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Custom Citation

Durkin, A., Sta. Maria, P. A., Willmore, B., & Kapczynski, A. (2021). Addressing the risks that trade secret protections pose for health and rights. *Health and Human Rights Journal*, 23(1), 129–143.

<https://www.hhrjournal.org/2021/06/addressing-the-risks-that-trade-secret-protections-pose-for-health-and-rights/>

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Addressing the Risks That Trade Secret Protections Pose for Health and Rights

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Abstract

Human rights frameworks afford everyone the right to health and the right to enjoy the benefits of scientific progress and its applications. Both come together to create state obligations to ensure access to medicines and other health technologies. Though the impact of patents on access to high-quality, affordable medicines and health technologies has been well described, there has been little attention to the impact of trade secrecy law in this context. In this paper, we describe how trade secrecy protection comes into conflict with access to medicines—for example, by preventing researchers from accessing clinical trial data, undermining the scale-up of manufacturing in pandemics, and deterring whistleblowers from reporting industry misconduct. The paper proposes measures to diminish the conflict between trade secrecy and health that are consistent with international law and will advance health without undermining innovation.

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Competing interests: None declared.

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Introduction

The right to health is widely recognized in international treaties,¹ and every state has ratified at least one of the several international agreements that recognize it.² The affirmative right to health necessarily entails access to medicines and other health technologies such as vaccines and diagnostics, as recognized by international bodies and domestic courts alike.³ (In this paper, we use the shorthand “access to medicines” to refer to access to a variety of health technologies, including vaccines and diagnostics.) Access to medicines, in turn, requires institutional and legal arrangements that ensure that appropriate medicines are developed, tested, and made available equitably and at affordable prices.

Realizing health rights, as one of us has emphasized, requires interventions in law and political economy.⁴ Political economy approaches to law recognize that law constructs markets and that the shape law gives to markets implicates values of equality and democracy—for example, by shaping who has access to health technologies. Intellectual property law is a key component of how law structures markets in, and access to, scientific advances. Patents, for example, are legally granted temporary monopolies that create both incentives for the development of medicines and barriers to affordable medicines. Safeguarding the right to health requires the international community and individual states to balance, adjust, or even override intellectual property provisions.

A great deal of work has been done to illuminate the relationship between patents and access to medicines. But the role that trade secrecy law, another type of intellectual property, plays in limiting access to quality and affordable medicines has received far less attention. An emerging literature has begun to explicate how the protection of trade secrets and confidential corporate information creates barriers to data and information that the public has vital interests in accessing, including information about voting technologies, criminal justice and surveillance technologies, and environmental hazards. This opaqueness compromises important public interests in democratic accountability and public health and safety.⁵ This paper adds to that

literature, detailing how trade secrecy can also impede access to information that is needed to ensure quality, affordable medicines, thereby burdening the public’s right to health and its right to enjoy the benefits of scientific progress and its applications.⁶ As we describe, trade secrecy may be invoked in a manner that prevents public access to clinical trial data, drug pricing data, evidence of corporate wrongdoing, manufacturing information needed to decentralize production, or biologic resources important to treatment and vaccine development.

Access to these resources is particularly acute now, while the world is struggling to respond to the COVID-19 pandemic. On October 2, 2020, India and South Africa submitted a communication to the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) proposing a waiver of sections 1, 4, 5, and 7 of part II of the TRIPS Agreement in order to support measures to prevent, treat, and contain COVID-19.⁷ The proposal suggests waiving protections of undisclosed information, described in TRIPS section 7. This is of special importance due to the rapid development of treatments and vaccines for COVID-19, and the dramatic global disparities in access to these technologies. Although the public made extraordinary investments in private companies’ vaccine research and development, details of clinical trial data and government contracts remain secret. For example, when immense public pressure led to the release of US vaccine contracts in November 2020, the public learned that the Johnson & Johnson contract explicitly allowed the company to keep secret “production/manufacturing know-how, trade secrets, [and] clinical data.”⁸ Similarly, the European Commission’s first two publicly released vaccine contracts include generous redactions of alleged “confidential information,” including the price per dose, the amount paid up front, and the rollout schedule.⁹ We show why access to information that companies may (rightly or wrongly) designate as trade secrets can be important for public health, why the problem is becoming more acute, and how states can interpret or revise trade secrecy protections to enable them to promote access to medicines.

