Volume 30 | Issue 1
WINTER 2021

LOYOLA UNIVERSITY CHICAGO
SCHOOL *of* LAW

BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY

Annals of Health Law and Life Sciences

The Health Policy and Law Review of
LOYOLA UNIVERSITY CHICAGO SCHOOL *of* LAW

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INFORMATION FOR CONTRIBUTORS

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ANNALS OF HEALTH LAW AND LIFE SCIENCES

**THE HEALTH POLICY AND LAW REVIEW OF
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To date, pharmaceutical spending in the United States is significantly higher than in other countries, a fact which is especially true of spending under Medicare Part B. To address the high cost of pharmaceuticals under Medicare Part B, the United States' Department of Health and Human Services has proposed a policy, the International Price Index. This policy would change the regulations on Medicare reimbursement of physicians and other consumers drugs covered under Part B. Currently, Medicare's reimbursement for Part B drugs is not limited to any specific price point, the International Price Index would establish an upper limit on the amount that Medicare is allowed to pay. This limit would be based upon the average price that other countries pay, thus bringing the price in the United States closer to international prices.

Critics speculate the International Price Index will drive the price of drugs covered by Medicare Part B so low that the pharmaceutical industry will lose revenue, which will have the unintended consequence of slowing down the pace of pharmaceutical development as companies will no longer invest in research and development at the same rate. This paper responds to these criticisms in two ways. First, it analyzes the relationship between revenue and research and development in the pharmaceutical industry. Second, it predicts the International Price Index's effect on the prices of pharmaceuticals in the countries that are referenced within the policy. This prediction is based on an analysis of the economics in the pharmaceutical industry and a comparison to the Robinson Patman Act. The result shows that investments into research and development will likely be unchanged because the International Price Index need only have a moderate degree of success in spreading out the costs of pharmaceuticals in order to avoid any substantial change in revenue within the pharmaceutical industry.

better health infrastructure and efficient accessibility to healthcare services. COVID-19 has presented numerous challenges because of dispute resolution including general international and investment claims and trade law violations. Against this backdrop, this paper proposes the formation of a health index– the Health Infrastructure Index (HII) – as an alternative to the existing Human Development Index (HDI) and Healthcare Access and Quality (HAQ). In order to understand and tackle domestic health vulnerability, the HII includes the availability of skilled medical professionals, government expenditure on healthcare and the likelihood of international funding. International cooperation as a response is emerging as a key factor to fight against COVID-19. The HII index highlights critical areas where domestic or multilateral interventions are required. With the inherent limitations of conventional health indices, the HII offers both the possibility of evidence- and research-based international coordination of health-related policies and encourages participatory development.

Foreword

The *Annals of Health Law & Life Sciences* Editorial Board is proud to present the Winter 2021 Issue, the first edition of our thirtieth volume to date. Due to the global COVID-19 pandemic, the year 2020 was unprecedented in many respects, and doubly so in the health and life sciences spaces. The pandemic forced individuals to isolate and schools and businesses to operate virtually, yet scholarship persevered. As the scale of the COVID-19 pandemic dawned upon the world, scientific data and evidence became more important than ever for institutions and individuals alike. As such, I am honored to introduce the following works of scholarship which take a critical look at current policies in health law and life sciences, and show a better way forward.

Combining economics with health policy, Alexander C. Davis's *The International Price Index's Impact on Revenue in the Pharmaceutical Industry* begins by analyzing the current economic and regulatory policies in the pharmaceutical sphere. Davis introduces the International Price Index, first proposed by former Health & Human Services Secretary Alex Azar in 2018 to reduce drug prices under Medicare Part B. Davis outlines how the International Price Index would set a ceiling on Medicare reimbursement for certain drugs, putting pressure on other countries to be more flexible in their price regulations of pharmaceuticals in order to reduce drug costs in the United States. He acknowledges concerns that reducing reimbursement for pharmaceuticals may stifle innovation, but argues that marketing and other business expenses make up a greater share of pharmaceutical companies' budgets than research and development, and thus a reduction in reimbursement would not categorically stifle innovation. Davis concludes that the International Price Index will address the astronomical price of pharmaceuticals under Medicare Part B without stifling innovation, and echoes Secretary Azar's advocacy through his unique economic analysis.

In our second selection, Matthew R. Davison explores mental health trials in Illinois and how virtual trials due to the COVID-19 pandemic risk the violation of individuals' fundamental rights in *No Ordinary Process: The Flaws in Illinois Courts' Use of Remote Video*

Technology in Mental Health Trials. Davison, an attorney for the State of Illinois Guardianship & Advocacy Commission, examines the experimental use of video technology in trials before cities and municipalities were forced to shelter in place in 2020, and how subsequent stay-at-home orders accelerated its implementation. He focuses on important safeguards in mental health proceedings which can be neglected in the push to go remote. Davison explores the fundamental rights of these patients, their expectations of these trials, and where Illinois policies have fallen short and contradicted one another. Davison's piece is a crucial example of advocacy for those whose voices often go unheard.

Walter G. Johnson's *Catching Up with Convergence: Strategies for Bringing Together the Fragmented Regulatory Governance of Brain-Machine Interfaces In the United States* next explores the world of neurological technology, examines the evolution of brain-machine interface devices, and suggests possible consequences of allowing this technology to be developed without oversight. Johnson details the fragmented regulation of this emerging technology, which can variously come from the Food & Drug Administration, the Federal Trade Commission, and even federal courts. After evaluating this fast-growing industry and its patchwork regulation, Johnson proposes a solution which would allow this technology to flourish, while also providing consumers with the protections of a unified regulatory scheme.

Finally, Dr. Julien Chaisse and Dr. Nilanjan Banik address health governance in *Global Health Law & Governance Amidst the Pandemic*. This timely work identifies the vulnerabilities the COVID-19 pandemic exposed in various health systems, and introduces the Health Infrastructure Index, a tool which uses metrics to better index countries' health infrastructure. By applying indexing innovations to their critical analysis of these complicated systems, Dr. Julien Chaisse and Dr. Nilanjan Banik provide a solution to allow governments and international agencies to better allocate funds and improve global health overall, even amidst a pandemic.

On behalf of all staff members of *Annals of Health Law and Life Sciences*, I would like to thank Alexander C. Davis, Matthew R. Davison, Walter G. Johnson, Dr. Julien Chaisse, and Dr. Nilanjan

Banik for bringing their extraordinary work in the field of health law and life sciences to the pages of *Annals*. This issue shows that even in the face of unprecedented global challenges, innovation, scholarship, and advocacy persist. The Editorial Board and I would like to thank each student editor at *Annals* for their dedication, scholarship, and tenacity. Additionally, I would like to recognize the outstanding work of Daniel Duffy, *Annals* Publications Editor, for his commitment to exceptional scholarly work. Further, I would be remiss not to recognize the remarkable effort of our Advance Directive and Technical Editor, Peggy Frazier, who went above and beyond in ensuring this issue was published. I would also like to thank Marketing & Coordinating Editor, Natasha Shukla, for spearheading the curation of these articles; Symposium Editor, Krystal Tysdal, and Advance Directive Editors, Lauren Koch, and Harte Brick. Your tireless efforts have brought this issue to life. Furthermore, I would like to recognize and thank our remarkable Senior Editors: Mallory Burney, Raminta Kizyte, Damyan Kolomayets, Nicole Harris, Julian Florio, and Sunaina Ramesh. And finally, I would like to thank our supportive advisors at the Beazley Institute for Health Law and Policy, including Professors Nadia Sawicki and Kristin Finn, for their valued guidance.

Karin M. Long, Editor-in-Chief

The International Price Index's Impact on Revenue in the Pharmaceutical Industry

Alexander C. Davis[*]

INTRODUCTION

The costs of pharmaceuticals have been steadily increasing in many countries, including those in the Organization for Economic Cooperation and Development ("OECD"), a cohort of nations with similarly developed economies as the United States.[1] Since 1998, OECD countries have collectively increased their spending on pharmaceuticals by an average of thirty-two percent, after adjusting for inflation.[2] In 2013, pharmaceutical spending across OECD countries reached approximately $800 billion, which accounted for nearly twenty percent of total health spending on average.[3] This trend is even more pronounced in the United States, where retail prescription drug spending has increased from $90 per person in 1960 to $1,025 per person in 2017.[4] While a significant portion of this increase in spending represents the cost of buying new and innovative products, part of the increase is the result of the incentives on pharmaceutical companies and a balancing act in which individual countries engage.[5]

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* Alex Davis has long been enthralled by public policy. He studied philosophy and economics at Georgia State University and recently graduated from Emory University School of Law where he focused on regulatory issues and corporate transactions. He intends to devote his career to assisting policy makers in crafting regulations that incentivize businesses and protect public interests.

[1] Neeraj Sood et al., *The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries*, HEALTH AFF.: WEB EXCLUSIVE (2008), www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.1.w125; *Our Global Reach*, OECD, https://www.oecd.org/about/members-and-partners/ (last visited on Dec. 31, 2020).

[2] Sood et al., *supra* note 1, at w125.

[3] Ed Silverman, *Soaring Prescription Drug Prices Take Big Bite Out of National Budgets*, STAT NEWS (Nov. 4, 2015), https://www.statnews.com/2015/11/04/soaring-prescription-drug-prices-take-big-bite-out-of-national-budgets/.

[4] Rabah Kamal et al., *What are the Recent and Forecasted Trends in Prescription Drug Spending?*, HEALTH SYS. TRACKER (Apr. 14, 2020), www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-nominal-and-inflation-adjusted-increase-in-rx-spending_2017.

[5] Toon van der Gronde et al., *Addressing the Challenge of High-Priced Prescription Drugs in the Era of Precision Medicine*, 12 PLOS ONE 1, 22–23 (2017).

Pharmaceutical companies are incentivized to differentiate prices on a country-to-country basis in order to achieve the highest possible profits in each country.[6] This leaves governments with conflicting internal incentives. On the one hand, governments have good reason to expedite their price negotiations by accepting pharmaceutical companies' sticker prices to avoid delaying the introduction of innovative new drugs; however, they also want to reduce healthcare spending by negotiating prices that consumers can afford to pay.[7] The idea is that when governments agree to pay premium prices, drug companies are incentivized to develop and launch new drugs faster, but consumers are left with higher costs as a result.[8] Unlike almost every other OECD country, the U.S. government does not control reimbursement prices for pharmaceuticals and drug companies are therefore free to set their own prices based on market calculations aimed at maximizing profits.[9] As a result, U.S. prescription drug prices are among the highest in the world,[10] which results in clinical as well as economic consequences for U.S. patients who pay an increasing share of drug expenses in the form of co-payments.[11]

While patients face these high costs, the pharmaceutical industry enjoys higher profit margins than many other industries.[12] For example, in 2002, the median profit margin of the top ten drug companies in the United States was seventeen percent, compared to a margin of 3.1% for all the other industries on the Fortune 500 list.[13] Even more striking, those ten companies generated more in profits that year than the remainder of the Fortune 500 list combined.[14] Some researchers contend that these abnormally high profit margins justify regulatory interventions that improve access and affordability by reducing the costs of pharmaceuticals.[15] On the other hand, some analysts point to research that suggests that the high cost and low output nature of drug development causes investments in new pharmaceuticals to be more of

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[6] *Id*.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] So-Yeon Kang et al., *Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries*, 38 HEALTH AFF. 804, 804–11 (2019).
[11] Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 864 (2016).
[12] Marcia Angell, *Excess in the Pharmaceutical Industry*, 171 CAN. MED. ASS'N J. 1451, 1451–53 (2004).
[13] *Id*.
[14] *Id*.
[15] Sood et al., *supra* note 1, at w131.

a gamble than other investments.[16] These analysts argue that such high profits are necessary to incentivize drug companies to engage in the high risk process of pharmaceutical research and development ("R&D") which facilitates the creation of new medications.[17]

This paper seeks to add to the debate regarding regulatory intervention in the pharmaceutical industry by focusing on a recently proposed policy called the International Price Index ("IPI"). Part I will explain the structure of the IPI, the issues it seeks to address, and criticisms from those who claim that it will have devastating effects on revenue in the pharmaceutical industry. Part II analyzes these criticisms through an economic analysis of market power in the pharmaceutical industry and the capacity of consumers to negotiate. Part III compares the IPI to another regulatory intervention with a similar policy mechanism. Part IV predicts the effect that the IPI will have on prices and revenue based on an analysis of the elasticity of demand for pharmaceuticals. Part V then offers a brief conclusion.

I. THE INTERNATIONAL PRICE INDEX

A. Background of Medicare Part B and Structure of the IPI

The IPI was proposed by U.S. Health and Human Services Secretary, Alex Azar, in 2018 as a way to reduce the costs of Medicare Part B drugs.[18] Medicare Part B covers physician-administered therapies such as biologics, injectables, IVIG, immunoglobulins, and other products.[19] Medicare Part B plays an important role in the market for cancer, ophthalmic, and rheumatology therapies because manufacturers' pricing strategies are influenced by Medicare Part B's reimbursement.[20] In other words, the Part B program affects pricing patterns in private markets.[21] The drugs covered

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[16] WAYNE WINEGARDEN, THE ECONOMICS OF PHARMACEUTICAL PRICING 6 (Pac. Res. Inst., June 2014), https://www.pacificresearch.org/wp-content/uploads/2017/06/Phama PricingF.pdf (explaining that the cost of capital for investments into research and development for new pharmaceuticals must compensate investors for the risks and cost associated with bringing new pharmaceuticals to market).
[17] Sood et al., *supra* note 1, at w126.
[18] Susan Peschin & Duane Schulthess, *International Pricing Index 'Accomplishes Nothing it Sets Out to Do,'* STAT NEWS (Oct. 21, 2019), https://www.statnews.com/2019/10/21/international-pricing-index-research-development/.
[19] Adam J. Fein, *Follow the Vial: The Buy-and-Bill System for Distribution and Reimbursement of Provider-Administered Outpatient Drugs*, DRUG CHANNELS (Oct. 14, 2016), https://www.drugchannels.net/2016/10/follow-vial-buy-and-bill-system-for.html.
[20] Cole Werble, *Health Policy Brief: Medicare Part B*, HEALTH AFF., 1, 1 (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000171/full/healthpolicybrief_171.pdf.
[21] *Id.*

under Medicare Part B are often some of the most innovative and expensive, and thus expenditures on Part B drugs have increased faster than other Medicare expenditures over the last twenty years.[22] As a result, Medicare Part B is both a controversial, as well as a potentially fruitful, area for policy reform.

As calculated under the IPI model, Medicare currently pays 180% of the average international price for the drugs covered under the Part B program.[23] This disparity has led industry and U.S. government officials to argue that, because of foreign governments' regulations on drug prices, they are not paying for their fair share of R&D costs and thus unfairly benefit from the innovation for which the United States pays.[24] While such claims may not be entirely accurate,[25] it is clear that these arguments were a motivating force behind the IPI.[26] The IPI's central purpose, then, is to pressure other countries to be more flexible in their current price regulations of pharmaceuticals.[27] The IPI would create this pressure on other countries to increase prices by setting a price ceiling on Medicare's reimbursement for various drugs.[28]

Currently, Medicare Part B reimbursement is a "buy-and-bill" process.[29] Under this process, a doctor or other provider purchases the drugs they require using their own source of funds.[30] Then, after administering the drugs

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[22] *Id*.

[23] Duane Schulthess et al., *Tying Medicare Part B Drug Prices to International Reference Pricing Will Devastate R&D*, 53 THERAPEUTIC INNOVATION & REG. SCI. 746, 746–748 (2019).

[24] Salomeh Keyhani et al., *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075, 1075–81 (2010).

[25] Donald W. Light & Joel Lexchin, *Foreign Free Riders and the High Price of US Medicines*, 331 BMJ PUB. GROUP 958, 958–60 (2005) (A "free rider" is a term economists use in the context of an accounting method that assigns the fixed costs of a product to different groups based on the prices that each group pays. To illustrate, "if Group A (call it Europe) pays $1 per pill and Group B (call it the U.S.) pays $2 a pill and each buys a million pills, then this accounting method would assign half as much of the fixed cost to Group A as to Group B." The term can be misleading, though depending on various circumstances. For example, "[i]f, however, the fixed costs are only $300,000 (a tenth of the total revenue) for the two million pills, the fixed costs could be allocated by volume rather than by price ($150,000 for each group) and [one could] conclude that Group A more than pays the fixed costs and Group B pays much more than it has to.").

[26] Keyhani, *supra* note 24, at 1.

[27] *What You Need to Know about President Trump Cutting Down on Foreign Freeloading*, DEP'T. HEALTH & HUM. SERVS. (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html.

[28] Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546, 54,556 (Oct. 30, 2018) [hereinafter Pricing Index Model, 83 Fed. Reg.].

[29] Fein, *supra* note 19.

[30] *Id*.

to a patient, the provider files a reimbursement claim to Medicare.[31] Medicare pays the provider the portion of the cost for which it is responsible and the provider is responsible for collecting the patient's share of the drug reimbursement.[32]Under the IPI model, the amount of reimbursement that Medicare could provide for Part B drugs would be limited based on the average prices in the Indexed Countries,[33] which include Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy,[34] CMS would determine the average international price for each drug included in the model based on a standard equivalent units of drugs in the Indexed Countries.[35] The ceiling for the reimbursement of each unit of the particular drugs would be set by multiplying the average international price by 126%.[36]

The IPI is proposed to be implemented over a five-year period, during which its ramifications will be examined.[37] CMS stated that it would examine whether the model affects the quality of care that U.S. patients receive, the availability of drugs, and the IPI's overall costs.[38] Reimbursement prices during the rollout of the model would be calculated based on a mixture of average sales prices ("ASP") in the United States and the indexed price, adjusted to not exceed a thirty percent decrease from current prices, using the following compositions:

Year 1: eighty percent of ASP + twenty percent of target price
Year 2: sixty percent of ASP + forty percent of target price
Year 3: forty percent of ASP + sixty percent of target price
Year 4: twenty percent of ASP + eighty percent of target price
Year 5: 100% of target price.[39]

For each phase-in year, CMS plans to set the limits on the prices that Medicare can pay by using the ASP prices for the included drugs and

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[31] *Id*.
[32] *Id.*
[33] Pricing Index Model, 83 Fed. Reg. at 54,547.
[34] Emily Cook et al., The International Pricing Index Model: Breaking Down CMS's Proposed Drug Pricing Model, MCDERMOTT WILL & EMERY 16 (Nov. 19, 2018) https://www.mcdermottplus.com/wp-content/uploads/2018/11/IPI-Webinar-Slides.pdf (mentioning vendors will have the responsibility to negotiate drug prices with manufacturers).
[35] Pricing Index Model, 83 Fed. Reg. at 54,556.
[36] U.S. DEP'T. HEALTH & HUM. SERVS., *supra* note 27.
[37] Cook et al., *supra* note 34, at 11.
[38] *Fact Sheet, ANPRM International Pricing Index Model for Medicare Part B Drugs,* CMS (Oct. 2018), https://www.cms.gov/ newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs.
[39] Cook et al, *supra* note 34, at 14.

estimated international prices for comparable drugs.[40] CMS would then arrive at the final values by multiplying the amount of Part B drugs purchased by the ASP price portion, and then by the international price portion.[41] By the fifth year, U.S. prices would be phased down to reflect 126% of the prices calculated in the IPI.[42]

The model would also phase in the drugs that are included.[43] Examples of the types of drugs that the model would include are drugs for cancer and cancer related conditions, drugs for macular degeneration, and biologicals used to treat rheumatoid arthritis and other immune mediated conditions.[44] By the end of the phase-in period, CMS intends for the IPI to include drugs that make up seventy-five percent of all the charges under Medicare Part B.[45]

The IPI model also addresses a problem within the current buy-and-bill payment process by eliminating inefficient incentives that have led to physicians prescribing higher priced drugs.[46] As discussed above, under the current structure, Medicare calculates the reimbursement payment after a physician files a claim by calculating the ASP of the administered drug plus an "add-on" fee.[47] This "add-on" fee has resulted in incentives for physicians to prescribe more expensive drugs because it is calculated as a percentage of the ASP of the particular drug that the physician prescribes.[48] Research shows that when doctors are given the option of two drugs and one is financially beneficial to the doctor, doctors are more likely to prescribe the drug with the financial benefit.[49] Because Medicare accepts Part B drug prices without negotiation,[50] physicians are incentivized to prescribe the most expensive of the already high priced drugs to take advantage of the add-on fee calculation.[51] This ultimately means higher out-of-pocket drug expenses for U.S. patients, especially seniors.[52]

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[40] Pricing Index Model, 83 Fed. Reg. at 54,556.
[41] *Id*.
[42] Cook et al., *supra* note 34, at 14 (noting that the reimbursement price in year five would be 100 percent of the target price); U.S. DEP'T. HEALTH & HUM. SERVS., *supra* note 27 (explaining that the final target price is 126% of the average international price).
[43] *See* Cook et al., *supra* note 34, at 11.
[44] Pricing Index Model, 83 Fed. Reg. at 54,554.
[45] *Id*. at 54,555.
[46] *Id*. at 54,547.
[47] Werble, *supra* note 20, at 1.
[48] *Id.*
[49] Gronde et al., *supra* note 5, at 11.
[50] *See HHS Advances Payment Model to Lower Drug Costs for Patients*, U.S. DEP'T. HEALTH & HUM. SERVS. (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html (stating Medicare accepts sales prices for Part B drugs with no negotiation).
[51] Pricing Index Model, 83 Fed. Reg. at 54,547.
[52] U.S. DEP'T. HEALTH & HUM. SERVS., *supra* note 50.

The IPI would eliminate the incentive to prescribe higher priced drugs by changing the calculation method for the physician add-on payments.[53] Providers and hospitals would still receive an add-on payment for administering, storing and handling drugs, but payment would not be tied to the prices of individual drugs.[54] Instead, the payment would be based on (1) the class of drugs administered; (2) the physician's specialty; or (3) the physician's practice.[55] The add-on payment change is intended to be budget-neutral, as CMS stated that the purpose of the model is to remove the incentive for physicians to prescribe higher priced drugs, not to reduce costs through decreasing add-on payments.[56] Even so, the reality is that providers who currently administer the most expensive products will likely see a decrease in revenue, while providers who administer the least expensive alternatives will likely see an increase in revenue.[57]

B. Concerns about the Impact on R&D and Stifling Innovation

Some commentators fear that pursuing these goals through the IPI will have substantial unintended consequences on pharmaceutical innovation.[58] In a widely cited study, the authors argue that implementing the IPI would result in a decrease in pharmaceutical innovation because of the decrease in revenue caused by the IPI.[59] In making their argument, the authors begin by making three assertions. First, the Indexed Countries would not accede to demands from pharmaceutical companies to accept higher prices.[60] Second, pharmaceutical companies' total revenue is directly tied to aggregate investments into R&D.[61] And third, the current price levels of

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[53] Pricing Index Model, 83 Fed. Reg. at 54,547.
[54] *Id.*
[55] *Id.*
[56] Jacqueline LaPointe, *Would the IPI Model Reduce Medicare Reimbursement for Providers?*, RECYCLE INTELLIGENCE (Nov. 5, 2018), https://revcycleintelligence.com/news/would-the-ipi-model-reduce-medicare-reimbursement-for-providers (reporting that the Department of Health & Hum. Services addressed concerned physicians by explaining that its goal is not to reduce costs through reducing the add-on payment and that the purpose of the change is to make compensation independent of pricing).
[57] Joseph R. Antos & James C. Capretta, *A Market-Oriented Framework for Reforming Medicare Part B Drug Payment*, HEALTH AFF.: BLOG (July 9, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190708.831097/ full/ ("In general, practices using the highest-priced products today, with the highest ASPs, would stand to lose under the administration's proposal, while those using lower-priced products would stand to gain.").
[58] Duane Schulthess et al., *Tying Medicare Part B Drug Prices to International Reference Pricing Will Devastate R&D*, 53 THERAPEUTIC INNOVATION & REG. SCI. 746, 746–748 (2019).
[59] *Id.*
[60] *Id.*
[61] *Id.*

pharmaceuticals are necessary to maintain R&D within the industry.[62] Based on these three assertions the study concludes that pharmaceutical R&D budgets would decrease by millions of dollars under the IPI.[63] The authors come to this conclusion by calculating the decrease in revenue that pharmaceutical companies would experience under an implementation of the IPI, given the assumption that prices in the Indexed Countries would not change.[64] They then conclude that the IPI would put R&D at risk by calculating the decrease in companies' R&D budgets under the assumption that such budgets would be decreased by one-fifth of their total loss in revenue.[65] While this study is widely referenced by IPI critics, its foreboding conclusion that a reduction in drug prices necessarily comes with a loss in innovation is unlikely to actualize.

