2007 MICH. STATE L. REV. 71, 98 (2007) (noting that the balancing role of articles 7–8 have not "received full support in the WTO case law").

219. *See e.g.*, Yu, *Objectives and Principles of the TRIPS Agreement*, *supra* note 217, at 1000–04 (noting that, whereas TRIPS initially focused primarily on the interests of developed countries, the interests of developing countries are reflected in articles 7–8). Indeed, as noted by one scholar, interpreting TRIPS in light of its principles and objectives "does not dictate any particular outcome" with respect to balancing between protection of patent rights and the right to compulsory licensing. Gathii, *supra* note 210, at 305. Nonetheless, articles 7–8 provide a basis for arguing in favor of public policies and bar interpretation solely from the perspective of rights holders. *See e.g.*, *id.* at 305–07; CORREA, *supra* note 206, at 104.

220. TRIPS, *supra* note 6, art. 7. The entirety of article 7 provides:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

221. Submission by the African Group et al., *Developing Country Group's Paper*, ¶ 18, IP/C/W/296 (June 19, 2001); *see also* CORREA, *supra* note 206, at 101 (noting that article 7 "confirms that IPRs can be seen neither as an end in itself nor as absolute rights, but subject to appropriate balances").

222. *See* CORREA, *supra* note 206, at 94; UNCTAD-ICSTD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 125–26 (2005); *see also* U.N. Sub-Commission on the Promotion and Protection of Human Rights, Res. 2000/7, ¶ 2, U.N. Doc. E/CN.4/SUB.2/RES/2000/7 (Aug. 17, 2000) (finding conflict between TRIPS and human rights and arguing that human rights should prevail).

"balance of rights and obligations."[223] This reference, in conjunction with the acknowledgement of competing interests, suggests that TRIPS exceptions are as important to acknowledge as rights, which is not a radical idea since commentators have argued that domestic laws should also have exceptions.[224] In other words, although some may view IP to be primarily or even exclusively for the benefit of its owners, article 7 provides a balanced view that emphasizes the dangers of maximizing IP protection since that would negatively impact IP users to the detriment of social and economic welfare.

Article 8 reinforces the need for balance by explicitly noting that members may sometimes be permitted to protect public health and other social interests. It explicitly notes that members may adopt measures "necessary to protect public health" as well as "public interest, albeit not in an unrestricted way that would provide an exception to all provisions of TRIPS."[225] In particular, article 8 limits the measures to protect public health to those that are necessary and likely objectively necessary based on the wording.[226] Moreover, article 8 clearly states that such measures must be consistent with TRIPS.[227] However, consistency with TRIPS should be considered in the appropriate context, including articles 7–8.[228] One scholar suggests that the TRIPS consistency limitation does not necessarily preclude domestic action necessary to protect interests mentioned in article 8; in particular, given the WTO members' adoption of the Doha Public Health Declaration which states that TRIPS can and should be interpreted to promote public health, the goal of promoting public health can be considered a purpose of the agreement.[229]

Unlike article 7, article 8 is not focused exclusively on IP. In particular, it refers to domestic IP laws that aim to promote the goals of article 8 as well as non-IP laws.[230] So, whereas article 7 states the goals of IP laws,

223. TRIPS, *supra* note 6, art. 7.

224. Yu, *Objectives and Principles of the TRIPS Agreement*, *supra* note 217, at 1007. Moreover, given that TRIPS is the first ever agreement to require countries to mandate protection of IP rights which used to be solely within national discretion, article 7 arguably is important to ensure balancing of interests. UNCTAD-ICTSD, *supra* note 222, at 119.

225. TRIPS, *supra* note 6, art. 8 ("Members may, in formulating or amending their laws and regulations, adopt measures *necessary* to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.").

226. Yu, *Objectives and Principles of the TRIPS Agreement*, *supra* note 217, at 1013–14.

227. TRIPS, *supra* note 6, art. 8.

228. CORREA, *supra* note 206, at 104; Abdulqawi A. Yusuf, *TRIPS: Background, Principles and General Provisions*, *in* INTELL. PROP. & INT'L TRADE: THE TRIPS AGREEMENT 3, 14 (Carlos M. Correa & Abdulqawi Yusuf eds., 2d ed 2008).

229. CORREA, *supra* note 206, at 108–09; *see also* SHAIKH, *supra* note 210, at 56 (arguing that since TRIPS does not have a general exceptions clause unlike GATT and GATS, TRIPS should be interpreted broadly within the confines of the TRIPS consistency test); UNCTAD-ICSTD, *supra* note 222, at 127 (noting article 8 should be construed to presume measures taken in light of its goals, such as to address public health are consistent with TRIPS).

230. CORREA, *supra* note 206, at 104.

article 8 confirms domestic discretion to adopt non-IP laws that can impact IP rights.[231] Article 8 is clearly pertinent to domestic laws permitting disclosure of clinical data, which impact public health, and would also be relevant to non-IP laws that might impact IP, such as price controls on drugs.[232]

ii. Article 39 Overall and Interpretation in Light of Context

Now that the TRIPS context is explained, it is time to turn to article 39 overall. The entirety of Article 39, i.e., provisions (1)–(3), is the most pertinent context for article 39(3) given that this single article is the only one that deals with information not protected by other IP rights such as patents, copyrights, or trademarks.[233] As noted in article 39(1), the entirety of article 39 is intended to provide protection against "unfair competition," which is consistent with a prior international agreement, the Paris Convention.[234] Since all rights created under article 39 are to be consistent with this obligation regarding "unfair competition," the scope of this term is important to delineating subsections of article 39.

The referenced section of the Paris Convention states that members shall bar "any act of competition contrary to honest practices in industrial or commercial matters."[235] The Paris Convention provides some specific examples of what is definitely barred, including misleading the public concerning goods and creating confusion with a competitor.[236] However, these do not restrict member states from barring other activities. Indeed, the term "honest practices" has been noted as inherently flexible.[237]

The emphasis on "unfair competition" in article 39 is particularly important in contrast to the overall context of TRIPS. Although all IP under TRIPS requires member nations to ensure the existence of private IP rights, this one is notably different from other rights.[238] First, rights

231. *Id.* at 108.

232. *Id.* at 104.

233. Unlike most other IP rights protected by TRIPS, trade secrets and other undisclosed information is governed by only a single TRIPS article.

234. TRIPS, *supra* note 6, art. 39(1) (requiring member states to provide "effective protection against unfair competition as provided in Article 10^{bis} of the Paris Convention (1967)).

235. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, revised July 14, 1967, WO020EN, U.N. Doc. No. 11851, art. 10^{bis}(2) [hereinafter Paris Convention].

236. DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 426 (3d ed. 2008) (citing G. BODENHAUSEN, WIPO GUIDE TO THE PARIS CONVENTION 144 (1969)).

237. A traditional interpretation of "honest practices" considers this to include not only practices in the country where protection is sought, but also those established in international trade. G. H. C. BODENHAUSEN, WIPO GUIDE TO THE PARIS CONVENTION 144 (1969).

238. *See generally* Appellate Body Report (Australia), *supra* note 204 (noting that TRIPS focuses on private rights that require active intervention of government through existence of domestic laws to effectuate such rights). Even the type of IP right provided by article 39 is worded ambiguously as "protection of undisclosed information." This ambiguity was apparently chosen to avoid a reference to one legal system given lack of uniformity in how countries protect such information. GERVAIS, *supra* note 236, at 424. In addition, the term is itself arguably misleading in that the information is not truly

under article 39 are focused on policing unfairness, without providing any affirmative right to exclude in the same manner as other TRIPS rights, such as patents. In other words, whereas TRIPS clearly articulates what specific activity the patent owner is able to bar and for what period of time, it does not delineate what owners of information covered by article 39 can bar.[239] Second, whereas most IP rights under TRIPS require no government intervention after ensuring that such rights exist under domestic law, the second sentence of article 39(3) in particular is unusual in that it imposes an obligation on regulatory authorities, rather than creating a private right of action.

Now that the overall approach of article 39 has been delineated, a closer examination of the operative provisions of article 39 is in order. Notably, whereas article 39(1) principally focuses on ensuring that member states comply with an obligation of the Paris Convention, the remainder of article 39 imposes new and specific obligations that relate to protecting certain information consistent with that Convention.

Article 39(2) requires member states to provide what many nations would consider a right to prevent misappropriation of trade secrets given that the definition of what information is protected matches that of trade secrets. This requires that member states ask those who have such a trade secret to prevent it from being used, disclosed, or acquired in a manner "contrary to honest commercial practices."[240]

Article 39(3) imposes a different type of obligation on member states than article 39(2). Rather than provide a right focused on protection of information that rises to the level of a trade secret in its commercial value, it requires nations to protect data submitted to regulatory agencies for marketing approval from "unfair commercial use" if it involved considerable effort. Moreover, separate from the duty to protect the data from the vague

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undisclosed since that would prevent its use; rather, the information is disclosed selectively and under specific conditions.

239. For example, TRIPS art. 27 explicitly states that the owner of a patent has an affirmative right to exclude others from a number of activities regarding the patented invention, such as making and selling it. In contrast, TRIPS article 39 imposes on member states a murkier obligation to grant protection from the undefined term of "unfair competition." *E.g.*, UNCTAD-ICSTD, *supra* note 222, at 527. That said, the second sentence of TRIPS article 39(3) seems to focus on excluding people from accessing data if member states are barred from disclosing it. However, this is fundamentally different in that countries are told to generally not disclose, but no private right is given to individuals that created this data to bar others from accessing it, or relying on it, contrary to what some had previously proposed.

240. TRIPS defines in a footnote some examples of what would fit this definition, which again mirrors traditional definitions of trade secret misappropriation. *Compare* TRIPS, *supra* note 6, art. 39 n.10 ("at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition) *with* UTSA, *supra* note 15, § 1.1–1.2 (defining misappropriation to include acquiring trade secrets by improper means such as theft, bribery, misrepresentation and breach of a duty, as well as acquiring information from someone who knew or had treason to know information was acquired by improper means); *see also* UNCTAD-ICTSD, *supra* note 222 (noting similarity of TRIPS art 39(2) and UTSA).

term of "unfair commercial use," nations must also protect the data from disclosure. Since these are stated as two separate obligations, simply not disclosing data would not be adequate to protect data from unfair commercial use, or the clauses would be redundant.

Notably, the pivotal term "unfair commercial use" is not defined. Member states should have leeway to consider how to interpret this term. Granting nations the ability to do so would be consistent with interpreting article 39 in light of the emphasis of article 7 on ensuring the balance of IP rights between owners and users of IP. In addition, the Doha Public Health Declaration provides additional support for this approach. Although the Declaration does not explicitly reference article 39, it emphasizes that nations can properly self-define undefined TRIPS terms.[241] As will be discussed in the next section concerning article 39(3), "unfair commercial use" is one such term.

3. *Obligation to Protect Undisclosed Information—art. 39(3) (First Sentence)*

An initial question is when countries have an obligation to protect "undisclosed test . . . data" from "unfair commercial use." This obligation only applies to countries that require submission of clinical data to grant marketing approval of drugs, such as Canada, the United States, and EU member states.[242] Notably, the obligation only applies for data that is "undisclosed" (i.e., not previously made public). As previously discussed, although companies often publish scientific articles based on *some* data, that is a mere fraction of the information submitted to regulatory authorities. In addition, because companies consider this information proprietary and only share the information with regulatory authorities to obtain approval, it would typically be undisclosed to the general public.[243] Of course, the obligation to protect the data from "unfair commercial use" only arises if the data's creation required "considerable effort." Although the term "considerable effort" is not defined, the ordinary meaning of the term would seem to encompass most clinical data that traditionally require considerable time and expense to develop.[244]

The duty to protect data from unfair commercial use only applies to pharmaceutical products that utilize "new chemical entities."[245] The

241. Doha Public Health Declaration, *supra* note 204, art. 5(a).

242. Although this is typical of industrialized countries, TRIPS article 39(3) does not apply to countries that grant regulatory approval to sell drugs based on decisions made by other countries; this approach is typically taken by developing countries that lack resources to independently evaluate data. *See id.*

243. Case C-175/18P, PTC, *supra* note 157, ¶ 40 (noting that companies consider data submitted to regulatory agencies to be proprietary).

244. *Cost of Clinical Trials for New Drug FDA Approval Are Fraction of Total Tab*, JOHNS HOPKINS (Sept. 24, 2018), https://www.jhsph.edu/news/news-releases/2018/cost-of-clinical-trials-for-new-drug-FDA-approval-are-fraction-of-total-tab.html [https://perma.cc/V36R-96AW].