The rise of trade secret protections

Trade secrecy law generally protects information that is secret, commercially valuable because it is secret, and subject to reasonable efforts to protect its secrecy. Trade secret protections are distinct from patents and copyrights. In certain ways, they are weaker: unlike patents, trade secrets are not protected from independent invention, and they can be used or disclosed if they are discovered by “fair” means. In other ways, they are stronger: both patents and copyright protection are limited to a specific number of years, but trade secret protections can be indefinite. Companies can claim trade secret protection without any registration, and the scope of these rights often become clear only after litigation. Trade secret protections are also not subject to clear exceptions and limitations, such as the “fair use” right in copyright.

The history of trade secrecy law is obscure and disputed, and no major body of scholarship summarizes the transnational evolution of trade secret protection. Broadly speaking, however, protection for trade secrecy follows an arc similar to other forms of intellectual property, growing stronger in many jurisdictions in recent decades.¹⁰

One difficulty tracing the evolution of trade secrecy law around the world is the wide array of ways that states protect trade secrets. Many common law legal traditions, for example, have long protected certain kinds of business information through the rubric of unfair competition law or contract law.¹¹ A competitor stealing information from another could be liable in tort, and an employee who reveals a secret they promised to protect could be liable in contract. Over time, courts have expanded these rights—for example, by implying contracts in certain settings and by preventing the use of trade secrets by some third parties who obtain them improperly. In civil law settings, commercial secrets have commonly received protection under regulation and statute, such as general laws protecting fair competition.¹² Many Asian countries have historically protected trade secrets through informal norms and business relationships rather than through legal means. Countries have thus not always had—and still today do not necessarily

have—a special domain of “trade secrets law.” In India, for example, commercial secrets are not protected as such, but can be protected via the law of contracts and misappropriation. In Germany, trade secrets are protected in a general fair competition statute. In Malaysia, the law of confidence generally governs confidential commercial information, while in Chile the only reference to trade secrets is in criminal law provisions.

In the United States, however, there are a few clear inflection points that show the increased strength of this area of law. Until the 1980s, the leading source of guidance for courts was the Restatement (First) on Torts, which made it clear that trade secrets were protected only in tort, as a violation of “of relationally specific duties,” and did not reflect any “right of property in the idea.”¹³ In 1984, however, the US Supreme Court declared that trade secret rights were indeed a kind of property for the purposes of the US Constitution and thus could be protected from unlawful “takings” of private property—meaning that a government that improperly revealed a trade secret would be required to pay compensation.¹⁴ Early cases in the US and the First Restatement often treated the core information protectable by trade secrecy as technical information about industrial processes and formulas.¹⁵ Today, the US legal framework, shaped largely by the Uniform Trade Secrets Act, defines the scope of trade secrets far more broadly, as covering any “information” that is commercially valuable, secret, and subject to reasonable efforts to keep it secret.¹⁶ In 2016, the US Congress additionally passed the Defend Trade Secrets Act, expanding the law again by providing federal jurisdiction for cases involving the misappropriation of trade secrets. After advocacy regarding the conflict of trade secrets with public interests in access to information, the law also incorporated limited “whistleblower” protections, limiting criminal and civil liability for those disclosing a trade secret pursuant to reporting a suspected violation of the law.¹⁷

In combination with the rise of information technologies and the “informationalization” of the economy, these shifts have had substantial implications. Businesses in the United States can now

claim as their property not just secret formulas but an almost limitless range of information and data, even if such claims might not hold up in court. The implications for public access to information are formidable. In 2001, for example, a US appeals court held that a state could not require the public disclosure of all of the ingredients in cigarettes, even if this disclosure might benefit public health, unless the state first paid the company for “taking” its trade secrets.¹⁸

The 1980s and 1990s also marked a moment when the United States and other wealthy countries made strengthened intellectual property law a significant trade priority, pressing developing countries in particular to adopt stronger intellectual property rights.¹⁹ The WTO’s 1995 TRIPS Agreement played a significant role here. All members of the WTO must adhere to it, and violations of TRIPS are actionable in dispute resolution. Trade sanctions are also possible where countries do not bring their law into compliance.²⁰ Under article 39 of TRIPS, countries must provide protection for “undisclosed information,” provided that the information is sufficiently secret, “has commercial value because it is secret,” and has been “subject to reasonable steps under the circumstances” to keep it secret. Drafters refrained from using the term “trade secret” to avoid associations with any particular legal system, and the requirement of protection for “undisclosed information” does not require a US-style trade secrets law.²¹ International commitments thus give countries many flexibilities with respect to how they implement protection.²²