The argument that the high prices of pharmaceuticals are justified by the costs and labor involved in developing them is not new, as pharmaceutical companies and their lobbyists in Washington, D.C. have long argued that revenue from high prices today is necessary to facilitate future R&D.[66] They argue that restricting the price of drugs will have the unintended consequence of negatively impacting the rate at which new medications are developed.[67] Some in the pharmaceutical industry have posited that $2.6 billion is required to develop a successful new drug.[68] However, "the rigor of this widely cited number has been disputed" and there are several reasons to question the idea that current prices are a result of the need for future R&D investments.[69]

First, this argument incorrectly assumes that pharmaceutical companies spur innovation. The fact is that academic institutions and financial support from public sources, such as the National Institutes of Health ("NIH"), are the sources of much of the innovation that leads to new drug products.[70] A

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[62] *Id.*
[63] *Id*.
[64] *Id.*
[65] *Id.*
[66] Kesselheim et al., *supra* note 11, at 863; *see also* Angell, *supra* note 12 ("The pharmaceutical industry has the largest lobby in Washington, DC — there are more pharmaceutical lobbyists there than members of Congress — and it gives copiously to political campaigns.").
[67] *See* BOB YOUNG ET AL., RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" 7–8 (Public Citizen, July 2001), https://www.citizen.org/wp-content/uploads/rdmyths.pdf (explaining that drug companies stress how difficult it is to develop new drugs because of research costs).
[68] Kesselheim et al., *supra* note 11, at 863.
[69] *Id.*
[70] *See generally* Bhaven N. Sampat & Frank R. Lichtenberg, *What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFF. 332, 339 (2011) (arguing that direct government funding is crucially important in the development of innovative new drugs).

study on public spending in pharmaceutical development found that, in the 2001 fiscal year, the NIH had a $20.3 billion dollar budget and that a substantial portion of this was money to be spent on research for the purposes of discovering and developing new drugs.[71] The NIH study also found that researchers who were funded by U.S. tax dollars produced fifty-five percent of the published research that was responsible for the development of the top five selling drugs in 1995.[72] Further, large pharmaceutical companies frequently acquire startups and other small companies whose early-stage drug development research originated in academic laboratories.[73]

Second, the assertion that drug companies would cut R&D budgets by one-fifth of their total loss in revenue is contradicted by spending trends in the industry that show a disconnect between R&D investment and final price. In recent years, large pharmaceutical companies have invested an average of twenty percent of revenue in R&D,[74] a percentage which is markedly lower if one considers only innovative product development.[75] A much larger share of revenue goes instead to marketing expenditures aimed at doctors and pharmacists.[76] Pharmaceutical companies' marketing expenditures dwarf their R&D efforts since the 1990s when thirty-five percent of the top ten drug companies' expenditures was on marketing and administration, while just eleven to fourteen percent was spent on R&D.[77]

Third, the argument that drug companies price their products based on the cost of R&D is inaccurate because sunk costs do not determine price.[78] In other words, by the time a drug becomes available on the market, the cost of its R&D has already been largely paid for, therefore R&D expenditures are often considered sunk costs by the time a company is ready to sell its product.[79] Based on economic principles, these sunk costs should not impact how a profit-maximizing company prices its drugs.[80] Economists generally

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[71] YOUNG ET AL., *supra* note 67.
[72] *Id*.
[73] University of Cambridge, *Study: Acquisitions Threaten Access to Breakthrough Drugs*, PHARMACEUTICAL PROCESSING WORLD (Jul. 29, 2016), https://www.pharmaceutical processingworld.com/study-acquisitions-threaten-access-to-breakthrough-drugs/.
[74] *Spending of U.S. Pharmaceutical Industry for Research and Development as a Percentage of Total Revenues from 1990 to 2018*, STATISTA (2019), https://www.statista.com/statistics/ 265100/us-pharmaceutical-industry-spending-on-research-and-development-since-1990/.
[75] Kesselheim et al., *supra* note 11, at 863.
[76] Gronde et al., *supra* note 5, at 10.
[77] Angell, *supra* note 12, at 1452.
[78] Rena M. Conti & Darius N. Lakdawalla, *Putting More Value into Biopharmaceutical Value Assessments*, HEALTH AFF.: BLOG (Jan. 3, 2018), https://www.healthaffairs.org/ do/10.1377/hblog20171227.196339/full/.
[79] *Id.*
[80] *Id.*

believe that firms with market power price their products based on what the market is willing to pay – the demand – not cost of development and production.[81] In the pharmaceuticals market, this means that companies price their products based primarily on how much consumers value a drug and the availability of alternative therapies.[82] Companies consider both of these factors early on in the development process.[83] Companies will predict the cost of bringing a drug to market and then make estimates about its value based on the drug's ability to improve or extend people's lives, the existence of competitors, the target market's ability to pay, and the likely insurance coverage for the drug.[84] The demand for some drugs might enable a firm to generate revenue well above a particular drug's R&D costs, while other drugs may never recover their overhead costs.[85] A pharmaceutical company's long term business depends on its average profits, which provide an ordinary return over its costs, including the sunk costs of R&D.[86] It is likely an oversimplification to assume that investment in R&D will stay at a fixed portion of total revenue considering the extraordinary profits these companies currently generate.[87]

Critics do identify one legitimate drawback to the IPI, which is the possibility that some of the Indexed Countries could be deprived of essential medicines.[88] This is based on the idea that if a country traditionally has maintained drug prices far below the United States, pharmaceutical companies might not seek market access in that country after IPI implementation because of the downward pressure the low price would have on the international average price.[89] While the possibility of a pharmaceutical company refusing to sell to a country that rejects proposals for higher prices

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[81] *See* RUSSELL COOPER & ANDREW JOHN, ECONOMICS: THEORY THROUGH APPLICATIONS 244–48, 268 (Saylor Foundation, 2012) (explaining how price is calculated based on the intersection of a demand curve and supply curve).
[82] Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK (Mar. 17, 2017, 8:00 AM), www.newsweek.com/2017/04/14/prescription-drug-pricing-569444.html.
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *See id.* (explaining the various costs of developing a drug and stating that companies analyze how much they could charge for a drug to determine whether it is capable of recuperating these costs).
[87] MARC-ANDRE GAGNON & SIDNEY WOLFE, MIRROR, MIRROR ON THE WALL 13 (Carleton Univ., Sch. Pol'y & Admin., 2015), https://www.citizen.org/wp-content/uploads/2269a.pdf.
[88] Schulthess et al., *supra* note 58, at 750.
[89] *Id.*

is a concern, it also illustrates the pressure that the IPI would place on pharmaceutical companies to change their current practices.[90]

Whether this pressure would result in increased drug prices in the Indexed Countries is a central question in the debate over the IPI. If the IPI completely fails in pressuring the Indexed Countries to adjust the prices they pay for pharmaceuticals, as some critics claim it will, concerns over stifling future R&D might become more legitimate.[91] Given the disconnect between total revenue and investments into R&D discussed above, though, even a moderately successful price increase by the IPI would likely avert the significant consequences that its critics fear. To understand why the IPI is likely to succeed in its goal of pressuring other countries to modify their drug prices, it is helpful to understand the economic background in which pharmaceutical companies operate.

II. MARKET POWER, PRICING, AND CONSTRAINED NEGOTIATION

A. The Market Power of Pharmaceutical Companies

For pharmaceutical companies, "market power" refers to a company's ability to sell its products at prices above the marginal costs of those products.[92] In other words, in a competitive market where two companies are competing against each other, each will have an incentive to lower its prices until the price of each unit equals the cost of producing that unit, that cost being the marginal cost.[93] A company with market power has the ability to charge more than marginal cost and may earn additional revenue by doing so.[94] The primary reason pharmaceutical companies have enough market power to command such high prices is the market exclusivity granted by the U.S. Patent and Trademark Office and the Food & Drug Administration ("FDA").[95] A recent study found that brand-name drugs encompass ten percent of prescription in the United States and seventy-two percent of drug spending.[96] Further, from 2008 and 2015, prices increased 164% for the most

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[90] *See* discussion *infra* Section III(a) (explaining how the pressure the IPI would create could result in certain drugs being inaccessible in some countries).
[91] Schulthess et al., *supra* note 58, at 750 (noting the total decrease in revenue caused by Medicare paying 126% of the current price as calculated under the IPI).
[92] GLOSSARY OF INDUS. ORG. ECON. & COMPETITION LAW, ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT 57, (ebook).
[93] *See id*. at 31 (stating that profit maximizing firms will produce an output such that marginal cost equals marginal revenue).
[94] *Id*. at 34, 57.
[95] Kesselheim et al., *supra* note 11, at 860–61 (this "market exclusivity" means that no other manufacturer, generic or otherwise, may legally offer the approved drug for sale).
[96] *Id*. at 860.

common brand-name drugs, a shocking figure in comparison to the consumer price index, which recorded a twelve percent increase in prices.[97] In the past, such disproportionately high prices were limited to brand-name drugs used to treat rare conditions, but in recent years, even drugs treating common conditions have a high price tag.[98] Examples include new cancer drugs, which can cost more than $100,000 per course of therapy, as well as insulin, which increased 300% in price between 2002 and 2013.[99]

A brand name drug's market exclusivity arises from two forms of legal protection.[100] First, the regulatory exclusivity awarded by FDA approval protects new small-molecule drugs from competition for a guaranteed period of five to seven years and new biologic drugs for twelve years.[101] Second, patent law generates market protection that is often longer in duration than the FDA's protection.[102] Today, a new drug that is successfully patented will receive twenty years of protection starting from the date on which the application for the patent was filed.[103] However, the filing date often occurs years before a company can actually introduce the drug on the market because of the amount of time necessary to complete the development process and receive regulatory approvals.[104] Consequently, companies are therefore allowed to apply for extensions to make up for this lost time when the drug was not able to be sold, and may receive up to fifteen additional years of patent protection.[105]

When a brand-name drug loses its market exclusivity, generic drugs often become available and at a price that is, on average, eighty-five percent lower than their brand-name counterparts.[106] Interestingly, numerous studies have found that the availability of generic drugs does not lead to a price reduction in the branded alternative.[107] Rather, the brand-name drug retains a price similar to what it garnered during the period of market exclusivity and loses

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[97] *Id*.
[98] *Id*.
[99] *Id*.
[100] *Id*. at 861.
[101] *Id*.
[102] *Id*.
[103] Michael Dunn, *Timing of Patent Filing and Market Exclusivity*, 10 NATURE REV. DRUG DISCOVERY 487, 487–88 (July 2011).
[104] *Id*.
[105] *Id.*
[106] *Generic Drug Facts*, U.S. FOOD & DRUG ADMIN. (Apr. 15, 2020, 9:00 AM), https://www.fda.gov/drugs/ generic-drugs/generic-drug-facts.
[107] Joel Lexchin, *The Effect of Generic Competition on the Price of Brand-Name Drugs*, 68 HEALTH POL'Y 47, 52 (2004) (finding that entry of generic drugs into the Canadian market did not result in a statistically significant change in brand name drug prices and noting that several studies have found similar results regarding the entry of generic drugs in U.S. markets).

the majority of its share of the market.[108] The end of a brand-name drug's market exclusivity period thus marks a steep decline in cost for consumers and revenue for the manufacturer.

Pharmaceutical manufacturers often address this eventual decline in revenue by engaging in "pay for delay" activities and "product life-cycle management."[109] "Pay for delay" refers to the large cash transfers that brand-name pharmaceutical companies pay to the manufacturers of generics to settle litigation challenging the validity of the brand-name's drug patent.[110] The fact that brand-name companies are willing to pay such large sums of cash to quell generic manufacturers is telling of how valuable it can be to maintain their market exclusivity. Brand-name manufacturers can also delay a generic drug's introduction into the market through life cycle management, which involves extending a drug's market exclusivity period through what are often referred to as "me-too" drugs.[111]

"Me-too" drugs are drugs that allow companies to prolong market exclusivity by filing for patents on specific features of a drug, including a pill's coating, the drug's salt moiety, its formulation, or the administration method.[112] This is often a successful strategy because the permissive standards for "novelty or usefulness" under the U.S. Patent and Trademark Office allow for nontherapeutic aspects to be patented after the drug's initial patent expires.[113] Me-too drugs do not require the large investments in R&D needed to develop innovative drugs, nor do they carry the same risks as innovative drugs in the clinical trial and development processes.[114] Thus, me-too drugs are cheaper to develop and have become staples in the industry.[115] From 1998 through 2003, the FDA approved a total of 487 drugs.[116] Of these drugs, 379 had similar therapeutic qualities as drugs already available on the market, while only sixty-seven of them offered benefits over previous medications.[117] The pharmaceutical industry has attempted to justify me-too drugs by arguing that they help lower prices by creating competition.[118] The prices for these drugs, however, are often substantially the same as the original brand name drug, and manufacturers often promote them to

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[108] *Id.*
[109] Kesselheim et al., *supra* note 11, at 860–61.
[110] *Id.*
[111] Angell, *supra* note 12, at 1451.
[112] Kesselheim et al., *supra* note 11, at 860–61.
[113] *Id.*
[114] Angell, *supra* note 12, at 1451.
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.* at 1452.

consumers as improved products instead of cheaper alternatives.[119] This raises a central question; how do pharmaceutical companies decide the price of a drug?

B. The Price Determinants of Pharmaceuticals

Many pharmaceutical companies that sell brand-name drugs have enough market power for economists to consider them monopolies.[120] A monopolist benefits from its market power by having a large amount of control over the price of the products it sells.[121] In the pharmaceutical industry, this market power results from the fact that medications are not suitable substitutes for each other, and there is often only one company in the market that produces a particular medication[122] In fact, as explained above,[123] the U.S. government guarantees pharmaceutical companies that it will protect them from potential competitors that seek to sell similar products through granting patents.[124]

One way to measure the monopoly power of pharmaceutical companies is by using the Learner Index.[125] The Lerner Index is a tool that economists use to quantify monopoly power and is calculated by subtracting the marginal cost that a company incurs for producing a product from the price the company charges for that product.[126] The Lerner Index is expressed as $L = (P – MC) / P$, where P represents price and MC represents marginal cost.[127] When there is a large difference between marginal cost and price, L will be close to one, signifying a large amount of monopoly power.[128] The Lerner index for drug companies is typically 0.72 at a minimum because the marginal cost of producing a drug is much lower than its price.[129]

A monopolist may utilize its market power to maximize profit and may engage in price discrimination to do so.[130] Price discrimination describes the

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[119] *Id.*
[120] Gail Rattinger et al., *Principles of Economics Crucial to Pharmacy Students' Understanding of the Prescription Drug Market*, 72 AM. J. PHARMACEUTICAL EDU. 1, 1–3 (2008) (discussing the principles of economics within the pharmaceutical industry).
[121] MARK ARMSTRONG, RECENT DEVELOPMENTS IN THE ECONOMICS OF PRICE DISCRIMINATION 2 (Univ. C. London, 2006).
[122] Rattinger, *supra* note 120.
[123] *See* discussion *infra* Section II(a).
[124] Rattinger, *supra* note 120.
[125] STUART O. SCHWEITZER & JOHN Z. LU, PHARMACEUTICAL ECONOMICS AND POLICY: PERSPECTIVES, PROMISES, AND PROBLEMS 213–214 (Oxford Univ. Press 3rd ed., 2018).
[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] ARMSTRONG, *supra* note 121.

situation wherein a company sells multiple products, each with equal marginal cost, at different prices.[131]

> There are many forms of price discrimination, including: charging different consumers different prices for the same good (third-degree price discrimination); making the marginal price depend on the number of units purchased (nonlinear pricing); making the marginal price depend on whether other products are also purchased from the same firm (bundling); making the price depend on whether this is the first time a consumer has purchased from the firm (introductory offers; customer "poaching").[132]

Price discrimination thus accurately describes the current state of the pharmaceuticals market in which drug companies maximize their profits by charging U.S. consumers more than their counterparts in other OECD countries. A perfect price discriminator requires complete information about both its customers and the world so that it knows what the perfect price would be for each person in each situation; however, not many, if any, companies are able to achieve such precise discrimination.[133] Although drug companies do not have a perfect price schedule — one that would account for a multitude of customer categories — they are able to identify customers who have substantial negotiating power and those who do not, as explained below.[134]

Compared to competitive pricing, monopoly pricing and price discrimination each have the effect of leaving sellers better off and buyers worse off. [135] The differences between competitive pricing, nondiscriminatory monopoly pricing, and perfect price discrimination can be seen in Figure 1.[136]

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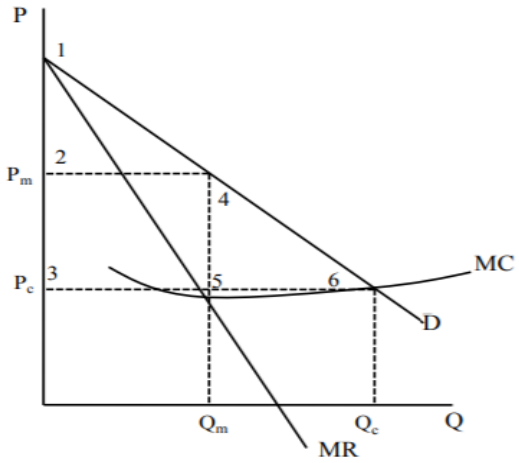
[131] *Id.*
[132] *Id.*
[133] Hayne E. Leland & Robert A. Meyer, *Monopoly Pricing Structures with Imperfect Discrimination*, 7 BELL J. ECON. 449, 450 (1976).
[134] *See* discussion *infra* Section II(c) (describing the price negotiation process and negotiation power).
[135] E. Thomas Sullivan et al., *Chapter 8: Secondary-Line Differential Pricing and the Robinson-Patman Act, in* 7 PENN LAW: LEGAL SCHOLARSHIP REPOSITORY 1, at 3 (ebook, 2013).
[136] *Id.* at 3–4.

Figure 1: Pricing Comparisons[137]



The demand curve "D" represents total consumer demand for an entire market.[138] The line "MC" represents marginal cost, and the line "MR" represents marginal revenue.[139] In a competitive industry, prices would be pressured downward towards marginal cost and "the price of each unit of output would be determined by the point where marginal cost is equal to demand."[140] The intersection of MC and D thus represents the competitive price, noted as "P_c," on the vertical axis.[141] When price is at this level, demand will be high.[142] Some consumers, though, "would have been willing to pay more than the competitive price, and triangle 1-3-6 represents [this] 'consumers' surplus' — the amount of wealth created by the fact that many consumers can purchase the product for less than the value they place on it."[143]

Any company that desires to achieve the highest possible profit would want to convert as much consumer surplus into producer surplus as possible.[144] This is where the monopolist's ability to decide on price provides

[137] *Id.* at 4 ("Figure 1 illustrates the differences between competitive pricing, nondiscriminatory monopolistic pricing, and perfect price discrimination").
[138] *Id.* at 3.
[139] *Id.*
[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] *Id.* at 4.

an advantage.[145] "If the seller sells at its nondiscriminatory profit-maximizing price, P_m . . . , then the seller has created for itself a producers' surplus equal to rectangle 2-3-5-4, which represents revenues in excess of marginal cost."[146] As a result, consumers' surplus is "reduced to triangle 1-2-4," and "triangle 4-5-6 represents deadweight loss[,]" the value that neither consumers nor producers receive.[147] This value is lost because customers are unwilling to pay price P_m and instead chose to buy what would have been a less appealing substitute in a competitive market.[148] If the seller had the ability to perfectly determine the price that each buyer was willing to accept, the seller could eliminate the deadweight loss by making every sale at the determined price, and the seller would effectively translate the 1-3-6 triangle into producer surplus.[149]

The result under perfect price discrimination is therefore an allocation with similar efficiency as that under perfect competition.[150] Compared to their outcomes in the discriminatory market, however, some consumers would be better off in the monopoly-priced market.[151] In the monopoly-priced market, all consumers would pay price P_m but some of them value the product more than that price, and thus would have paid more under perfect price discrimination.[152] In the international pharmaceuticals market, this group is representative of U.S. consumers. U.S. consumers "value" life-saving drugs higher than P_m because, as a result of government-granted market exclusivity, there are often no comparable substitutes for those drugs.[153] The IPI, then, is essentially a policy mechanism meant to curtail the pharmaceutical industry's exercise of price discrimination; the IPI is meant to drive the U.S. price closer to the monopoly price.

C. Constrained Negotiating Power of the United States

A buyer's capacity to effectively negotiate is the primary countervailing force against the market power of pharmaceutical firms.[154] There is a unique landscape of negotiating power in the United States because, unlike most

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[145] *See id.* (describing how a single firm with substantial market power may influence the demand, cost, and revenues curves).
[146] *Id.* at 5.
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] *Id.*
[153] SCHWEITZER & LU, *supra* note 125, at 13 (explaining that the U.S. government provides market protections for brand name drugs which prevent access to substitutes).
[154] Kesselheim et al., *supra* note 11, at 862.

other OECD countries, the United States does not regulate pharmaceutical prices.[155] In the United Kingdom ("U.K."), the National Institute for Health and Care Excellence ("NICE") performs careful appraisals of new pharmaceutical products before they can be introduced into the U.K. market.[156] The National Health Service, the U.K.'s publicly-funded healthcare system, will only cover drugs that are recommended by NICE, and since 2000, NICE has only recommended twenty percent of drugs considered.[157] In Germany, drug manufacturers must prove that the additional benefits of new therapies justify higher prices when negotiating with the government, and it is unlikely for a newly approved drug that offers little to no clinical improvement over existing treatments to receive a higher coverage price from public insurance plans.[158] In Australia, drug companies undergo similar scrutiny, as they must submit an application to the Pharmaceutical Benefit Advisory Committee, and produce evidence showing that their drug offers better clinical value than what is already on the market.[159]

In contrast, when companies seek to introduce new drugs into the U.S. market, they have the freedom to set their own prices.[160] Further, public as well as private buyers each suffer from limited negotiating power. While Medicare makes up twenty-nine percent of U.S. prescription drug spending, it is not only prevented by federal law from negotiating drug pricing and leveraging its massive purchasing power, but also required to cover a large number of drugs, including every available product in some categories, like oncology.[161] Congress established this restrictive framework after hearing input from representatives in the pharmaceutical industry who argued that, if the U.S. government was able to negotiate, revenues in the industry would suffer.[162] Further, state Medicaid organizations must provide insurance coverage for all drugs approved by the FDA and have no authority to exercise discretion based on the clinical value or cost-effectiveness of a particular drug.[163] The Veterans Health Administration, on the other hand, is permitted to exercise discretion in selecting which drugs it will cover.[164] Research

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[155] *Id.*
[156] Schweitzer & Lu, *supra* note 125, at 125.
[157] *Id.*
[158] Victoria D. Lauenroth & Tom Stargardt, *Pharmaceutical Pricing in Germany: How is Value Determined Within the Scope of AMNOG?*, 20 VALUE HEALTH 927, 933 (2017).
[159] Andrew Wilson & Joshua Cohen, *Patient Access to New Cancer Drugs in the United States and Australia*, 14 VALUE HEALTH 944, 945 (2011).
[160] Gronde et al., *supra* note 5, at 9.
[161] Kesselheim et al., *supra* note 11, at 862.
[162] *Id.*
[163] *Id.*
[164] *Id.*

shows that because of this discretion, the Veterans Health Administration is able to attain lower drug costs in comparison to the Medicare drug program and state Medicaid organizations.[165]

Private buyers, although not as directly hindered by law, face unique negotiating difficulties. Private buyers, such as insurance companies, are often able to effectively negotiate with pharmaceutical companies by leveraging the list of drugs included in their insurance plans.[166] Medicare, however, often requires private buyers to include certain drugs in their insurance policies and, because drug companies have the ability to negotiate with each private insurance company individually, these private buyers suffer from unequal bargaining power at the negotiating table.[167] Studies have shown that the enrollment of 100,000 additional members came with a 2.5% decrease in pharmaceutical prices and five percent decrease in drug profits earned on prescriptions filled because when insurers experienced an enrollment increase after the Medicare Part D implementation, they were able to negotiate lower drug prices.[168] This suggests that the scattering of buying power in the United States has resulted in a multitude of insurance companies that are unable to effectively negotiate with pharmaceutical companies.

III) REGULATING AGAINST PRICE DISCRIMINATION

A. The Robinson-Patman Act

The IPI would not be the first instance in which the United States has engaged in regulatory intervention against price discrimination.[169] Examining the results of these previous interventions can provide insight when predicting the potential results of the IPI. The Robinson-Patman Act, though it does not operate within the pharmaceuticals market, is a perfect example of a regulatory intervention against price discrimination. The most relevant section of the Act is section 2(a), 15 U.S.C. § 13(a), which makes it unlawful:

> [T]o discriminate in price between different purchasers of commodities of like grade and quality . . . where the effect of such

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[165] *Id.*
[166] John B. Kirkwood, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253, 263–64 (2015).
[167] *Id.*
[168] Nat'l. Bureau of Econ. Res., *How Insurers' Bargaining Power Affects Drug Prices in Medicare Part D*, NAT'L BUREAU ECON. RES. BULL. AGING & HEALTH, Dec. 2009, at 1.
[169] Thomas W. Ross, *Winners and Losers Under the Robinson-Patman Act*, 27 J.L. ECON. 243, 244 (1984).

> discrimination may be substantially to lessen competition or tend to create a monopoly in any line of commerce, or to injure, destroy, or prevent competition with any person who either grants or knowingly receives the benefit of such discrimination, or with customers of either of them.[170]

This section came about as a result of a revolution in distribution during the late nineteenth and early twentieth centuries.[171] The rise of large chain stores disrupted the typical supply chain from manufacturer to wholesaler to retailer.[172] The chain stores represented a new group of buyers — one that could bypass the wholesaler and demand lower prices for goods than the typical small independent store.[173] Manufacturers started promoting bulk discounts and eventually the chain stores, especially grocery stores, were able to undercut their smaller competitors by offering lower prices to consumers.[174]

There are several parallels that one can draw between the Robinson-Patman Act and the IPI. First, the Robinson-Patman Act is an intervention against price discrimination, promulgated for the purpose of raising prices for a certain group of buyers.[175] Its purpose, then, is similar to the purpose of the IPI, which, as explained in Part II(b), is intended to pressure the Indexed Countries to raise the prices they pay for pharmaceuticals.[176] The Robinson-Patman Act accomplished its purpose by forcing manufacturers to justify the asymmetrical prices they offered and limiting the difference between prices to the difference between marginal costs.[177] Figure 2 illustrates the effect of the Robinson-Patman Act in a situation in which a seller is selling the same product to two different groups of buyers.[178]

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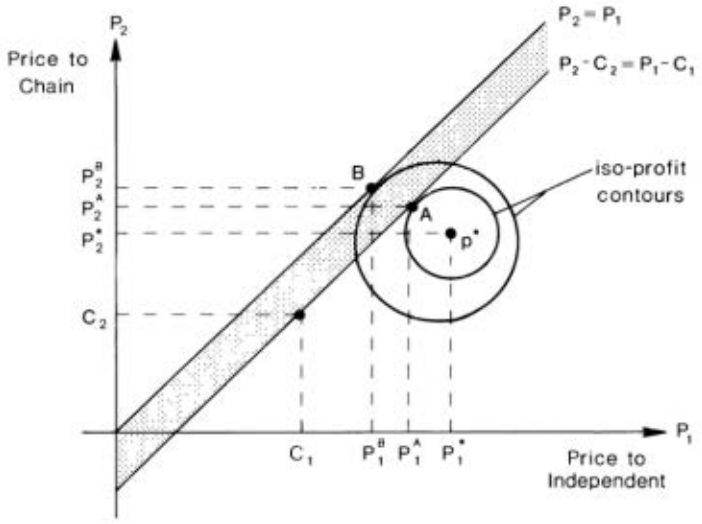
[170] The Robinson-Patman Act § 2, 15 U.S.C. § 13 (2020).
[171] Ross, *supra* note 169.
[172] *Id.* at 244–245.
[173] *Id.* at 245.
[174] *See id.* (stating that the chain stores were large organizations that threatened smaller, higher-cost independent retailers because the chain stores gained economic advantages by integrating the wholesale and retail functions).
[175] Wesley J. Liebeler, *Let's Repeal It*, 45 ANTITRUST L.J. 18, 27 (1976).
[176] *See* discussion *infra* Section II(b).
[177] *See* Liebeler, *supra* note 175, at 27-28 (noting that the Act contributes to higher prices by inhibiting the competitive price setting process and encouraging behavior that tends to stabilize prices).
[178] Ross, *supra* note 169, at 250–52.