245. Although not directly relevant to the issue of disclosure of clinical study reports that this article focuses on, TRIPS also provides the same requirement concerning data submitted for marketing of agricultural chemical products. TRIPS, *supra* note 6, art.

phrase "new chemical entities" is not defined, but it is a phrase that is used by some domestic regulatory agencies to refer to traditional, chemically made drugs.[246] There could also be an issue concerning whether "new chemical entities" cover newer types of drugs referred to as biologics that are technically made from living organisms, rather than chemicals.[247] At the time TRIPS was concluded, biologics generally did not exist and there were no domestic regulatory pathways to approve similar versions of previously approved biologics using a regulatory shortcut that relied on the earlier clinical data. Although scientists may note that biologics are more than chemical entities, negotiators of TRIPS and even the pharmaceutical industry may have assumed that this term referred to any compound evaluated by a regulatory agency.[248] However, even if TRIPS did not technically cover biologics, companies are still seeking approval of non-biologic drugs, and these actually constitute a larger percentage of drugs.[249]

The most difficult question regarding the interpretation of this sentence is what it means to protect data submitted to regulatory agencies from "unfair commercial use." As noted earlier, article 39(3) governs unfair commercial use, whereas article 39(2) polices dishonest "commercial practices," though both provisions are required to be consistent with overall protection against unfair competition. A key question is what "unfair commercial use" means; there have been strident debates concerning whether a generic company that relies on the existence of another company's data is a "use."[250] As discussed earlier, a proper interpretation of any disputed TRIPS term considers the ordinary meaning. The ordinary meaning of the word "use" would include affirmative use of information

39(3). Domestic regulators, however, may treat agricultural versus pharmaceutical products differently; for example, in the US, whereas data exclusivity clearly applies to pharmaceuticals, in the agricultural context, after an initial data exclusivity period, there is a period during which subsequent applicants are permitted to rely on prior data, subject to payment of a fee. 7 U.S.C. § 136a(3)(c)(1)(F)(iii).

246. *E.g.*, 21 C.F.R. § 314.108 (2019) (defining new chemical entity as a drug that contains no "active moiety" previously approved).

247. SHAIKH, *supra* note 210, at 82–83 (concluding that TRIPS does not require protection for biologics based on the ordinary use of the term "new chemical entity" as opposed to the term "active moiety" usually used to refer to both chemical and biological entities); Yu, *Data Exclusivities*, *supra* note 11, at 650 (finding TRIPS does not cover biologics); Srividhya Ragavan, *Re(newed) Barrier to Access to Medicine*, 51 AKRON L. REV. 1163, 1185–86 (2017) (arguing that because biologic compounds would not be patentable, they should not be entitled to data exclusivity, even though there is no requirement for data exclusivity to be only granted for compounds that are patentable).

248. Indeed, PhRMA relies on this provision to complain about TRIPS issues relating to biologics. *E.g.*, PhRMA, *supra* note 13, at 62, 77–78, 173 (2018) (citing China, Malaysia, and Mexico for failing to apply data exclusivity to biologics at all, or in a different manner than small molecule drugs).

249. *E.g.*, Beatriz G. de la Torre & Fernando Albericio, *The Pharmaceutical Industry in 2019. An Analysis of FDA Drug Approvals from the Perspective of Molecules,* 25 MOLECULES 1, 1 (2021) (noting that of 53 drugs approved in 2020 by FDA, only 13 were biologics).

250. *E.g.*, Rosario Cartagena & Amir Attaran, *A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened?*, 17 HEALTH L. J. 269, 275 (2009) (noting that this provision is one of the most contentious provisions in TRIPS); Fellmeth, *supra* note 19, at 448 (noting that whether TRIPS requires data exclusivity is a critical contention in debates concerning drug access).

that would seem to require physical access to the information, rather than simply reliance on the fact of its existence. So far, there has been no WTO panel ruling; the United States initiated a dispute against Argentina, but the parties settled.[251] However, that does not mean there is consensus. To the contrary, whereas some argue that TRIPS article 39(3) requires data exclusivity,[252] others conclude that data exclusivity is not required.[253] Another view is that although data exclusivity may not be required, reliance on the data is not possible without at least some monetary compensation,[254] though this argument is inconsistent with the negotiating history.[255]

TRIPS negotiators considered—but rejected—language that specifically stated that "*data may not be relied upon* for the approval of competing products for a reasonable time."[256] Instead, the negotiators adopted the far more ambiguous language of simply barring "unfair commercial use."[257] The rejection of language that would have explicitly required data exclusivity in favor of a more ambiguous obligation establishes that data exclusiv-

251. Notification of Mutually Agreed Solution from the Permanent Mission of Argentina & the Permanent Mission of the United States to the Chairman of the Dispute Settlement Body, *Argentina - Patent Protection for Pharmaceuticals and Test Data for Agricultural Chemicals (WT/DS 171)*; *Argentina - Certain Measures on the Protection of Patents and Test Data (WT/DS 196)*, WTO Doc. WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1 (adopted June 20, 2002).

252. *E.g.*, Request for Consultation by the United States, *Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, WT/DS171/1 (adopted June 6, 2000); ORG. PHARMA. PRODUCERS INDIA, OPPI OPPOSITION PAPER, REGULATORY DATA PROTECTION – A BUILDING BLOCK FOR PHARMACEUTICAL R&D (2008); Communication from the European Communities, IP/C/W/280, *supra* note 12, at 4.

253. *See* U.N. HIGH LEVEL PANEL, *supra* note 4, at 25 (noting data exclusivity as a TRIPS-plus provision); HO, *supra* note 30, at 79–80; YAMANE, *supra* note 202, at 470–71 (2011); Diependael et al., *supra* note 12.

254. *E.g.*, Shamnad Basheer, *Protection of Regulatory Data Under Article 39.3 of TRIPS: The Indian Context*, IP INSTITUTE 1, 28–29 (July 11, 2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=934269; Fellmeth, *supra* note 19, at 464.

255. The negotiating history reveals specific proposals to require payment that were obviously not adopted. *E.g.*, Draft Agreement on Trade Related Aspects of intellectual Property Rights, Communication from the United States, art. 33, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990) ("contracting parties . . . shall not use the trade secrets for the commercial or competitive benefit of . . . any person other than the right holder except with the right holder's consent, *on payment of the reasonable value of the* use."); *id.,* Draft of July 23, 1990 (W/76), § 3A.b.1, *reprinted in* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 422, 423 (3d ed. 2008) (noting that if trade secrets are submitted to carry out governmental functions, countries shall not use the trade secrets for commercial or competitive benefit except on payment of "reasonable value") [hereinafter Draft of July 23, 1990 (W/76)].

256. Draft Agreement on Trade Related Aspects of intellectual Property Rights, *supra* note 255, Brussels Draft, ¶ 4A, *reprinted in* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 421 (3d ed. 2008) (emphasis added) [hereinafter Brussels Draft]; *see also Agreement on Trade-Related Aspects of Intellectual Property Rights*, Communication from the European Communities, art. 28, GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990) (explicitly stating that countries should protect clinical data "against *unfair exploitation by competitors*") (emphasis added); *id.*, May 1990 Communication from the United States (stating that where countries require trade secrets be submitted to carry out governmental functions, countries "shall not use the trade secret").

257. TRIPS, *supra* note 6, at art. 39(3).

ity is not required.[258] This approach is consistent with the well-established principle of TRIPS flexibilities; countries are permitted to self-define "unfair commercial use" to include, but not require, data exclusivity.[259]

The other parts of TRIPS article 39 also support this interpretation. As discussed earlier, the entirety of article 39 focuses on "unfair competition,"[260] with a focus on protection from dishonest commercial practices, but it does not provide exclusive rights.[261] Since data exclusivity by definition gives its owner the right to exclude others from relying on the data, data exclusivity seems broader than the general protection from dishonest commercial practices in the Paris Convention. Moreover, whereas TRIPS explicitly states that the patent owner has the right to "exclude" others, there is nothing in all of article 39 regarding exclusive rights.[262] This further underscores that article 39 is not intended to provide exclusive rights, meaning that it does not provide data exclusivity.

A question may remain regarding what countries must do to comply with TRIPS article 39(3). Notably, although not *required,* a country could comply by providing data exclusivity since TRIPS permits countries to demand more than what is required.[263] However, the tougher question is how to comply with the minimum obligation without data exclusivity. This Article agrees with scholars and policymakers who conclude that a country can comply by barring dishonest appropriation of the clinical data, including possibly passing this off as its own data for purpose of regulatory approval.[264] In such a case, the unscrupulous company would be affirmatively using the data by submitting it to a domestic agency rather than merely relying on the existence of the data for expedited regulatory

258. *See supra* note 215 and accompanying text (explaining *in dubio mutius* obligation).

259. HO, *supra* note 30, at 79–80; *see also* CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 382 (2007) (noting that this is left to domestic discretion); Yu, *Data Exclusivities*, *supra* note 11, at 655–58 (providing similar analysis).

260. TRIPS, *supra* note 6, at art. 39. The difference amongst the sub-provisions has to do with *who* has obligations: Article 39(2) requires to individual obligations whereas article 39(3) refers to government obligations.

261. Paris Convention, *supra* note 235, art. 10^{bis}(1)–(2) (prohibiting acts of unfair competition, such as false allegations to discredit a competitor or mislead the public, or to create confusion with a competitor).

262. *Compare* TRIPS, *supra* note 6, art. 28, *with id.* art. 39(3).

263. *Id.* art. 1.1 (stating that TRIPS only imposes minimum standards, which can be exceeded).

264. U.N. HIGH LEVEL PANEL, *supra* note 4, at 25; UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 531 (2005); YAMANE, *supra* note 202, at 471 (noting data exclusivity is not required, though countries must prevent leakage to competitors); CORREA, *supra* note 206, at 387, 391; SHAIKH, *supra* note 210, at 91–92; Ellen F.M.'t Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in the European Pharmaceutical Legislation,* 10 J. PHARMA. POL'Y & PRAC. 1, 2 (2017); Lamping et al., *supra* note 216, at 11; Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach,* 13 MARQ. IP L. REV. 1, 18–22 (2009); Yu, *Data Exclusivities*, *supra* note 11, at 656; Peter Yu, *Data Exclusivities in the Age of Big Data, Biologics and Plurilaterals*, 6 TEX. A&M L. REV. Arguendo 22 (2019); *see also* WHO, DATA EXCLUSIVITY AND "TRIPS-PLUS" MEASURES, UHC TECHNICAL BRIEF 2–3 (2017) (explaining TRIPS does not require data exclusivity).

approval.[265] This would seem to fall clearly within the Paris Convention explanation of unfair commercial use that unduly creates confusion with a competitor.[266] It would also be consistent with the ordinary meaning of the word "use" since reliance on the existence of data is not an actual use of data. Of course, TRIPS does not specify the legal means for achieving such an outcome, which could result in compliance through laws that police dishonesty through various legal doctrines, such as breach of confidence or tort law.[267]

4. *Obligation to Protect Undisclosed Information Against Disclosure (Second Sentence)*

Under TRIPS, all countries that require submission of test data for regulatory approval of drugs have an obligation to "protect such data against disclosure," subject to two possible exceptions.[268] In other words, TRIPS explicitly contemplates that data *will* be disclosed, as spelled out in the exceptions. As will be discussed below, these exceptions are critical to analyzing whether EMA and Canadian disclosure comply with TRIPS. This Section provides an analysis of each of the two exceptions.

a. Disclosure Exception 1: Necessary to Protect the Public

The first exception to the general obligation to protect submitted data from disclosure is when disclosure is "necessary to protect the public." Notably, TRIPS provides no definition of this phrase.[269] Although some public health advocates might be tempted to assume that actions they consider necessary from a policy standpoint would automatically fall within this exception, a proper TRIPS interpretation requires a more detailed analysis.

As noted earlier, the starting point for interpretation is the "ordinary meaning" of key terms. In this case, the terms "necessary" and "protect" need to be defined. The Oxford English dictionary, which is typically used by WTO panels to ascertain ordinary meaning, defines "necessary" as "[i]ndispensable, vital, essential . . ."[270] In addition, "protect" means "[t]o defend or guard from danger or injury," but not necessarily physical

265. This interpretation is consistent with the approach of some domestic courts. *E.g.*, Bayer v. Canada, 1999 1 F.C. 533, aff'd. 87 CPR 3d 293 (May 19, 1999); CORREA, *supra* note 206, at 382 (noting that many countries consider such a practice not unfair). In addition, some consider this to be legitimate exploitation of a condition created through legitimate market competition. CORREA, *supra* note 206, at 381. Some WTO members such as the EU and US do not support this interpretation. *E.g.*, GERVAIS, *supra* note 236, at 429.

266. Paris Convention, *supra* note 235, art. $10^{bis}(3)(1)$.

267. CORREA, *supra* note 206, at 388; *see also* GERVAIS, *supra* note 236, at 426. In addition, although not required, a country could require the subsequent user to pay compensation for reliance. CORREA, *supra* note 206, at 388–89.

268. TRIPS, *supra* note 6, art. 39(3).

269. *Id.*

270. *Necessary,* OXFORD ENGLISH ONLINE DICTIONARY (3d ed. 2003), https://www.oed.com/view/Entry/125629 [https://perma.cc/2RLB-LT6R].

injury.[271] So, protection of the public could include economic injury, damage, or loss. For example, the public may suffer economic damage by paying for drugs that are not worthwhile. Even though "protect" could encompass a wide range of activity, the modifying requirement that it be "necessary" might suggest that this is a high bar.[272] However, there is good reason to consider more than the default dictionary definition in this situation, as explained below.