Wealthy countries have regularly sought to increase protections for trade secrets in bilateral and multilateral agreements.²³ For example, the recent United States-Mexico-Canada Agreement, the result of the renegotiation of the North American Free Trade Agreement, includes “the most robust protection for trade secrets of any prior [US] agreement.”²⁴ It obligates parties to provide both civil and criminal remedies for the misappropriation of trade secrets, judicial procedures to prevent the disclosure of trade secrets during litigation, and corresponding penalties. These measures were not required by earlier instruments such as TRIPS. The

agreement also makes it more difficult for regulators to seek “confidential business information” from commercial entities for certain products.²⁵ This and other bilateral and multilateral agreements contribute to the rising floor of international trade secrecy protections.

As noted above, there do remain meaningful cross-jurisdiction differences in the scope of trade secret protections. But continued trade pressure and efforts to attract foreign investment have led to a recent wave of standardization, with major laws protecting trade secrets recently passed around the world, including in China, Thailand, Taiwan, and Japan.²⁶ The European Parliament and Council adopted a directive in 2016, which requires all European Union (EU) member states to amend their existing laws to comply with a minimum level of trade secrecy protection. Importantly, the directive provides some room for local variation in implementation and also provides exceptions to the enforcement of trade secret laws where, for example, disclosure of the trade secret was for purposes of reporting wrongdoing or protecting a “legitimate interest recognized by Union or national law.”²⁷

Uses of trade secrets and consequences for access to medicines

As the scope of protectable trade secrets has expanded, companies have claimed trade secret or trade secret-like protections for many types of information relevant to health. The consequences for the ability of all people to access safe and affordable medicines are significant.

Clinical trial data

Understanding the safety and efficacy of medicines on the market is crucial for public health.²⁸ Pharmaceutical companies regularly collect safety and efficacy data, including individual participant data, metadata (such as trial protocols for interpreting results), and summary-level data.²⁹ Health regulators require companies to submit clinical trial data to assess the safety and efficacy of proposed medicines. (Fewer data may be required for technologies such as diagnostics, and there is no clear regulatory

framework yet for newer technologies such as health apps.) Companies do, however, commonly invoke trade secret protections to prevent or limit the disclosure of data to outside researchers or the public.

Keeping such data secret has significant consequences. First, regulators are often understaffed and under pressure to approve medicines quickly, and they sometimes make mistakes. Without access to clinical trial data, researchers cannot verify or investigate a medicine's claimed benefits and risks. There are many examples where serious—sometimes deadly—side effects, or a lack of efficacy, were revealed only many years after a drug has been on the market, because clinical trial data were kept secret from researchers. Prominent examples include rofecoxib (Vioxx), estrogen hormone therapy (Prempro), and extended-release oxycodone (OxyContin).³⁰

Clinical trial secrecy can also obstruct the proper operation of health technology assessments, which contribute to health care provision and reform. Health technology assessments “provide a range of stakeholders ... with accessible, usable and evidence-based information to guide decisions about the use and diffusion of technology and efficient allocation of resources.”³¹ For example, they are used to make recommendations about the proper pricing of medicines and how to channel funds toward research that will have the most value for patients. However, health technology assessments can only function when they have sufficient information about the drugs and devices they are assessing.

Researchers can also make new uses of clinical trial data where they are available, such as to predict how subgroups will respond to a medicine or to understand the natural course of a disease. In the case of COVID-19 vaccines, for example, access to clinical trial data and post-market surveillance data may help researchers understand more about COVID-19 infection and immune responses, as well as ask new questions about the safety and efficacy of the vaccines.³² Strong advocacy around access to data has had a significant impact in this context. US regulators released detailed summaries—although

not all data—about vaccines during the regulatory process, and companies have published key trials relatively quickly. These measures have helped scientists understand and debate their efficacy and have likely bolstered public trust in regulatory processes and vaccines.

Access to study protocols is critical for allowing researchers to interpret trial results and to evaluate whether a study's design can produce the information needed. For example, when several companies testing COVID-19 vaccines, after public pressure, voluntarily agreed to release the secret protocols for their studies, this allowed researchers to evaluate the endpoints used, enabling debate about how well the vaccines will protect against transmission and not just against severe disease. When protocols are public, it is also possible to identify improper “outcome switching” or “data dredging,” which occurs when researchers change the primary outcome measures during the analysis stage from those identified in the study protocol to those that make their study results appear more favorable.³³

Second, inhibiting public access to clinical trial data undermines the development of new drugs. Under the current regime, companies and regulators need not disclose the existence of, much less the data from, failed or abandoned preclinical studies and clinical trials.³⁴ This practice drives up the costs of drug development and undermines innovation because researchers cannot “learn from the failures of previous medical products in subsequent research programs.”³⁵ Lack of access to this information may result in unnecessary and unethical human and animal experimentation as companies remake and retest unsuccessful compounds.