Figure 2: Robinson-Patman Constraint[179]



The seller's goal is to maximize profits by selecting prices (P1, P2).[180] Independent retailers represent the first group of buyers, and chain stores represent the second.[181] Each group of buyers experiences constant but different marginal costs.[182] When the seller sells a unit to a chain store, "C2", the seller incurs a lower marginal cost than that incurred when selling a unit to an independent retailer, "C1."[183] This seller would have the freedom to choose any price, or any point in space, without the Robinson-Patman Act, and would presumably select p* to maximize profits.[184] The iso-profit contours around p* denote the decreasing levels of profit resulting from price moving further from p*.[185] The Robinson-Patman Act mandates that the difference between two prices for the same product may not exceed the difference between the cost of selling to one consumer and the cost of selling to the other consumer; that is, P1 - P2 must be less than or equal to C1 - C2.[186] The legal price vectors are characterized by the shaded area between lines

[179] *Id*. at 251, Figure, Profit Maximizing Prices Under the Robinson-Patman Act.
[180] *Id.* at 249.
[181] *Id.* at 249.
[182] *Id.*
[183] *Id.* at 250.
[184] *Id.*
[185] *Id.*
[186] *Id.*

P1= P2 and P1 - P2 = C1 - C2.[187] To maximize profits while complying with the Act, the seller will move to point A where P1 = P^A1 and P2 = P^A2.[188]

The seller thereby reduces prices for the independent retailers and raises them for the chain stores.[189] This redistribution of prices is exactly what the Robinson-Patman Act intended to accomplish, and it is almost exactly what policy makers today hope to accomplish through implementing the IPI.[190] In Figure 2, the shaded area could be formulated to represent legal price vectors under the IPI by changing it to a single line where the price to the independent stores equals 126% of the price to the chain stores. It is reasonable to expect that sellers would still experience the same pressure to conform to the new vector.[191]

The empirical evidence of the results of the Robinson-Patman Act confirm the predictions of this model. The act had a negative effect on grocery store chain profits because the prices they paid for inventory increased.[192] This result was found through analyzing the changes in a stock portfolio of chain stores before and after the Robinson-Patman Act.[193] From June 1935 to December 1937, the chain store portfolio lost to the market, having a negative abnormal return between ten and twenty percent.[194] It is clear, then, that the Robinson-Patman Act takes from both the seller and the chains and gives to the independent retailers; the fact that the negative abnormal returns were only ten to twenty percent suggests that both the manufacturers and the chain stores shouldered the burden of the act.[195] In other words, when the manufacturer was forced to curtail its use of price discrimination, it did not simply lower prices for the independent stores, but raised prices for the chain stores as well.[196] This is exactly the result that the IPI is designed to

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[187] *Id.*
[188] *Id.*
[189] *Id.* at 250–51.
[190] Liebeler, *supra* note 175, at 28; Pricing Index Model, 83 Fed. Reg. at 54,547.
[191] *See generally*, Thomas Ross, *The Costs of Regulating Price Differences*, 59 J. BUS. 143 (1986) (stating that price setting equations and derivatives show that the Robinson-Patman Act results in a lower price to small business and a higher price to chains and is likely to be representative of many real-world cases where firms attempt to maximize profits while staying within constraints of the law).
[192] Ross, *supra* note 169, at 253–59.
[193] *Id.*
[194] *Id.* at 258.
[195] *Id.* at 258–59.
[196] *Id.* at 258 ("In the first years after Robinson-Patman was passed, chains continued to lose ground to independents. As revealed in Table 3, the share of total retail sales going to chains of four or more stores fell from 1933 to 1935 and continued to decline through to 1939. Leading this decline were the grocery chains, which accounted for about 30 percent of total chain retail sales. The losses of the drug, shoe, and variety chains were much smaller.").

achieve—making the results of the Robinson-Patman Act a pertinent parallel to consider when predicting the effects of the IPI.

Another potential parallel between the IPI and the Robinson-Patman Act is their unintended consequences. The Robinson-Patman Act was somewhat controversial due in part to the incentives it created for manufacturers to simply refuse to deal with smaller retailers or specialized outlets that did not handle a large volume of a particular product.[197] For example, there was a case brought against a furniture manufacturer because the manufacturer was offering substantial discounts to bulk buyers and charging small designers more.[198] The Robinson-Patman Act forced the manufacturer to decide between equalizing prices or selling exclusively to bulk buyers.[199] The manufacturer chose the latter, forcing the small designer firms to pay more elsewhere.[200] The IPI could cause a similar result; if a pharmaceutical company is offering lower prices to one of the Indexed Countries, the IPI would pressure the company to choose between either raising the price in that country or refusing to sell to that country.[201] The company would face this pressure because the price the company offers the Indexed Country would affect the price the United States pays.[202] If the company agrees to a low price for a particular Indexed Country, it will also lose revenue from a corresponding decrease in the price in the United States. If that Indexed Country is unable or unwilling to accept a higher price, the company might generate more revenue by simply refusing to sell to that country and maintaining the higher U.S. price.[203] This consequence was even alluded to by the CEO of Allergan when he said, "companies could raise prices or stop selling entirely in those countries, or not launch new products in those countries . . . I don't think we'd really be impacted by the IPI [pricing model]."[204]

When considering the interests of the United States, though, the potential benefits from implementing the IPI still likely outweigh the costs. If the IPI achieves a similar redistribution of costs as the Robinson-Patman Act, the United States is likely to see a net benefit in the form of lower drug prices. Whereas the Robinson-Patman Act was controversial, in large part, because

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[197] Liebeler, *supra* note 175, at 32.
[198] *Id.* at 33.
[199] *Id.*
[200] *Id.*
[201] *See* discussion *supra* Section I(b).
[202] Liebeler, *supra* note 175, at 32.
[203] *Id.*
[204] Ed Silverman & Mathew Herper, *Allergan CEO: We Stuck to the Spirit of our Social Contract with Recent Price Hikes*, STAT (Jan. 8, 2019), https://www.statnews.com/pharmalot/2019/01/08/allergan-drug-prices-social-contract/.

of competing ideas about what constitutes an ideal welfare function,[205] the common interests that U.S. policy makers have should cause an *effective* redistribution under the IPI to be more palatable. Whether such a redistribution is effective, though, depends on the willingness of the Indexed Countries to accept increased prices.[206] The price change caused by the Robinson-Patman Act modeled in Figure 2 relies on the assumption that the buyer's demand function does not change.[207] There is reason to believe, however, that these functions actually changed significantly because the Robinson-Patman Act applied to every firm in the market; thus, just as the seller in the model could not continue to provide the chain stores with discounts, the other sellers in the market were also unable to do so.[208] The chain stores therefore sacrifice some bargaining power in transactions with suppliers, essentially decreasing their elasticity of demand.[209] Similarly, the IPI would apply to every pharmaceutical firm that participates in the Medicare Part B market. Because so many pharmaceutical companies participate in the U.S. market, European buyers may likewise experience a shift in their demand functions.

IV) PREDICTING PRICE CHANGES UNDER THE IPI

A. Elasticity of Demand

Whether the demand curves of the Indexed Countries would shift is determinative of whether the Indexed Countries would accept higher prices for pharmaceuticals. As explained below, static demand curves would mean that the Indexed Countries would not accept higher prices, causing greater revenue loss for pharmaceutical companies, whereas responsive demand curves would mean less or no loss in revenue. Therefore, any prediction about the IPI's effect on revenue must include an analysis on the elasticity of demand of the Indexed Countries.

Demand for a good or service is defined as inelastic if price changes do not affect the demand for that good or service.[210] In other words, inelastic demand means that the amount of goods demanded changes by less than one

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[205] Ross, *supra* note 169, at 251–53.
[206] *Id.* at 252 (noting that that the price redistribution under the Robinson Patman Act depended on changing demand functions).
[207] *Id.*
[208] *Id.*
[209] *Id.*
[210] *Elasticity of Demand*, LIBR. ECON. & LIBERTY (Apr. 16, 2020, 12:00 PM), https://www.econlib.org/library/ Topics/College/elasticityofdemand.html.

percent even when there is a one percent change in the price of those goods.[211] A perfectly inelastic demand curve appears as a vertical line which represents that a change in price has no impact on quantity demanded.[212] There are likely no real-life examples of goods with perfect inelasticity, but there are some products that come close because of a lack of suitable substitutes.[213] Prescription drugs are among the most common products with inelastic demand, along with food and tobacco.[214]

The inelasticity of the demand for pharmaceuticals is well-documented and researched.[215] Several studies found that the elasticity of demand for prescription drugs in various European countries ranged from -0.09 to -0.64, with the most frequent findings falling in the middle of this range.[216] An elasticity of -0.09 means that for every percentage point that prescription drug prices increased, the quantity of prescription drugs purchased decreased by 0.09%.[217] These values thus represent a highly inelastic demand. Further, demand for the newest, most innovative drugs is often especially inelastic because the alternative therapies for those products are not adequate substitutes.[218]

Countries that have high rates of insurance coverage also tend to have less elastic demand for pharmaceutical drugs because insured patients are less price sensitive, or less affected by the price of drugs covered by their insurance.[219] Consumers in many of the Indexed Countries have higher rates of insurance coverage than consumers in the United States.[220] Therefore, the consumers in many of the Indexed Countries are likely to have less elastic

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[211] *Id.*
[212] RICE UNIV., PRINCIPLES OF ECONOMICS, POLAR CASES OF ELASTICITY AND CONSTANT ELASTICITY 3, loc. 5.2 (2014) (ebook).
[213] *Id.*
[214] Mary Hall, *Elasticity Vs. Inelasticity of Demand*, INVESTOPEDIA (Aug. 9, 2020), https://www.investopedia.com/ ask/answers/012915/what-difference-between-inelasticity-and-elasticity-demand.asp.
[215] Marin Gemmil, The Price Elasticity of Demand for Prescription Drugs: An Exploration of Demand in Different Settings 58–61 (Jan. 2008) (unpublished Ph.D thesis, London Sch. Econ. & Pol. Sci.), https://etheses.lse.ac.uk/2944/ 1/U615895.pdf.
[216] *Id.* at 60 (several of these studies were based on relatively small sample sizes though).
[217] *Id*. at vii. ("Price elasticity of demand - the percentage change in the quantity demanded brought about by a one percentage change in the price of the good or service.").
[218] *Id.* at 49.
[219] Patricia Danzon & Eric Keuffel, *Regulation of the Pharmaceutical-Biotechnology Industry*, *in* ECONOMIC REGULATION AND ITS REFORM: WHAT HAVE WE LEARNED? 407, 407 (Nancy L. Rose ed., U. Chi. Press 2014) (noting that produces can charger higher prices on those who are insured).
[220] Eric Schneider et al., *International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, COMMONWEALTH FUND (Apr. 16, 2020, 12:20 PM), https://interactives.commonwealthfund.org/2017/july/mirror-mirror/.

demand than their U.S. counterparts. Although co-payments can make insured consumers more price sensitive, demand for prescription drugs remains highly inelastic.[221]

B. Pharmaceutical Review Agencies

The highly inelastic demand for prescription drugs is one of the reasons that so many European countries have pharmaceutical review agencies that act as a negotiating agent for their respective countries.[222] These agencies are meant to mitigate the inelasticity of demand for consumers who might otherwise accept higher prices.[223] Their role in negotiating with pharmaceutical companies will therefore cause some variation in the general measurements of elasticity.[224] Accordingly, an accurate prediction of price changes under the IPI must account for this and analyze the parameters of these countries' negotiating capacities. The largest foreign markets referenced in the IPI, such as Japan, Germany, and France, all have governmental agencies with the specific tasks of determining the value and cost-effectiveness of new drugs before they enter their respective markets.[225] These agencies often allow for price premiums for drugs that are "more cost-effective or support a small market or pediatric indication" and will calculate "price adjustments if the proposed prices vary significantly from the average sales price in comparable foreign markets."[226]

Similar to the U.S. health care system, the German health care system arrives at pharmaceutical prices primarily through negotiation, instead of regulation, and is financially supported through multiple private payers.[227]

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[221] Danzon & Keuffel, *supra* note 219, at 442 (noting that copayments can mitigate the insurance effect, but because copayments also reduce financial protection, in practice most public insurance plans include only very modest copayments).

[222] *See generally* Jacob Morey & Daniel Charytonowicz, *International Pricing Index: Outsourcing Negotiations will Continue the US Drug Cost Crisis*, HEALTH AFF. (Apr. 16, 2020, 12:00 PM), https://www.healthaffairs.org/do/ 10.1377/hbl-og20190307.887201/full/ ("These countries all have governmental agencies with the specific tasks of developing cost-effectiveness analyses and calculating price adjustments if the proposed prices vary significantly from the average sales price in comparable foreign markets.").

[223] *Id.*

[224] *See id.* (describing how these agencies act as a mediator between the pharmaceutical companies and consumers, and their cost-effectiveness analyses and price calculations represent more than merely the quantity demanded by the consumers within their respective countries).

[225] *Id.*

[226] *Id.*

[227] James C. Robinson et al., *Reference Pricing in Germany: Implications for U.S. Pharmaceutical Purchasing*, COMMONWEALTH FUND (Apr. 16, 2020, 1:10 PM), https://www.commonwealthfund.org/publications/issue-briefs/2019/jan/reference-pricing-germany-implications.

Where the German system differs is in its two-tiered pricing system; the prices for drugs that offer benefits over currently available medications are determined by negotiating with pharmaceutical companies, but reference pricing is used when a drug offers little or no benefit over these other medications.[228] This two-tiered pricing system allows German consumers to access drugs at considerable lower prices than U.S. consumers.[229] Germany enforces this system by limiting the amount that insurance companies can pay for drugs with therapeutically equivalent alternatives.[230] This allows pharmaceutical companies to set their own prices, but limits insurance payments for new drugs based on the amount that insurance companies provide for similar drugs unless a new drug offers a clinical benefit that its competition does not.[231]

Unlike many frameworks used by European countries, Germany and the United States do not directly evaluate the relative clinical benefit of new pharmaceuticals or negotiate prices,[232] but the German system has several features which are distinct from the U.S. system.[233] In Germany, all pharmaceuticals authorized by the European equivalent to the FDA, the European Medicines Agency ("EMA"), may be prescribed by physicians immediately after approval.[234] In this initial period, pharmaceutical companies are free to set the price of the new drug as they see fit and receive full reimbursement.[235] But over the course of the initial one year period, Germany analyzes the new drug's clinical safety and effectiveness as compared to other available alternatives.[236] If the German government determines the new drug has incremental benefits, it may increase the price it pays in comparison to a specified comparator drug within the same class of medication.[237] And conversely, if no such finding is made, the price will fall to the lowest price bracket within the class.[238]

Despite Germany's evaluation system, many new drugs gain access to the German market, including less innovative drugs.[239] Research shows that

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[228] *Id.*
[229] *Id.*
[230] *Id.*
[231] *Id.*
[232] *Id.*
[233] *Id.*
[234] *Id.*
[235] *Id.*
[236] *Id.*
[237] *Id.*
[238] *Id.*
[239] *No Evidence of Added Benefit for Most New Drugs, Say Researchers*, BMJ (Apr. 16, 2020, 1:20 PM), https://www.bmj.com/company/newsroom/no-evidence-of-added-benefit-for-most-new-drugs-say-researchers/.

over half of the drugs that Germany approves have no added benefit over their alternatives.[240] In Germany, from 2011 to 2017, their pharmaceutical review agency approved 216 drugs, the vast majority of which had already received EMA approval.[241] Fifty-four of the drugs were found to have a "considerable or major added benefit."[242] For thirty-five of the drugs, "the added benefit was either minor or could not be quantified," and 125 of them showed no added benefit compared to the alternative products that were already available.[243] Further, an assessment of oncology pharmaceuticals authorized by the EMA between 2009 and 2013 showed that a majority had been approved with zero evidence of "clinically meaningful benefit on patient relevant outcomes (survival and quality of life)," an outcome which did not change over time.[244]

In France, the Comité Economique des Produits de Santé ("CEPS") is the primary economic decision maker in the realm of pharmaceuticals and it negotiates the final reimbursement rate for all new pharmaceuticals based on an assessment from a medical evaluation commission.[245] The technical assessment that the commission provides includes three findings.[246] First, the commission estimates the Medical Benefit ("SMR") by determining a drug's reimbursement eligibility and the recommended parameters of the potential reimbursement rate.[247] The SMR assessment includes investigations into a variety of factors, including: (a) a drug's efficacy and safety, (b) the position of the medicine in the therapeutic strategy and whether there are any close alternatives available, (c) the severity of the relevant disease, (d) whether the treatment is preventive, curative or symptomatic, and (e) the public health impact.[248] Using those elements, the commission determines the drug's medical benefit, the levels of which range from major, important, moderate, weak, and insufficient to reimburse.[249] Second, it provides an Improvement of Medical Benefit assessment ("ASMR"), which establishes a target price

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[240] *Id.*
[241] *Id.*
[242] *Id.*
[243] *Id.*
[244] *Id.*
[245] Alexander Natz & Marie-Geneviève Campion, *Pricing and Reimbursement of Innovative Pharmaceuticals in France and the New Healthcare Reform*, 13 FARMECONOMIA HEALTH ECON. & THERAPEUTIC PATHWAYS 49, 50–51 (2012). "The Comité Economique des Produits de Santé" translates to "The Healthcare Products Pricing." Committee."
[246] Annie Chicoye et al., *France – Pharmaceuticals*, ISPOR (Apr. 16, 2020), https://tools.ispor.org/htaroadmaps/ France.asp.
[247] *Id.*
[248] *Id.*
[249] *Id.*

by comparing the new drug to currently available alternatives.[250] Except for cases involving drugs that use unique mechanisms to treat a condition, the agency performs this comparison by looking at alternatives within the same therapeutic class.[251] The agency then provides one of five ASMR levels ranging from major innovation, important improvement, significant improvement, minor improvement, and no improvement.[252]

CEPS then uses these findings as a basis for its negotiations with pharmaceutical companies.[253] The drugs recognized as major or irreplaceable, like HIV drugs, and drugs that treat chronic and severe diseases are reimbursable at 100% — that is, the consumer or other buyer is reimbursed for 100% of the cost of the drug.[254] In 2007, the average reimbursement rate for retail pharmacist drugs was 76.77%.[255] This broad insurance coverage means that demand for pharmaceuticals in France is particularly inelastic. Thus, even in this complex framework, spending on pharmaceuticals in France is rapidly increasing.[256]

The French regulatory scheme for hospital drugs provides drug companies more flexibility in setting prices.[257] This fact is especially relevant because these drugs would likely include those drugs covered under Medicare Part B.[258] In France, hospitals have authority to agree to drug prices with pharmaceutical companies independent from the government, however, for the more expensive drugs that will be charged to health insurance, the company must thereafter disclose to the government the price they intend to charge, as well as the prices they offer in other European countries.[259] If CEPS does not approve the declared price, it will intervene and negotiate with the drug company.[260] These negotiations are based on similar considerations as the SMR and ASMR ratings.[261]

In Italy, the Italian Medical Agency ("AIFA") negotiates with pharmaceutical companies using similar parameters as Germany and France,

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[250] *Id.*
[251] *Id.*
[252] *Id.*
[253] *Id.*
[254] *Id.*
[255] *Id.*
[256] Nathalie Grandfils, *Drug Price Setting and Regulation in France* 2 (IRDES Working Paper N. DT16, Sept. 2008), https://www.irdes.fr/EspaceAnglais/Publications/WorkingPapers/DT16DrugPriceSettingRegulationFrance.pdf.
[257] *Chicove* et al., *supra* note 246.
[258] *See* Fein, *supra* note 19 (explaining that Medicare Part B includes physician-administered drugs).
[259] *Chicove* et al., *supra* note 246.
[260] *Id.*
[261] *Id.*

but provides greater flexibility for highly innovative drugs.[262] During their negotiation with AIFA, companies may request approval for status as an innovative drug.[263] Italy has established separate funds to cover expenditures for innovative drugs which are not subject to the same reimbursement constraints of other drugs.[264] AIFA may grant full "innovative status," which provides access to these separate funds, or "conditional status," which means the drug will be included in Italy's Regional Therapeutic Handbooks.[265] AIFA determines how innovative a drug is for a particular indication by considering three evaluation criteria: unmet therapeutic need, added therapeutic value, and quality of evidence.[266] In 2017, Italy introduced a new algorithm to assess whether a drug should receive this status and increased its innovative drug fund to $1.2 billion.[267] The new algorithm is expected to provide more flexibility and room for reviewer discretion.[268] The new algorithm and increased funding will likely cause demand for innovative pharmaceuticals to become more inelastic.

C. The IPI's Effect on Revenue

It is clear that the pharmaceutical review agencies in Indexed Countries mitigate the inelastic demand of consumers; however, it is also clear that the negotiating processes described above consider a wide variety of factors and allow pharmaceutical companies opportunities to justify prices for new drugs. Critics of the IPI are not alone in their fears that decreased revenue will lead to a decrease in innovation as the policies of Germany, France, and Italy demonstrate that these countries understand the high costs involved in pharmaceutical development and that they are willing to pay more for more innovative drugs.[269] For example, the French system is sometimes praised as an exemplary method of controlling spending on pharmaceuticals compared

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[262] Mauro Putignano & Sonia Selletti, *Pricing & Reimbursement 2019: Italy*, GLOBAL LEGAL INSIGHTS (Apr. 16, 2020, 2:20 PM), https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/Italy.
[263] *Id.*
[264] *Id.*
[265] *Id.*
[266] Yulia Privolnev, *What is Pharmaceutical Innovation, Anyway? Italy's New Algorithm & the Global Trend*, PHARMACEUTICAL ONLINE (April 16, 2020, 2:30 PM), https://www.pharmaceuticalonline.com/doc/what-is-pharmaceutical-innovation-anyway-italy-s-new-algorithm-the-global-trend-0001.
[267] *Id.*
[268] *Id.*
[269] *See generally* discussion *supra* Section IV(b).

to other countries,[270] yet drug companies have been consistently successful in negotiating prices in France.[271]Further, when drug companies are pushed to charge higher prices in these countries as a result of the IPI, they will likely benefit from some of the reference pricing mechanisms described above.[272] This is because companies will likely put pressure on multiple countries that reference each other's prices, thus pushing the reference points higher.

The result of pharmaceutical review agencies, then, is not transforming demand for pharmaceuticals from highly inelastic to highly elastic. Rather, the result is a change from highly inelastic demand to a moderately inelastic demand. Therefore, when considering the potential effects of the IPI, the relevant inquiry is not whether prices in the Indexed Countries will change but how much prices will change.

The fact that the IPI would cause prices in the Indexed Countries to increase provides a basis to estimate net revenue changes. In other words, by modeling various potential price changes in the Indexed Countries, it is possible to more clearly understand the extent to which total revenue would change under the IPI. The charts below provide several models of how revenue may change by using fictional sales data from a hypothetical drug ("Hypothimta").[273] Assume that, for each of the Indexed Countries, 0.03% of their populations suffer from a condition and that Hypothimta is the only treatment or has no close substitutes. Each person who is afflicted by the condition needs a total of ten grams of Hypothimta to recover from the disease.

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[270] *See* David Andelman, *The French Solution to US Drug Prices*, CNN (Apr. 16, 2020, 2:00 PM), https://www.cnn.com/2019/04/30/opinions/healthcare-drug-prices-compared-france-intl/index.html (explaining that France has enormous bargaining power with drug manufacturers because the government runs the country's universal healthcare program, which make it's by the far the largest purchaser for most drugs, and thus successfully sets price ceilings for drug makers).

[271] *Grandfils*, *supra* note 256, at 17.

[272] *See generally supra* Section IV(b) (explaining that reference pricing ties the price of a drug in one country to its price in other countries).

[273] *See World Population Clock*, WORLDOMETER, https://www.worldometers.info/world-population/ (last visited Oct. 31, 2020) (explaining data on populations of each country); *Medicare Fast Facts*, NAT'L COMMITTEE TO PRESERVE SOC. SEC. & MEDICARE (June 2, 2020), https://www.ncpssm.org/our-issues/medicare/medicare-fast-facts/ (explaining data on Medicare Part B population).

Figure 3: Pre-IPI Revenue[274]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,642	0.03%	8,955,102	26,865	$70,978,138
Belgium	$2,736	0.03%	11,539,328	34,618	$94,714,804
Canada	$2,840	0.03%	37,411,047	112,233	$318,742,120
Czech Republic	$3,030	0.03%	10,689,209	32,068	$97,164,910
Denmark	$2,710	0.03%	5,786,561	17,360	$47,044,741
Finland	$2,793	0.03%	5,532,156	16,596	$46,353,935
France	$2,755	0.03%	65,129,728	195,389	$538,297,202
Germany	$2,783	0.03%	83,517,045	250,551	$697,283,809
Greece	$2,693	0.03%	10,473,455	31,420	$84,615,043
Ireland	$2,400	0.03%	4,882,495	14,647	$35,153,964
Italy	$2,800	0.03%	60,550,075	181,650	$508,620,630
Japan	$2,725	0.03%	126,860,301	380,581	$1,037,082,961
Netherlands	$2,810	0.03%	17,124,402	51,373	$144,358,709
United Kingdom	$3,173	0.03%	67,530,172	202,591	$642,819,707
AVERAGE	$2,778				
US (Medicare)	$5,000	0.05%	52,100,000	260,500	$1,302,500,000
TOTAL					$5,665,730,673

The price that each country pays per gram of Hypothimta differs between these countries up to a margin of fifteen percent above or below the index average, which is consistent with real world data for many of the top Medicare Part B drugs.[275] The Medicare price per gram is 180% of the index average, and, because the Medicare population includes a higher percentage of sick people than the general population of the United States, the incidence of the disease is higher in the Medicare population.[276] Figure 3 models the revenue generated from the Indexed Countries for Hypothimta before the IPI is implemented. Here, Hypothimta generates a total of $5,665,730,673 in revenue.

[274] Figure 3 illustrates the likely kinds of *percentage changes* in revenue that the IPI would cause, the exact dollar amounts are arbitrary; any index average would result in informative results given that the price that each Indexed Country pays are not wildly different from each other, and the price that Medicare pays is 180% of the index average.

[275] U.S. DEPT. HEALTH & HUM. SERVS., COMPARISON OF U.S. AND INTERNATIONAL PRICES FOR TOP MEDICARE PART B DRUGS BY TOTAL EXPENDITURES at13Table 2 (2018), https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf.

[276] MELISSA ALDRIDGE & AMY KELLEY, DYING IN AMERICA: IMPROVING QUALITY & HONORING INDIVIDUAL PREFERENCES NEAR THE END OF LIFE, Appendix E: Epidemiology of Serious Illness and High Utilization of Health Care 310, 517 (2015) (ebook).