The word "necessary" appears in other WTO agreements that can be considered relevant context. In particular, these agreements provide a general exception to requirements for domestic action when "necessary to protect human life or health."[273] WTO panels and the Appellate Body (AB) have noted two separate analyses relevant to assessing this.[274] First, the "necessary" domestic measures must be *designed to achieve the policy objective* of protecting human life or health, which is in turn assessed based on policy in the domestic law (and accompanying documents) at issue.[275] Second, the domestic measure must be *necessary to achieve the stated objective*.[276] In evaluating whether the policy is necessary to achieve the stated objective, the WTO has applied a pragmatic approach and found this standard can be met if other options would be unduly cost prohibitive or

271. *Protect*, OXFORD ENGLISH ONLINE DICTIONARY (3d ed. 2007), https://www.oed.com/view/Entry/153127 [https://perma.cc/7YUK-Z4CY].

272. Indeed, one commentator has previously suggested that this is only met if there is "no reasonable alternative" to disclosure and the public is inevitably threatened. Fellmeth, *supra* note 19, at 451. However, as will be explained, the basis for this interpretation is not supported by more current WTO jurisprudence.

273. In GATT (regarding trade) as well as GATS (regarding services), there is a general exception to the other requirements if domestic action is "necessary to protect human, animal or plant life or health" so long as the domestic measure does not constitute "means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade." General Agreement on Tariffs and Trade arts. XX(b), XX(d), Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]; General Agreement on Trade and Services art. XIV(b), Apr. 15, 1994, Annex 1B, 1869 U.N.T.S. 183, 33 I.L.M. 1167 [hereinafter GATS]; *see also* Agreement on the Application of Sanitary and Phytosanitary Measures art. 5.6, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120; Agreement on Technical Barriers to Trade art. 2.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Agreement, Annex 1A, 1868 U.N.T.S. 120 (containing "necessary" clause, but requiring defending country to show that the measure is not more trade restrictive than necessary). Notably, TRIPS article 39 has no similar requirement that the measure not constitute unjustifiable discrimination.

274. There are actually three separate analyses, although the last one focuses on the nondiscrimination clause that does not appear in TRIPS article 39. *E.g.*, Panel Report, *European Communities—Conditions for the Granting of Tariff Preferences to Developing Countries*, ¶¶ 7.198–7.199, WTO Doc. WT/DS246/R (adopted Dec. 1, 2003) [hereinafter EC Tariff Panel Report]; Andrew Mitchell & Caroline Henckels, *Variations on a Theme: Comparing the Concept of Necessity in International Investment Law and WTO Law*, 14 CHIC. J. INT'L L. 93, 126–127 (2013).

275. *E.g.*, EC Tariff Panel Report, *supra* note 274, ¶¶ 7.201–7.202 (finding no stated policy of protecting human life and health in the Council regulation and explanatory memo that discussed eradication of poverty in developing countries as a general goal).

276. *E.g.*, Panel Report, *United States—Standards for Reformulated and Conventional Gasoline*, ¶ 6.20, WTO Doc. WT/DS2/R (adopted January 29, 1996).

impose substantial technical difficulties.[277]

Whether a measure is necessary to achieve its stated objective requires a nuanced analysis and holistic consideration of values. In particular, this requires considering the extent to which the domestic measure at issue contributes to its objective as well as possible alternatives.[278] WTO jurisprudence notes that protecting human life and health against diseases is "both vital and important in the highest degree."[279] That said, a domestic measure intended to protect life must adequately contribute to the measure by being closer to "indispensable" rather than simply making any contribution.[280] In addition, the more a domestic law contributes to the objective, the more likely it will be considered necessary.[281] Evaluation of this contribution may involve considering different methodologies without needing to quantify risk of human life or health.[282] Indeed, the AB has noted that in some situations, a domestic measure could be deemed necessary if it is "apt to produce a material contribution to the achievement of its objective," even if the objective may not be immediately observable in the short term, such as reducing incidences of disease or global warming over a longer period of time.[283] However, not all stated domestic policies will be consid-

277. Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶¶ 307–08, WTO Doc. WT/DS285/AB/R (adopted April 20, 2005) [hereinafter U.S. Gambling Appellate Body Report] (interpreting whether a domestic measure was "necessary" to protect public morals under GATS art. XIV). Previously the WTO indicated that the "necessary" standard required a country to have exhausted all other options. Report of the Panel, *United States – Restrictions on Imports of Tuna*, ¶ 5.28, DS29/R (June 16, 1994), GATT BISD (39th Supp.), at 155 (1993) (not adopted) (finding a measure barring imports of tuna to save dolphin lives not permissible where there was inadequate showing that all other options had been exhausted).

278. Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 156, WTO Doc. WT/DS332/AB/R (adopted Dec. 17, 2007) [hereinafter Brazil–Retreaded Tyres Panel Report] (noting that weighing and balancing competing interests is a "holistic operation" that considers contribution of the domestic measure to its objective against other interests at stake, as well as possible alternatives); *see also* U.S. Gambling Appellate Body Report, *supra* note 277, ¶ 304 (objective), ¶¶ 306–07 (balance of factors).

279. Brazil–Retreaded Tyres Panel Report, *supra* note 278, ¶ 179 (evaluating import ban of tires that can cause risk of dengue fever and malaria and finding that preventing such diseases is vital and important, such that they outweigh trade restrictiveness); Panel Report, *Indonesia—Measures Concerning the Importation of Chicken Meat and Chicken Products*, ¶ 7.225, WTO Doc. WT/DS484/R (adopted Nov. 22, 2017) [hereinafter Indonesia Chicken Panel Report] (noting that protection of human health is an interest of highest importance); Panel Report, *Brazil—Certain Measures Concerning Taxation and Charges*, ¶¶ 7.913–7.916, WTO Doc. WT/DS472/R, WT/DS497/R (adopted Aug. 30, 2017) (noting that "few interests are more vital and important than protecting human beings from health risks" in finding that increasing vehicle safety and reduction of CO2 emissions were interests of high importance).

280. EC Tariff Panel Report, *supra* note 274, ¶¶ 7.211–7.213.

281. Appellate Body Report, *China—Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, ¶ 251, WTO Doc. WT/DS363/AB/R (adopted Jan. 19, 2010) [hereinafter China AV Appellate Body Report].

282. Brazil–Retreaded Tyres Panel Report, *supra* note 278, ¶ 145.

283. *Id.* at ¶ 151. Accordingly, the AB has stated that sometimes a measure can be deemed necessary based on qualitative reasoning established by hypotheses that are

ered necessary. For example, in one case, a country alleged a measure was necessary to prevent health risks caused by thawing chicken at tropical temperatures. The WTO panel found this did not justify barring frozen chicken in non-tropical temperatures without the same health risks.[284]

Of course, there still remains a question of what it means to be necessary to "protect the public" per article 39(3). The lack of any reference to human life or health here suggests it refers to domestic action that protects the public *without* a direct impact on physical health. In other words, resources wasted on drugs that are not as effective as promoted would fit such a definition. This conclusion is consistent with interpreting this provision in light of TRIPS articles 7 and 8. As noted earlier, article 7 emphasizes that TRIPS should contribute to a balance of rights and obligations, meaning that exceptions to rights, such as this one, should be given full effect. Moreover, article 8's reference to measures "necessary to protect public health" consistent with TRIPS also supports this conclusion. It is clear that protection of the public does not require any consideration of tradeoffs with other interests since none are listed here, unlike other TRIPS exceptions.[285]

This interpretation is supported by the negotiation history of TRIPS. An earlier draft stated that disclosure was only permitted to the extent it was "*indispensable* to inform the general public about the *actual or potential danger of a product.*"[286] Elimination of this restrictive wording from the final text indicates that countries did not consent to such a narrow approach—and that danger is not required.

Lastly, this "necessary to protect the public" exception does not impose any requirement on how disclosed information is used. The same earlier draft that limited disclosure to situations of actual danger from a specific product also imposed a restriction on use of information for commercial purposes which does not appear in the final text.[287] As with other proposed requirements more onerous than current TRIPS language, this cannot be considered part of the final text.

The above interpretation that information can be "necessary" to disclose without immediate danger to health is confirmed by the negotiating history, which, as discussed earlier, can be used to confirm the meaning of terms. Notably, TRIPS article 39 was the first international provision to

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supported by adequate evidence. China AV Appellate Body Report, *supra* note 281, ¶¶ 251-53.

284. Indonesia Chicken Panel Report, *supra* note 279, at ¶ 7.228.

285. For example, unlike the exception to usual patent rights under TRIPS that lists multiple factors to consider, this exception only states that it is necessary to protect the public. *Compare* TRIPS, *supra* note 6, art. 39(3) *with id.* art. 30. Moreover, article 39(3) notably does not require what is "necessary" to be balanced against another interest contrary to the general exception clause in the GATT. *See* GATT, *supra* note 273, art. XX (permitting exception to usual requirements if necessary, but only so long as domestic measure is not trade restrictive).

286. GERVAIS, *supra* note 236 (emphasis added).

287. *Id.* ("They shall not be entitled to use the information for commercial purposes.").

ever protect trade secrets, and it was highly contentious.[288] The United States strongly favored inclusion of trade secrecy protection, including information submitted to regulatory agencies to prevent free-riding.[289] However, other countries opposed protection of trade secrets, noting that, unlike other types of IP, trade secrecy inherently bars disclosure of information to the public, which they viewed as essential to constitute IP.[290] These very different views to protecting trade secrets[291] suggest that TRIPS article 39(3) should be interpreted to support differing views, including ones that are concerned about protection of intellectual property rights without public disclosure.[292]

In addition, many developing countries were initially resistant to any IP standards separate from those that impacted trade based on the original document forming the basis for TRIPS negotiations that emphasized trade-related IP, as well as the fact that IP rights might exacerbate wealth disparities between developed and developing countries.[293] In addition, if TRIPS is to be considered a legitimate bargain between developed and developing countries, it is essential to permit interpretation of ambiguous terms in light of articles 7–8 since these articles form the crux of what developing countries had proposed.[294] In contrast, all of the requirements for protecting IP reflect the desires and positions of developed countries.

b. Disclosure Exception 2: Steps to Ensure Data Is Protected Against Unfair Commercial Use

The second exception that would permit regulatory agencies to disclose submitted data is if "steps are taken to ensure that the data is protected against unfair commercial use."[295] The same phrase, "unfair

288. GERVAIS, *supra* note 236, at 424; CORREA, *supra* note 206, at 374.

289. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Meeting of Negotiating Group of Oct. 30–Nov. 21, 1989,* para. 63, MTN.GNG/NG11/16 [hereinafter Meeting Notes of Oct.–Nov. 1989]; Meeting of Negotiating Group of 12–14 July 1989, MTN.GNG/NG11/14, para. 89 (Sept. 12, 1989) (U.S. comments to prevent free-riding) [hereinafter Meeting Notes of July 1989]. In fact, the U.S. proposal was among the most extensive initial proposals for trade secrets, including test data in particular, which the EU did not initially suggest. *E.g.*, SHAIKH, *supra* note 210, at 66–67.

290. Meeting Notes of July 1989, *supra* note 289, ¶ 90; Meeting Notes of Oct–Nov 1989, *supra* note 289, ¶ 63. Although it is not surprising that developing countries opposed inclusion of trade secrets, even some developed countries such as Japan and New Zealand did not initially propose inclusion of trade secrets. *E.g.*, SHAIKH, *supra* note 210, at 67.

291. In addition, TRIPS article 39(3) technically does not even require the protected information to be a trade secret such that it arguably could get less protection than trade secrets. *Compare* TRIPS, *supra* note 6, art. 39(2) *with id.* art. 39(3).

292. This is especially true given that TRIPS objectives and principles already require consideration of balance between owners and users. TRIPS, *supra* note 6, arts. 7–8.

293. Meeting Notes of July 1989, *supra* note 289, at 4–5 (emphasizing India's concerns that IP is essentially monopolistic and that members should have freedom to tailor rights to "their own needs and conditions"); *see also* UNCTAD-ICSTD, *supra* note 222, at 121–22 (discussing developing country position as explained by India's submission).

294. Yu, *Objectives and Principles of the TRIPS Agreement*, *supra* note 217, at 1023–24.

295. TRIPS, *supra* note 6, art. 39(3).

commercial use," is used in first sentence of TRIPS article 39(3). However, it now focuses on what the government must do to protect the data, as opposed to the government potentially policing what third parties can do. Although what constitutes "use" was briefly explored earlier in the context of the first sentence, since this exception is pivotal to evaluating whether domestic laws disclosing clinical data comply with this exception, a more detailed discussion of the entire phrase "unfair commercial use" will be provided.