Engineering and manufacturing data

Even after patent and data exclusivity periods for drugs expire, trade secret protections permit pharmaceutical companies to keep the precise composition or manufacturing process for medications confidential. This effectively slows the release of generic competitor drugs by preventing their reliance on existing engineering and manufacturing data. As a consequence, drug companies can pre-

serve monopolies on medications that are difficult to reverse engineer.

Trade secret protections can effectively lengthen exclusivity periods for biological medicines in particular. In the case of “small molecule” medicines, which are synthesized in chemical reactions, a researcher can chemically reverse engineer the product. However, biologics, a newer group of medications that are often grown in or derived from living organisms, are more difficult to replicate. Biologics, composed of complex protein or other macromolecules and compositions, are comparatively difficult to produce, and their efficacy and safety depend on the specific conditions of their manufacture.³⁶ To produce follow-on biologics, researchers would benefit from access to manufacturing information, which includes the specific cell line used, the host organism from which the cells were taken, the variable introduced to arrive at the final cell line selection, the method of optimization for the culture medium, the production environment used to grow the cells, and the procedure for isolation and purification of the relevant protein, among other data.³⁷

Access to these alleged trade secret resources and information would also lighten the regulatory burden and therefore hasten consumers’ access to critical medicines. Health regulators treat biosimilars differently from small-molecule medications. For example, the US Food and Drug Administration (FDA) currently approves biosimilars only if testing demonstrates that they are sufficiently biosimilar to the original product.³⁸ However, these time-consuming testing requirements could be simplified if regulators could be confident that the biosimilar was produced with high fidelity to the originator’s production. The licensing of trade secrets can allow production under the originator’s regulatory approval, and information exchange can also enable independent production of biological generics or biosimilars. Without access to alleged trade secret biologic resources and production information, the approval of biosimilars can take longer, leading to higher prices for originator products.³⁹ This ultimately drives up the cost of health care and reduces patients’ access to critical, cutting-edge biological

vaccines and treatments for conditions, including rheumatoid arthritis, anemia, multiple sclerosis, and cancer.⁴⁰ Given the importance of the rapid scale-up of COVID-19 vaccines around the world, many have advocated for the need for the transfer and licensing of manufacturing information in this context.⁴¹

Trade secret protections may also be used to inhibit access to engineering and manufacturing data for vaccines and diagnostics, such as those critical to resolving the ongoing COVID-19 crisis.⁴² Most diagnostics, such as those used for rapid testing for the virus, “are being developed commercially and with proprietary technology,” meaning that concerns about proprietary barriers to scale-up are particularly acute.⁴³ And while a great deal of public funding is being dedicated to developing vaccines and therapeutics, there does not appear to be any concerted effort on the part of funders to insist on either open access to resulting data or the sharing of trade secrets to ensure the possibility of competitive manufacture.⁴⁴ To resolve this pandemic, a coordinated effort must be made to increase capacity for testing, tracing, vaccinating, and treating, particularly among developing and the least developed countries. Sharing data and manufacturing know-how for diagnostics and vaccines will be crucial for enhancing production and ultimately mitigating the harms of the COVID-19 pandemic. Trade secrecy laws obstruct these efforts.

Data related to artificial intelligence

Artificial intelligence will likely permit important advances in health care in the coming years and decades. A subset of artificial intelligence known as “machine learning” uses computer algorithms to analyze large amounts of data, to identify patterns, and to use these patterns to make predictions. The technology is already widely deployed to determine who receives health and disability benefits, to improve patient outcomes, to connect eligible patients to clinical trials, and to promote drug development.⁴⁵

Without access to the algorithm and its underlying raw data, it can be difficult to identify problems with these systems. This is a serious

concern, because despite the perception of these systems as “intelligent,” well-known biases can affect them.⁴⁶ Access to algorithms and training data not only allows for better evaluation but also allows researchers with public health priorities in mind to improve these technologies. Yet companies may invoke trade secrets to guard predictive algorithms, related artificial intelligence and machine learning techniques, and the large datasets that these require to function.