Figure 4: No-Price-Change Revenue[277]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,642	0.03%	8,955,102	26,865	$70,978,138
Belgium	$2,736	0.03%	11,539,328	34,618	$94,714,804
Canada	$2,840	0.03%	37,411,047	112,233	$318,742,120
Czech Republic	$3,030	0.03%	10,689,209	32,068	$97,164,910
Denmark	$2,710	0.03%	5,786,561	17,360	$47,044,741
Finland	$2,793	0.03%	5,532,156	16,596	$46,353,935
France	$2,755	0.03%	65,129,728	195,389	$538,297,202
Germany	$2,783	0.03%	83,517,045	250,551	$697,283,809
Greece	$2,693	0.03%	10,473,455	31,420	$84,615,043
Ireland	$2,400	0.03%	4,882,495	14,647	$35,153,964
Italy	$2,800	0.03%	60,550,075	181,650	$508,620,630
Japan	$2,725	0.03%	126,860,301	380,581	$1,037,082,961
Netherlands	$2,810	0.03%	17,124,402	51,373	$144,358,709
United Kingdom	$3,173	0.03%	67,530,172	202,591	$642,819,707
AVERAGE	$2,778				
US (Medicare)	$3,500	0.05%	52,100,000	260,500	$911,776,050
TOTAL					$5,275,006,723

Figure 4 illustrates the change in revenue if prices do not change in the Indexed Countries and the U.S. price becomes 126% of the current average. This result is unlikely. Based on the market power that pharmaceutical companies have, the inelastic demand for pharmaceuticals, and the results of similar regulations against price discrimination, it is unreasonable to think that the IPI would create results comparable to those in Figure 4. Revenue in Figure 4 is decreased to $5,275,006,723, a decrease of almost seven percent. However, this decrease in revenue likely overstates the percentage of revenue that most companies would actually lose because if the revenue from sales to countries other than the Indexed Countries was included, total revenue would be higher, making the change a smaller percentage of total revenue.

[277] Figure 4, data consistent with U.S. DEPT. HEALTH & HUM. SERVS., *supra* note 275.

Figure 5: Price-Changes Revenue[278]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,774	0.03%	8,955,102	26,865	$74,527,045
Belgium	$2,873	0.03%	11,539,328	34,618	$99,450,544
Canada	$2,982	0.03%	37,411,047	112,233	$334,679,226
Czech Republic	$3,182	0.03%	10,689,209	32,068	$102,023,155
Denmark	$2,846	0.03%	5,786,561	17,360	$49,396,978
Finland	$2,933	0.03%	5,532,156	16,596	$48,671,632
France	$2,893	0.03%	65,129,728	195,389	$565,212,062
Germany	$2,922	0.03%	83,517,045	250,551	$732,147,999
Greece	$2,828	0.03%	10,473,455	31,420	$88,845,795
Ireland	$2,520	0.03%	4,882,495	14,647	$36,911,662
Italy	$2,940	0.03%	60,550,075	181,650	$534,051,662
Japan	$2,861	0.03%	126,860,301	380,581	$1,088,937,109
Netherlands	$2,951	0.03%	17,124,402	51,373	$151,576,644
United Kingdom	$3,332	0.03%	67,530,172	202,591	$674,960,693
AVERAGE	$2,917				
US (Medicare)	$3,675	0.05%	52,100,000	260,500	$957,364,853
TOTAL					$5,538,757,060

Figure 5 illustrates revenue when prices in each Indexed Country increase by five percent. The actual result of the IPI would not be so uniform; prices in some countries would likely increase substantially while other countries would experience moderate or small increases. The model, however, still makes several important points. First, the five percent increase in price is a modest increase in expenditure for each of the Indexed Countries. For example, Italy would need to pay approximately twenty-five million dollars more in total for Hypothimta, an increase slightly more than two percent of its yearly funds for innovative pharmaceuticals alone. Second, a five percent price increase in the Indexed Countries pushes the Medicare price up. This result is an anticipated part of the IPI.[279] The goal of implementing the IPI is not to decrease Medicare prices to 126% of current prices but to 126% of higher future prices.[280] Medicare still benefits though, as Figure 5 indicates that Medicare would save approximately $345 million on the total cost of Hypothimta under the IPI. The Hypothimta manufacturer loses $126,973,613.8 in Hypothimta revenue, representing a decrease in revenue of approximately 2.24%.

[278] Figure 5, data consistent with U.S. DEPT. HEALTH & HUM. SERVS., *supra* note 275.
[279] Pricing Index Model, 83 Fed. Reg. 54,556.
[280] Cook et al., *supra* note 34, at 1.

Figure 6: Excluding Small Buyers[281]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,774	0.03%	8,955,102	26,865	$74,527,045
Belgium	$2,873	0.03%	11,539,328	34,618	$99,450,544
Canada	$2,982	0.03%	37,411,047	112,233	$334,679,226
Czech Republic	$3,182	0.03%	10,689,209	32,068	$102,023,155
Denmark	$2,846	0.03%	5,786,561	17,360	$49,396,978
Finland	$2,933	0.03%	5,532,156	16,596	$48,671,632
France	$2,893	0.03%	65,129,728	195,389	$565,212,062
Germany	$2,922	0.03%	83,517,045	250,551	$732,147,999
Greece	$2,828	0.03%	10,473,455	31,420	$88,845,795
Ireland	$2,400	0.010%	4,882,495	4,882	$11,717,988
Italy	$2,940	0.03%	60,550,075	181,650	$534,051,662
Japan	$2,861	0.03%	126,860,301	380,581	$1,088,937,109
Netherlands	$2,951	0.03%	17,124,402	51,373	$151,576,644
United Kingdom	$3,332	0.03%	67,530,172	202,591	$674,960,693
AVERAGE	$2,908				
US (Medicare)	$3,664	0.05%	52,100,000	260,500	$954,551,453
TOTAL					$5,510,749,985

Figure 6 illustrates a potential unintended consequence of the IPI. Here, assume that Ireland refuses to accept a higher price, and that Ireland does not want to buy as much of Hypothimta as other countries, either because it happens to have a lower incidence of the underlying disease or because it has access to some alternative therapy. Hypothimta's manufacturer would be better off refusing to sell to Ireland because of the downward pressure Ireland's price would have on the Medicare price limit. Figure 6 shows that total revenue for Hypothimta when the manufacturer sells to Ireland is $5,510,749,985; conversely, if the manufacturer excluded Ireland, total revenue would be $5,511,862,724.

The above models illustrate the pressure that the IPI will put on prices in the Indexed Countries and the resulting decreases in revenue. This framework and analysis should assist in providing some context to claims that the IPI will devastate R&D investments. Given that revenue decreases in a similar way as is illustrated in Figure 6, it is unclear whether the IPI would significantly affect R&D budgets or merely decrease profit margins. One study, which analyzed ten of the world's largest pharmaceutical companies' annual accounting reports from 1996 to 2005, found that the reports disclosed net operating profits of $413 billion after tax, and a 29% net return on shareholders' investments.[282] This is not a normal return on

[281] Figure 6, data consistent with U.S. DEPT. HEALTH & HUM. SERVS., *supra* note 275.
[282] GAGNON & Wolfe, *supra* note 87.

investment in any other industry.[283] Further, of their net earnings, the ten companies allocated 77%, or $317 billion, to shareholders, and 16%, or $65 billion, to future mergers and acquisitions.[284]

V. CONCLUSION

Arguments claiming that the IPI will reduce the pace of innovation likely overstate its potential impact on revenue and understate, both, the amount of revenue generated from un-innovative pharmaceuticals, such as "me-too" drugs, and the amount of revenue that is distributed as profits rather than invested in R&D. Pharmaceutical companies' market power provides substantial leverage in their negotiations with consumers who attach a high value to innovative drugs, and thus it is reasonable to conclude that the IPI's upwards pressure on prices in the Indexed Countries will be at least moderately successful. In support of this conclusion, the Robinson Patman Act illustrates that policy mechanisms that create this kind of upwards price pressure are effective. The IPI is thus likely to be a successful mechanism in addressing the high cost of pharmaceuticals under Medicare Part B without causing substantial decreases in investments into R&D.

[283] *Id.*
[284] *Id.*

No Ordinary Process: The Flaws in Illinois Courts' Use of Remote Video Technology in Mental Health Trials.

Matthew R. Davison[*]

INTRODUCTION

There is an inherent tension between any state or federal crisis response and such efforts infringing upon or undermining important legal rights.[1] Hurricanes,[2] terrorism,[3] plagues,[4] and wars (both actual[5] and cold[6])

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[1] *See* Lindsay F. Wiley & Stephen I. Vladeck, *Coronavirus, Civil Liberties, and the Courts: The Case Against "Suspending" Judicial Review*, 133 HARV. L. REV. 179, 183 (2020); *see also* Conor Friedersdorf, *How to Protect Civil Liberties in a Pandemic*, ATLANTIC (Apr. 24, 2020), https://www.theatlantic.com/ideas/archive/2020/04/civil-libertarians-coronavirus/610624/.

[2] *See generally* Michael Cook, *"Get Out Now or Risk Being Taken Out by Force": Judicial Review of State Government Emergency Power Following a Natural Disaster*, 57 CASE W. RES. L. REV. 265, 289 (2006) (summarizing and analyzing various government responses to hurricanes, such as curfews, forced evacuations, and seizure of firearms); *see also* Rebecca Mae Salokar, *After the Winds: Hurricane Andrew's Impact on Judicial Institutions in South Florida*, 37 JUDGES' J. 26, 30 (1998) (giving an example where a curfew was enforced to ensure safety).

[3] *See generally* David Cole, *Where Liberty Lies: Civil Society and Individual Rights After 9/11*, 57 WAYNE L. REV. 1203, 1216 (2012) (giving an example of how the Central Intelligence Agency was authorized to use forms of waterboarding and torture after 9/11).

[4] *See generally* Charles McClain, *Of Medicine, Race, and American Law: The Bubonic Plague Outbreak of 1900*, 13 L. & SOC. INQUIRY 447, 453 (1998) (discussing San Francisco's efforts to combat the bubonic plague).

[5] *See generally* Thomas Y. Fujita-Rony, *Korematsu's Civil Rights Challenges: Plaintiffs' Personal Understandings of Constitutionally Guaranteed Freedoms, the Defense of Civil Liberties, and Historical Context*, 13 TEMP. POL. & CIV. RTS. L. REV. 51, 62 (2003) (giving an example where a suspected war enemy was taken into jail without any hearing or trial afforded to him).

[6] *See generally* Martin H. Redish, *Unlawful Advocacy and Free Speech Theory: Rethinking the Lessons of the McCarthy Era*, 73 U. CIN. L. REV. 9, 16 (2004) (stating that "historians

demonstrate that, in times of emergency, individual safeguards often have been set aside in favor of efficiency and safety.[7] After President Abraham Lincoln suspended writs of *habeas corpus* in 1861, he defended his action to Congress and asked for its endorsement by arguing, in part, that arrests and detentions of individuals "without resort[ing] to ordinary processes" was necessary to ensure the safety of both the public and the republic.[8]

The emergence of a new crisis, COVID-19,[9] presented courts and government leadership with an uncomfortable choice: shut down altogether or set aside ordinary processes and improvise. Courts' answer to this choice was not uniform, especially early on during the pandemic, where some courts that insisted on in-person proceedings quickly learned how grievous the virus is and had to reverse course.[10] Across the United States, many courts opted to postpone the majority of pending matters and entered a series of orders aimed at reducing in-person interactions to curtail any transmission of the

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seem to be unaware of the important implications of foundational free speech theory for the proper assessment of the treatment received by American Communists during the Cold War").

[7] Elizabeth Goitein, *The Alarming Scope of the President's Emergency Powers,* ATLANTIC (Jan./Feb. 2019), https://www.theatlantic.com/magazine/archive/2019/01/presidential-emergency-powers/576418/ ("At key points in American history, presidents have cited inherent constitutional powers when taking drastic actions that were not authorized—or, in some cases, were explicitly prohibited—by Congress. Notorious examples include Franklin D. Roosevelt's internment of U.S. citizens and residents of Japanese descent during World War II and George W. Bush's programs of warrantless wiretapping and torture after the 9/11 terrorist attacks. Abraham Lincoln conceded that his unilateral suspension of habeas corpus during the Civil War was constitutionally questionable but defended it as necessary to preserve the Union.").

[8] Abraham Lincoln, Pres., July 4th Message to Congress (Jul. 4, 1861).

[9] See *generally COVID-19 Facts,* CORONAVIRUS.GOV, https://faq.coronavirus.gov/covid-19-facts/ (last visited Nov. 1, 2020) ("Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. There are many types of human coronaviruses, including some that commonly cause mild upper-respiratory tract illnesses. COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans."); *see also Coronavirus Disease 2019 (COVID-19),* CDC, https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html (last visited Nov. 15, 2020) (explaining that symptoms of the virus include "fever or chills, cough shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea").

[10] Cory Shaffer, *An Ohio Judge Determined to Hold a Trial, a Defendant Removed from the Courtroom with Coronavirus Symptoms Illustrate Perils of Pandemic-era Trials,* CLEVELAND.COM (May 1, 2020), https://www. cleveland.com/court-justice/2020/05/an-ohio-judge-determined-to-hold-a-trial-a-defendant-removed-from-the-courtroom-with-coronavirus-symptoms-illustrate-perils-of-pandemic-era-trials.html (describing how an Ohio trial court judge who insisted on in-person proceedings during the state's stay-at-home order was ultimately forced to postpone a trial after the defendant presented with a fever and was carried from the courtroom on a stretcher).

disease.[11] Even the United States Supreme Court resorted to hearing oral arguments by teleconference, which was not without a small amount of drama.[12] Meanwhile, in cases involving exigent issues or true emergencies, courts improvised and adapted by hearing cases remotely through video conference technology.[13] During this hurried transition, other, non-exigent proceedings, such as mental health trials in Illinois, were also relegated to a remote video conference format with little scrutiny or notice.[14] For example, when members of the judiciary touted in a local publication that Cook County successfully conducted its "first" civil trial-by-video, they overlooked that civil mental health trials had already been occurring by video in that very same county for weeks.[15]

While many other cases were postponed or delayed at the introduction of COVID-19, courts across Illinois continued to adjudicate mental health trials concerning the involuntary commitment of individuals and forced medication of the same by using popular video platforms such as Microsoft's Zoom.[16] The rushed effort to adopt the remote format was largely rooted in the pre-pandemic supposition that these hearings are necessary for the individual to start receiving treatment as untreated mental illness might

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[11] *See generally Coronavirus & the Courts*, NAT'L CTR. FOR ST. CTS., https://www.ncsc.org/__data/assets/ pdf_file/0021/ 42870/Coronavirus-and-the-Courts-State-Profiles-7-29-2020.pdf (last visited Nov. 1, 2020) (continuously updating list of what individual states are doing about jury trials in response to COVID-19).

[12] *See* Adam Liptak, *Were the Supreme Court's Phone Arguments a Success?*, N.Y. TIMES (May 18, 2020), https://www.nytimes.com/2020/05/18/us/politics/supreme-court-phone-arguments-lyle-denniston.html (describing at least one oral argument over telephone where scrupulous listeners may notice the sound of a toilet flushing).

[13] Allie Reed & Madison Alder, *Zoom Courts Will Stick Around as Virus Forces Seismic Change*, BLOOMBERG L. (July 30, 2020) https://news.bloomberglaw.com/us-law-week/zoom-courts-will-stick-around-as-virus-forces-seismic-change.

[14] Press Release, Ill. S. Ct., Illinois Court Procedures for COVID-19; Supreme Court Livestream (Mar. 13, 2020) courts.illinois.gov/Media/PressRel/2020/031320.pdf [hereinafter Press Release, Livestream].

[15] Jordyn Reiland, *Cook County's Debut Virtual Civil Trial Goes Smoothly,* CHI. DAILY L. BULL. (June 23, 2020), https://www.chicagolawbulletin.com/cook-county-judge-presides-over-zoom-bench-trial-20200623.

[16] *See, e.g.*, CIR. CT. COOK CNTY. , GEN. ADMIN. ORD. NO. 2020-3 (Apr. 13, 2020), http://www.cookcountycourt.org/Portals/0/County%20Division/General%20Administrative%20Orders/Administrative%20Order%20County%202020-3.pdf?ver=2020-04-15-105509-380 [hereinafter APR. 13 ADMIN. ORD. 2020-3] (administrative order indicating, *inter alia*, "all [mental health] hearings will be heard remotely by zoom video conferencing or telephone") (as detailed *infra* text accompanying note 47, once COVID-19 was declared a pandemic, the Illinois Supreme Court issued orders and announcements declaring certain cases like mental health matters "essential" and encouraged the adoption and use of remote video technology to avoid any interruptions in scheduling such trials to ensure that cases went before the circuit court in a timely fashion).

contribute to grievous developments in symptomology and any delays should be avoided, if possible.[17] As set forth in Part II.C, such concerns are overstated and should not be used to justify the exclusive use of video conference for mental health trials.[18]

This article details why, however noble the impetus for such implementation, the current framework throughout Illinois for remote video conference proceedings in mental health cases is too rigid, and likely unlawful. Part I of this article provides a national backdrop of how courts have generally incorporated remote video proceedings due to the ongoing pandemic and then narrows its focus to the current configuration for remote trials in Illinois. Part II goes into detail about the specific challenges of remote video conference technology in Illinois mental health matters and highlights the existing practical gaps to such an approach as well as some outright substantive problems with conducting remote video conference trials under the current scheme. As discussed in Part II, these issues are more than mere shortcomings and are instead inconsistent with Illinois law, as well as federal equity safeguards, such as the Americans with Disabilities Act ("ADA"). Finally, this article concludes that, while the reasoning for resorting to video technology during a crisis was logical, the current framework must be reimagined in a manner that safeguards individuals' rights and ensures public access to these critical proceedings. If the framework is left uncorrected, there is a risk that this extraordinary process, where fundamental liberty interests are litigated via video conference —over the respondents' objection and without any public access or oversight—will be normalized.

I. REMOTE COURT PROCEEDINGS DURING COVID-19

A. An Overview of State Courts' Use of Remote Video Technology During COVID-19

Before COVID-19, courts were becoming increasingly familiar with video technology.[19] Throughout the past decade, courts across the United States engaged in exploratory projects to see how video technology could assist in

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[17] Jhilam Biswa et al., *Treatment Delayed is Treatment Denied*, 46 J. AM. ACAD. PSYCHIATRY & L. 447, 447 (2018) (describing that delays could turn into life-long psychiatric problems).

[18] *See infra* at Part II.C (detailing how individuals may be held at a local health facility while their case is pending and, further, how emergency treatment may be administered to an individual, without court oversight, while that person's case is pending).

[19] Herbert B. Dixon, *The Evolution of a High-Technology Courtroom*, 2011 TRENDS ST. CTS. 28, 28 (giving an example of how some court rooms are technology-enabled and have video displays that are more affordable).

civil and criminal proceedings.[20] This video experiment included the federal courts, where, between 2011 and 2015, a pilot project of the Judicial Conference of the United States recorded and publicized a wide variety of civil hearings and trials.[21] COVID-19 accelerated the relationship between courts and video conference technology.[22] For example, between late March and mid-July of 2020, there were over 500,000 hours of video conferenced hearings in Michigan's court system.[23] Similarly, by early June, New Jersey had already conducted 31,000 virtual hearings, which included 262,000 individual litigants.[24] As such, the breadth of this implementation in various corners of the country has left commentators wondering whether the transition to remote proceedings will ultimately be permanent rather than temporary.[25]

To guide courts through this transition, most state supreme courts, or their functional equivalents, have created respective online repositories of COVID-19 information, including restrictions on in-person hearings as well as orders and announcements related to the use of video conference

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[20] *See Case Video Archive*, U.S. CTS., https://www.uscourts.gov/about-federal-courts/judicial-administration/cameras-courts/case-video-archive (last visited Dec. 30, 2020) (detailing a multi-year pilot project in the judicial conference of the federal courts aimed at allowing video broadcasts of certain civil cases); *see also* U.S. DEP'T JUST., RESEARCH ON VIDEOCONFERENCING AT POST-ARRAIGNMENT RELEASE HEARINGS: PHASE I FINAL REPORT 1 (2015) (reporting on various considerations applicable to adjudicating when aspects of criminal cases over videoconferencing).

[21] *See* U.S. DEP'T JUST., *supra* note 20; *see also History of Cameras in Courts*, U.S. CTS., https://www.uscourts.gov/about-federal-courts/judicial-administration/cameras-courts/history-cameras-courts (summarizing the history of cameras in federal courtrooms).

[22] *COVID-19 Forces Courts to Hold Proceedings Online*, ECONOMIST (June 14, 2020), https://www.economist. com/international/2020/06/14/covid-19-forces-courts-to-hold-proceedings-online (describing how the "coronavirus pandemic has forced courts around the globe to [modernize] with unprecedented haste").

[23] Press Release, John Nevin, Communications Director, Michigan Supreme Court, Michigan's 'Virtual' Courtrooms Surpass 500,000 Hours of Zoom Hearings (July 14, 2020), https://courts.michigan.gov/NewsEvents/press_releases/Documents/Zoom%20500000%20Media%20Release.pdf.

[24] Tom Nobile & Richard Cowen, *Reopening NJ: Why Virtual Jury Trials Face Pushback from Attorneys*, N.J. HERALD (June 9, 2020), https://www.njherald.com/story/news/2020/06/09/reopening-nj-why-virtual-jury-trials-face-pushback-from-attorneys/113420898/.

[25] Zack Quaintance, *Will COVID-19 Cause Long-Term Tech Changes for Courts?*, GOV'T TECH. (May 29, 2020), https://www.govtech.com/public-safety/Will-COVID-19-Cause-Long-Term-Tech-Changes-for-Courts.html ("In effect, the courts are yet another segment of the public sector that is learning what some companies in the private sector have known for years — it is often easier to conduct business via phone or video chat, than it is to find time to gather a dozen-plus people in the same room. It's a lesson learned during the crisis, but as those involved point out, it's also a lesson that can shape the way work is done moving forward.").

technology in trials during the pandemic.[26] Each state's online repository for COVID-19 (if available) is presented in this article in Appendix A.[27] Supplementing online orders and announcements, many state supreme court websites have also hosted online courses for judges and attorneys with guidance on conducting hearings using video technology.[28]

The National Center for State Courts ("NCSC")[29] identified five common elements among state courts' efforts to adapt during COVID-19: (i) restricting or ending jury trials, (ii) generally suspending in-person proceedings, (iii) restricting entrances into courthouses, (iv) granting extensions on filing deadlines and on due dates for fees or costs;, and (v) encouraging or requiring teleconferences and video conferences in lieu of in-person hearings.[30] On June 22, 2020, the NCSC released its findings from a nationwide poll which assessed whether individuals would be comfortable appearing remotely for legal proceedings. The study found that sixty-four percent of respondents would be comfortable using such technology to appear remotely for a court proceeding.[31] Considering that only forty-three percent of responders felt that way in 2014, there has been a demonstrable shift of the public's willingness to engage with technology.[32]

Conversely, the same 2020 inquiry by the NCSC found that sixty-one percent of individuals polled were concerned about their ability to receive a fair and impartial trial in a virtual proceeding.[33] Public skepticism about the efficacy of virtual courtrooms appears warranted, as reports from around the country about courts using video conferencing for hearings during COVID-

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[26] *State Supreme Courts Gather by Videoconference to Hear Oral Arguments*, NAT'L CTR. FOR ST. CTS. (Apr. 17, 2020), https://www.ncsc.org/newsroom/backgrounder/2020/state-supreme-courts-gather-for-videoconferencing.

[27] *See infra* Appendix A.

[28] *See Recommendations on Using Zoom & Public Access for Court Proceedings*, JUD. INFO. SYS. (Aug. 7, 2020), https://info.courts.mi.gov/virtual-courtroom-info (explaining that there are webinars available for instruction).

[29] *See About Us*, NAT'L CTR. FOR ST. CTS., https://www.ncsc.org/about-us (last visited Jan. 3, 2021) ("The National Center for State Courts is an independent, nonprofit court improvement organization founded at the urging of Chief Justice of the Supreme Court Warren E. Burger. He envisioned NCSC as a clearinghouse for research information and comparative data to support improvement in judicial administration in state courts.").

[30] *5 of the Most Common Efforts State Courts are Taking to Combat Coronavirus*, NAT'L CTR. FOR ST. CTS., https://www.ncsc.org/__data/assets/image/0017/13058/coronavirus.png.

[31] Memorandum from GBAO to National Center for State Courts (June 22, 2020), https://www.ncsc.org/__data/assets/pdf_file/0006/41001/NCSC-Juries-Post-Pandemic-World-Survey-Analysis.pdf (containing a National Survey Analysis on Jury Trials in a Post-Pandemic World).

[32] *Id.*

[33] *Id.*

19 range from harmlessly amusing to outright concerning.[34] One attorney-participant described the gallery view on Zoom, which displays a mosaic of all the various attendees, as "the Brady Bunch on steroids."[35] In another remote hearing, an attorney had to assure the judge that he was human person after a cat filter had appeared over the attorney's face.[36] The gravity of the issues seem to only compound when courts expanded the use of video conferencing from mere status hearings to substantive matters such as jury trials.[37] The public opinion demonstrated by the above statistics, coupled with these anecdotes, illustrates a less-than-formal picture of what is normally considered an orderly judiciary and reliable system.

B. Illinois Courts and COVID-19

Three concentric tracks should be considered when assessing the dynamic between Illinois courts and remote mental health trials conducted during the COVID-19 outbreak and stay-at-home orders: the Illinois Supreme Court's response to the pandemic; the local circuit courts' general response; and the sub-divisions of local courts' specific handling of mental health proceedings.

The Illinois Supreme Court issued rule changes and published formal guidance on conducting proceedings via video conference.[38] Similarly, the largest circuit court in Illinois, the Circuit Court of Cook County,[39] responded to COVID-19 by entering a series of orders beginning in March 2020 that contained information and instructions about virtual proceedings throughout

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[34] David Ovalle, *Audio Glitches, Lousy WiFi, Shirtless Guests: Miami Zoom Court Expands Despite Limitations*, MIAMI HERALD (May 28, 2020), https://www.miamiherald.com/news/local/crime/article242820901.html (detailing disruptions from barking dogs to indecency, as well as misunderstandings causing a defendant to testify without his attorney present).

[35] Charles Scudder, *In a Test Case, Collin County Jury Renders Verdict on Zoom for the First Time; Too Risky for a Full Trial*, DALL. MORNING NEWS (May 22, 2020), https://www.dallasnews.com/news/courts/2020/05/22/in-a-test-case-collin-county-jury-meets-on-zoom-for-the-first-time-but-some-lawyers-say-its-too-risky-for-real-trial (a juror remained offscreen, engaged in a personal phone call, until the judge shouted loudly enough to alert the juror to return to the hearing).

[36] Daniel Victor, *'I'm Not a Cat,' Says Lawyer Having Zoom Difficulties*, N.Y. TIMES (Feb. 9, 2021), https://www.nytimes.com/2021/02/09/style/cat-lawyer-zoom.html.