An important first step in this analysis is defining what constitutes "unfair commercial use" against which the government must protect if it discloses data. As discussed earlier, since "unfair commercial use" is not defined, countries have the flexibility to self-define the phrase, at least consistent with the ordinary meaning of its terms. The ordinary definition of "unfair" is "not fair or equitable," which does not immediately help define this term.[296] There seem to be a few scenarios that could be arguably unfair to the company that submitted data to the government that were previously discussed in Part II.B, concerning corporate objections to data disclosure. First, it would be unfair for a third party to use disclosed data to seek regulatory approval in another country, passing it off as its own. Second, a third party using data to expedite its own development of a drug similar to an existing drug could obtain an unfair competitive advantage.[297] Third, it may seem unfair for a generic manufacturer to rely on the existence of another company's data to obtain faster approval; however, as explained below, though this would seem to fit within the broad scope of the term "unfair commercial use," other context and prior negotiating history clarify this is not the appropriate definition. Lastly, in the situation where a nation discloses clinical data, a company could argue that it would be unfair for a competitor to use disclosed data to point out inadequacies in its drug (to the competitor's advantage). Although this would be affirmative use by a competitor for a commercial purpose, it would not necessarily be *unfair* commercial use given the larger interpretive context. The broader interpretive context of articles 7–8, as well as the Doha Public Health Declaration would all seem to consider such use to not be unfair when considered in the context of ensuring that IP rights do not unduly hinder public health. This seems especially true given the reality discussed earlier that there are simply too few independent scientists with sufficient resources and incentives to verify all clinical data. Accordingly, this last possibility won't be further discussed.

The question is then what it means for a nation "to take steps to ensure" against the remaining scenarios for which companies have a legitimate basis to argue unfair commercial use based on TRIPS—i.e., a competitor relying on another's data to obtain regulatory approval in another

296. *Unfair*, OXFORD ENGLISH DICTIONARY (3d ed. 2007). This seems analogous to the definition of what is unfair competition in the Paris Convention concerning "honest practices" being considered "inherently flexible." *See supra* note 237 and accompanying text.

297. *E.g.*, *id.*

country, or using the data to expedite its own drug development. The ordinary meaning of "ensure" is to protect against risks, which would seem to refer in this case to the two risks previously outlined.[298] Although there is no WTO jurisprudence concerning the interpretation of "ensure," the prior discussion of how the WTO has pragmatically interpreted "necessary" suggests that pragmatism is also appropriate here. This seems especially true given that the optimal way to ensure against unfair commercial use would be to bar any government disclosure, yet TRIPS clearly contemplates that nations *can* disclose.

This raises the question: How can a country take steps to protect against the risk that a competitor will use disclosed data to obtain regulatory approval in another country? A country could make disclosure contingent on a promise not to use the data for subsequent regulatory approval processes. Granted, such a promise is not a guarantee—especially since it would seem legally impossible for one country to enforce activity in a second country. However, this is consistent with the ordinary meaning of "ensure." Notably, only an outdated definition of "ensure" refers to a guarantee.[299] In addition, TRIPS obligations generally only impose obligations on countries regarding what happens within their borders, with different language used for cross-border activities.[300] Accordingly, it seems plausible that a country could make disclosure contingent on a promise not to use data for subsequent regulatory approval.

The broader interpretative context of articles 7–8, as well as the Doha Public Health Declaration, support this interpretation. As noted earlier, article 7 emphasizes a proper balance between IP owners and users so that IP rights do not negatively impact social and economic welfare. A pragmatic, rather than maximalist, interpretation of when steps to protect data from unfair commercial use are adequate would be consistent with the balance required by article 7. Moreover, interpretation of this exception to permit disclosure that would be supportive of public health would be consistent with the public health focus of both article 8 as well as the Doha Public Health Declaration.

In addition, although a country could impose a contractual obligation to ensure that data is not used in another country, a proper TRIPS interpretation indicates that countries are not required to impose such an obligation. An earlier draft stated that countries could require right holders to disclose trade secrets to third parties to protect human health or safety *only if* the right holder is given an opportunity to enter into confidentiality agreements that prevent further disclosure.[301] This statement admittedly imposes a requirement on data owners, rather than the government. None-

298. OED defines "ensure" to mean "to secure, make safe (against, *from* risks)." *Ensure*, OXFORD ENGLISH ONLINE DICTIONARY (2d ed. 1989) (definition 6), https://www.oed.com/view/Entry/62745 [https://perma.cc/TM8M-63ND].

299. *Id.* (definition 4).

300. *See, e.g.*, TRIPS, *supra* note 6, art. 52 (referring to "country of importation").

301. *See* Draft of July 23, 1990, (W/76), *supra* note 255, § 3Ab.3. Although this provision is about trade secrets, rather than data submitted to government that may not constitute trade secret, it is part of the same interpretive context.

theless, this language indicates that negotiating parties knew about the availability of confidentiality agreements but elected not to impose one. Similarly, another jettisoned proposal explicitly stated that third parties are prevented from "further disclosure and commercial use."[302] The lack of any similar language in the final text underscores that TRIPS does not require countries to impose such an obligation.

The final question is what steps a country must take under this provision to prevent disclosed clinical data from providing a competitive advantage to third parties in the development of new drugs. As just noted, TRIPS does not require countries to demand a contractual agreement since prior drafts, but not the final language, mention an agreement. Although countries can of course impose a contractual agreement in providing more than the TRIPS minimum, that is not the only possibility for compliance. Countries could prevent competitive advantage for drug development by redacting information that would promote development of new drugs. Of course, companies and countries are likely to disagree on what information would provide a competitive advantage. However, this seems well within the scope of national discretion to determine given that TRIPS is silent on this issue.[303]

A pragmatic approach to assessing steps to protect disclosed data from unfair commercial use is confirmed by the negotiating history, which, as discussed earlier, can be used to confirm the meaning of terms. In particular, just as the contentious history of article 39 (as well as the entirety of TRIPS) supports interpretation of the word "necessary to protect health" to not require immediate danger of health, that same history should provide deference to domestic actions concerning this exception and what is adequate to "protect" such data.

B. Do Domestic Laws Permitting Disclosure of Clinical Data Violate TRIPS?

The ultimate question is whether domestic laws that require disclosure of clinical study reports violate the second sentence of TRIPS article 39, which only permits countries to disclose data submitted to regulators if one of the two exceptions is met. This Section primarily analyzes whether current law or policies in EMA and Canada satisfy these exceptions. It begins with a brief overview of the domestic laws at issue, followed by a discussion of whether each exception is applicable. The TRIPS analysis of each exception will first consider the more contested issue of domestic laws permitting proactive disclosure of recently reviewed drugs, followed by laws permitting disclosure of older drugs.

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302. *Id.*, § 3Ac.2. Although this restriction was in the context of disclosure of proprietary information to obtain IP protection, rather than regulatory approval, it indicates contemporaneous consideration and rejection of such restriction.

303. *See supra* note 241 and accompanying text (noting countries have flexibility to self-define undefined TRIPS requirements).

1. Domestic Laws Arguably at Issue

There are essentially three sets of domestic laws relevant to disclosure of clinical data. First, there are European and Canadian laws permitting disclosure under general provisions that apply to obtaining any information in government possession. Second, Canada's Food and Drug Laws provide for limited disclosure to certain individuals. Lastly, both jurisdictions permit proactive disclosure of recently reviewed drug data.

In both jurisdictions, there are long-standing laws permitting individuals to seek documents in government possession to promote accountability, which are somewhat similar to the U.S. statute permitting Freedom of Information requests from governmental entities. In both the EU and Canada, requests for clinical data under these general rules require protection of commercially confidential information unless there is overriding public interest in disclosure.[304] This can result in time-consuming litigation concerning what is or is not commercially confidential.[305] Although the legal bases for requests apply to any information in government possession, the EMA enacted policy 43 in 2010 to clarify that clinical data could be obtained, at least with redactions, after an EU Ombudsman chastised its former approach to considering the entirety of clinical study reports to be confidential and not subject to disclosure.[306]

In 2014, Canada provided new bases for disclosure of clinical data without any consultation of the owner, let alone redaction in an amendment to its Food and Drug Laws.[307] First, the Canadian Health Minister can disclose clinical data if the Minister believes a drug may present a serious risk of injury to human health based on documented evidence.[308] Second, even if there is no such risk, individuals may seek data if they carry out a function relating to protection of public health if the purpose of obtaining the data is to protect or promote human health.[309] Disclosure to such individuals is not guaranteed; permission is to be granted judiciously and evaluated based on a variety of factors, including the severity of the health issue and potential impact.[310] In addition to providing avenues for disclosure, the amendment granted the government the power to create reg-

304. *See* Access to Information Act, *supra* note 153, § 20(1)–(6) (stating that the government generally should refuse to disclose confidential third party information, but may do so if it is in the interest of public health and public interest in disclosure outweighs financial loss of competitive disadvantage to the third party); Commission Regulation 1049/2001, art. 4(2), O.J. (L 145/43) 3 (providing exception to disclosure if it would undermine commercial interests unless there is an overriding public interest in disclosure).

305. *See, e.g.*, Peter Doshi v. Att'y Gen. Can., [2018] F.C. 710, para. 14 (Can.).

306. *See* Gotzsche & Jorgensen, *supra* note 158, at 3. The EMA policy also provided the first explanation for what constitutes confidential commercial information since that was not part of EC Regulation. EMA Policy 43, *supra* note 5, § 4.1.2.

307. *See* Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), S.C. 2014, c 24, § 21.1(3) (Can.) [hereinafter Vanessa's Law].

308. *Id.* § 21.1(2).

309. *Id.* § 21.1(3).

310. Canada Guidance ¶ 21.1(3)(c), *supra* note 105, § 3.1, .3.

ulations that specify when information is not confidential.[311] This could then be relevant for requests under the older law permitting documents in government possession to be disclosed, except for commercially confidential information.

The EU and Canada also provide for proactive disclosure of clinical study reports for recently reviewed drug applications. A 2014 EU Regulation that applies to all clinical studies performed in the EU requires publication of clinical study reports after regulatory decisions are completed and permits even commercially confidential information to be disclosed if there is overriding public interest.[312] That same year, EMA adopted a policy that provides proactive disclosure of drugs whose regulatory decision has been completed after January 1, 2015.[313] Canada adopted a similar policy in 2019.[314] Importantly, neither of the jurisdictions consider clinical trial information to be generally confidential, and they both permit disclosure to individuals seeking noncommercial use through an online portal.[315]

2. Exception 1: Necessary to Protect the Public?

As stated earlier, since TRIPS article 39 is broadly framed in terms of what is necessary to protect the public without including the word "health" or "life," a strong argument can be made that the traditional policy arguments in favor of disclosure of CSRs are in fact necessary to protect the public. However, there remain many questions concerning the scope of disclosure. In other words, this Section addresses *what* can be disclosed, as well as whether there should be restrictions, such as *to whom* information can be disclosed.

a. Proactive Disclosure of Newly Reviewed Drug Applications—Necessary?

The first step in evaluating whether domestic laws are "necessary" is to consider the policy objectives under existing laws. As previously discussed, WTO jurisprudence requires that domestic measures be designed to achieve the stated policy objective and be necessary to achieve the stated objective, with measures more likely to be necessary to the extent it contributes more to the stated objective.[316] EMA Policy 70, which makes clinical

311. *See* Doshi v. Att'y Gen. Can., *supra* note 305, paras. 17, 20.
312. *See* Commission Regulation 536/2014, *supra* note 5, art. 1, 81(4)-(5).
313. *See* EMA Policy 70, *supra* note 5, § 4.1.
314. Canada 2019 Guidance, *supra* note 5.
315. *See* EMA Policy 70, *supra* note 5, § 4.1 ("in general. . . clinical data cannot be considered CCI"); *see also* Commission Regulation 536/2014, *supra* note 5, Preamble, ¶ 68 (stating that "in general data included in a clinical study report is not considered commercially confidential once a marketing authorization has been granted" or "the proceeding for the marketing authorization has been completed"); Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information) SOR/2019-62, C.R.C., c. 870, Amend. 3 (Can.) (clinical trial information that was confidential business information *ceases* to be confidential once a drug approval application is granted based on such information, or the application is denied without amendment).
316. *See infra* Part III.A.2.a.

data proactively available to the public after regulatory review, is stated to enable public scrutiny as well as new knowledge for future research in the interest of public health.[317] This includes the ability to allow third parties to verify original conclusions and conduct further analyses.[318] Similarly, Health Canada's guidance document states that its goal is to make information available following completion of its regulatory review process for non-commercial purposes to "enable independent re-analysis of data," promote "new research," and promote "informed decisions" about health.[319] Such objectives provide a framework for analyzing whether these laws adequately contribute to those objectives considered "necessary," as discussed below.