Drug pricing data

Pharmaceutical companies have invoked trade secret protections and trade secret-like protections to limit access to various types of financial information, including drug prices, research and development costs, manufacturing costs, and details regarding financial arrangements. In the United States, for example, companies have litigated against transparency laws that sought to require them to make the prices of their medicines known to the public (when they might otherwise remain obscured by secret rebates or other deals). Collectively, we refer to these as “drug pricing data” because they are all relevant to the matter of fair pricing. The consequences of protecting this information are significant. A lack of transparent pricing information fuels high drug prices, while obscuring the research and development costs limits our ability to calibrate innovation policy and to identify price gouging.

Information about wrongdoing

Whistleblowers are individuals—commonly employees—who reveal secret corporate information in order to hold companies accountable for causing public harm. In some jurisdictions, trade secret law recognizes an exception when the disclosure involves “information that is relevant to public health or safety, or to the commission of a crime or a tort, or to other matters of substantial public concern.”⁴⁷ However, such exceptions may provide little solace to whistleblowers. In practice, “potential whistleblowers face a gauntlet of legal impediments, indoctrination policies, financial risks, and workplace and social pressures discour-

aging reporting of illegal conduct.”⁴⁸ For example, in the United States, employees have been found liable for misappropriation for giving corporate files to their attorneys, even in instances where they were seeking to disclose illegal conduct.⁴⁹

The stakes for establishing robust whistleblowing exceptions are high: insufficient protections coupled with broad trade secrecy law can pose a risk to public health. Without these protections, employees may not disclose misconduct or errors made by health care providers or firms.

Harmonizing trade secrecy law with the right to health

Proponents of trade secrecy protections contend that these protections encourage innovation by limiting the flow of proprietary information. However, many of the kinds of data being claimed as trade secrets are not clearly trade secrets.

One problem, to which some of the solutions we describe below are addressed, is that trade secret law is very fact specific, making it hard to rule out the possibility of trade secret protection for any particular kind of information. However, it is important to recognize that close scrutiny often reveals trade secret claims to be inappropriate and that careful studies have concluded that trade secret law, properly understood, does not protect many categories of information relevant to health. For example, although courts in the United States have at times accepted the idea that prices can be trade secrets with little analysis, there are good arguments based on the theory and purpose of trade secrets law that the price alone should not be afforded such protection. One argument is that price is simply a deal point representing the culmination of adverse negotiations between buyers and sellers and is not “an origin point for future development.”⁵⁰ Concealing prices does not further innovation; it simply undermines the capacity of competitors to provide competitive pricing—hardly a purpose of trade secrecy.⁵¹

Many types of clinical trial data should also not be properly considered trade secrets. Most safety and efficacy data, for example, will not confer an

advantage to competitors of the relevant kind—they cannot, for instance, be used to market another product or to reduce the costs of a competitor.⁵² The data might be privately valuable to the originator because they would reveal its product as harmful, but that is not the kind of value that trade secrecy law protects. Notably, the European Medical Association (EMA) has recognized in data-sharing regulations that many kinds of safety and efficacy data, such as trial endpoints, statistical methods, and adverse event information, are not protected confidential commercial information.⁵³ The EMA has also concluded that clinical trial protocols do not qualify.⁵⁴ US courts have held the same, noting that they contain “no information about secret formulas or rare treatment methods” and do not identify innovative procedures or techniques.⁵⁵

Timing can also influence whether the disclosure of information would produce a competitive harm. For example, releasing research and development costs after sending the relevant product to market would be unlikely to produce a competitive disadvantage.⁵⁶ In addition, the disclosure of aggregated data is unlikely to result in competitive harm.

How, then, can states create or expand safeguards against overly expansive trade secret protections? Three areas deserve particular attention. First, states should guard against the entrenchment of trade secrets as human rights or constitutional rights and reject attempts to enshrine stronger trade secrets law in international law, particularly without adequate and explicit protection of safeguards. Second, states should protect the public’s interest in health data by limiting trade secret law and allowing it to be overridden where public health benefits are salient. Third, countries should adopt robust whistleblower safeguards.

Avoiding the entrenchment of trade secret protections

Trade secret law has not been upwardly harmonized in international law to the same degree as other kinds of intellectual property. It will be important for countries to maintain policy space to modify and adjust domestic trade secret law, particularly given how rapidly information technologies are

evolving and the broad scope of trade secret law today.