[37] Scudder, *supra* note 35.

[38] *See* discussion *infra* Part I.B.1.

[39] *See Organization of the Circuit Court*, CIR. CT. COOK CNTY. (Oct. 31, 2020), http://www.cookcountycourt.org/ABOUTTHECOURT/OrganizationoftheCircuitCourt.aspx ("The Circuit Court of Cook County of the State of Illinois is the largest of the twenty-four judicial circuits in Illinois and one of the largest unified court systems in the world. It has about 400 judges who serve the 5.2 million residents of Cook County within the City of Chicago and its 126 surrounding suburbs. More than one million cases are filed each year.").

the county.[40] Within the Circuit Court of Cook County, specific divisions then entered orders that addressed particular areas of law and provided information about virtual hearings.[41] For example, the County Division in Cook County oversees mental health trials.[42] Accordingly, the Chief Judge of the County Division within Cook County entered a sequence of orders during COVID-19 addressing mental health trials and remote technology.[43] The variations and commonalities of all three channels—the Illinois Supreme Court, the Circuit Court of Cook County, and the County Division—are now presented.

1. Illinois Supreme Court

The Illinois Supreme Court's responses to COVID-19 promote a common theme of safety and flexibility by directing lower courts to conduct hearings remotely, when possible.[44] Like other state judiciaries,[45] the Illinois Supreme Court established a dedicated web resource to host the most recent orders entered by itself and by lower courts for how day-to-day operations have been altered in response to the onset of COVID-19.[46] This online resource and its timeline demonstrate how the court first addressed which legal matters were considered "essential" (including mental health cases),[47] and then went

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[40] *See, e.g.*, *Court Operations and the Coronavirus*, CIR. CT. COOK CNTY., http://www.cookcountycourt.org/HOME/INFORMATION-REGARDING-CORONA-VIRUS (last visited Dec. 30, 2020) (sequentially listing all COVID-19 orders from the various districts and divisions within Cook County).

[41] *Id.*

[42] *See* CIR. CT. COOK CNTY GEN ORD NO. 1.2, 2.1 (Sept. 15, 2017), http://www.cookcountycourt.org/Manage/Division-Orders/View-Division-Order/ArticleId/188/GENERAL-ORDER-NO-1-2-2-1-County-Department [hereinafter GEN. ORD. NO. 1.2, 2.1]; *see also* Matt Ford, *America's Largest Mental Hospital is a Jail*, ATLANTIC (June 8, 2015), https://www.theatlantic.com/politics/archive/2015/06/americas-largest-mental-hospital-is-a-jail/395012/ (Cook County also happens to contain one of America's largest, *de facto*, mental-health facilities: Cook County Jail).

[43] *See* COVID-19 Emergency tab within County Division subpage, CIR. CT. COOK CNTY., http://www.cookcountycourt.org/ABOUT-THE-COURT/County-Department/County-Division.

[44] ILL. S. CT., SUPREME COURT GUIDELINES FOR RESUMING ILLINOIS JUDICIAL BRANCH OPERATIONS DURING THE COVID-19 PANDEMIC, (2020), https://courts.illinois.gov/Administrative/covid/052020_SC_GL.pdf. *See also* ILL. S. CT., M.R.30370 (Mar. 17, 2020), https://courts.illinois.gov/SUPREMECOURT/Announce/2020/031720-3.pdf (stating that "essential court matters and proceedings shall continue to be heard by the Illinois. If feasible and subject to constitutional limitations, essential matters and proceedings shall be heard remotely via telephone or video or other electronic means.").

[45] *See infra* Appendix A.

[46] *See COVID-19 Information and Updates*, ILL. CTS. (last visited Dec. 25, 2020), http://illinoiscourts.gov/Administrative/covid-19.asp.

[47] *See* Press Release, Livestream, *supra* note 14.

on to offer specific guidance and changes to promote a viable (but remote) legal system to ensure vital cases continued during the pandemic.

An initial action taken by the Illinois Supreme Court was releasing new and amended modifications to the Illinois Supreme Court Rules.[48] Specifically, Illinois Supreme Court Rule 45, an amendment to Illinois Supreme Court Rule 46, and an amendment Illinois Supreme Court Rule 241.[49] As discussed herein, all three of these rules advance and promote the practice of law through remote means.[50] Similarly, the Illinois Supreme Court also published a document titled "Remote Court Proceedings — Guidance Document" ("Guidance Document").[51] The Guidance Document details the key components needed to ensure an effective remote proceeding.[52] Like the Guidance Document and the various rule changes, the Illinois Supreme Court also issued the Illinois Supreme Court Policy on Remote Court Appearances in Civil Proceedings memorandum ("ISC Remote Memo").[53] All three of these initiatives (developed more fully below) promote the remote practice of law in a manner consistent with access to justice and applicable limitations.[54]

a. New and Amended Illinois Supreme Court Rules for Virtual Practice.

On May 22, 2020, the Illinois Supreme Court repealed Illinois Supreme Court Rule 185, issued Rule 45, and amended Rule 46 and 241.[55] Each change relates remote hearings.[56] The Illinois Supreme Court developed and adopted these updates to "improve the administration of justice, increase

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[48] ILL. S. CT., M.R. 3140 (eff. May 22, 2020), https://courts.illinois.gov/SupremeCourt/Announce/2020/052220-1.pdf.
[49] Press Release, Ill. S. Ct., Illinois Supreme Court Amends Rules to Support use of Remote Hearings in Court Proceedings (2020), https://courts.illinois.gov/Media/PressRel/2020/052220-1.pdf [hereinafter Press Release, Amendment].
[50] *Id.*
[51] *See* ILL. S. CT., REMOTE COURT PROCEEDINGS – GUIDANCE DOCUMENT (2020), https://courts.illinois.gov/Administrative/covid/052220-SC_RHG.pdf [hereinafter GUIDANCE DOCUMENT].
[52] *Id*.
[53] ILL. S. CT., ILLINOIS SUPREME COURT POLICY ON REMOTE COURT APPEARANCES IN CIVIL PROCEEDINGS (2020), https://courts.illinois.gov/SupremeCourt/Policies/Pdf/ATJ_Commission_Policy_on_Remote_Court_Appearances_in_Civil_Proceedings.pdf [hereinafter ISC REMOTE MEMO].
[54] *Id.* at 2–4.
[55] Press Release, Amendment, *supra* note 49.
[56] *Id*.

efficiency and reduce costs."[57] For instance, the repeal of Rule 185 and the creation of Rule 45 grants courts "broad discretion to allow Remote Court Appearances."[58] Indeed, the ISC Remote Memo asserts that, under the new Rule 45, an individual's inquiry about appearing remotely for court "should be easy to request and liberally allowed."[59] Similarly, the amendment to Rule 46 allows for the recording from a video hearing "to be used by the official court reporter to make the transcript that becomes the official record of the proceeding."[60] Finally, the amendment to Rule 241 addresses civil trials , which includes mental health proceedings. The updated version of Rule 241 reads:

> The court may, upon request or on its own order, for good cause shown and upon appropriate safeguards, allow a case participant to testify or otherwise participate in a civil trial or evidentiary hearing by video conferencing from a remote location. Where the court or case participant does not have video conference services available, the court may consider the presentation of the testimony by telephone conference in compelling circumstances with good cause shown and upon appropriate safeguards. The court may further direct which party shall pay the cost, if any, associated with the remote conference and shall take whatever action is necessary to ensure that the cost of remote participation is not a barrier to access to the courts.[61]

Unlike earlier language of Rule 241, this current form now expressly recognizes that the court itself has discretion to allow and order a participant to attend by remote means.[62]

The committee comments for these rules provide additional context. In Illinois, a Supreme Court Rules Committee is responsible for collecting any proposed rules by the public or judiciary and vetting such suggestions before ultimately recommending whether the change should or should not be adopted by the Illinois Supreme Court.[63] The committee comments to Rule 241 are longer than the rule itself.[64] The comments first emphasize the preference for and importance of live testimony.[65] The comments provide a balancing test for trial courts to employ if a case-participant seeks to testify

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[57] *Id*.
[58] ISC REMOTE MEMO, *supra* note 53, at 2.
[59] *Id*.
[60] Press Release, Amendment, *supra* note 49, at 1.
[61] ILL. S. CT., M.R. 3140, *supra* note 48, at 4.
[62] *Id*.
[63] *How a Proposal Becomes a Supreme Court Rule*, ILL. CTS., http://illinoiscourts.gov/SupremeCourt/Rules/Process.asp (last visited Nov. 1, 2020).
[64] ILL. S. CT., M.R. 3140, *supra* note 48, at 4–6.
[65] *Id.* at 4.

remotely.[66] In addition, there are proposed instructions for attorneys to provide to their clients who may be appearing remotely so that they are not improperly relying on extrinsic assistance or unknown third parties.[67] For those attending a video hearing without a lawyer, the comments direct that the trial court should provide those same admonishments to the unrepresented participant.[68]

This collection of changes reflects a judiciary in motion. As Chief Justice Anne Burke acknowledged when these amendments were announced, the onset of COVID-19 accelerated the Court's previous exploration and endorsement of remote proceedings.[69]

b. The Illinois Supreme Court's Remote Court Proceedings Guidance Document

In conjunction with the new rules highlighted above, the Court also released the aforementioned Guidance Document for remote court proceedings.[70] The Guidance Document addresses: (i) public access to such proceedings, (ii) general considerations, (iii) conduct at the virtual hearing, and (iv) management of the electronic record.[71] Notably, it explicitly states that the guidelines are meant to assist lower courts interested in overseeing virtual proceedings "in the pandemic *and beyond*" (emphasis added).[72] Further, the Court commits to reviewing ongoing implementation of remote hearings to identify areas for improvements and best practices.[73] This is so that the endorsed guidance does not become outdated, but may be updated as more hearings occur.[74]

This Guidance Document is similar to the ISC Remote Memo because it acknowledges and emphasizes the importance of public access to court

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[66] *Id*. at 5.
[67] *Id*. ("In furtherance of their obligations under Illinois Rules of Professional Conduct 3.3 (Candor Toward the Tribunal), 3.4 (Fairness to Opposing Party and Counsel), and 8.4(d) (Misconduct), counsel representing a case participant should instruct the case participant that (a) he or she may not communicate with anyone during the examination other than the examining attorney or the court reporter and (b) he or she may not consult any written, printed, or electronic information during the examination other than information provided by the examining attorney.").
[68] *Id*.
[69] Press Release, Amendment, *supra* note 49, at 1.
[70] GUIDANCE DOCUMENT, *supra* note 51.
[71] *Id*.
[72] *Id* at 1.
[73] *Id*.
[74] *Id*.

proceedings.[75] Accordingly, the Court specifically states that any hearing hosted over a virtual platform such as Zoom should also be capable of livestreaming on a public website service like YouTube.[76] It goes on to provide a suggested label for each YouTube hearing so that the public may identify the judge and proceeding.[77] In almost all jurisdictions where Illinois courts are conducting hearings and trials over remote video, the public has access to a court-provided website so they may observe the proceedings.[78] Yet, as discussed *infra* at II.A.1,[79] there is currently no public access to virtual mental health trials in most Illinois counties.

The Guidance Document also reminds trial courts to remain mindful of any difficulties a participant may face when attempting to connect remotely, such as a lack of internet or a disability.[80] Similarly, when an interpreter is necessary for a video hearing, the Court recommends implementing a consecutive method of interpretation as opposed to simultaneous interpretation.[81] Finally, the Guidance Document provides sample admonishments for a judge to deliver at the outset of a remote hearing.[82]

c. Illinois Supreme Court Policy on Remote Court Appearances in Civil Proceedings

The ISC Remote Memo contains additional considerations for overseeing civil trials by remote means.[83] While it shares many sentiments of the Guidance Document, the ISC Remote Memo provides a more detailed blueprint for virtual court proceedings and outlines key considerations from a nuts-and-bolts perspective, as well highlighting substantive pitfalls that may come with such efforts.[84]

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[75] *Id*.
[76] *Id*.
[77] *Id.*
[78] *See Remote Hearings Directory*, ILL. CTS., http://illinoiscourts.gov/Media/Remote Hearings/default.asp (last visited Nov. 15, 2020) (demonstrating the remote hearings directory for Illinois Courts which links any trial to be viewed over remote video).
[79] *See infra* Part II, Section A, Subsection 1.
[80] GUIDANCE DOCUMENT, *supra* note 51.
[81] *Id.*
[82] *See e.g., id.* at 4 ("When you want to speak, unmute yourself and identify yourself by stating your last name. Identify yourself each time we change who is speaking, otherwise, the court reporter may have a difficult time determining who you are. If you have an objection, you may want to state "Objection by [Name or other identifying title/party/etc.]").
[83] *See generally* ISC REMOTE MEMO, *supra* note 53 (detailing the Illinois Supreme Court's policy on remote court proceedings).
[84] *See id*. Part VI (discussing details such as what to do in the case of an objection and that there shall be no penalties for technical failures).

The ISC Remote Memo acknowledges "the need for Remote Court Appearances and innovative methods for allowing access to our courts became acute during the COVID-19 crisis."[85] Further, it enumerates topics that courts should consider as each creates its respective remote appearance procedures.[86] For video hearings, it also specifies what type of technology and internet access each case-participant will need to have on-hand.[87] While the ISC Remote Memo touts the various benefits of remote proceedings, it also contains express regard for public access to such hearings and a section about accommodations for those individuals that qualify under the Americans with Disabilities Act ("ADA").[88]

Further evidenced by the ISC Remote Memo is the Court's awareness that some litigants may be unable or unwilling to participate by remote means. For example, it directs courts to reconsider their own local, pre-COVID-19 rules to ensure none of them have the effect of creating financial or other barriers to appearing remotely.[89] Like Rule 241, the ISC Remote Memo also anticipates situations where someone objections to a request to appear remotely.[90] However, the Court's guidance on how to assess a request to attend court by video is disjointed or, at the least, inconsistent.[91] Consider this side-by-side comparison:

Illinois Supreme Court Policy on Remote Court Appearances in Civil Proceedings[92]		**Illinois Supreme Court Rule 241[93]**
"When ruling on a request to appear remotely where there is an objection, a court may consider:		*"A court has broad discretion to determine if video testimony is appropriate for a particular case.*
1. Access to the courts. 2. The court's available technology.		A court should take into consideration and balance any

[85] *Id*.
[86] *Id*.
[87] *Id*. (reciting, at a minimum, each video participant will require "[a] computer, telephone, or mobile device with a webcam or embedded video camera, an internal or external microphone, and internal or external speakers" along with "high-speed internet connection and access to the same Video Conference service used by the court.").
[88] *Id*.
[89] *Id*.
[90] *See id*. (discussing factors to take into consideration in the event someone objects to a request to appear remotely); *see also* ILL. SUP. CT. R. 241 (eff. May 22, 2020).
[91] ISC REMOTE MEMO, *supra* note 53 ; *see also* ILL. SUP. CT. R. 241 (eff. May 22, 2020).
[92] ISC REMOTE MEMO, *supra* note 53.
[93] ILL. SUP. CT. R. 241 (eff. May 22, 2020).

3. Whether any undue prejudice would result. 4. The degree of inconvenience or hardship. 5. Whether there are security or safety concerns for allowing the Remote Court Appearance. 6. Whether the Case Participants have waived personal appearances or agreed to Remote Appearances. 7. The purpose of the court date. 8. Previous abuse of Remote Court Appearances by the requesting Case Participant or objections by the objecting Case Participant. 9. Any other factors or fairness considerations that the court may determine to be relevant. If the court denies the request, it should state the reasons for the denial."	due process concerns, the ability to question witnesses, hardships that would prevent the case participant from appearing in person, the type of case, any prejudice to the parties if testimony occurred by video conference, and any other issues of fairness. A court must balance these and other relevant factors in an individual case."

A possible explanation for this apparent inconsistency is that the ISC Remote Memo document sets forth specific considerations for matters where there is an objection to a remote appearance, while the committee comments to Rule 241 discuss how to assess and balance specific requests to allow for video testimony.[94] However, while Rule 241 installs a balancing methodology, the ISC Remote Memo expresses that such requests should be liberally allowed.[95]

As set forth in Section II,[96] further clarity should be provided by the Court, and, ideally, it should be promulgated and set forth in the actual rules relied upon by litigants and courts rather than in a policy document or buried in committee comments. Currently, there is too much opportunity for confusion and competing interpretations due to the interplay, or lack thereof, of the documents. Further, it is not clear whether practitioners will realize that other guidance exists outside formal supreme court rules. Additionally, assuming such resources are readily available and cited, if competing arguments are made that reference these various resources, local courts are likely to favor an actual supreme court rule.

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[94] ISC REMOTE MEMO, *supra* note 53; *see also* ILL. SUP. CT. R. 241 (eff. May 22, 2020).
[95] ISC REMOTE MEMO, *supra* note 53; *see also* ILL. SUP. CT. R. 241 (eff. May 22, 2020).
[96] *See infra* Part II.

Overall, though, the Illinois Supreme Court's concerted efforts to promote the integration of video technology into a wide variety of proceedings are practical because they are flexible. They allow for objections,[97] encourage public access,[98] and even contemplate the ADA.[99] Unfortunately, as set forth below, these practical considerations are critically absent from the local response to COVID-19, including those specific courts responsible for overseeing mental health cases.

2. Circuit Court of Cook County

Like the Illinois Supreme Court's ongoing response to COVID-19, local courts issued their own sequential orders and statements about practicing law during a pandemic. In Illinois, there are twenty-three circuit courts.[100] Cook County is the largest county in Illinois by population,[101] and has its own unified system of trial courts.[102] This circuit court entered its first order addressing COVID-19 on March 13, 2020.[103] In that order, Chief Judge Timothy Evans of the Circuit Court of Cook County expressed the circuit court's concern about COVID-19 and safety of the public and court personnel.[104] The order went on to address how or why certain matters would be delayed or postponed due to COVID-19.[105] Notably, the Order stated that "mental health hearings will continue as scheduled."[106] Early amendments to that Order reflect the same vague assertion that mental health hearings would be held "as scheduled."[107]

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[97] Press Release, Amendment, *supra* note 49.
[98] GUIDANCE DOCUMENT, *supra* note 51.
[99] ISC REMOTE MEMO, *supra* note 53.
[100] *About the Courts in Illinois*, ILL. CTS., http://www.illinoiscourts.gov/General/CourtsInIL.asp. (last visited Nov. 5, 2020).
[101] *Illinois Counties by Population*, ILL. DEMOGRAPHICS BY CUBIT, https://www.illinois-demographics.com/counties_by_population (last visited Nov. 5, 2020).
[102] *Organization of the Circuit Court*, *supra* note 39.
[103] CIR. CT. COOK CNTY., GEN. ADMIN. ORD. 2020-01 (Mar. 13, 2020), http://www.cookcountycourt.org/Manage/Division-Orders/View-Division-Order/ArticleId/2737/General-Administrative-Order-2020-01-COVID-10-EMERGENCY-MEASURES.
[104] *Id.*
[105] *See generally id.* (outlining each division and the status of the hearings, arbitrations, etc.).
[106] *Id.*
[107] *See, e.g.*, CIR. CT. COOK CNTY., GEN. ADMIN. ORD. 2020-01 (May 28, 2020), http://www.cookcountycourt.org/Portals/0/Portal/Rules.Orders/5_28_20%20GAO%202020-01%20(amended).pdf?ver=2020-05-28-154237-623 [hereinafter May 28 GEN. ADMIN. ORD. 2020-01].

On June 26, 2020, the original countywide administrative order was again superseded.[108] The new circuit court order provided additional guidance for trial court matters with aim on reopening most proceedings on July 6, 2020, with the exception of jury trials.[109] The June 26, 2020 order further stated that all matters in all Cook County districts should be conducted via video conference to the extent reasonably possible—subject to any constitutional limitations.[110] The same order expressly gave trial judges discretion over objections to video proceedings and deciding whether proceedings be conducted by teleconference, video conference in person, or a combination.[111]

These sequential countywide orders provide key glimpses into the Circuit Court of Cook County's priorities during COVID-19. For instance, by comparing the earlier administrative order from March 16, 2020, alongside a superseding order from June 26, 2020, it is clear that Cook County initially focused its message on postponing in-person matters, whereas later on it focused its instructions on video hearings and promoting the remote practice of law.

Absent from these countywide orders, though, is any specific commentary on mental health trials (other than they will continue as scheduled).[112] Instead, the specific division within the same circuit court that oversees mental health trials entered its own orders that contain more information on how such trials would occur exclusively by video during COVID-19.

3. County Division

So far, this piece has highlighted two separate, but related, continuums of Illinois courts' responses to COVID-19. That is, the overall guiding track of the Illinois Supreme Court's answer to COVID-19 and its push for consideration of remote video conference technology (tempered by the ADA, objections, and public access). And, parallel to that effort by the Illinois Supreme Court, the Circuit Court of Cook County's own measures to advance the same agenda at an intermediate level. A third and final track, then, is to consider the on-the-ground approach by trial courts charged with putting these policies into practice.

This third track, the County Division within the Circuit Court of Cook County, oversees adoptions, elections, real estate taxes, civil orders of

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[108] CIR. CT. COOK CNTY., GEN. ADMIN. ORD. 2020-02 (amended June 26, 2020), https://courts.illinois.gov/Administrative/covid/062620-Cook_AO.pdf.
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] MAY 28 GEN. ADMIN. ORD. 2020-01., *supra* note 107.

protection, and mental health trials.[113] Before the pandemic, mental health trials occurred at various on-site, court-approved hospitals.[114] Even before COVID-19, Circuit Court Rule 10.9 permitted the use of video conferencing software for mental health trials.[115] But this use of video technology was limited to situations when respondent-patient, and his or her attorney, agreed to a remote appearance and were not located in the same location as the judge and opposing party.[116] In conjunction with this local rule, a pilot program for remote video technology was also underway in Cook County for several months before the pandemic.[117] The program was launched on December 2, 2019 and continued through November 30, 2020.[118] This project included remote video use for ongoing mental health cases in the County Division, but did not contemplate or discuss contested mental health trials in which the respondent objected to the use of such means.[119] Instead, parties' use of the pilot program was relegated to agreed matters only, and utilized a different video system.[120]

Similar to the evolving nature of the Illinois Supreme Court and Circuit Court of Cook County orders, the County Division released several, sequential orders in response to COVID-19. First, on March 16, 2020, the Chief Judge of the County Division entered an order addressing COVID-19,

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[113] GEN. ORD. NO. 1.2, 2.1 *supra* note 42.

[114] *Mental Health Proceedings*, CIR. CT. COOK CNTY., www.cookcountycourt.org/ABOUTTHECOURT/CountyDepartment/CountyDivision/MentalHealthProceedings.aspx (from the Mental Health Proceedings tab, expand "Hearing Locations" from the dropdown options) (last visited Jan. 18, 2020).

[115] CIR. CT. COOK CNTY., 10.9 RULES GOVERNING THE USE OF VIDEOCONFERENCING EQUIPMENT IN HEARINGS UNDER THE MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES CODE (Sept. 2, 2016), www.cookcountycourt.org/FORATTORNEYSLITIGANTS/RulesoftheCourt/ReadLocalRule/tabid/1139/ArticleId/2478/10-9-Rules-Governing-the-Use-of-Videoconferencing-Equipment-in-Hearings-Under-the-Mental-Health-and-Developmental-Disabilities-Code.aspx [hereinafter CIR. CT. COOK CNTY., 10.9 RULES].

[116] *Id.*

[117] *See* Press Release, Ill. Sup. Ct., Remote Video Pilot Program Announced for Cook County Circuit Courts (Nov. 21, 2019), https://courts.illinois.gov/Media/PressRel/2019/112119.pdf [hereinafter Press Release, Pilot Program] (explaining that "The Remote Video Pilot program will launch on December 2, 2019 and run through November 30, 2020." Two judges from each of the Chancery, County, and Domestic Relations Division will oversee the use of remote video in their courtrooms).

[118] *Id.*

[119] *Id.* (explaining that "In the county division, remote video will be used for mental health proceedings, such as a mental health case management call, one day per week and for unique situations such as issues where a party is located in a different county or state and a video proceeding would allow a more efficient disposition.").

[120] *Mental Health Proceedings*, *supra* note 114, at "Video Conferencing" from the dropdown options.

stating mental health trials would continue and that "parties are encouraged to consider video conferencing."[121] Then, on April 13, 2020, the County Division entered a superseding COVID-19 order and indicated "[n]o [mental health] hearings will be held at the hospitals, all hearings will be done via video conferencing."[122] After this shift to trials-by-video, the division released another order on July 28, 2020 that stated "only attorneys, respondents, court personnel, and designated witnesses will be provided with the meeting information to preserve any confidentiality associated with the proceeding."[123] Meaning, no public access link would be posted or available for any mental health trials, an approach which directly conflicts with state law requiring open and public trials.[124]

In sum, in a few short weeks, the County Division of the Circuit Court of Cook County went from encouraging parties to consider video conferencing for mental health trials to requiring it, without exception.[125] In stark contrast to the direct sentiments of the Illinois Supreme Court's various efforts that highlighted flexibility and accommodation, these County Division orders contained no exceptions, no balancing tests, no consideration to the ADA, or any accommodations for participants who desire an in-person hearing or an alternative method of participation.[126] This is concerning given that respondents, almost exclusively, qualify as having a disability recognized by the ADA.[127] Further concerning is the fact that the respondent may be in an inpatient facility where they do not have the autonomy to make their own technological choices.

As previously noted, at the start of the COVID-19 pandemic, the Illinois Supreme Court published various rule changes and guidance that permitted

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[121] CIR. CT. COOK CNTY, DEPT., CNTY. DIV., ADMIN. ORD. 2020-1 (Mar. 16, 2020), www.cookcountycourt.org/Portals/0/County%20Division/General%20Administrative%20Orders/corrected%20admin%20order%202020-0103182020%20(1).pdf [hereinafter MAR. 16 ADMIN. ORD. 2020-1].

[122] APR. 13 ADMIN. ORD. 2020-3 *supra* note 16.

[123] CIR. CT. COOK CNTY. DEPT., CNTY. DIV., ADMIN. ORD. 2020-7 (July 28, 2020), www.cookcountycourt.org/Portals/0/County%20Division/General%20Administrative%20Orders/7-28-20%20Admin_%20Order%202020-7FINAL%20amended.pdf?ver=g0p6c7vpnNtYayJlycGv1g%3D%3D [hereinafter JULY 28 ADMIN. ORD. 2020-7].

[124] CH. 405 ILL. COMP. STAT. § 5/3-800(c) (2015).