A major question is whether proactive disclosure of clinical study reports from all recently approved new drug applications and those denied regulatory review is necessary to protect the public even absent an indication of impending risk to public health. As discussed earlier, a proper TRIPS interpretation of what is "necessary to protect the public" does not include any showing of actual or possible risk of physical injury. Rather, it can be necessary to protect the public from wasted resources on drugs that are not as valuable as advertised. In addition, possible health risks cannot be known without disclosure of data. Accordingly, this policy seems to strongly support the stated policy objectives of permitting independent analysis of clinical data, and also promoting informed decisions about health with regard to approved drugs. As discussed in Part II, third parties cannot verify clinical results without access to clinical study reports, and informed decisions are impossible without this data. Although unapproved drug applications are not necessary for clinical decisions, this data can still help promote future research, which is a policy for both jurisdictions.

A related question is how the clinical study reports are disclosed and whether restrictions are required. For example, the EMA makes such reports available in two ways, with the data provided in a more useful format (i.e., downloadable, as opposed to being viewed only on screen) only for academic researchers who provide identifying detail.[320] Providing information in this format is necessary to verify original conclusions and especially to conduct further analysis that might involve combining data sets from different studies.[321]

317. EMA Policy 70, *supra* note 5, § 4.1.
318. *Id.*
319. Canada 2019 Guidance, *supra* note 5, § 1.1.
320. EMA Policy 70, *supra* note 5, § 4.2.1.
321. Scientists, patient advocacy groups, and the European Ombudsman all criticized an earlier proposed policy that sought to limit even researchers to accessing information only via screen. *See* Press Release, AIM et al., Backpedaling on EMA's "proactive publication of clinical-data" draft policy: Was it all just a window-dressing exercise? Who or what is the EMA afraid of? (May 20, 2014), https://www.prescrire.org/Docu/DOCS EUROPE/20140520_EMATransparencyPolicy.pdf [https://perma.cc/CS86-F4EF]; European Ombudsman Press Release No. 13/2014, Ombudsman Concerned about Policy at Medicines Agency on Clinical Trial Data Transparency (May 16, 2014), https://www.ombudsman.europa.eu/en/press-release/en/54348 [https://perma.cc/XGT3-

A final question is whether individual patient data is necessary to be disclosed along with clinical study reports as contemplated by EMA. As discussed earlier, although such data would provide the most complete audit of a clinical study report, there are logistical difficulties of protecting the identity of individuals such that there is no consensus on whether such information should be disclosed.[322] This information is arguably necessary to promote optimal independent analysis, although the stated objectives do not aim to achieve the optimal analyses. In addition, although TRIPS does not explicitly require consideration of harm to individuals, that seems pertinent to consider in terms of whether the objectives are necessary. Accordingly, making such data available seems less necessary as an additional component beyond the clinical study reports.

b. Disclosure of Older Drugs—Necessary?

As with more recent drug submissions, the first step in evaluating whether countries may properly disclose data for previously approved drugs pursuant to TRIPS is to consider the domestic policy objectives. As noted earlier, the EU and Canada have general laws and policies that aim to promote government transparency and accountability while also protecting confidential information.[323] In addition, Canada's Food and Drug Laws permit disclosure of confidential business information without any notification to the business whose information is subject to disclosure in circumstances where public information is inadequate to improve health outcomes for patients and assist health researchers.[324]

Now that the policy criteria have been outlined, the question is whether these objectives adequately support the disclosure at issue. Admittedly, the longer a drug is marketed, the more likely it is that doctors and researchers will have discovered any major health threats. However, even if public health is not at immediate risk, there could be a waste of resources spent on drugs that are not as useful as marketed and for which public information is incomplete. The general government disclosure laws in the EU and Canada provide for the disclosure of information only if the public interest outweighs commercial interests.[325] Although TRIPS does

6MH4]; Trudo Lemmens, *EMA's Proposed Data Release Policy: Promoting Transparency or Expanding Pharma Control over Data?*, PLOS BLOG (May 30, 2014), https://speakingofmedicine.plos.org/2014/05/30/emas-new-data-release-policy-promoting-transparency-expanding-pharma-control-data/ [https://perma.cc/TB5E-5MLC].

322. *See supra* notes 137–143 and accompanying text (noting lack of consensus concerning sharing of IPD).

323. *See, e.g.*, EMA Policy 43, *supra* note 5, § 4.1.1; Access to Information Act, *supra* note 153, § 2(1).

324. Canada Guidance ¶ 21.1(3)(c), *supra* note 105, § 21.1(1).

325. *See e.g.*, Commission Regulation 1049/2001, *supra* note 304, art. 4(2) (noting that institutions shall refuse access to information if its "disclosure would undermine commercial interests unless there is an overriding public interest in disclosure"); Access to Information Act, *supra* note 153, § 20(6) (permitting government to decline to provide information in agency possession that is confidential information from third party unless disclosure is in the public interest as it relates to public health and disclosure "clearly outweighs in importance any financial loss or gain to a third party").

not require consideration of commercial interests under this exception, doing so seems appropriate as a matter of fairness—and otherwise a possible breach of domestic laws if companies had no expectation that their confidential information would be revealed.

Whether disclosure of clinical data under the Canadian Food and Drug laws is necessary under TRIPS is a tougher question and involves two types of disclosure. First, the Health Minister may disclose clinical data if, based on documented evidence, she believes a drug may present a serious risk of injury to human health; this disclosure seems necessary to further prevent public exposure to unnecessary drug risks.[326] Second, clinical data may be disclosed to individuals who carry out "functions relating to the protection or promotion of human health or the safety of the public," and information related to such functions is arguably still necessary to the policy goal of contributing to better health outcomes given that publicly available information is incomplete.[327] Although disclosure under these two circumstances may seem overly broad because there is no specific protection for confidential commercial information, this TRIPS exception does not call for such consideration; rather, the focus is exclusively on whether the information is necessary to promote the stated objectives. Arguably, it is necessary especially since the procedure for individuals to obtain access requires consideration of various factors weighed, including the importance of the request and its impact.[328]

Lastly, there may be a question concerning whether the Guidance Document for the Canadian Food and Drug law that imposes restrictions on how disclosed data is used is necessary under TRIPS. Individuals cannot obtain clinical data unless they sign an agreement promising to keep the data secret.[329] Such an approach would seem to *not* protect the public from drug risks since it would preclude publication of discovered information; indeed, a Canadian court found such a provision inconsistent with legislative intent to improve transparency and invalidated it.[330] Since TRIPS permits disclosure if necessary to protect the public and limiting publication of results based on disclosure is essential to protection, such a limit is not required by TRIPS.

3. *Exception 2: Steps Taken to Ensure Data Is Protected Against Unfair Commercial Use?*

The alternate basis for permitting disclosure of clinical data submitted to regulatory officials is if steps are taken to ensure the data is protected from unfair commercial use. As with the discussion of the other exception to TRIPS, this will first consider proactive disclosure policies for newer drugs, then discuss laws permitting disclosure of older drugs. In both cases, unfair commercial use should be guarded against if a third party

326. Vanessa's Law, §21.1(2).
327. *Id.* § 21.1(3)(c).
328. Canada Guidance ¶ 21.1(3)(c), *supra* note 105, ¶¶ 7–8.
329. *Id.* ¶ 6.
330. Doshi v. Att'y Gen. Can., *supra* note 305, para. 82.

could use the disclosed data to seek regulatory approval in another country or if the third party could use the data to expedite its own development of a similar drug. Moreover, as discussed previously, although there is no WTO jurisprudence concerning "ensure," a pragmatic approach to application of the term similar to the WTO's pragmatic approach to the word "necessary" seems reasonable. This is especially true since optimal protection would require complete nondisclosure, which is completely contrary to the existence of this exception.

a. Proactive Disclosure—Are Steps Adequate?

A country may seek to directly limit unfair commercial use by requiring a third party using published data of another company to seek regulatory approval in another country.[331] Although the EMA and Canada prohibit unfair commercial use, the steps they take to prevent such use differ. Canada's online portal provides a long list of terms of use that clearly requires data be used noncommercially and that data be attributed to the original manufacturer.[332] However, this list can be easily agreed to with a single computer click, and it is commonplace for individuals to agree to terms without first reading them.[333] Nonetheless, Canada and the EMA provide a watermark on published information to indicate that the information may not be used for commercial purposes.[334] Notably, the EMA requires that academics seeking downloadable data provide identifying information. The EMA policy also provides additional protection. First, it limits the availability of information to screen use (without printing) for those who are not academics.[335] Second, the EMA states that failure to comply with its conditions on use will result in revocation of the right to use the database.[336] Thus, the EMA provides for revocation of access of non-compliant individuals.[337] The EMA's multi-pronged

331. Although companies may assert that disclosure also limits their potential data exclusivity in another country, a proper TRIPS interpretation does not include loss of data exclusivity as within the scope of unfair commercial use.

332. *See Terms of Use*, HEALTH CAN., https://clinical-information.canada.ca/ci-rc/terms?id=187330 [https://perma.cc/PD6D-PAZR] (last visited Mar. 11, 2022); Canada 2019 Guidance, *supra* note 5, §§1.1, 2.1, 4.7.

333. *See* David Berreby, *Click to Agree with What? No One Reads Terms of Service, Studies Confirm*, GUARDIAN (Mar. 3, 2017), https://www.theguardian.com/technology/2017/mar/03/terms-of-service-online-contracts-fine-print [https://perma.cc/U7WQ-2JXE]; Editorial Board, *How the Silicon Valley Puts the "Con" in Consent,* N.Y. TIMES (Feb. 2, 2019), https://www.nytimes.com/2019/02/02/opinion/internet-facebook-google-consent.html [https://perma.cc/UV68-A7Y3]. Although the Canadian portal notifies visitors the site in bold letters to read the information carefully, it is doubtful whether this has an impact.

334. EMA Policy 70, *supra* note 5, § 4.2.1; Canada 2019 Guidance, *supra* note 5, at § 4.7

335. EMA Policy 70, *supra* note 5, § 4.2.1.

336. *Id.,* Annex 1, ¶ 3 ("If the user fails to . . . comply with these conditions, or uses the *Clinical Reports* in breach of these Terms, the rights to access and use of *the Clinical Reports* will be revoked."). The EMA also includes a broader clause that states: a user may not "make any unfair commercial use" that seems to provide blanket coverage for additional situations yet to be determined. *Id.*

337. *Id.* § 4.2.1.

approach appears consistent with steps taken to protect data whereas Canada's minimalistic approach is more questionable. Although a watermark should clearly alert regulatory authorities, it is unclear whether a WTO panel would consider that to adequately ensure data is protected.

A slightly different analysis applies to possible unfair commercial use based on gaining competitive advantage from knowing scientific information. To the extent that there might be confidential information that could provide a competitive advantage, such as a trade secret method, both jurisdictions permit redaction—if a company can establish why such information is confidential.[338] Of course, determining what should be redacted is difficult since nations and companies may disagree. Nonetheless, the scope of redaction seems well within domestic discretion. Thus, a nation that has a redaction process to protect confidential commercial information is taking steps consistent with TRIPS to protect against unfair commercial use.

The next issue is whether countries must impose limitations on what CSRs are disclosed (beyond redacted components), as well as limits on use of disclosed CSRs to protect it from any unfair commercial use. A proper TRIPS interpretation would not require contractual restrictions, such as confidentiality agreements, since a proposal for such a requirement was rejected during TRIPS negotiations. That said, since TRIPS only imposes minimum standards, a nation could still impose such a requirement. However, this does not seem to be a good approach for the goal of public transparency.[339] An alternative TRIPS-consistent limitation would be for a country to limit disclosure of CSRs to only approved drugs, rather than all drugs for which a decision has been made. This would address corporate concerns that their interests might be impaired in seeking subsequent approval in the same country if the data were disclosed. Neither Canada nor EMA currently follow this approach.

b. Disclosure of Older Drugs—Are Steps Taken Adequate?

As discussed earlier, both the EMA and Canada permit disclosure of older drugs upon request. Some of the issues discussed with proactive disclosure apply equally here in that there are mechanisms to protect against unfair commercial use to obtain regulatory approval and/or drug development. Generally, there must be a specific request before regulatory authorities will consider disclosure and the procedure for granting the request inherently includes consideration of how to protect any confidential information, typically through redaction.

338. *See, e.g.*, *id.* § 4.2.2.1; Canadian 2019 Guidance, *supra* note 5, § 4.4. Under the alternate exception to disclosure, even this information could be available since that exception focuses on public interest without regard to the impact on commercial interests. Indeed, public health advocates have noted that there is generally an overriding public health interest in disclosure of commercially valuable information. *See also*, Sarah Sorscher & Michael Carome, PUB. CITIZEN'S HEALTH RSCH. GRP., *Submission of Comments on Policy 0070 on publication and access to clinical trial Data*, at 5, EMA 240810/2013 (2013).

339. *See* Mantel, *supra* note 109.