Like other forms of intellectual property, trade secret rights are predominantly held by corporations and do not have the status of human rights, nor should they. These rights emerged out of practices that protected commercial morality and fairness between business competitors, and they have no grounding in the rights reflected in international human rights treaties.

States should also consider carefully the implications of treating trade secrecy as a form of property subject to protection under domestic constitutional law. The US experience shows that treating trade secrets as constitutionally protected property creates real risks for the publicity of health information, as in the tobacco case mentioned above. If trade secrets are protected as property, states are more limited in their ability to require the sharing of health data to improve outcomes or to develop new technologies, for example, because they may only do so after compensating the originator. Trade secret law is also plausibly understood more as a means to regulate behavior in the commercial sphere—a kind of tort or unfair competition law—rather than a right that is “good against the world” that should properly be deemed “property” for constitutional purposes. It is also not obvious that judicial review and mandatory compensation are essential to protect private interests: states can voluntarily afford compensation to companies when needed to protect incentives without judicial mandates.

Allowing public interest exceptions to trade secrecy

Public interest exceptions to trade secrecy can help ensure that data can be shared to benefit public health. These exceptions can be codified in at least four ways: first, states can require the proactive disclosure of health information where there is no conflict with trade secrecy law; second, states can exclude information from the scope of trade secret protections; third, states can adopt “balancing tests” that allow the release of trade secrets where the public’s interest outweighs private harm; and

fourth, states can use post hoc techniques such as intellectual property “pools” and compensation schemes to overcome barriers to data sharing.

First, mandatory, proactive disclosure requirements for certain health and safety information can advance the public interest. The scope and timing of these disclosure requirements can be carefully tailored to balance industry interests and public health concerns. For example, in the United States, as part of a settlement in a lawsuit brought by Public Citizen, the FDA began releasing key advisory committee materials, such as safety and efficacy data and FDA reviews of new drug applications, on its website 24 hours before advisory committee meetings.⁵⁷ Previously, these materials were accessible to the public only after a drug was approved. The careful timing requirements on these mandatory disclosures allow interested parties to participate meaningfully in committee meetings, while also negating industry arguments that disclosure will unduly benefit competitors. The United States also releases a substantial amount of summary data via a website called ClinicalTrials.gov, under a statutory mandate that requires such data to be shared. The data involved—summary information about trials underway and their results—are general enough that companies have not argued that the law “takes” their property or improperly discloses trade secrets. A great deal of important summary information that would otherwise be held in secret has been disclosed in this fashion. A key requirement for this disclosure is a regulatory requirement for data sharing from the private company to regulators; countries should ensure that the right to market medicines is contingent on the transfer of relevant data to regulators and should make clear that they will disclose such information to the public as needed to protect public health.

Proactive disclosure statutes can also be styled to create a presumption of transparency rather than confidentiality. Vanessa’s Law, adopted in Canada in 2014, requires manufacturers to release certain clinical trial data and provides the minister of health discretion to release additional information (including confidential business information) without the drug maker’s consent, if the minister

“believes that the product may present a serious risk of injury to human health.”⁵⁸ While Vanessa’s Law and its amendments provide procedures for companies to object to disclosures, the public’s interest is presumptively safeguarded.⁵⁹ There must also be efforts to monitor how laws providing for mandatory disclosure are implemented at the regulatory level.

Second, excluding certain public health information from the scope of trade secret protections can advance the public interest. Some information can be released, as described above, because it does not meet the definition of a trade secret. But states can also amend existing trade secret laws to broaden the ability to safely disclose information, wherever it would benefit health and safety. A narrower definition of trade secrets that excludes information of public interest could help enable more information to be disclosed through public information requests and limit measures that companies might take to threaten whistleblowers. It may also disincentivize companies from filing gratuitous trade secrets lawsuits. An exclusion of health and safety information from the proprietary scope of trade secrecy also resolves concerns that mandated disclosures constitute illegal government takings.