[125] *Compare* MAR. 16 ADMIN. ORD. 2020-1, *supra* note 121 ("The parties are encouraged to consider videoconferencing. . ."), *with* APR. 13 ADMIN. ORD. 2020-3 *supra* note 16 ("No hearings will be held at the hospitals, all hearings will be done via zoom conferencing.").

[126] MAR. 16 ADMIN. ORD. 2020-1, *supra* note 121; APR. 13 ADMIN. ORD. 2020-3 *supra* note 16; JULY 28 ADMIN. ORD. 2020-7, *supra* note 123.

[127] *Enforcement Guidance on the ADA and Psychiatric Disabilities,* U.S. EQUAL EMP. OPPORTUNITY COMM'N, https://www.eeoc.gov/laws/guidance/enforcement-guidance-ada-and-psychiatric-disabilities (last visited Dec. 30, 2020).

more cases to be heard remotely by video conference.[128] Then, the circuit courts were tasked with actually implementing the shift to remote video proceedings consistent with the law.[129] Yet, despite the Illinois Supreme Court's repeated, overt commitment to ADA accommodations and public access, the largest circuit court in Illinois disregarded this commitment by requiring all mental health trials be conducted on video conference, regardless of a respondent's preference or agreement.[130] Further, the County Division openly ordered that mental health proceedings would not contain an accompanying public access link,[131] a practice which is in stark contrast to all other active proceedings in the state[132] and inconsistent with the law, which states "Court hearings under this Chapter, including hearings under Section 2-107.1, shall be open to the press and public unless the respondent or some other party requests that they be closed."[133] Remarkably, this "new normal" developed in mere weeks and, as the administrative orders compounded, respondents' preferences and public access faded from view.

The County Division oversees the largest caseload of mental health matters in Illinois.[134] Unfortunately, and despite its size and scope, this circuit court's one-size-fits-all approach to mental health trials during COVID-19 is bereft of the nuances and considerations espoused by the Illinois Supreme Court during the same crisis. As set forth next, this failure matters because the rights and interests of those involved in these proceedings are significant and require strict adherence with state and federal law.

II. REMOTE VIDEO TECHNOLOGY AND ILLINOIS MENTAL HEALTH PROCEEDINGS

As Part I briefly mentions, courts across the country were already conducting pilot projects for remote hearings prior to the stay-at-home orders.[135] With the emergence of COVID-19, courts went from casually dipping their toes into these virtual waters to plunging straight into the deep end. As this section demonstrates, this forced implementation of video

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[128] Press Release, Amendment, *supra* note 49.
[129] *Id*.
[130] APR. 13 ADMIN. ORD. 2020-3, *supra* note 16.
[131] *See* JULY 28 ADMIN. ORD. 2020-7., *supra* note 123 (stating "only attorneys, respondents, court personnel, and designated witnesses will be provided with the meeting information to preserve any confidentiality associated with the proceeding").
[132] *See Remote Hearings Directory, supra* note 78.
[133] CH. 405 ILL. COMP. STAT. § 5/3-800(c) (2015).
[134] ILL. COURTS, 2019 STATISTICAL SUMMARY (2019) https://courts.illinois.gov/SupremeCourt/AnnualReport/2020/2019_Statistical_Summary.pdf.
[135] Press Release, Pilot Program, *supra* note 117.

conference technology in mental health trials in Illinois overlooked, or otherwise disregarded, important safeguards. This section will conclude with a discussion on how current processes in Illinois mental health proceedings are incompatible with both law and policy.

An involuntary commitment to a mental facility is a significant curtailment of liberty and, as a result, this proceeding requires constitutional due process protections.[136] Similarly, the involuntary administration of psychotropic medication against a patient's wishes involves fundamental liberty interests that are also constitutionally protected by due process.[137] These liberty interests "must be balanced against the State's interests (1) to provide care for persons unable to care for themselves and (2) to protect society from dangerous [persons living with mental illness]."[138] This is because the State's aim is "not to punish [a recipient], but to treat him."[139] Consequently, the State's role in advocating at mental health trials is anchored in its *parens patriae*[140] and its police powers.[141] Only acting under these powers, may a State ultimately deprive individuals living with mental illnesses of their fundamental right to liberty.[142] Because these proceedings involve the State's interference with a person's liberty, they should not be conducted *pro forma*.[143] This requirement exists even when it is "abundantly clear" that a person may require mental health treatment.[144] Further, mere "public intolerance or animosity cannot constitutionally justify the

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[136] Vitek v. Jones, 445 U.S. 480, 491–492 (1980) (explaining that "the loss of liberty produced by an involuntary commitment is more than a loss of freedom from confinement" and it may "engender adverse social consequences to the individual" and that "[w]hether we label this phenomena 'stigma' or choose to call it something else . . . we recognize that it can occur and that it can have a very significant impact on the individual." (citing Addington v. Texas, 441 U.S. 418, 425–426 (1979))).

[137] *In re* Cynthia S., 326 Ill. App. 3d 65, 67 (2nd Dist. 2001).

[138] *In re* Torski C., 395 Ill. App. 3d 1010, 1017 (4th Dist. 2009), citing *In re* Robinson, 151 Ill.2d 126, 130–31 (1992).

[139] *Id*.

[140] *Parens Patriae*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("The state regarded as a sovereign; the state in its capacity as provider of protection to those unable to care for themselves <the attorney general acted as *parens patriae* in the administrative hearing>.").

[141] *In re* Torski C., 395 Ill. App. 3d at 1017.

[142] *Id*.

[143] *In re* John R., 339 Ill. App. 3d 778, 785 (5th Dist. 2003); *see also* Bruce J. Winick, *Therapeutic Jurisprudence and the Civil Commitment Hearing*, 10 J. CONTEMP. LEGAL ISSUES 37, 44 (1999) (citing Tom R. Tyler, *The Psychological Consequences of Judicial Procedures: Implications for Civil Commitment Hearings*, 46 SMU L. REV. 433 (1992) ("Civil commitment hearings that appear to patients to be a sham violate their need to be treated with 'respect, politeness, and dignity,' and to feel that 'their rights as citizens are acknowledged.").

[144] *In re* Louis S., 361 Ill. App. 3d 774, 783 (4th Dist. 2005).

deprivation of a person's physical liberty."[145] Accordingly, Illinois provides a specific statutory framework for when and how the State may override a person's liberty interests.[146] Illinois courts have repeatedly held that these various statutory safeguards "are not mere technicalities" but essential components designed to protect these liberty interests.[147]

In Illinois, commitment proceedings and treatment proceedings are separate matters.[148] While a patient may be voluntarily residing at an in-patient mental health facility, they may still be subject to a petition for involuntary administration of medication or electroconvulsive therapy.[149] Conversely, someone may be consenting to various medications but contesting her ongoing detention at a facility.[150] Each proceeding, involuntary commitment and involuntary treatment, contain different criteria[151] but impose a clear and convincing standard of proof.[152] A respondent has the right to request a jury in an involuntary commitment trial, but is denied that same right in a forced treatment proceeding.[153]

A. Attendance at Trial and Access to Justice

In mental health proceedings, it has "long been recognized that procedural due process guarantees a respondent the right to be present at his hearing in

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[145] O'Connor v. Donaldson, 422 U.S. 563, 575 (1975).
[146] *In re* of Gardner, 121 Ill. App. 3d 7, 10 (4th Dist. 1984) ("The [Mental Health Code] contains an elaborate and complex system of procedures designed to protect the rights of [those living with mental illnesses].").
[147] *In re* Cynthia S., 326 Ill. App. 3d 65, 69 (2nd Dist. 2001); *In re* Nancy A., 344 Ill. App. 3d 540, 549 (1st Dist. 2003); *In re* Robert D., 345 Ill. App. 3d 769, 771, (2nd Dist. 2004).
[148] CH. 405 ILL. COMP. STAT. § 5/2–107.1(a-5)(2) (2015) ("The hearing shall be separate from a judicial proceeding held to determine whether a person is subject to involuntary admission but may be heard immediately preceding or following such a judicial proceeding and may be heard by the same trier of fact or law as in that judicial proceeding"); *see also In re* E.F., 2014 IL App (3d) 130814 (reversing a circuit court that failed to bifurcate such hearings.)
[149] *Id.*
[150] *Id.*
[151] CH. 405 ILL. COMP. STAT. § 5/1-119 (2010) (laying out the criteria for inpatient admission); *id.* (laying out the criteria for involuntary administration of medication or electroconvulsive therapy).
[152] CH. 405 ILL. COMP. STAT. § 5/2–107.1 ("(4) Psychotropic medication and electroconvulsive therapy may be administered to the recipient if and only if it has been determined by clear and convincing evidence."); CH. 405 ILL. COMP. STAT. § 5/4-608 (the burden is reiterated with respect to involuntary admission).
[153] CH. 405 ILL. COMP. STAT. § 5/3–802 (2010) ("A respondent is not entitled to a jury on the question of whether psychotropic medication or electroconvulsive therapy may be administered under Section 2-107.1.").

order to protect his liberty interest."[154] Ensuring a respondent has the opportunity to attend a trial that implicates fundamental interests is a keystone of our legal system.[155] Illinois law also carves out statutory protections for those respondents that prefer not to attend their hearing by disallowing any adverse inferences to be drawn from a respondent's non-attendance.[156]

In any event, ongoing research in the field of therapeutic jurisprudence makes a compelling argument that, even if a respondent does not prevail at his or her mental health trial, the opportunity to observe and participate in that proceeding may have lasting, positive effects on that person.[157] This may be because, in part, "people with mental illness already have been marginalized and stigmatized by a variety of social mechanisms, self-respect and their sense of their value as members of society are of special importance to them."[158] In support, research yields consistent, positive findings about treatment compliance and overall engagement with the legal system when respondents are provided the opportunity to testify like any other party-participant.[159] As one comment suggests, it may increase a person's perceptions of "fairness, respect, and dignity in the process, with a resulting increase in their receptivity to treatment."[160]

This concept of attending one's trial goes hand-in-hand with ensuring the participants have a meaningful courtroom experience. This does not suggest every trial should conform to expectations set by television, but, instead, it is understandable why some participants may desire more than what appears to be a perfunctory video conference for an adversarial trial that involves grievous topics like irreversible side effects,[161] electroconvulsive therapy,[162] or forced confinement for up to ninety days.[163] As one study notes, "if procedural safeguards are informalized to the point of becoming non-

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[154] *In re* of Perona, 294 Ill. App. 3d 755, 763 (4th Dist. 1998) (citing Specht v. Patterson, 386 U.S. 605, 610 (1967)).
[155] *See In re* Barbara H., 183 Ill. 2d 482, 496 (1998) ("[Respondent] was stripped of the opportunity to be present at the hearing through the actions of an attorney she did not know and did not want to represent her. In effect, the circuit court allowed [respondent's] rights to be surrendered by a stranger.").
[156] CH. 405 ILL. COMP. STAT. § 5/3-806(c) (1996) ("No inference may be drawn from the recipient's non-attendance pursuant to either subsection (a) or (b) of this Section.").
[157] Winick, *supra* note 143.
[158] *Id*. at 45.
[159] *Id*. at 54.
[160] *Id*. at 47.
[161] Bruce J. Winick, *Legal Limitations on Correctional Therapy and Research*, 65 MINN. L. REV. 331, 366–67 (1981).
[162] *Id*. at 365.
[163] CH. 725 ILL. COMP. STAT. § 5/104–20 (2020).

existent, the hearing may be more traumatic than any formal adherence to procedural safeguards could possibly be."[164] Here, I submit that procedural safeguards in Illinois have in fact been informalized to a dangerous degree.

1. Public Access to Open Mental Health Hearings

The Illinois Mental Health and Developmental Disabilities Code provides that, to the extent possible, mental health "hearings shall be held in the mental health facility where the respondent is hospitalized."[165] These hearings "shall be open to the press and public unless the respondent or some other party requests that they be closed."[166] Open and public trials are critical to our democracy. Time and again, courts recognize that a core purpose of public hearings is "to guarantee that the accused would be fairly dealt with and not unjustly condemned. History had proven that secret tribunals were effective instruments of oppression."[167] Indeed, the United States Supreme Court has repeatedly emphasized that open trials are "bulwarks of our free and democratic government" and public access to such trials may safeguard against abuses of judicial power.[168]

During COVID-19, there is no fidelity between Illinois circuit courts and the bedrock principle of open mental health hearings. Outside of mental health proceedings, most Illinois courts have public access links to livestreams and archived footage for other types of hearings throughout the state on their respective websites.[169] If a member of the public wants to view a criminal proceeding or a personal injury dispute, or attend an online hearing for domestic relations, all of the information to do so is readily available and

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[164] David Wexler et al., *The Administration of Psychiatric Justice: Theory and Practice in Arizona*, 13 AZ. L. REV. 1, 5 (1971).
[165] CH. 405 ILL. COMP. STAT. § 5/3–800 (2020).
[166] *Id*. at (c) ("The court may also indicate its intention to close a hearing, including when it determines that the respondent may be unable to make a reasoned decision to request that the hearing be closed. A request that a hearing be closed shall be granted unless there is an objection to closing the hearing by a party or any other person. If an objection is made, the court shall not close the hearing unless, following a hearing, it determines that the patient's interest in having the hearing closed is compelling. The court shall support its determination with written findings of fact and conclusions of law. The court shall not close the hearing if the respondent objects to its closure. Whenever a court determines that a hearing shall be closed, access to the records of the hearing, including but not limited to transcripts and pleadings, shall be limited to the parties involved in the hearing, court personnel, and any person or agency providing mental health services that are the subject of the hearing.").
[167] Estes v. Texas, 381 U.S. 532, 538–39 (1965).
[168] Richmond Newspapers, Inc. v. Virginia, 448 U.S. 555, 592 (1980) citing *In re* Oliver, 333 U.S. 257, 271–72 (1948).
[169] *Remote Hearings Directory*, *supra* note 78.

posted online.[170] However, if a member of the public wishes to observe mental health proceedings, which, by statute are considered open,[171] no such information is available.[172] A developing commentary attributes a lack of transparency in some online hearings to the hurried transition to the format.[173] The wholesale exclusion of the public from remote video conference hearings that involve the forced administration of neuroleptics or electroconvulsive therapy upon a person is disconcerting. Transparency for such trials is paramount, particularly during a crisis.[174] Some prominent groups associated with ensuring court oversight are quick to highlight that, in time of crisis, it is important for the public to feel confident in its state agencies and official entities.[175] The American Bar Association adopted a resolution addressing public access to courts during COVID-19, noting "as courts have moved online, many have not prioritized public access. Some do not have public access at all."[176]

There is an easy fix for this oversight. If circuit courts are reluctant to publish the details of ongoing mental health trials, the Illinois Supreme Court must remind them that these proceedings are open to the public and the press, absent an approved request by a party for the proceedings to be closed.[177] Too often, it seems that courts presume mental health hearings are "confidential" by default because they involve sensitive details that may further stigmatize participants.[178] This is a kind, but mistaken, position; a result of a conflation or misinterpretation of the Mental Health and

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[170] *Id.*
[171] CH. 405 ILL. COMP. STAT. § 5/3-800(c) (2015).
[172] *Remote Hearings Directory*, *supra* note 78.
[173] Jamiles Lartey, *The Judge Will See You on Zoom, but the Public is Mostly Left Out*, MARSHALL PROJECT (Apr. 13, 2020, 6:00 AM), www.themarshallproject.org/2020/04/13/the-judge-will-see-you-on-zoom-but-the-public-is-mostly-left-out.
[174] *Id.*
[175] *Id.*
[176] AM. B. ASS'N, RESOLUTION NO. 117, at 12 (2020), https://www.americanbar.org/content/dam/aba/directories/policy/annual-2020/117-annual-2020.pdf (The resolution goes on to detail further concerns, such as "[i]n jurisdictions providing public access, that access is typically via a YouTube or Facebook Live Feed, rather than the court website. In watching or listening to a streamed or broadcast hearing, no header is provided concerning the case, the personnel, or even the type of docket. In in-person criminal proceedings, the judge, prosecutor, defense attorney and accused are identifiable by where they stand or sit in the courtroom. Most online platforms do not similarly allow a party to lock a view into place, and there is therefore no discernable way to distinguish attorneys from the court personnel or from the litigants.").
[177] CH. 405 ILL. COMP. STAT. § 5/3-800 (2020).
[178] *See, e.g.*, JULY 28 ADMIN. ORD. 2020-7., *supra* note 123, (detailing that "[o]nly attorneys, respondents, court personnel, and designated witnesses will be provided with the meeting information *to preserve any confidentiality associated with the proceeding*.") (emphasis added).

Developmental Disabilities Confidentiality Act[179] and the Health Insurance Portability and Accountability Act,[180] and it should be corrected.

2. Meaningful Participation in Mental Health Trials

At first blush, one may assume that remote video services would encourage or increase inpatient respondent attendance. After all, the ability to log onto court from just about anywhere would seem to suggest that more people may feel comfortable or capable of participating in their own case and also allow for better public access to such cases. Indeed, the Illinois Supreme Court cited these very ideas in its policy release when it touted the benefits of virtual proceedings.[181] Notably, when immigration courts previously championed nearly identical benefits when transitioning to video court for some asylum matters, the resulting data was anything but heartening for actual participants.[182]

Indeed, some mental health respondents take issue with this new process because, to them, a trial-by-Zoom presents a sharp contrast between the invasive degree of the relief sought and the inverse, informal appearance of a video conference.[183] Concerned patients are joined by courts who also recognize that video trials have their shortcomings.[184] Courts acknowledge that "virtual reality is rarely a substitute for actual presence and that, even in an age of advancing technology, watching an event on the screen remains less than the complete equivalent of actually attending it."[185] Courts have also expressed concern that the "ability to observe demeanor, central to the fact-finding process, may be lessened in a particular case by video conferencing."[186] This is especially concerning because personal impression may be a dispositive factor in whether or not a particular position carries the day.[187] Another shortcoming of the platform occurs when a participant has an unstable internet connection, which can result in an interruption in

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[179] CH. 740 ILL. COMP. STAT. § 110/1 et seq. (2020).
[180] HHS Security and Privacy Rule, 45 C.F.R. § 164 (2000).
[181] GUIDANCE DOCUMENT, *supra* note 51; ISC REMOTE MEMO, *supra* note 53.
[182] *See* Frank M. Walsh & Edward M. Walsh, *Effective Processing or Assembly-Line Justice? The Use of Teleconferencing in Asylum Removal Hearings*, 22 GEO. IMMIGR. L.J. 259 (2008) (detailing how video court should not be considered a panacea and contends that the switch to video conferencing nearly doubled the amount of denials of asylum applications).
[183] Thornton v. Snyder, 428 F.3d 690, 697 (7th Cir. 2005).
[184] *Id.*
[185] United States v. Lawrence, 248 F.3d 300, 304 (4th Cir. 2001).
[186] Edwards v. Logan, 38 F. Supp. 2d 463, 467 (W.D. Va. 1999).
[187] *Id*.

testimony. An unstable connection or atypical distractions can also undermine a court report's ability to accurately take testimony.[188] Similarly, an unclear video connection may directly affect a court's ability to scrutinize whether a petitioner has provided clear and convincing evidence of certain facts.[189]

Prior to COVID-19, one commitment matter, involving an already-incarcerated respondent, addressed the constitutionality of remote appearance via video conference .[190] The Court found that the remote appearance did not undermine protections of due process because there was only a slight risk of error compared to the substantial government interests in favor of such a method.[191] However, the facts of that particular matter insulate it from any broader takeaways due to, in part, what the dissent described as "singularly inappropriate as a test case to determine the validity of [video conferencing]" because the case was largely uncontested and risked minimal errors as a result.[192] Further, the Court expressly recognized the lower court's finding that there may be cases where particular respondents have a specific aversion to technology and in such cases, video conference would be inappropriate.[193]

In addition to the patients' considerations, courts and judges, attorneys and advocates have also expressed concern about video conference in proceedings involving fundamental rights. At the onset of COVID-19 stay at home orders, some New Jersey attorneys stated they preferred waiting until in-person trials resumed because too much uncertainty existed with remote

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[188] *See, e.g.*, Victoria Hudgins, *Dog Barks, Zoom Conferences: Courtroom Reporters' New Normal Working Remotely*, LAW.COM (May 11, 2020, 11:30 AM), https://www.law.com/legaltechnews/2020/05/11/dog-barks-zoom-conferences-court-reporters-new-normal-working-remotely/ (wherein one professional court reporter noted, how "[a] distorted or muted microphone could send a statement 'into the digital ether.'").

[189] For instance, in cases of involuntary commitment, a petitioner may assert that, due to a serious mental illness, a respondent is unable to attend to his basic needs. *See* CH. 405 ILL. COMP. STAT. § 5/1–119 (2) (2020). In support of this, a petitioner may often allege that a respondent is unable to take care of certain basic needs, such as showering or maintaining one's hygiene. *See, e.g.*, *In re* Miller, 301 Ill. App. 3d 1060, 1064 (1998) ("When [the doctor] examined respondent on January 19, 1998, pursuant to the trial court's order, respondent had a "dirty" appearance and did not seem able to take care of his basic needs, such as bathing.").

[190] United States v. Baker, 45 F.3d 837, 845 (4th Cir. 1995).

[191] *Id*.

[192] *Id.* at 850 (Widener, J., dissenting).

[193] *Id*. at 845–46. This decision avoids any lengthy discussion about certain symptoms of illnesses that may overlap with a court's utilization of technology such as paranoia about televisions and screens. These concerns have merit but are not required to prove my instant points and I would prefer not to inadvertently sensationalize mental illness or further stigmatize those with such symptoms.

proceedings, such as a witness's credibility as there are no safeguards to prevent improper assistance to a third party.[194]

Further, a majority of the public doubt that a trial-by-video would be fair and impartial.[195] The public's instinct about video conferenced proceedings aligns with a local project that found that Cook County's introduction of video bond hearings resulted in the average amount of bails that were set increased by sixty-five percent.[196] The study went on to suggest that the quality of the remote video conference technology, and how it was even installed, may have affected how a judge assessed a particular defendant.[197] It is also unclear whether certain witnesses or non-parties can provide quality testimony on behalf of the respondent at a video trial.[198] For instance, one study found that nearly forty percent of those polled would be unable to isolate themselves in a quiet setting for several hours without interruption.[199] If a witness is in the lowest income bracket, that number increased to fifty-eight percent.[200] There is also a concern about whether the imposition of video conferencing software, in general, disproportionately affects those participants who are without reliable internet or phone service plans.[201]

It appears, then, that courts, attorneys, litigants, and the public share similar concerns regarding the appropriateness and effectiveness of remote video conference proceedings. Given the significant liberty interests at stake

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[194] Nobile & Cowen, *supra* note 24.
[195] Memorandum from GBAO to National Center for State Courts, *supra* note 31, at 8.
[196] Shari S. Diamond, Letter to Professor Locke Bowman Re: Mason v. County of Cook, et al. (Dec. 5, 2008), www.law.northwestern.edu/legalclinic/macarthur/projects/indigent/documents/ProfBowman_DiamondStudy.pdf; Shari S. Diamond, et al., *Efficiency and Cost: The Impact of Videoconferenced Hearings on Bail Decisions*, 100 J. CRIM. L. & CRIMINOLOGY 869, 898 (2010).
[197] *Id*. at 899 ("It may be that the quality of the available video display was too degraded or the size of the video monitor was too small to enable the judge to adequately view the defendant. In addition, in order to watch the judge in the courtroom on the monitor, the defendant in Cook County had to look at the monitor rather than at the camera that was capturing his own image and projecting it into the courtroom. He thus could appear on the courtroom monitor as if he was avoiding direct eye contact. Modern technology with a camera embedded in the viewing monitor would be able to eliminate this problem. The inability of the defendant to see the judge clearly may also have discouraged the defendant from speaking up when it would have helped him to say something.").
[198] *See, e.g.*, Jason Tashea, *The Legal and Technical Danger in Moving Criminal Courts Online*, BROOKINGS (Aug. 6, 2020), https://www.brookings.edu/techstream/the-legal-and-technical-danger-in-moving-criminal-courts-online/ (describing the technical and financial hurdles for litigants who are low-income or who live in rural areas without reliable internet).
[199] Memorandum from GBAO to National Center for State Courts, *supra* note 31.
[200] *Id*.
[201] *Id*. at 3.

during mental health cases,[202] mental health respondents are justified in their unwillingness to undergo a trial-by-video conference.

B. The Americans With Disabilities Act

Even if one were to set aside all of section A of this Part, there is an ongoing concern about those parties or participants who may require accommodation due to a disability and it is unclear whether any circuit courts are engaged in alternative planning for such requests during COVID-19. The interplay between COVID-19 and application of the ADA is dynamic. For instance, the Equal Employment Opportunity Commission issued guidance on how COVID-19 does and does not affect workplace considerations under Title I of the ADA.[203] This is an important consideration because someone with a standalone mental illness may qualify for protections under the ADA.[204] Additionally, there is an alarming rate of comorbidity in individuals with a mental illness and a separate, overlapping disability.[205] This discussion is not limited to a mental health respondent as a party but may include all sorts of court users such as jurors, witnesses, and attorneys.

Grounded in the Rehabilitation Act,[206] the enactment of the ADA in 1990 was a watershed moment for those living among us with disabilities. Put simply, it greatly expanded the application and scope of overdue and necessary protections.[207] A core purpose of the ADA is to provide a "clear and comprehensive national mandate for the elimination of discrimination

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[202] SAMHSA, CIVIL COMMITMENT AND THE MENTAL HEALTH CARE CONTINUUM: HISTORICAL TRENDS AND PRINCIPLES FOR LAW AND PRACTICE 23 (2019), ("Involuntary commitment, whether associated with hospitalization or a community treatment program, involves a significant limitation of liberty—the kind of limitation that is rare outside of the criminal justice system.").

[203] *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, U.S. EQUAL EMP. OPPORTUNITY COMM'N (June 17, 2020), www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

[204] *Mental Health Conditions in the Workplace and the ADA*, ADA NAT'L NETWORK (Oct. 2020), https://adata.org/factsheet/health.

[205] Kimberly Kendall & Michael J. Owen, *Intellectual Disability and Psychiatric Comorbidity: Challenges and Clinical Issues*, PSYCHIATRIC TIMES (May 26, 2015), www.psychiatrictimes.com/view/intellectual-disability-and-psychiatric-comorbidity-challenges-and-clinical-issues.

[206] Julia Carmel, *Before the A.D.A., There was Section 504*, N.Y. TIMES (July 22, 2020), https://www.nytimes.com /2020/07/22/us/504-sit-in-disability-rights.html.