There are two provisions in Canadian Food and Drug law that arguably provide less protection against unfair commercial use and need further discussion. First, Canada's Health Minister may disclose confidential business information if the Minister believes a drug may present a serious risk of injury to human health based on documented evidence.[340] Second, even if there is no such risk, confidential business information may be disclosed to a person who carries functions relating to protection of public health if the purpose is to protect or promote human health.[341] The first exception permitting disclosure in the event of a serious risk of injury is a fairly narrow one considering that there is typically little, if any, evidence of health risks, let alone those creating a *serious* risk to human health before clinical study reports are released.[342] Given the narrow circumstances of this possible disclosure and the need to avoid serious health risks, it is arguably reasonable to disclose the information. The second one may seem quite broad. However, there are additional steps to protect such information not only by limiting the information disclosure to those with legitimate needs, i.e., not competitors, but also imposing additional limits on how the information can be used through confidentiality agreements. As previously discussed, such limitations are less helpful for dissemination of results to the public, even though restrictions protect industry interests.

4. Optimizing Domestic Disclosure of Clinical Data Consistent with TRIPS

This Section provides an overview of the issues involved in enacting TRIPS-consistent domestic laws that permit disclosure of clinical study reports. As discussed above, disclosure of such reports for recently reviewed drugs is "necessary" and permissible under the first TRIPS exception, even if regulatory approval is denied—so long as there is a stated policy basis that disclosure is necessary to promote further research. The disclosed information should be available to academic researchers in fully downloadable format since, otherwise, it is not truly useful. Although this Article has concluded that this TRIPS exception supports disclosure, given that there is no prior WTO jurisprudence, nations that want to avoid a formal WTO challenge may want to also ensure that the disclosure satisfies the other TRIPS exception (concerning steps taken to ensure the data is protected against unfair commercial use).[343] In particular, countries should provide a mechanism to redact arguably confidential information, unlike the situation with Canada's Food and Drug Laws.[344] In addition, countries should disclose the information only for noncommercial use and provide a watermark on disclosed information to help ensure that the data

340. Vanessa's Law, § 21.1(2).
341. *Id.* § 21.1(3).
342. For example, it took years for the data concerning the harmful effects of Vioxx to be publicized.
343. Of course, even if there is a TRIPS challenge, a WTO panel can only order countries to bring its laws into compliance. *See supra* note 7 and accompanying text.
344. Of course, as some have noted, redactions can seriously limit the utility of data.

is not inappropriately used to obtain regulatory approval in another country. While additional steps along the lines of the EMA policy could be imposed, it may not be needed to satisfy this exception.

However, disclosure of individual patient data related to newly reviewed drugs may not be necessary unless the stated policy is to provide *optimal* verification of original data, or unless it can be argued that such data promotes new research. This information would seem more pertinent if the objectives stated that the goal was not simply new research, but research that promotes use of the drug on different subpopulations than originally studied, as well as alternative uses and exploratory research—all things that scholars have noted such data is useful for. Although this analysis is consistent with WTO jurisprudence concerning somewhat analogous language about when domestic measures are necessary to protect human life or health, whether a WTO panel would use this analysis for an objective that was less central to protecting human health is admittedly an open question.

Disclosure of data relating to older approved drugs also can satisfy the TRIPS exceptions. As discussed earlier, this information is still necessary given incomplete data otherwise available to the public. Confidentiality restrictions on use of this information are not required by TRIPS and would have no bearing on whether the information is necessary to protect public health. That said, a government might be tempted to impose such a restriction as a way to satisfy the alternative exception that there are adequate steps taken to ensure data is protected against unfair commercial use. However, that is likely not a good policy since that would undermine the utility of information disclosed. Rather, countries should take the same actions to protect data such as only providing it for noncommercial use and with a watermark. In addition, to optimally protect commercial interests, a country could permit a process of redaction for even this older data. It is possible that there is less information for older data that would likely be proprietary; however, if there is no redaction process at all, such as in the case of Canadian Food and Drug laws, that seems to fail to provide reasonable steps to prevent others from obtaining a competitive advantage. After all, even if an academic researcher has no intent to gain a competitive advantage, a publication by such researcher could arguably reveal information that terminates a trade secret.

IV. Policy Implications and Next Steps

A. International Lawmaking

1. Minimizing International Constraints Governing Domestic IP

The tension between clinical trial transparency and the rights of IP owners should be a warning for future international treaties. At the time that TRIPS was concluded, there was no perceived need for transparency of clinical data—arguments for transparency happened more than a decade later. This situation parallels the situation of legislatures that often craft legislation to anticipate future unknown situations. However, unlike

domestic legislation, international agreements are difficult to revise. For example, since TRIPS was concluded in 1994, there has only been one amendment. Notably, despite widespread recognition of its need to assist least developed countries in 2001,[345] it took until 2017 for the requisite two-thirds of member countries to ratify the amendment.[346] In addition, even amendments may not fully anticipate future circumstances. For example, when the 2017 TRIPS amendment became effective, a number of wealthy countries stated that they would not use the procedure permitted under the amendment.[347] However, today, some argue that countries that previously agreed not to use this amendment should no longer be expected to do so given the unexpected Covid-19 pandemic.[348] Beyond attempting to amend an agreement, sometimes countries will try to exit an agreement.[349] However, even when a country takes steps to exit international agreements, there may be an interim period during which the agreement still controls.[350] All of these issues suggest that nations should act cautiously before imposing new international norms.

In addition, even though this Article has explained why publication of clinical data can be consistent with TRIPS, the fact that legitimate domestic health policy could be limited by an international agreement underscores the need for more balanced and transparent future negotiations of international agreements.[351] Although it may seem obvious that all stakeholders should be involved in negotiations, that has generally not been the practice with negotiation of international agreements concerning intellectual property.[352] In fact, the very existence of TRIPS can be attributed to a powerful,

345. Doha Public Health Declaration, *supra* note 204, ¶ 6. The Doha Public Health Declaration notes that poor countries were unable to effectively issue compulsory licenses—a typical mechanism to lower prices of patented goods—because TRIPS generally requires these to be issued for domestic use. Such countries lack the infrastructure to make drugs and countries with resources were barred from exporting drugs.

346. Press Release, WTO, WTO IP Rules Amended to Make Access to Affordable Medicine (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm [https://perma.cc/5ZXJ-45NV].

347. *Id.*

348. *See, e.g.*, Christopher Garrison, *Never say Never - Why the High Income Countries that Opted-out from Article 31bis WTO TRIPS System Must Urgently Reconsider their Decision in the Face of the Covid-19 Pandemic*, MED. L. & POL'Y BLOG (Apr. 8, 2020), https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/ [https://perma.cc/TCD9-3XPV].

349. *See generally* Laurence R. Helfer, *Exiting Treaties*, 91 VA. L. REV. 1579 (2005); Catherine Brolmann et al., *Exiting International Organizations*, 15 INT'L ORG. L. REV. 243 (2018); STEPHEN P. MULLIGAN, U.S. CONG. RSCH. SERV., WITHDRAWAL FROM INTERNATIONAL LEGAL AGREEMENTS: LEGAL FRAMEWORK, THE PARIS CONVENTION AND THE IRAN NUCLEAR WAR, R44761 (May 4, 2018).

350. *E.g.*, Vienna Convention, *supra* note 201, art. 70(1).

351. Of course, TRIPS itself began a trend of limiting domestic discretion by imposing mandatory IP norms. However, given the more recent recognition of the importance of disclosing clinical study data, this suggests that TRIPS negotiators did not realize the full extent to which they were limiting public health options.

352. *E.g.*, *Transatlantic Trade and Investment Partnership—TTIP: A Civil Society Response to the Big Pharma Wish List*, COMMONS NETWORK 4 (Mar. 24, 2014) (noting corporations with access to negotiations but not the broader public); Margot Kaminski,

yet small, coalition of companies, including the pharmaceutical industry that stood to gain from such an agreement and persuaded their countries to act on their behalf.[353] Not only has this dynamic not dramatically changed,[354] but companies often have an official channel to provide input to government negotiators whereas policy advocates likely to provide a contrary view may not.[355] Unbalanced international norms may be particularly likely to result given that some negotiations have involved secret draft texts.[356]

Although the recent past reflects many examples of what should not be repeated, there is reason for some optimism. In particular, the most recent renegotiation of the UMCA—the new version of the prior North American Free Trade Agreement (NAFTA) between the United States, Canada, and Mexico—has actually resulted in a better balance of interests between pharmaceutical companies and public health. The original agreement signed in November 2018 would have significantly increased intellectual property protections for member countries.[357] Congressional Democrats refused to agree to the signed agreement without changes after more than seventy consumer groups demanded change.[358] Ultimately, the United States actually *reduced*, rather than increased, intellectual property protections in the recently revised UMCA.[359] However, Congressional

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Enough Already: The SOPA Debate Ignores How Much Copyright Protection We Already Have, ATLANTIC (Feb. 8, 2012) (noting that SOPA and other international agreements are negotiated without public input or transparency).

353. *See, e.g.*, SUSAN SELL, PUBLIC LAW, PRIVATE POWER *passim* (2003).

354. As noted by many commentators, companies have persuaded countries to advocate for higher IP standards than TRIPS in creating TRIPS-plus agreements. *E.g.*, *id.*

355. *See* Margo Kaminski, *The Capture of International Intellectual Property Through the US Trade Regime*, 87 S. CAL. L. REV 977 (2014); *see also* Margo Kaminski, *The US Trade Representative's Democracy Problem*, 35 SUFFOLK TRANSNAT'L L. REV. 519, 522 (2012) (noting that Anti-Counterfeiting Treaty Agreement was negotiated without even Congressional input); Taylor Wofford, *What is the Trans-Pacific Partnership and Why are Critics Upset By It?*, NEWSWEEK (June 12, 2015), https://www.newsweek.com/what-tpp-trade-deal-342449 [https://perma.cc/K728-V4FR] (discussing the lack of publicly available information concerning agreement negotiated over a decade and concerning aspects through leaked drafts).

356. *E.g.*, Timothy Vollmer, *Secret Negotiations, Empty Promises: Copyright Policymaking Needs Sunlight for Better Outcomes*, CREATIVE COMMONS BLOG (Jan. 17, 2018), https://creativecommons.org/2018/01/17/secret-negotiations-empty-promises-copyright-policymaking-needs-sunlight-better-outcomes/ [https://perma.cc/ATG3-8SBR].

357. *E.g.*, Robert Labonte et al., *USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health*, 15 GLOBALIZATION & HEALTH 1 (2019).

358. *E.g.*, Debbie Dingell, *USMCA Needs Upgrades Before Democrats Sign*, WASH. POST (Sept. 16, 2019), https://www.washingtonpost.com/business/2019/12/10/usmca-is-finally-done-deal-after-democrats-sign-off-heres-what-is-it/ [https://perma.cc/X3VS-QTCC]; Letter from the American Federation of Labor and Congress of Industrial Organizations [AFL-CIO] et al. to Congress (Jan. 22, 2019), https://www.citizen.org/wp-content/uploads/migration/civil-society-nafta-rx-pricing-letter-to-congress-january-2019.pdf [https://perma.cc/8G8Q-86VL].

359. *E.g.*, Heather Long, *The USMCA is Finally Done. Here's What is In It*, WASH. POST (Dec. 10, 2019), https://www.washingtonpost.com/business/2019/12/10/usmca-is-finally-done-deal-after-democrats-sign-off-heres-what-is-it/ [https://perma.cc/DA5H-GD5Q]; Nathaniel Weixel, *Democrats Declare Victory for Eliminating Drug Protections in Trade Deal*, HILL (Dec. 10, 2019), https://thehill.com/policy/healthcare/473953-demo-

Democrats that spearheaded this modification had unique leverage that typically does not exist.[360]

2. Re-evaluating Non-IP International Obligations and Needs

Even if international norms regarding IP do not further increase, domestic discretion is not a complete panacea on its own; rather, non-IP international norms may also need attention and possible modification. First, there are some international agreements that are not necessarily focused on IP that could still be used by IP owners to limit domestic actions to promote public health. Second, even if there are no additional international constraints, nations may need additional incentives to take domestic actions that promote public interest.

An important issue that could still threaten domestic efforts to promote clinical trial transparency is the possibility that a company could bring a dispute based on international agreements that promote investments under so-called "investor-state dispute actions." There is a web of over 1,000 different agreements that permit "foreign" companies to assert claims against countries that compromise their "investments" under these agreements,[361] which can include intellectual property rights.[362] So, for example, a company foreign to Canada could potentially assert a claim against Canada that challenges its data disclosure.[363] Moreover, even if Canada prevails, simply defending such a dispute is very expensive.[364]

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crats-declare-victory-for-eliminating-drug-protections-in-trade-deal [https://perma.cc/JG5X-XNA5]; Erik Wasson, *Plan NAFTA Vote as Pelosi Lauds Revised Deal*, BLOOMBERG NEWS (Dec. 10, 2019), https://www.bnnbloomberg.ca/house-democrats-plan-usmca-vote-as-pelosi-lauds-revised-deal-1.1360441 [https://perma.cc/MK6M-4AT7].