Third, affording public health weight in balancing tests can advance the public interest. Many countries already incorporate public interest overrides or balancing tests into their information access laws. The aforementioned EU directive explicitly allows for EU or national rules that require the public disclosure of trade secrets for the purpose of protecting the public interest.⁶⁰ In the United Kingdom, the Freedom of Information Act “subjects its ‘commercial interests’ exemption to a public interest balancing test: a public authority may only refuse to provide confidential information if it believes that, ‘in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosing the information.’”⁶¹ Similarly, in India, the Right to Information Act of 2005 stipulates that protected information may be disclosed once a “competent authority is satisfied that larger public interest warrants the disclosure of such information.” The law further states that “a

public authority may allow access to information, if the public interest in disclosure outweighs the harm to the protected interests.”⁶²

Countries that do not have such balancing tests should consider adopting them. In the United States, for example, the Freedom of Information Act lacks clarity on when the public interest should be balanced against private rights. US courts regularly weigh the public interest when parties seek to withhold information under exemption 6 (personal privacy interests) and exemption 7 (governing information collected for law enforcement purposes). Recent cases arguing that the same balancing applies under exemption 4, which governs trade secrets and confidential commercial information, are currently pending in courts.⁶³

Fourth, developing mechanisms such as involuntary licenses or intellectual property “pools” can override previously established in appropriate situations. If data have already been declared protected as trade secrets, post hoc approaches for disclosure may be necessary.

Where such data need to be pooled from many sources, governments can seek to create voluntary or mandatory “pools” that organize the terms under which such data will be shared. Recently, for example, the president and minister of health of Costa Rica wrote to the World Health Organization, urging it to “undertake an effort to pool rights and technologies ... useful for the detection, prevention, control, and treatment of the COVID-19 pandemic.”⁶⁴ This effort would make available via voluntary contribution all relevant research and other information related to the COVID-19 response without conventional intellectual property barriers, in order to encourage “follow-on” research and fast-track development of emerging technology.⁶⁵ The pool also ideally would provide manufacturers license to use needed data once a working technology is found.⁶⁶ States may also need to revise their laws to enable the entrance of generics and biosimilars where compulsory licenses on patents and data have been issued, but data exclusivity barriers exist. This post hoc approach to pooling trade secrecy information (among other intellectual property) may be particularly import-

ant in emergencies, when longer-term solutions may be impractical and a focus on particular technologies may be justified. However, a large-scale voluntary waiver of numerous intellectual property protections may work only when there is near universal consensus regarding the urgency of the public health interests at play, and non-voluntary sharing may be required.

Outside of pools, narrower mechanisms such as involuntary licenses for the disclosure of specific information, similar to compulsory licenses available in patents, should also be made available. These licenses can be granted whenever public health events arise that make the disclosure of data necessary, despite previous judgments or declarations regarding their protected status. This is especially important when the use of such data would lead to more accessible medical products, such as is the case with biosimilar or bioequivalent drugs and vaccines, which often rely on clinical trial data from originator drugs during the approval process.

Compensation can be afforded in these cases, where disclosure is to or for the benefit of competitors. For example, in some instances when regulators have allowed test data to be relied on by subsequent entrants to a market, they have also established liability schemes to ensure some limited payment to those who funded the creation of the data.⁶⁷ These schemes both dampen opposition from originator companies and address concerns about takings in the rare cases where these might have merit.

Strengthening whistleblower protections

In order to safeguard access to safe and affordable medicines, trade secrecy law must provide sufficient protections for whistleblowers. A model whistleblower protection regime would (1) include a reasonable belief standard and cover both illegal conduct and wrongdoing; (2) reduce the risk of negative consequences for whistleblowers; and (3) provide for infrastructure, resources, and reporting channels that facilitate disclosure.⁶⁸

Laws should facilitate disclosures by anyone who has a reasonable belief that they may expose illegal conduct or wrongdoing—even where disclo-

asures may contain trade secrets.⁶⁹ The reasonable belief standard helps ensure that whistleblowers do not bear too heavy a burden of proof. For example, the EU directive protects the disclosure of information that the whistleblower perceives as either illegal conduct or wrongdoing, in contrast to US federal law, which protects the disclosure only of illegal conduct. The EU standard protects those without legal expertise and those who seek to report unethical behavior that harms the public interest.

Whistleblower protections must also ensure the welfare of those making disclosures. Wherever possible, whistleblowers should be allowed anonymity to prevent workplace retaliation. Interim relief from courts is also necessary where workplace harassment does occur. To alleviate risk further, when disclosures fail to meet a reasonable belief standard, the law should not provide for onerous remedies against whistleblowers, as these disincentivize disclosures that may be valuable to the public.

Regulatory protections for whistleblowers are meaningful only if accompanied by infrastructure and resources that support disclosure. Organizations and individuals that facilitate whistleblowing—such as attorneys and nongovernmental organizations—must be afforded the same protections as whistleblowers themselves. Employees must also be informed of their rights as potential whistleblowers and must have access to pro bono legal representation when needed.