[207] Elizabeth Malloy, *Mental Health Courts and Title II of the ADA: Accessibility to State Court Systems for Individuals with Mental Disabilities and the Need for Diversion*, 25 ST. LOUIS U. PUB. L. REV. 307, 310 (2006).

against individuals with disabilities."[208] Title II of the ADA applies to state and local governments, including courts.[209]

A person qualifies for protection under the ADA if they can set forth that they meet the definition "disabled"[210] and demonstrate that they are eligible for services or actions covered by the entity.[211] Federal regulations support a broad interpretation of disability, which may include a "mental or psychological disorder such as [intellectual disability], organic brain syndrome, emotional or mental illness, and specific learning disability."[212] The definition should be applied broadly "in favor of expansive coverage."[213] The disability must "substantially limit[] one or more major life activities of such individual."[214] Discrimination occurs in this setting when someone, "by reason of such disability, [is] excluded from participation in or [is] denied the benefits of the services, programs, or activities of a public entity, or [is] subjected to discrimination by any such entity."[215]

Under the ADA, courts "must ensure their services, programs, and activities are 'readily accessible and usable' by people with disabilities when viewed in the entirety."[216] Some courts have construed this to mean an "affirmative accommodation to ensure meaningful access to a public service" must be provided in order to meet the access element.[217] Ostensibly, courts employing various remote-video services for attendance and participation seem to fit the spirit and goals of the ADA.[218] However, where a video conference hearing is the *only* option, there may be scenarios where individuals with symptoms that causes them to be uncomfortable or unable

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[208] 42 U.S.C.§ 12101(b) (2006); Dep't of Just. Nondiscrimination on the Basis of Disability in State and Local Government Services, Purpose and Broad Coverage, 28 C.F.R. § 35.101 (2016).
[209] Tennessee v. Lane, 541 U.S. 509, 513, 533-34 (2004).
[210] 42 U.S.C. § 12102; 28 C.F.R. § 35.108(a)(1) (2016) (defining "disability" under the ADA).
[211] 42 U.S.C. § 12131(2); Dep't of Lab. Equal Opportunity Clause, Definitions 41 C.F.R. § 60-741.2 (2020) (defining "qualified individual").
[212] *See The Americans with Disabilities Act: Title II Technical Assistance Manual*, U.S. DEP'T JUST., at II-2.2000, hup://www.usdoj.gov/crt/ada/taman2.html (last visited Jan. 15, 2021).
[213] 28 C.F.R § 35.108(a)(2)(i) (2016).
[214] 28 C.F.R. § 35.108(a)(1) (2016); *see also* Bragdon v. Abbott, 524 U.S. 624, 637, 639 (1998).
[215] 42 U.S.C. § 12132.
[216] Chelsea Marx, *Accommodations for All—The Importance of Meaningful Access to Courts for Pro Se Litigants with Mental Disabilities*, 95 DENV. L. REV. ONLINE 152, 154 (2018).
[217] *Id*. at 154 (citing Nunes v. Mass. Dept. of Correction 766 F.3d 136, 145 (5th Cir. 2014) (quoting Henrietta D. v. Bloomberg, 331 F.3d 261, 273–76 (2d Cir. 2003)).
[218] 28 C.F.R. § 35.104 (2016) (defining "public entity").

to sit before a video screen for long periods of time, or prevents them from engaging in such a medium in any meaningful manner.[219]

Here, a qualifying individual may assert that the only available manner for accessing the Illinois courts, through video conferencing, is insufficient due to a disability. This argument is a modern iteration of *Tennessee v. Lane*, where the United States Supreme Court held that individuals who were unable to access certain *physical* courthouse services and areas were permitted to sue the state under the ADA in federal court.[220] Here, access to a virtual courthouse may present difficulties for some mental health respondents. For example, some participants may have difficulty viewing the screens provided by certain hospitals;[221] some participants may distrust or have active paranoia regarding such screens and technology;[222] other participants may have heightened sensory issues that are aggravated by the introduction of such audio and visual equipment.[223] These are real concerns

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[219] Tashea, *supra* note 198.

[220] Tennessee v. Lane, 541 U.S. 509, 513, 533–34 (2004); *see also* Ronda Cress et al., *Mental Health Courts and Title II of the ADA: Accessibility to State Court Systems for Individuals with Mental Disabilities and the Need for Diversion*, 25 ST. LOUIS U. PUB. L. REV. 307, 320 (2006).

[221] *See* Dan Robotham et al, *Do We Still Have a Digital Divide in Mental Health? A Five-Year Survey Follow-up*, 18 J. MED. INTERNET RES. (Nov. 22, 2016) (concluding that "fewer people with psychosis had access to the Internet…either via computers…or mobile phones…" and "fewer people with psychosis were confident in using the Internet…with computers…or mobile phones.").

[222] *See* Benedict Carey, *The Psychiatrist Will See You Online Now*, N.Y. TIMES (Sept. 8, 2020), https://www.nytimes.com/2020/08/28/health/virtual-therapy-psychiatry-coronavirus.html (describing the various benefits of telepsychiatry during COVID-19 but warning "[f]or people who are deeply delusional, who are scared, paranoid and alone, for instance, a Zoom call in these situations can be an invitation to confusion, or much worse. The rich sensory experience of full human interaction with a gifted therapist — that quality that defies measurement and study, in any randomized trial—is what many such people need."). *But see* APA COUNCIL ON PSYCHIATRY & LAW, RESOURCE DOCUMENT ON TELEPSYCHIATRY AND RELATED TECHNOLOGIES IN CLINICAL PSYCHIATRY (Jan. 2014), https://www.psychiatry.org/File%20Library/Psychiatrists/Directories/Library-and-Archive/resource_documents/Resource-2014-Telepsychiatry-Clinical-Psychiatry.pdf (acknowledging the risks of treating individuals experiencing paranoia or psychosis but countering that some studies "found no evidence for the inferiority of video conferencing telemental health for patients with psychosis, and one other report concluded that even psychotic patients with delusions pertaining to television were able to respond appropriately to teleconferencing and did not incorporate their telemedicine experience into their delusional system.").

[223] Daniel Young & Elizabeth Edwards, *Telehealth and Disability: Challenges and Opportunities for Care,* NAT'L HEALTH L. PROGRAM (May 6, 2020), https://healthlaw.org/telehealth-and-disability-challenges-and-opportunities-for-care/ ("A provider may be inclined to visually examine patients with a videoconference, but the movements and positioning often necessary for a physical exam may be hard for people with mobility and

and courts should consider, along with ongoing litigation trends that confirm how issues with "access to courts" tend to favor plaintiffs.[224] And further, the Illinois Mental Health and Developmental Disabilities Code echoes these very concerns by outright favoring requests for reasonable accommodations regarding the location of the hearing.[225]

In reaction, state courts may assert that any modification or compliance with Title II of the ADA would "fundamentally alter the nature of a service, program, or activity or would result in undue financial and administrative burdens."[226] However, this argument may carry little weight since most participants may simply assert that a postponement for an in-person hearing at a traditional, pre-pandemic courtroom is all that is required and no special setting or alternative location is needed. If that is the case, most entities may have a difficult task asserting that existing venues are somehow impractical when an individual is willing to wait until that traditional location is available for safe occupancy and use.

States are mindful of this issue and have incorporated ongoing ADA concerns into the new video conference landscape. For example, one state's access to justice resource recommends that judges specifically inquire about whether a video conference participant desires any ADA modifications or alternatives.[227] The Illinois Supreme Court recommends that trial courts "consider the capabilities of court patrons to participate via video conference or telephone and whether the selected method is accessible for persons with disabilities."[228] Consequently, any participant in a mental health matter during COVID-19 that seeks a modification for purposes of accessing the

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sensory disabilities to perform. This problem increases when a person's disability causes them to be unaware of symptoms indicating they have developing health issues.").

[224] *See* Marc Charmatz & Antoinette McRae, *Access to the Courts: A Blueprint for Successful Litigation Under the Americans With Disabilities Act and the Rehabilitation Act*, 3 UNIV. MD. L.J. RACE RELIGION GENDER & CLASS 333, 370 (2003) ("Notwithstanding some disappointments, the obvious trend in litigation involving 'access to the courts' for individuals with disabilities indicates that future plaintiffs in these cases will be successful. Further, the lessons learned in 'access to the court' cases serve the disability community well in other instances, such as reasonable accommodations in employment, auxiliary aids and services in education, challenging stereotypical notions about the abilities of individuals with disabilities in both employment and education contexts.").

[225] CH. 405 ILL. COMP. STAT. § 5/3-806(b) (1996).

[226] Dep't Just. Nondiscrimination of on the Basis of Disability in State and Local Governments, 28 C.F.R. § 35.130 (2016).

[227] TEX. ACCESS TO JUSTICE COMM'N, BEST PRACTICES FOR COURT IN ZOOM HEARINGS INVOLVING SELF REPRESENTED LITIGANTS 2 (2020), https://www.txcourts.gov/media/1446335/zoomsrlbestpractices.pdf.

[228] GUIDANCE DOCUMENT, *supra* note 51.

proceeding should utilize existing contracts and forms to secure a response by the local court prior to any substantive hearing.

C. A Solution in Plain Sight

Given these concerns, orders like the ones entered by County Division of the Circuit Court of Cook County in Illinois are problematic. There, the circuit court expressly stated that mental health trials would occur during the pandemic by video only, no hearings would occur in-person where the respondent was located, and no public access links exist for any of the ongoing hearings.[229] Before COVID-19 rose to pandemic levels, Cook County's pilot project and local rules contemplated virtual mental health hearings, but only where the case participants agreed.[230] The requirement of a respondent's consent is an important safeguard, but has now become a distant notion.[231] Illinois's regression in this area is similar to other states which also originally required a defendant's consent for a remote trial, but as the pandemic continued, eliminated it as a prerequisite safeguard.[232]

However, a mechanism already exists in Illinois for respondents who prefer an in-person proceeding: such respondents may request a continuance until such a proceeding can be safely overseen.[233] In commitment matters, continuances may be granted by the court or by motion of the parties and cannot extend beyond fifteen days unless requested by the respondent.[234] Similarly, in forced treatment cases, respondents are entitled to a continuance of up to seven days and additional continuances are permitted upon a showing that additional time is needed in order to adequately prepare or under exceptional circumstances."[235] Both provisions, then, contain safeguards to allow respondents to ask for additional time, if the situation warrants the request.[236] Additionally, if an individual seeks accommodation

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[229] APR. 13 ADMIN. ORD. 2020-3 *supra* note 16; JULY 28 ADMIN. ORD. 2020-7, *supra* note 123.
[230] CIR. CT. COOK CNTY., 10.9 RULES, *supra* note 115.
[231] *Compare* CIR. CT. COOK CNTY., 10.9 RULES, *supra* note 115 (limiting pre-pandemic use of video conference technology to cases were attorney and respondent agree), *with* APR. 13 ADMIN. ORD. 2020-3 *supra* note 16 (requiring that all proceedings be conducted via video conference during pandemic).
[232] Nobile & Cowen, *supra* note 24.
[233] *See* CH. 405 ILL. COMP. STAT. 5/3–800 (2020) (discussing a respondent's request of continuance).
[234] *Id.*
[235] CH. 405 ILL. COMP. STAT. § 5/2–107.1 (2018).
[236] *Id.*; CH. 405 ILL. COMP. STAT. §5/3–800 (2020).

pursuant to Title II of the ADA, that request should be adjudicated and resolved prior to any trial on the underlying merits.[237]

Despite those statutory mechanisms, there is no clear record or indication of where circuit courts in Illinois during COVID-19 have postponed matters so a mental health respondent may experience an in-person hearing.[238] Nor are there any local orders or records of courts in mental health cases applying any of the balancing tests set forth by Illinois Supreme Court's policy document for remote video testimony or the framework articulated in the committee comments to Rule 241.[239] Worse, because there is no public access to mental health proceedings, no outside oversight exists for these virtual hearings where some respondents may otherwise prefer to wait for an in-person courtroom. Unlike years prior (pre-COVID-19), where mental health trials were held open to the public and on-site at hospitals, the majority of Cook County's mental health trials for the year 2020 have occurred over video conference without any public access. Given that circuit courts do not appear to be allowing these continuances for certain mental health respondents, the Illinois Supreme Court should expressly address the issue by ensuring its rules reflect that such requests should be honored.

Some medical practitioners may caution that delays in these matters will only cause respondents to further deteriorate or be deprived of what doctors consider to be much-needed medication.[240] One can always easily envision a parade of horribles occurring if a respondent who is subject to a forced medication petition is allowed to postpone that trial for several weeks. However, the inimitable Karl Llewellyn reminds us that if law makes blind, more law is the cure.[241]

Illinois law already contemplates scenarios where medical treatment is urgently needed but a case is postponed or delayed. For instance, "a treater may administer involuntary medication upon a respondent while a case remains pending and unresolved if such measures are to prevent that person

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[237] *See* Charmatz & McRae, *supra* note 224; *see* Dep't Just. Nondiscrimination of on the Basis of Disability in State and Local Governments, 28 C.F.R. § 35.130 (2016) ("No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in employment under any service, program, or activity conducted by a public entity.").

[238] My own experience can confirm that such requests are politely set aside by trial judges in every occurrence.

[239] *Id*.; SUP. CT. ILL. R. 241.

[240] *See generally Mental Health Courts: Challenges, Questions and Tensions*, CTR. FOR CRT. INNOVATION (Aug. 8, 2005) (outlining issues and challenges seen regarding mental health patients and the court system).

[241] Karl Llewellyn, THE BRAMBLE BUSH: THE CLASSIC LECTURES ON THE LAW AND LAW SCHOOL 122 (Oxford University Press, Inc., 11th ed. 1930).

from causing serious and imminent physical harm to himself or others, and no less restrictive alternative is available."[242] Unlike the limitations imposed on health care providers if no petition is pending, this avenue of emergency treatment is not as limited, so long as specific statutory elements are met and memorialized.[243] Accordingly, in the event a respondent requests a postponement of his or her mental health trial so that it may occur in an actual courtroom, the treater is not without interim relief if an emergency arises. Similarly, if a respondent in an involuntary commitment case seeks a continuance so that the matter may be adjudicated in person or by a live jury, then that request can be honored, and the Mental Health Code allows the hospital to continue to detain the until the time of trial.[244]

CONCLUSION

It is undeniable that the existence of a crisis requires all stakeholders to demonstrate flexibility. However, systems like the judiciary cannot impose measures in the name of efficiency and safety when they result in a rigid, closed system in which even justice feels remote, as has occurred as a result of the Illinois courts' response to COVID-19. While it is admirable that local courts have singled out mental health hearings as a priority for proceedings via video conference, in those instances where participants are uncomfortable or unwilling to have his or her liberty interest adjudicated over a screen, the judiciary should give these respondents the consideration they deserve. As one jurist has previously noted, "[m]ental-health cases are treated differently than other proceedings because we have permitted them to become different."[245] Here, again, mental health cases are being treated differently by our courts and it should not continue. Otherwise, our procedural safeguards and due process protections remain relegated in exchange for novel but injudicious processes.

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[242] CH. 405 ILL. COMP. STAT. § 5/2–107 (2015).
[243] *Id.*; s*ee also* Sarah Berkowitz & Matthew R. Davison, *Recognizing and Respecting the Limitations of Emergency Medications*, ILL. ST. B. ASS'N (Dec. 2018), https://www.isba.org/sections/mentalhealth/newsletter/2018/12/recognizingandrespectingthelimitati.
[244] CH. 405 ILL. COMP. STAT. § 5/3–800(b) (2015).
[245] *In re* Lisa G.C., 373 Ill. App. 3d 586, 598 (2nd Dist. 2007) (Knecht, dissenting).

APPENDIX

State	Resource
Alabama	https://judicial.alabama.gov/Announcement/COVID_19 [https://perma.cc/J6Y2-TP33]
Alaska	https://courts.alaska.gov/covid19/index.htm [https://perma.cc/EP9R-TDNU]
Arizona	https://www.azcourts.gov/covid19/Info [https://perma.cc/ZF6U-K3A8]
Arkansas	https://www.arcourts.gov/arkansas-supreme-court-statement-novel-coronavirus-outbreak-and-courts [https://perma.cc/TZ98-MYS5]
California	https://newsroom.courts.ca.gov/covid-19-and-courts/judicial-branch-emergency-actions [https://perma.cc/XJ7W-Y8MA]
Colorado	https://www.courts.state.co.us/announcements/COVID-19.cfm [https://perma.cc/82KB-NWF2]
Connecticut	https://jud.ct.gov/COVID19.htm [https://perma.cc/J9RP-88EV]
Delaware	https://courts.delaware.gov/aoc/covid-19 [https://perma.cc/3D8P-Y3YD]
Florida	https://www.floridasupremecourt.org/Emergency [https://perma.cc/YBW5-XVJQ]
Georgia	https://georgiacourts.gov/covid-19-preparedness/ [https://perma.cc/MNL9-WFLY]
Hawaii	https://www.courts.state.hi.us/covid-19-information-page [https://perma.cc/M6DM-C4RQ]

Idaho	https://isc.idaho.gov/Emergency%20Orders [https://perma.cc/LJH4-8P2N]
Illinois	http://illinoiscourts.gov/Administrative/covid-19.asp [https://perma.cc/AX8H-XY69]
Indiana	https://www.in.gov/judiciary/5575.htm [https://perma.cc/ZPM6-A3UX]
Iowa	https://www.iowacourts.gov/iowa-courts/covid-19-information-and-updates/ [https://perma.cc/W93X-BZM7]
Kansas	https://www.kscourts.org/About-the-Courts/Court-Administration/OJA/Kansas-Courts-Response-to-Coronavirus-(COVID-19) [https://perma.cc/9U6M-W6JL]
Kentucky	https://kycourts.gov/pages/Coronavirus.aspx [https://perma.cc/6G7W-Q356]
Louisiana	https://www.lasc.org/COVID19/ [https://perma.cc/XM2P-TTGY]
Maine	https://www.courts.maine.gov/covid19.shtml [https://perma.cc/D2V2-8MGQ]
Maryland	https://www.mdcourts.gov/coronavirusupdate [https://perma.cc/L938-Q6R7]
Massachusetts	https://www.mass.gov/guides/court-system-response-to-covid-19 [https://perma.cc/YSS2-SPSG]
Michigan	https://courts.michigan.gov/News-Events/covid19-resources/Pages/COVID-19.aspx [https://perma.cc/SFH6-FMMG]
Minnesota	http://www.mncourts.gov/Emergency.aspx [https://perma.cc/Z5C4-2LE2]

Mississippi	No dedicated URL, but general information and orders available at home page of the court: https://courts.ms.gov/index.php [https://perma.cc/7EGQ-7K7Q]
Missouri	https://www.courts.mo.gov/pandemic/ **[https://perma.cc/KBW8-5Q6L]**
Montana	No dedicated URL, but general information and orders available at home page of the court: https://courts.mt.gov/ [https://perma.cc/3Y3G-LCK9]
Nebraska	https://supremecourt.nebraska.gov/administration/nebraska-judicial-branch-emergency-status-information [https://perma.cc/L4BC-UWRE]
Nevada	No dedicated URL, but general information and orders available at home page of the court: https://nvcourts.gov/ [https://perma.cc/2FA5-TEJC]
New Hampshire	https://www.courts.state.nh.us/aoc/corona-covid-19.html [https://perma.cc/KGX5-8B5K]
New Jersey	https://njcourts.gov/public/covid19.html [https://perma.cc/5DQT-GHGF]
New Mexico	https://www.nmcourts.gov/covid-19.aspx [https://perma.cc/M2TT-ZXRZ]
New York	https://www.nycourts.gov/index.shtml [https://perma.cc/3CXD-PZ9M]
North Carolina	https://www.nccourts.gov/covid-19 [https://perma.cc/Y3FJ-E6JR]
North Dakota	https://www.ndcourts.gov/emergency-order-and-pandemic-response [https://perma.cc/5BFV-7RC2]

Ohio	https://www.supremecourt.ohio.gov/coronavirus/courts/default.aspx [https://perma.cc/3PCU-QR8N]
Oklahoma	https://www.oscn.net/news/2003171536/covid19-notices [https://perma.cc/U4KP-57N9]
Oregon	https://www.courts.oregon.gov/courts/Pages/coronavirus.aspx [https://perma.cc/A9CF-Z2A7]
Pennsylvania	http://www.pacourts.us/ujs-coronavirus-information [https://perma.cc/N9LG-Q2AB]
Rhode Island	https://www.courts.ri.gov/Courts/SupremeCourt/Pages/COVID-19.aspx [https://perma.cc/T4N6-JX3J]
South Carolina	https://www.sccourts.org/coronavirus/covid-19/ [https://perma.cc/6WGH-GWUU]
South Dakota	https://ujs.sd.gov/uploads/news/COVID19UJSProcedures.pdf [https://perma.cc/EB73-8KAJ]
Tennessee	https://www.tncourts.gov/Coronavirus [https://perma.cc/D4Q2-XC7V]
Texas	https://www.txcourts.gov/court-coronavirus-information/ [https://perma.cc/5H78-LGQG]
Utah	https://www.utcourts.gov/alerts/ [https://perma.cc/74MS-UYKM]
Vermont	https://www.vermontjudiciary.org/about-vermont-judiciary/covid-19-and-court-operations [https://perma.cc/P4JP-A8C2]

Virginia	http://www.courts.state.va.us/news/items/covid/scv_emergency_orders.pdf [https://perma.cc/2AKG-SBW4]
Washington	http://www.courts.wa.gov/newsinfo/index.cfm?fa=newsinfo.COVID19 [https://perma.cc/N9GM-8S3B]
West Virginia	http://www.courtswv.gov/covid19/COVID19.html [https://perma.cc/R6SG-MRAT]
Wisconsin	https://www.wicourts.gov/covid19.htm [https://perma.cc/2HJQ-MSZF]
Wyoming	https://www.courts.state.wy.us/coronavirus-covid-19-updates/ [https://perma.cc/M9GN-LBEA]

Catching Up with Convergence: Strategies for Bringing Together the Fragmented Regulatory Governance of Brain-Machine Interfaces in the United States

Walter G. Johnson[*]

INTRODUCTION

After a decade of stalled innovation, the past five years have seen neurotechnologies such as brain-machine interfaces ("BMIs") make rapid advances by synthesizing ideas from and progress in multiple other emerging technologies.[1] In short, BMIs connect an individual's central nervous system to a computer or machine,[2] an innovation which could lead to better prosthetics and new potential treatments for neurological and mental health conditions, or even applications in entertainment and gaming.[3] In practice, however, the sheer technical complexity of these neurotechnologies will produce a complicated and incomplete regulatory environment because health, privacy, and equity concerns will likely be handled by different or overlapping decision-making bodies across governmental branches.[4] This may not only delay the potential benefits these innovations offer, but also cause a failure in the management of the risks BMIs may create for patients, consumers, and society.[5] This article traces both the technical underpinnings

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[1] *See generally* THE ROYAL SOC'Y, IHUMAN: BLURRING LINES BETWEEN MIND AND MACHINE 24 (2019) (demonstrating rapid development of BMIs and varied application to medicine and other disciplines).

[2] *Id*. at 9.

[3] Thomas Baldwin, *Foreword to* NUFFIELD COUNCIL ON BIOETHICS, NOVEL NEUROTECHNOLOGIES: INTERVENING IN THE BRAIN vii–viii (2013).

[4] *See* Part II, *infra*.

[5] *E.g.*, Anna Wexler & Peter B. Reiner, *Oversight of Direct-to-Consumer Neurotechnologies*, 363 SCIENCE 234, 235 (2019) (discussing how neurotechnology investors are reluctant to pursue technologies requiring FDA approval due to the costs and time involved).

and regulatory intricacies of BMIs which will create various challenges for decisionmakers.

BMIs have been made possible by what innovation scholars have termed "technological convergence."[6] Convergence is the process of combining multiple different technological and scientific disciplines together in order to accelerate innovation and create entirely new types of products and services.[7] In particular, BMIs have emerged and gained a wider set of potential uses due to the fusion of neuroscience, big data, artificial intelligence ("AI"), materials science, and engineering.[8] Yet, technological convergence can also result in significant challenges and problems greater than the sum of its parts.[9] Regulating these neurotechnologies will demand managing risks at the intersection of safety, effectiveness, cybersecurity, consumer protection, equity, and data privacy.[10] Further, these initially observable risks can blend to generate new risks ranging from cognitive enhancement to military applications to deep user reliance on BMI developers.[11]

Some BMIs have already become available in North America, Europe, and Japan.[12] These include products developed by various start-up companies, such as NeuroSky and Emotiv, as well as several high-profile, well-funded projects, including a Facebook project and Elon Musk's Neuralink.[13] Some

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[6] *See* William S. Bainbridge & Mihail C. Roco, *The Era of Convergence*, *in* HANDBOOK OF SCIENCE AND TECHNOLOGY CONVERGENCE 3 (Mihail C. Roco & William S. Bainbridge eds., 2016) (discussing the convergence of "nano-bio-information-cognitive technologies" as the result of the synthesis of efforts and expertise in multiple fields of science and technology).
[7] *See id.* (discussing that convergence is more than multidisciplinary collaboration and allows for the development of innovative and transformative technologies).
[8] Hermann Garden et al., *Responsible Innovation in Neurotechnology Enterprises* 9 (OECD, Working Paper No.5, 2019).
[9] ANDREW MAYNARD, FILMS FROM THE FUTURE: THE TECHNOLOGY AND MORALITY OF SCI-FI FILMS 20–21 (2018).
[10] *See* Hermann Garden & David Winickoff, *Issues in Neurotechnology Governance* 8, 12–13 (OECD Working Paper No. 11, 2018) (listing various concerns that BMIs raise); *see also* NUFFIELD COUNCIL ON BIOETHICS, NOVEL NEUROTECHNOLOGIES: INTERVENING IN THE BRAIN 134 (2013) (discussing how regulation needs to address safety and effectiveness in emerging technologies).
[11] Andrew D. Maynard & Marissa Scragg, *The Ethical and Responsible Development and Application of Advanced Brain Machine Interfaces*, 21 J. MED. INTERNET RES. 1, 3 (2019).
[12] *See* Marcello Ienca et al., *Brain Leaks and Consumer Neurotechnology* 36 NATURE BIOTECHNOLOGY 805, 806 (2018) (providing examples of BMIs already on the market in varying countries).
[13] *See, e.g.*, Elon Musk & Neuralink, *An Integrated Brain-Machine Interface Platform with Thousands of Channels*, 21 J. MED. INTERNET RES. 755, 756 (2019) (providing an example of Neuralink's BMI technology); *see also*, Tekla S. Perry, *Here's How Facebook's Brain-Computer Interface Development is Progressing*, IEEE SPECTRUM (Feb. 25, 2020),

BMIs are available direct-to-consumer, while others may require a prescription from a physician.[14] Some higher-risk products have required approval by regulatory institutions before entering the market, while others have escaped the existing legislative mandates of federal agencies.[15] The most complex BMIs, involving invasive brain implants operating with continuously learning software, will certainly require regulatory oversight.[16] Yet, even when such neurotechnological devices clearly fall into an agency's jurisdiction, the applicable standards often remain uncertain.[17] This wave of sophisticated BMIs approaching and entering the market calls for regulatory action and clarity.