360. Although renegotiating NAFTA was a presidential campaign promise, the deal had previously languished until after impeachment proceedings. *E.g.*, Emily Cochrane, *Senate Passes Revised NAFTA, Sending Pact to Trump's Desk*, N.Y. TIMES (Jan. 16, 2020), https://www.nytimes.com/2020/01/16/us/politics/usmca-vote.html [https://perma.cc/KL6L-R9SP]; Eric Levitz, *Trump Mulls Throwing Big Pharma Under the Bus to Save New NAFTA*, N.Y. MAG. (Dec. 5, 2019), https://nymag.com/intelligencer/2019/12/usmca-trump-biologics-pelosi-drug-prices-nafta.html [https://perma.cc/4XBN-E6T9].

361. There are over 2000 bilateral investment treaties in force, and at least three treaties with investment provisions in force. UNCTAD, INV. POL'Y HUB, https://investmentpolicy.unctad.org/international-investment-agreements [https://perma.cc/K4DT-JNKQ] (last visited June 3, 2021).

362. Some companies have suggested that alleged violations of TRIPS would be a viable claim under such agreements. *E.g.*, Philip Morris Asia Ltd. (Hong Kong) v. Commonwealth of Austl. (H.K. v. Austl.), UNCITRAL, PCA Case No. 2012-12 , Notice of Arbitration (Perm. Ct. Arb. 2011), https://www.italaw.com/sites/default/files/case-documents/ita0665.pdf [https://perma.cc/QF8V-ERSD]. Indeed, even if there is no alleged TRIPS violation, such agreements can create new threats to domestic sovereignty based on IP as an investment. *E.g.*, James Gathii & Cynthia Ho, *Regime Shift of IP Lawmaking and Enforcement from WTO to Investment Regime,* 18 MINN. J. L. SCI. & TECH. 427 (2017).

363. Although the United States cannot assert such a claim under the recently renegotiated UMCA which eliminates this option, Canada has signed agreements with other countries that permit this option. For example, EU companies could sue under the EU-Canada Comprehensive Free Trade Agreement. Comprehensive Trade and Economic Agreement, Can.-EU, Oct. 30, 2016, 2017 O.J. (L 11) 23.

364. Matthew Hodgson & Alastair Campbell, *Investment Treaty Arbitration: Cost, Duration, Size of Claims All Show Steady Increase*, ALLEN & OVERY (Dec. 14, 2017), http:/

While a comprehensive discussion of the danger of investment claims for domestic actions that may be an issue under TRIPS is beyond the scope of this Article, it is important to at least recognize that this is yet another international norm that may potentially limit domestic action.[365] Accordingly, just as nations should be cautious of entering into more agreements permitting new international IP norms, nations should similarly be cautious of agreeing to more agreements permitting investor-state disputes. In addition, although in recent years these agreements have already been criticized, their potential to bar disclosure of clinical data provides yet another concrete example of why such agreements should be further scrutinized and reformed.[366]

Even if there are no further international constraints limiting countries from promoting public health, international policymaking could affirmatively encourage countries to promote more transparency of clinical data, and potentially other public health issues as well. Although this cannot be accomplished immediately, there are a number of different avenues that can be used to pursue this norm. For example, action at the UN level and/or by the WHO to recognize the importance and need to promote disclosure of clinical study reports would be an important first step. Such action may help countries counter complaints by private companies that resist transparency. In addition, an international agreement along the lines of the Tobacco Framework Convention could promote more clinical transparency.[367] Essentially, a "framework convention" sets legally binding commitments among multiple nations, while still permitting domestic discretion, or, alternatively, the possibility for subsequent, more detailed agreements.[368] The Tobacco Framework Convention was negotiated by the WHO to limit unnecessary deaths from tobacco. It has helped to establish tobacco control mechanisms and also helped countries counter legal challenges by tobacco companies.[369] Similarly, other international agreements

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/www.allenovery.com/publications/en-gb/Pages/Investment-Treaty-Arbitration-cost-duration-and-size-of-claims-all-show-steady-increase.aspx [https://perma.cc/67X5-QTU5] (noting average cost for respondent states of over USD $4.559 million); *see also* DIANA ROSERT, INT'L INST. FOR SUSTAINABLE DEV., THE STAKES ARE HIGH: A REVIEW OF THE FINANCIAL COSTS OF INVESTMENT TREATY ARBITRATION 8 (2014) (noting costs in some disputes of USD $40 to $80 million).

365. For more details, see Cynthia M. Ho, *A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings*, 6 UC IRVINE L. REV. 101 (2016).

366. *E.g.*, Lisa Sachs, *ISDS Reform at UNCITRAL: Two Guiding Principles,* COLUM. CTR. ON SUSTAINABLE INV. (Oct. 16, 2019), http://wordpress.ei.columbia.edu/vcc/2019/10/17/isds-reform-at-uncitral-two-guiding-principles/ [https://perma.cc/39TV-NQ7C]; Cynthia Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERK. TECH. L. J. 213, 220–21 (2015).

367. *See generally* WORLD HEALTH ORG. [WHO], FRAMEWORK CONVENTION ON TOBACCO CONTROL (2003).

368. *E.g.*, U.N. Econ. Comm'n Eur. [UNECE], Note by the Secretariat to the Comm. on Housing & Land Mgmt., 72nd Session: Framework Convention Concept (Oct. 3–4, 2011), https://unece.org/fileadmin/DAM/hlm/sessions/docs2011/informal.notice.5.pdf [https://perma.cc/A97T-YMP5].

369. *E.g.*, Janet Chung-Hall et al., *Impact of the WHO FCTC Over the First Decade: A Global Evidence Review Prepared for the Impact Assessment Expert Group*, 28 TOBACCO CONTROLS 119 (2019); Susan Zhou et al., *The Impact of the WHO Framework Convention*

that promote public health, but do not require clinical data transparency, could also be revisited. For example, some policymakers have previously recommended international agreements to set norms to promote greater respect for public interest in the context of intellectual property rights.[370] Although more explicit global requirements concerning clinical trial transparency would be better, this could still be a step in the right direction and ultimately lead to global norms to promote more clinical trial transparency.

B. Domestic Levers to Promote Clinical Trial Transparency

An important complement to reconsidering international obligations is to also reconsider domestic opportunities. As discussed earlier, clinical study reports are a valuable *part* of clinical trial transparency that countries can and should promote. There are a variety of mechanisms that can be more effectively utilized to promote better transparency. Although this is true in all countries, this section primarily focuses on the United States as an example.

1. Enforce Existing Laws

At a minimum, the FDA should enforce existing laws that require researchers to timely and accurately record summary results in ClinicalTrials.gov, which is publicly accessible and, in fact, used by doctors and patients.[371] The law mandating such reporting has existed since 2007,[372] with possible financial penalties of up to $10,000 per day in existence since 2018,[373] but the FDA only threatened penalties for the first time in 2021.[374] Along somewhat similar lines, the National Institutes of Health (NIH) has previously stated that it would terminate grants to those who ignore the reporting requirements, but has yet to do so.[375]

Although investigative reporting has revealed repeat offenders and resulted in some improvement, compliance is still problematic. There are

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on Tobacco Control in Defending Against Tobacco Control Measures, 28 TOBACCO CONTROLS 113 (2019).

370. *E.g.*, *Draft Treaty on Access to Knowledge*, CONSUMER PROTECTION ON TECH. (May 9, 2005), http://www.cptech.org/a2k/ a2k_treaty_may9.pdf [https://perma.cc/66DV-HT5T]; *The Paris Accord, Draft of June 17, 2006*, CONSUMER PROTECTION ON TECH. (2005), http://www.cptech.org/a2k/pa/ParisAccord-june17draft.pdf [https://perma.cc/685C-FQN3]; *Medical Research and Development Treaty (MRDT), Discussion Draft 4*, CONSUMER PROTECTION ON TECH. (Feb. 7, 2005), http://www.cptech.org/workingdrafts/rnd-treaty4.pdf [https://perma.cc/Y9UL-HHJW].

371. There are 215 million monthly views. Piller, *supra* note 73, at 241.

372. *E.g.*, Darrow et al., *supra* note 113, at 2101 (noting 2007 change that required all clinical trials to be included instead of only serious or life-threatening conditions).

373. 21 U.S.C. § 333(f)(3)(B) (2018) (authorizing penalties of up to $10,000 a day).

374. Letter from the FDA to Acceleron Pharma, Inc. (Apr. 27, 2021), https://www.fda.gov/media/148036/download [https://perma.cc/S2CA-GX7Q]; *see also* Ed Silverman, *For the First Time, the FDA May Fine a Drug Maker for Failing to Post Clinical Trial Results*, STAT (Apr. 28, 2021), https://www.statnews.com/pharmalot/2021/04/28/fda-acceleron-clinical-trials-transparency/ [https://perma.cc/V3MX-7DPC] (discussing FDA letter); FDAAA TRIALSTRACKER, *supra* note 59.

375. Piller, *supra* note 73, at 241.

thirty entities that have never met a *single* deadline.[376] Major public institutions and NIH grant awardees, such as Boston Children's Hospital and Baylor College of Medicine, are among the violators.[377] Although private companies have a better compliance rate on paper for meeting deadlines than universities, the actual disclosure can be substandard: Half of initial registrations are rejected, and some suggest that companies intentionally file incomplete information to delay availability of information that they view as proprietary.[378]

Moreover, the FDA should enforce *Siefe v. HSS*, a March 2020 ruling that found that a full decade of summary results are missing from ClinicalTrials.gov.[379] As noted by the Southern District of New York, NIH regulations that exempted certain clinical trials conducted between 2007 and 2017 from reporting summary results were inconsistent with statutory requirements.[380] The court ordered summary results from trials concluded during this period to be posted.[381] Although this decision impacts previously approved drugs, such data is still relevant and could result in hundreds and potentially more than 1,000 trial results becoming available.[382] For example, one of the plaintiffs was seeking a clinical study supporting controversial approval of a treatment for Duchenne muscular disease that was retracted from publication such that the only possible available data would be from ClinicalTrials.gov, yet it was missing.[383]

The *Seife* case also underscores that the FDA can—even though it thus far has not—post noncompliance notices for failure to register and/or report summary clinical trial data.[384] Although the *Seife* plaintiffs asked the court to require the NIH to post notices on ClinicalTrials.gov regarding noncompliance with reporting requirements, the court rejected this claim as not yet subject to judicial review until the FDA first issues a notice of compliance to the violator.[385] Accordingly, an important step to help

376. *Id.* at 240.

377. *Id.* at 240–241. Public entities may lack adequate infrastructure for such reporting. *See* Deborah A. Zarin et al., *10-year Update on Study Results Submitted to Clincialtrials.gov.,* 381 NEW. ENG. J. MED 1966, 1970 (2019) [hereinafter Zarin 2019].

378. Piller, *supra* note 73, at 243; Zarin 2019, *supra* note 377, at 1970.

379. Seife v. United States Dep't of Health & Hum. Servs., 440 F.Supp.3d 254, 283 (S.D.N.Y. 2020).

380. *Id.* HHS had considered that clinical trials completed after the 2007 law but before the effective date of the 2016 regulation did not need to provide summary results if the FDA approval happened after the trial was concluded. *Id.* at 268. The court rejected this argument since the 2007 legislation clearly required summary results to clinical study results for every approved product and companies were only exempted by regulation six years after the statutory deadline for the rule was created. *Id.* at 278.

381. *Id.* at 284.

382. Lev Facher, *Federal judge rules clinical trial sponsors must publish a decade's worth of missing data,* STAT (Feb. 25, 2020), https://www.statnews.com/2020/02/25/clinical-trial-sponsors-publish-missing-data/ [https://perma.cc/8VLW-NRQ8]. Of course, whether companies will actually post their results or what consequences may exist if they do not, remains unclear. *Id.*

383. Seife, 440 F.Supp.3d at 269.

384. *Id.* at 281.

385. *Id.* at 266 (noting that FDA must give violator notice and an opportunity to remedy noncompliance within thirty days after notification); *see also* Director of National

enforce obligations is for the FDA to issue noncompliance notices. In addition, the NIH should create a function on ClinicalTrials.gov that searches for notices of compliance since this is required by statute.[386]

Even if the FDA does not issue noncompliance notices or impose monetary sanctions, it possesses other tools at its disposal to encourage greater compliance. For example, the FDA could compile and make publicly available a list of entities that fail to comply. Given that prior investigative reporting has prompted some companies to comply with the law, public disclosure of problems holds promise.[387] Moreover, such an approach is something that the FDA has recently used to attempt to encourage brand name companies to share drugs with generics.[388] In addition, the FDA has long used this approach with online publication of noncompliance and warning letters.[389] Of course, for maximum effectiveness, any such policy should be thoughtfully organized to make it broadly disseminated and easily understandable by all.[390]

Institutes of Health, 42 U.S.C. § 282(j)(5)(C)(ii) (2018). This is an essential step because the NIH notice must include information that only exists after the FDA provides notice, such as whether the responsible party has corrected the information on ClinicalTrials.gov and what penalties, if any, are imposed for the violation. *Seife*, at 267.

386. Siefe, 440 F.Supp.3d at 267; *see also* Director of National Institutes, 42 U.S.C. § 282 (j)(3)(G) (2018) (requiring NIH director to ensure the public can easily search the database for entries such as notice of compliance).