Addressing counter-arguments: International obligations and innovation

The measures promoted above will neither contravene international law nor unduly undermine innovation. As described in the first section, international law requires that states implement trade secrecy protections in a manner tailored to protect the right to access essential medicines. The TRIPS Agreement provides individual states broad leeway in interpreting the purposefully flexible requirements to prevent “undisclosed information” from being used “in a manner contrary to honest

commercial practices.”⁷⁰ Nothing in article 39.2 prohibits states from creating exceptions to trade secrecy protections, appropriately narrowing trade secret protections, or mandating the sharing of trade secrets where this would benefit health and competition. TRIPS also includes broadly stated purposes, for example noting in article 8 that members may “adopt measures necessary to protect public health,” “promote the public interest,” and “prevent the abuse of intellectual property rights” as long as the measures are otherwise consistent with the agreement.⁷¹ Article 7 also makes clear that intellectual property rights should be implemented in a manner that “contribute[s] 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.” To that end, not only do these proposed measures comply with TRIPS, but they also facilitate the realization of some of the agreement’s core principles.⁷²

In addition, state practice suggests that many of the measures we propose are considered by members to be consistent with the TRIPS Agreement. Various states have already adopted public interest measures similar to those recommended by this paper. For example, the FDA, the EMA, and Health Canada already proactively disclose certain clinical trial data. The laws of several countries—including England, Scotland, and India—compel the disclosure of confidential commercial information where there exists an overriding public interest.⁷³ Efforts to refine and limit trade secrecy laws through the countervailing safeguards for access to medicines that we describe, are, we believe, fully consistent with the flexible international protections for undisclosed information.

Advocates for broad trade secret protections contend that trade secrecy law encourages innovation and so serves the public good. Under this reasoning, trade secret protections ensure profits for innovators by discouraging “free riding.”⁷⁴ They also reduce the need for companies to invest in inefficient security measures.⁷⁵ Others see trade

secrecy protection as an important supplement to patent law because it does not require registration, application, or publication and is low cost and long lasting.⁷⁶

It is important to recognize, however, that overly broad trade secrecy law can impede innovation in a multitude of ways. Trade secrecy and other intellectual property protections can create dynamic inefficiencies by increasing the cost of inputs—especially in the research context—thereby frustrating innovation.⁷⁷ Restrictions on the exchange of information—for example, by discouraging the movement of employees to new employers—can also reduce spillovers of information to other firms. The unlimited duration of trade secret law is also problematic from an innovation perspective, because companies can prevent public access forever, avoiding the “quid pro quo” disclosures of patent law. Indefinite protection is also economically unnecessary under conventional assumptions that companies “discount” the present-day value of protection that exists many years in the future.

Moreover, in general, exclusive rights to information create inefficiencies because information has a marginal cost of zero: it is costless to allow others to enjoy knowledge once it is created, and so from a static perspective should be priced at zero. Limiting access to knowledge may be desirable if it is needed to prevent free-riding problems. But, even without trade secrecy protections, companies would still produce much of the information that trade secrecy laws cover today. For example, businesses create a great deal of secret information simply because it is required by their business, including data demanded by regulators, and prices. A lot of secret information is not expensive to create, meaning that it is not subject to real free-riding problems. In addition, as trade secrecy law has expanded, it has come to implicate public interests—including interests in access to information about products and corporate behavior—that are essential to democracy and the public good. Those who describe the incentive effects of trade secrets law rarely consider these broad public implications, the measures that may be needed to ensure that

trade secrets do not overprotect information that would be created anyway, or the law’s interference with important public interests.

Conclusion

Access to medicines is integral to the right to health. Today, commercial actors utilize trade secrecy to hide numerous types of health-related data, including clinical trial data, engineering and manufacturing data, data related to algorithms and machine learning, pricing data, and information on corporate wrongdoing. The consequences for access to medicines, and thus human rights, are significant, undermining patient-level health, the development of affordable treatments, and the effectiveness of health systems as a whole. This paper has proposed several measures that states could adopt to protect against overly expansive trade secrets regimes. By guarding against the entrenchment of trade secret law as creating “rights” protected under international and domestic law, by protecting the public interest in confidential commercial information by allowing or mandating data sharing, and by strengthening whistleblower protections, countries can protect the pressing public need for collaboration and transparency. In so doing, countries can expand access to medicines and promote the right to health.

Acknowledgments

We thank Talya Lockman-Fine and Xiangnong (George) Wang for critically important research in the preparation of this manuscript.

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