387. *E.g.*, Holly Fernandez Lynch, *It's time to levy penalties for failing to report clinical trial results*, STAT (Jan. 17, 2018), https://www.statnews.com/2018/01/17/time-levy-penalties-failing-report-clinical-trial-results/ [https://perma.cc/5G2W-MCPZ] (noting that trial sponsors disclosed 72% of required results on ClinicalTrials.gov as of 2017, which is an improvement compared to 58% compliance two years earlier).

388. Press Release, Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition (May 17, 2018); *see also* Sheila Kaplan, *F.D.A. Names and Shames Drug Makers to Encourage Generic Competition*, N.Y. TIMES (May 17, 2018), https://www.nytimes.com/2018/05/17/health/drug-prices-generics-fda.html [https://perma.cc/PF8Y-BFC8]; Sydney Lupkin, *Drugmakers Blamed For Blocking Generics Have Jacked Up Prices And Cost U.S. Billions*, KAISER HEALTH NEWS (May 23, 2018), https://khn.org/news/drugmakers-blamed-for-blocking-generics-have-milked-prices-and-cost-u-s-billions/ [https://perma.cc/7QVH-DVBE] (noting that FDA list includes fifty companies and also includes chart of some inaccessible drugs, together with changes in cost and number of inquiries to the FDA). Subsequently, Congress passed the CREATES Act, allowing generic companies to directly sue companies, which make this action unnecessary. *Access to Product Samples: The CREATES Act*, U.S. Food & Drug Administration (March 13, 2020), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act [https://perma.cc/C5NA-2DKU].

389. *Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, U.S. Food & Drug Administration (Feb. 17, 2021), https://www.fda.gov/drugs/enforcement-activities-fda/warning-letters-and-notice-violation-letters-pharmaceutical-companies [https://perma.cc/MV5U-Q5T9].

390. Sharon Yadin, *Shaming Big Pharma*, 36 YALE J. ON REGUL. BULL. 131, 140 (2019) (noting that prior FDA publication of firms that failed to provide drugs to generics provided ineffective shaming because of these issues).

2. Broaden Disclosure of Clinical Study Reports

Even though only two jurisdictions are prospectively disclosing clinical study reports, it is still important for the United States to do so. First, although drug companies tend to seek approval in multiple countries, it is possible that the FDA may approve a drug that the EMA and Canada do not. In such circumstances, doctors and patients will lack access to these reports. In addition, even if the EMA or Canada approves the same drug as the FDA, the FDA approval may happen earlier.[391] In such circumstances, U.S. patients and doctors will still be in the dark regarding recently marketed drugs until the reports are disclosed by other jurisdictions.

The most incremental step that the FDA can take to promote greater transparency would be to modify its approach and interpretation of the Freedom of Information (FOIA) requests. Traditionally, the FDA has asserted that all CSRs constitute commercial confidential information that cannot be disclosed.[392] However, the reality is that FOIA does not bar disclosure of such information; rather, it simply permits an agency to decline disclosure *if* the agency establishes that the information is in fact commercially confidential.[393] As discussed earlier, the entirety of CSRs are not confidential. Not only have scholars criticized the FDA position, but courts have also sometimes overruled FDA opposition during litigation.[394] However, even if the FDA modifies its approach, this will provide only modest information since a FOIA request may take years, even if successful.[395] This is especially true given recent Supreme Court precedent that might make it more challenging to obtain documents.[396] Moreover, FOIA requests are not a workable approach to address the information asymmetry that exists for *all* newly marketed drugs.

Promoting broader disclosure of CSR in the United States will require more affirmative action. One potential obstacle is that the FDA views disclosure of CSRs as barred by the Trade Secret Act. However, the FDA could more narrowly construe what constitutes a trade secret and also enact reg-

391. Nicholas Downing, *Regulatory Review of Novel Therapeutics - Comparison of Three Regulatory Agencies*, 366 NEW ENG. J. MED. 2284, 2284 (2012); Nicholas S. Dowing et al., *Regulatory Review of New Therapeutic Agents - FDA versus EMA, 2011–2015*, 376 NEW ENG. J. MED. 1386, 1386 (2017).

392. See sources collected and accompanying text, *supra* note 1.

393. Gov't Accountability Project v. United States Dep't of Health and Hum. Servs., 691 F.Supp.2d 170, 180 (2010); *see also* Chrysler Corp. v. Brown, 441 U.S. 281, 293 (1979) (noting that FOIA exemptions are not mandatory bars to disclosure).

394. *See supra* note 159 (citing court cases). The FDA's claim that total nondisclosure of clinical data is justified has been criticized. *E.g.*, Arti Rai, *Risk Regulation and Innovation: The Case of Rights-Encumbered Biomedical Data Silos*, 92 NOTRE DAME L. REV. 1641, 1655 (2017); Amy Kapczynski & Jeanie Kim, *Clinical Trial Transparency: The FDA Should and Can Do More,* 45 J. OF L., MED. & ETHICS 33 (2018).

395. *E.g.*, Doshi v. Att'y Gen. Can., *supra* note 305, ¶ 14 (noting time consuming and expensive process for seeking documents through litigation).

396. Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2363 (2019) (finding that FOIA exemption 4 regarding commercially confidential data no longer requires proof of substantial competitive harm and may instead cover what is simply customarily private).

ulation to prohibit liability.[397] In particular, although the Trade Secret Act prohibits disclosure of trade secret information if "not authorized by law," the FDA can (through its general rulemaking authority) enact a new regulation to permit or require disclosure of clinical study data.[398] Such a regulation would ensure that all such data could be disclosed without it being a liability. At the same time, the FDA would need to rescind 21 C.F.R. § 20.61(c), which unnecessarily promises organizations that data submitted to the FDA that constitutes a trade secret or confidential commercial information is not available for public disclosure.[399] Although this approach may seem radical, it is not only supported by what other regulatory agencies have done but is also consistent with judicial decisions finding clinical study reports are not entirely confidential. Nonetheless, actual FDA action is of course dependent on the political economy, and the reality is that the pharmaceutical industry is effectively the largest funder of the agency, such that it may not be inclined to take actions perceived as adverse to the industry even if in the public interest. Past experience with lack of FDA implementation of fines for failure to comply with even minimal reporting requirements suggest that logical recommendations may not take place. Moreover, although a new administration will be in place by the time this Article is published, recent history clearly indicates that the FDA's rule-making ability can be conditioned by the U.S. Department of Health and Human Services (HHS), such that this could occur again.[400]

Conclusion

Although this Article has explained why prospective disclosure of clinical study reports by the EMA and Canada should be consistent with

397. Morten & Kapczynski, *supra* note 176.

398. Of course, any U.S. action should be consistent with international obligations. However, as discussed, disclosure of clinical data is consistent with TRIPS. *See infra* Part III.B. Moreover, more recent FTAs are either consistent with TRIPS or are silent on the issue of whether a country may disclose data submitted for regulatory approval even though they clearly mandate data exclusivity, which only impacts when a second drug can be approved but not disclosure of underlying data. *E.g.*, United States-Mexico-Canada Agreement (USMCA) art. 20.48 (chap. 20, Intellectual Property), July 1, 2020, (requiring data exclusivity but no obligations concerning governmental disclosure of data); *id.* art. 20.77 (stating that countries shall bar unauthorized disclosure of trade secrets by government officials "outside the scope of that person's official duties," when trade secrets were provided for regulatory proceedings, which seems to imply that disclosure is permissible if part of the official duties as well as if the information does not rise to the level of a trade secret, which could be the case with clinical data). *See also* US-Panama Trade Promotion Agreement art. 15.10(2)(a), June 28, 2007, https://ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text [https://perma.cc/WQ9Z-9HHG] (requiring protection against disclosure except where disclosure is "necessary" or "steps are taken to ensure data is protected against unfair commercial use").

399. Morten & Kapczysnki, *supra* note 176, at 540. Similarly, the FDA would need to rescind various rules that promise secrecy for various aspects of safety and efficacy data. *Id.* n. 245.

400. *E.g.*, Sheila Kaplan, *In Power Grab, Health Secretary Azar Asserts Authority Over FDA*, N.Y. TIMES (Sept. 19, 2020), https://www.nytimes.com/2020/09/19/health/azar-hhs-fda.html [https://perma.cc/VUM3-W8H4] (reporting about HHS barring FDA from exercising rule making authority).

TRIPS, it is a cautionary tale. Notably, although the focus here is on an arguably narrow issue, an important takeaway is that this provides a concrete example of how international agreements protecting intellectual property rights can cast a shadow on domestic abilities to protect public health. While scholars have long noted that international IP obligations can negatively impact public health through higher drug costs, this Article highlights a generally overlooked issue—that promoting IP rights can impose unintended and unexpected constraints on domestic regulatory options.[401] As this Article has shown, even domestic regulations with strong public health support require a detailed analysis to assess compliance with TRIPS. This is not entirely surprising since TRIPS was designed largely by companies desiring maximal intellectual property protections rather than public health flexibilities. This Article underscores the importance for future negotiations of international agreements to maximize domestic discretion to accommodate unanticipated issues. In addition, to promote balance, new international norms promoting public health may be necessary to counter existing agreements promoting intellectual property. However, even new international norms will require vigilance to protect against creative arguments concerning the "need" to protect IP.[402]

This Article has provided a template of how the United States can promote greater transparency while complying with TRIPS. Although public disclosure of data by the EMA and Canada is valuable, it is not enough for U.S. patients and doctors. After all, regulatory decisions are not always consistent and companies may also seek approval in the United States first. Accordingly, U.S. patients and doctors cannot simply rely on disclosures from other jurisdictions. Of course, modifying U.S. laws to promote disclosure of clinical study reports would be a major change. However, as discussed, the EMA and Canada previously considered these reports confidential and modified their position. As evident, change is possible. In addition, as this Article has revealed, such change can comply with TRIPS.

However, since opposition to disclosure of clinical study reports often involves an alleged violation of intellectual property rights and/or decreased innovation, there is a need to address the tension between intellectual property rights and public health. Countries may want to consider whether trade secrecy as well as data exclusivity should be modified to

401. Whether TRIPS article 39 mandates data exclusivity and thus delays low-cost generics has long been discussed, but not whether article 39 constrains the ability of nations to exercise domestic regulatory authority to disclose data.

402. For example, although a Global Framework on Tobacco was created, that did not forestall a WTO challenge. Although a WTO panel eventually confirmed that Uruguay's public health approach consistent with the Global Framework was consistent with the WTO, Uruguay was only able to withstand this challenge due to the fortuitous funding by Michael Bloomberg, which is not always an option for most countries. *See, e.g.*, Eric Crosbie & Stanton Glantz, *Philip Morris Gets Its Ash Kicked in Uruguay*, THE CONVERSATION (July 31, 2016), https://theconversation.com/philip-morris-gets-its-ash-kicked-in-uruguay-where-will-it-next-blow-smoke-62933 [https://perma.cc/ZR5F-2CNF].

create exceptions, at least for public health.[403] Countries should also consider whether to permit multiple types of protection, such as patents and data exclusivity on drugs, which impede affordable access.[404] As this Article has shown, companies tend to overstate the relevance and need of intellectual property relevant to clinical study reports. Moreover, the underlying justification for intellectual property protection is to promote social good, which is not always true with maximum rights. To ensure that society is not unduly burdened with IP protection without adequate benefit, countries may want to consider providing companies with multiple types of intellectual property protection *only* if they publicly disclose clinical study reports.[405] Admittedly, such a proposal is currently far from reality. However, it can be something to work toward.

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403. *E.g.*, Ellen F. M. 't Hoen et al., *Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation*, 10 J. PHARM. POL'Y & PRAC. 1 (2017) (recommending exceptions for data exclusivity). Some suggest trade secret protection is not appropriate if it involves health and safety data, environmental concerns, or public infrastructure. David S. Levine, *Secrecy and Unaccountability: Trade Secrets in our Public infrastructure,* 59 FLA. L. REV. 135, 191 (2007); David S. Levine, *The People's Trade Secrets*, 18 MICH. TELECOMM. & TECH. L. REV. 61, 80 (2011); Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, 78 U. COLO. L. REV. 465, 497 (2007).

404. *E.g.*, Sarah Boseley, *Why Do New Medicines Cost So Much and What Can We Do About It?,* GUARDIAN (Apr. 9, 2018), https://www.theguardian.com/news/2018/apr/09/why-do-new-medicines-cost-so-much-and-what-can-we-do-about-it [https://perma.cc/NK6P-4YCM]; Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, ATLANTIC (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/ [https://perma.cc/87AY-KA9W]; Ed Silverman, *UN panel urges wider access to medicines, but pharma slams the report*, STAT (Sept. 14, 2016), https://www.statnews.com/pharmalot/2016/09/14/united-nations-drug-prices-patents/ [https://perma.cc/S78L-MW6W].

405. Morten & Kapczynski, *supra* note 176, at 49 (suggesting disclosure of drug data required in exchange for patent rights and/or the right to sell drugs).