This essay will explore how convergence in BMIs can foster fragmentation in regulatory governance and offer policy strategies for closing these gaps. Part I reviews the emergence of neurotechnologies including BMIs, their applications, and the role of convergence in generating governance issues. Part II then turns to jurisdictional issues that create redundant regulatory efforts or allow risks to fall through governance gaps. In the United States, the Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC") already have authority to regulate some neurotechnologies.[18] However, each of these agencies has jurisdiction over varying subject matters which overlap in BMIs through technological convergence.[19] This technological convergence will ultimately create significant regulatory problems for BMIs and neurotechnologies more broadly.[20] The split in regulatory authority combined with the inconsistencies of judicial opinions and potential lawmaker inaction could yield both

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https://spectrum.ieee.org/view-from-the-valley/consumer-electronics/portable-devices/heres-how-facebooks-braincomputer-interface-development-is-progressing (providing an example of how Facebook is also developing its own BMI technology).

[14] *See* Karola V. Kreitmair, *Dimensions of Ethical Direct-to-Consumer Neurotechnologies*, 10 AJOB NEUROSCIENCE 152, 152 (2019) (depicting the difference between direct-to-consumer products for "wellness" and medical products to treat patients).

[15] *See id*. at 155 (discussing how regulatory requirements can vary depending on whether the technology claims a health-related intended use).

[16] Lucille M. Tournas & Walter G. Johnson, *Elon Musk Wants to Hack Your Brain: How Will the FDA Manage That?*, SLATE (Aug. 5, 2019, 7:30 AM), https://slate.com/technology/2019/08/elon-musk-neuralink-facebook-brain-computer-interface-fda.html.

[17] *Id*.

[18] Ishan Dasgupta, *Ethical Oversight of Direct-to-Consumer Neurotechnologies: The FDA, the FTC, or Self-Regulation?*, 10 AJOB NEUROSCIENCE 200, 200–01 (2019).

[19] *Id*.

[20] *See generally* Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201 (2006) (discussing how overlapping and underlapping agency jurisdiction can lead to conflicts between regulatory authorities and compromise the effectiveness of oversight).

redundancies and governance gaps.[21] This fragmented regulatory governance could ultimately reduce the effectiveness and efficiency of oversight for emerging neurotechnological products such as BMIs. Part III will draw on the interagency coordination and technology assessment literatures to propose and assess potential strategies for more comprehensively responding to BMIs. Developing such strategies to overcome fragmentation merit prompt attention by policymakers to ensure that neurotechnological oversight can adequately manage risks at reduced costs and without stifling the innovation which could be helpful to patients and consumers.

I. CONVERGENCE IN BMI

Though the term "neurotechnology" is relatively new, the field it represents has several established applications in diagnosing, treating, and preventing medical conditions. Diagnostic neurotechnological devices such as electromyography ("EMG") or magnetic resonance imaging ("MRI") enable physicians to visualize the brain, spinal cord, or peripheral nerves to make diagnoses and plan surgeries.[22] Spinal cord stimulator devices allow patients to achieve some degree of control over their back and extremity pain by interfering with electrical signals encoding pain as they travel towards the brain.[23] BMIs should also readily fit within this umbrella of neurotechnologies, although fewer applications are currently developed and available on the market compared to older examples such as EMG, MRI, or spinal cord stimulators.[24] The British Royal Society highlights cochlear implants to address hearing loss as the most common and recognizable example of a BMI,[25] although defining hearing loss as a condition to be treated is heavily contested as marginalizing to the Deaf community.[26]

While EMGs or BMIs offer examples of this field, a definition of the word "neurotechnology" and the scope of the industries and innovations it encompasses remains under debate. At its broadest, the term

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[21] *See* Part II, *infra*.
[22] *Id*.
[23] *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 10, at 26 (describing spinal cord stimulator technology and their use in pain treatment by applying "low voltage electrical pulses to afferent nerve fibers via an epidural electrode that is implanted surgically or through the skin.").
[24] BMIs are slowly beginning to enter marketplaces around the world. *See* Ienca et al., *supra* note 12, at 805–07 (highlighting certain direct-to-consumer neurotechnologies available in different countries).
[25] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 9, 38–39 (defining neural interfaces and noting the prevalence of cochlear implants). For a definition of BMIs, *see* Part I.A, *infra*.
[26] *See generally* Robert Sparrow, *Implants and Ethnocide: Learning from the Cochlear Implant Controversy*, 25 DISABILITY & SOC'Y 455 (2010).

"neurotechnology" includes any technology that interacts, directly or indirectly, with human neurology and psychology.[27] This conceptualization includes mobile phone applications and wearable devices which do not directly interact with the nervous system but hypothetically can indirectly result in some degree of change to neural circuitry.[28] Many of the technologies implicated in this sweeping definition raise pertinent, but unresolved social and regulatory issues.[29] However, this expansive idea of neurotechnologies may be too broad and overlooks the nuanced differences between a sea of existing technologies and a smaller cohort of nascent but transformative innovations.

Instead, a more limited, but still robust, definition from bioethicist James Giordano would categorize this nascent field as "those devices that are utilized to investigate, assess, access, and manipulate the structure and function of neural systems."[30] This definition narrows the term "neurotechnology" to a conceptually more manageable scope and focuses on those innovations which interact with human neural systems more directly. Adopting this definition of neurotechnologies should better enable decisionmakers to tailor policy to the benefits and risks of products such as spinal cord stimulators and BMIs, rather than trying to address these devices alongside others with substantially different policy considerations such as mobile phone applications.

Yet, even within Giordano's narrower definition of neurotechnologies, new and rapidly emerging devices such as BMIs may require special policy attention. A second, distinct wave of neurotechnologies has surfaced and begun to approach and enter the market in the United States over the last decade, including innovations in areas such as transcranial magnetic stimulation ("TMS"), deep brain stimulation ("DBS"), and BMIs.[31] At least two factors distinguish the second wave of neurotechnologies from the original. First, companies have begun to develop and market many of these new products directly to consumers rather than reserving them for use by

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[27] *See* Kreitmair, *supra* note 14, at 153–54 (offering a broad definition of neurotechnology).
[28] *Id*. at 154.
[29] *See* Saba Akbar et al., *Safety Concerns with Consumer-Facing Mobile Health Applications and Their Consequences: A Scoping Review*, 27 J. AM. MED. INFO. ASS'N 330, 331 (2020) (generally describing the regulatory issues involved in implanting devices).
[30] James Giordano, *Neurotechnology as Demiurgical Force: Avoiding Icarus' Folly*, *in* NEUROTECHNOLOGY: PREMISES, POTENTIAL, AND PROBLEMS 4 (James Giordano ed., 2012).
[31] *Id*. The terms "BMI" and "BCI" (brain-computer interface) both appear in the technical literature and various definitions have been proposed to distinguish between them. This essay will primarily use BMI for consistency and because an emerging consensus appears to use BMI as the more comprehensive and inclusive term.

patients and health care providers in a medical setting.[32] Second, the products are the result of synthesizing multiple, distinct disciplines of science and technology.[33] These two distinguishing features of BMIs and other novel neurotechnologies will require policymakers to address these innovations with even greater attention than established neurotechnologies such as MRIs.

A. New Possibilities for BMIs

The concept of "technological convergence" describes how new innovations can result from bringing together different areas of science and technology and blending them to create something new.[34] In the world of neurotechnologies, a second, convergence-driven wave of innovation weaves together advances from multiple different scientific and technological disciplines to achieve potential benefits for patients and consumers not previously possible.[35] In particular, BMIs represent the perfect example of Bainbridge and Roco's original concept for technological convergence described in their report at the National Science Foundation.[36] Originally conceived in 2002, convergence was described as the process for bringing together insights and developments from "nanotechnology, biotechnology, information technology, and cognitive science" to create new possibilities, even enhancing human cognitive abilities.[37] Many neurotechnologies such as BMIs use information technologies to record and process data, applying cognitive science to interpret the information.[38] Neurotechnologies may also involve nano- or biotechnology, particularly in the materials of the interface selected.[39]

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[32] *See* Ienca et al., *supra* note 12, at 805 (demonstrating how rapid advances in neuroscience and neurotechnological development could have direct-to-consumer applications).
[33] Garden et al., *supra* note 8, at 9, 20.
[34] *Id*.; Suzy E. Park, U.S. Cong. Res. Serv., Technological Convergence: Regulatory, Digital Privacy, and Data Security Issues 1, 1–2 (2019), https://fas.org/sgp/crs/misc/R45746.pdf.
[35] Garden et al., *supra* note 8, at 9.
[36] *See generally* NAT'L SCI. FOUND., CONVERGING TECHNOLOGIES FOR IMPROVING HUMAN PERFORMANCE: NANOTECHNOLOGY, BIOTECHNOLOGY, INFORMATION TECHNOLOGY AND COGNITIVE SCIENCE ix (Mihail C. Roco & William S. Bainbridge eds., 2002) (discussing the concept of convergence and convergent technologies).
[37] *See id.* at ix–xi (defining the idea of technological convergence, especially in combining the fields of "nano-bio-info-cogno," and discussing the social and policy implications of such a phenomenon).
[38] *See generally* Gabriel A. Silva, *A New Frontier: The Convergence of Nanotechnology, Brain-Machine Interfaces, and Artificial Intelligence*, 12 FRONTIERS NEUROSCIENCE 1, 1 (2018) (discussing the use of advances in materials science and digital technologies, such as artificial intelligence, with BMIs).
[39] *Id*.

BMIs are devices which allow a patient or consumer's brain to "interface" with software, such as a computer cursor, or a piece of hardware, such as a prosthetic limb.[40] Such interfacing can involve the BMI either "reading" or "writing" human neural signals.[41] BMIs which "read" neural activity can allow the user to control or influence a machine's behavior, where the BMI reads and interprets signals from the brain (such as those associated with arm or finger movement) and translates those signals into an output such as moving a computer cursor, a prosthetic, or operating a device to replicate speech.[42] Read functions offer great promise to patients with paralysis or physical injuries, as these BMIs could enable new ways to interact with their environment and even enable "neurorehabilitation."[43] BMI "read" functions can also be used in consumer products, such as those used to help analyze an individual's level of concentration or meditation, by monitoring thought processes while the device is worn, and then providing an assessment and suggestions to the consumer.[44] Facebook is currently developing a commercial, wearable BMI to enable users to draft and send text-based messages solely using neural signals.[45]

While BMIs that "read" constitute the bulk of current products, another class of BMIs can also "write" by using electrical stimulation to modify brain signals or create new ones, rather than solely interpreting or "reading" those signals.[46] For example, existing cochlear implants operate by converting

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[40] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 3, 14 (discussing how neural interfaces interact with the nervous system to stimulate activity).

[41] *See* Richard A. Andersen, et al., *Selecting the Signals for a Brain-Machine Interface*, 14 CURRENT OPINION NEUROBIOLOGY 720, 720 (2004) (describing some processes behind read and write functions of current and emerging BMIs); *see generally* Pieter R. Roelfsema et.al., *Mind Reading and Writing: The Future of Neurotechnology*, 22 TRENDS COGNITIVE SCI. 598, 598 (2018) (describing progress in neurotechnologies towards the capacity to both "read" and "write" neural signals).

[42] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 22, 30, 72 (providing examples of BMIs); *see also* David A. Moses et al., *Real-Time Decoding of Question-and-Answer Speech Dialogue Using Human Cortical Activity*, 10 NATURE COMM., 1, 2, 8–9 (2019) (describing work towards BMIs which can interpret brain signals to produce speech for a user).

[43] *See generally* Yoji Okahara et al., *Long-Term Use of a Neural Prosthesis in Progressive Paralysis*, 8 SCI. REP. 1, 1 (2018) (explaining how BMI technology is expected to improve the quality of life for paralyzed individuals); Sylvan J. Albert & Jürg Kesselring, *Neurorehabilitation of Stroke*, 259 J. NEUROLOGY 817, 817 (2012).

[44] *See* Ienca et al., *supra* note 12, at 806 (describing the near-term potential of direct-to-consumer applications of neurotechnologies).

[45] Josh Constine, *Facebook is Building Brain-Computer Interfaces for Typing and Skin-Hearing*, TECHCRUNCH (Apr. 19, 2017, 12:55 PM), https://techcrunch.com/2017/04/19/facebook-brain-interface/.

[46] *See* Andersen et al., *supra* note 41, at 720 (describing how BMIs interface with brain tissue to "read" or "write" neural signals).

sound waves into electrical signals the brain can interpret as sound.[47] While further research and development is required, these BMIs offer novel possibilities to strengthen or correct deficient neural pathways associated with disease or injury, such as Parkinson's Disease or traumatic brain injuries.[48]

BMIs' reading and writing functionalities have benefited from progress in multiple disciplines.[49] Advances in neuroscience and neuropsychology have provided a higher-resolution and more quantitative understanding of how neural signals influence motor control, cognition, and mood.[50] Meanwhile, rapid progress in data sciences and AI has bolstered the ability to collect and analyze vast volumes of data quickly to better interpret and act on neural signals.[51] Engineering innovations in biocompatibility, micro- or nanoscale manufacturing, and materials science has facilitated new designs for devices with greater sensitivity to neural signals that pose fewer risks when placed on or in the body.[52] Convergence in these fields has sparked new possibilities for products to aid patients or offer novel benefits or services to consumers.[53]

B. New Risks for BMIs

While interdisciplinary collaboration has allowed for the creation of new products with potential benefits for people with neurological or other medical conditions, as well as for consumers, this technological convergence also blends and multiplies the risks and uncertainties posed by each technology individually.[54] Uncertainty in neuroscience, the potential of algorithmic error

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[47] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 38 (describing how cochlear implants operate). It should be reiterated here that defining hearing loss as a condition requiring treatment is a contested view of disability. *See* Sparrow, *supra* note 26.

[48] *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 10, at 2, 34 (describing the potential use of BMIs for rehabilitation in patients with impaired motor function from neurological injury or disease, such as Parkinson's Disease); *see generally* Dennis A. Turner, *Enhanced Functional Outcome from Traumatic Brain Injury with Brain-Machine Interface Neuromodulation*, *in* TRANSLATIONAL RESEARCH IN TRAUMATIC BRAIN INJURY (Daniel Laskowitz & Gerald Grant eds., 2016) (describing the potential use of BMIs to "facilitate recovery from the basic head injury" and restore function in the damaged areas).

[49] Garden et al., *supra* note 8, at 9, 12, 20.

[50] *Id*.

[51] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 49 (discussing the advantages AI may bring to neurotechnologies).

[52] Jong-ryul Choi et al., *Implantable Neural Probes for Brain-Machine Interfaces: Current Developments and Future Prospects*, 27 EXPERIMENTAL NEUROBIOLOGY 453, 463–64 (2018).

[53] *See e.g.*, Garden et al., *supra* note 8, at 11–17.

[54] *See* Garden & Winickoff, *supra* note 10, at 12–13 (listing potential ethical and governance issues in neurotechnology innovation and use); MAYNARD, *supra* note 9, at 20–21.

or cyberattacks, and the biocompatibility of new materials used in BMIs all present their own safety and effectiveness issues for these neurotechnologies.[55] For instance, devices implanted in the skull or spine can cause injury by damaging neural tissue where the device is placed, which could lead to chronic issues with muscle movement or psychological wellbeing.[56] For wearable and implantable BMIs alike, cyberattacks could reveal sensitive personal or medical data collected by devices or interfere with how the device operates.[57]

These individual safety and performance problems demand immediate oversight, but so do more complex risks which can arise at the nexus of the many technologies underlying BMIs. For example, data collected by BMI developers combined with advances in neuroscience could lead to "neuroprivacy" issues, where industry actors could gain increasingly invasive insights about the thoughts of its product's end users.[58] Particularly for implantable devices, the safety of materials and cybersecurity issues could combine to render patients or consumers reliant on BMI developers to keep cybersecurity protections updated and monitor for safety issues.[59] Should private actors not have strong incentives to provide these protections over time, or should they go out of business, the wellbeing of those BMI users could be jeopardized.[60] Additionally, knowledge gained from neuroscience and rapid insights from AI-driven big data may enable BMIs to enhance human performance, such as by improving cognitive performance or response times.[61] This enhancement may result in national security issues

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[55] *See* Garden & Winickoff, *supra* note 10, at 12–13 (listing potential ethical and governance issues in neurotechnology innovation and use).
[56] *See generally e.g.*, Stephanie Cernera et al., *A Review of Cognitive Outcomes Across Movement Disorder Patients Undergoing Deep Brain Stimulation*, 10 FRONTIERS NEUROLOGY 419 (2019); Jürgen Voges et al., *Thirty Days Complication Rate Following Surgery Performed for Deep-Brain-Stimulation*, 22 MOVEMENT DISORDERS 1486 (2007).
[57] *See* Marcello Ienca & Pim Haselager, *Hacking the Brain: Brain-Computer Interfacing Technology and the Ethics of Neurosecurity*, 18 ETHICS & INFO. 117, 120–21 (2016).
[58] Marcello Ienca, *Neuroprivacy, Neurosecurity and Brain-Hacking: Emerging Issues in Neural Engineering*, 8 BIOETHICA F. 51, 52 (2015); Maynard & Scragg, *supra* note 11, at 1, 2, 4 (noting concern for the "misuse of an individual's data" if "users have limited control over implanted brain machine interfaces and the data they produce").
[59] *See* MAYNARD, *supra* note 9, at chapter 7 (anticipating social risks to implantable BMI users who do not have the skills to perform maintenance on their own devices, placing their long-term wellbeing related to the device primarily in the hands of the BMI company).
[60] *Id*.
[61] Caterina Cinel et al., *Neurotechnologies for Human Cognitive Augmentation: Current State of the Art and Future Prospects*, 13 FRONTIERS HUM. NEUROSCIENCE 1, 5–14 (2019).

when applied in a military setting or widen the wealth gap if only accessible to individuals of means.[62]

The individual disciplines that come together to create emerging neurotechnologies such as BMIs each pose their own risks, from safety and performance to privacy and security, yet their convergence blends these challenges and may create new ones. Emerging technologies in general create a pacing problem, where accelerating technological innovation develops faster than public regulators' efforts to understand and manage their risks.[63] BMIs appear to have begun outpacing policymakers already, with non-invasive BMIs available to consumers already posing data privacy and security risks that current law and regulators in the United States have struggled to address.[64] And further, by mixing different types of risks, technological convergence may accelerate this thorny pacing problem. By posing not only risks associated with each individual type of science or technology, but also new risks only possible through blending multiple different types of innovations, decisionmakers could find themselves increasingly behind the novel governance challenges that develop in the wake of convergence around BMIs.[65]

II. FRAGMENTED REGULATORY GOVERNANCE OF BMIS IN THE UNITED STATES

Finding appropriate regulatory strategies for BMIs will require not only addressing safety issues for implantable devices, but also the complex social and ethical problems created by technological convergence.[66] Yet, the discussion on how to regulate the risks and benefits of emerging neurotechnology products has only just begun. As this discussion begins, the question of what broader goals regulation should accomplish is open for debate.[67] Specifically, scholars debate whether traditional regulatory agencies have the capacity to oversee these emerging products and whether

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[62] *Id*.
[63] Gary E. Marchant et al., *The Growing Gap Between Emerging Technologies and the Law, in THE* GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT 19–20 (2011).
[64] *See* Ienca et al., *supra* note 12, at 807–09.
[65] *Id.*; Marchant, *supra* note 63, at 5, 16–20.
[66] *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 10, at 222 (noting governance concerns extend beyond safety to also include issues including "autonomy, privacy, equity, and trust").
[67] *See* Garden & Winickoff, *supra* note 10, at 14–17 (illustrating issues in neurotechnological innovation and use).

their regulation will undercut innovation.[68] Legal scholars Marchant and Tournas have raised the possibility of governments or non-state actors using "soft law" instruments, meaning voluntary standards, to govern neurotechnologies around the globe.[69] In December 2019, the Organisation for Economic Co-operation and Development ("OECD") issued the first such global soft law standard calling for public and private entities to incorporate elements of "responsible innovation" into their neurotechnology research and development activities.[70]

While transnational standards, such as the OECD's, will provide a meaningful source of norms for governing complicated issues raised by neurotechnologies, the role of existing regulatory bodies should not be dismissed. The FDA and FTC have delegations from Congress that empower them to oversee, to an extent, products arriving in the second wave of neurotechnologies such as BMIs.[71] However, the existing regulatory frameworks which the FDA and FTC will apply to these novel products were not specifically designed for neurotechnologies.[72] Thus, these frameworks may be a poor fit for regulating the risks and benefits of these new products, though the agencies must ultimately apply them nonetheless, as these preexisting regulatory tools are the instruments the agencies have available to them.[73]

The possibility that these current oversight frameworks may be poorly tailored to emerging neurotechnologies presents policy challenges, starting with appropriately adapting regulation to risks. But a more immediate concern arises from the need to coordinate multiple agencies, each with their own set of rules and mandates. Both the FDA and the FTC have a jurisdictional claim over cybersecurity in these products, creating a potential redundancy or inconsistency in oversight (see Table 1). [74] Bifurcated review

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[68] Marchant, *supra* note 63, at 16.
[69] Gary Marchant & Lucy Tournas, *Filling the Governance Gap: International Principles for Responsible Development of Neurotechnologies*, 10 AJOB NEUROSCIENCE 176, 177 (2019).
[70] ORG. FOR ECON. CO-OPERATION & DEV., RECOMMENDATION OF THE COUNCIL ON RESPONSIBLE INNOVATION IN NEUROTECHNOLOGY 3 (2019).
[71] INST. OF MED. ET AL., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 41-46 (2011); *see* Parts II.A & II.B, *infra*.
[72] *See* Elen Stokes, *Nanotechnology and the Products of Inherited Regulation*, 39 J.L. & SOC'Y. 93, 94 (2012) (arguing that existing provisions may be ill-suited to regulate new technologies).
[73] *Id*.
[74] *See* Ishan Dasgupta, *Assessing Current Mechanisms for the Regulation of Direct-to-Consumer Neurotechnology*, DEV. NEUROETHICS & BIOETHICS 233, 246–50 (outlining how

of neurotechnology products for their safety and effectiveness by the FDA and for consumer protection concerns by the FTC could pose issues of regulatory inefficiency by needlessly duplicating resources spent by agencies and developers alike. Further, neither agency has jurisdiction to review the broader ethical and social concerns posed by neurotechnologies, opening gaps in the federal governance scheme for these technologies.[75] Without an adequate policy framework, these governance gaps on ethical and social issues, combined with overlapping or bifurcated risk regulation by the FDA and FTC, could lead to a system that is both inefficient and ineffective for BMI oversight. Further, the potential for litigation challenging new regulatory efforts, in which courts could become involved in new efforts to regulate the space through reviews of agency discretion, further complicates the stability of governance for BMIs.

This Part reviews the "regulatory space" into which BMIs fall, by taking stock of some major public decision-making institutions and regulatory regimes that apply,[76] and considers how these overlapping systems can drive fragmentation.

Table 1. Divergent Roles and Mandates for the FDA and FTC

	FDA	FTC
Mandate	Public Health	Consumer Protection
Guiding Standard	Safety and Effectiveness	Unfair or Deceptive Practices
Scope of Authority	Health Risks and Benefits; Health Claims	Marketing Claims; Data Protection

the FDA has authority to regulate any "device intended for use in the diagnoses of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of man," while the FTC regulates consumer privacy and data).

[75] *See generally* Gersen, *supra* note 20, at 208–09 (explaining lack of jurisdiction).

[76] Colin Scott, *Analysing Regulatory Space: Fragmented Resources and Institutional Design*, 2001 PUB. L. 329, 331 (2001) ("The 'regulatory space' metaphor draws attention to the fact that regulatory authority and responsibility are frequently dispersed between a number of actors . . . . The regulatory space approach is 'holistic' in the sense that it looks at the interactions of each of the players in the space, and can recognize plural systems of authority.").

A. FDA Regulation

The FDA oversees medical devices sold on the market in the United States to patients or consumers that make distinct health claims, acting as a gatekeeper to the marketplace.[77] Authorized by statutory authorities beginning with the Medical Device Amendments of 1976, the FDA uses a risk-based regulatory framework to evaluate the safety and effectiveness of devices and then applies increasing scrutiny to devices with higher risks.[78]

The agency uses a three-tiered classification scheme to determine the level of risk posed by a potential medical device and the degree of oversight required.[79] Class I devices, which may include personal protective equipment such as medical gloves, are considered low risk and must comply primarily with basic rules on manufacturing.[80] Class II devices generally involve medium-risk and an intermediate level of regulatory scrutiny by the FDA, and their route to the market can vary depending on whether they require significant premarket review.[81] The most common pathway to market for Class II devices involves limited premarket review by the FDA through its 510(k) process, which requires developers to show their device is "substantially equivalent" to an existing device on the market.[82] Conversely, Class III devices present higher risks to patient health and safety and may

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[77] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351–360 (2020); *see also* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 1 (2010).

[78] *Overview of Medical Device Classification and Reclassification*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2017), https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification.

[79] *Id.* In seeking approval, device developers must select one of the FDA's pre-existing regulatory pathways and send the appropriate materials to the FDA. *See Overview of Medical Device Classification and Reclassification*, *supra* note 78 (outlining information developers must provide the FDA based on the review mechanism selected and noting device types exempt from premarket requirements).

[80] *See General Controls for Reclassification Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2018), https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices. For an overview of FDA device classification and regulatory requirements for each class, *see generally*, *Regulatory Controls*, U.S. FOOD & DRUG ADMIN. (Mar. 27, 2018), https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.

[81] *See* JUDITH A. JOHNSON, U.S. CONG. RES. SERV., FDA REGULATION OF MEDICAL DEVICES 1, 6 (2016), https://fas.org/sgp/crs/misc/R42130.pdf.

[82] *Id.*; *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2020), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-190, FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 9, 16–19 (2009), https://www.gao.gov/assets/290/284882.pdf (illustrating how most Class II submissions to the FDA are through the 510(k) pathway).

involve implantable devices,[83] typically requiring extensive review through a Premarket Approval ("PMA") involving clinical trials.[84]

Placing emerging neurotechnological medical devices on the market will require classifying the device under the FDA's risk-based regime and then working with the agency to determine what requirements should be met prior to marketing the device.[85] Some neurotechnologies have already undergone FDA clearance or approval,[86] including implantable spinal cord stimulators and DBS devices.[87] The FDA retains regulatory authority over these devices in the post-market setting, and has previously exercised its recall powers on, for example, cochlear implants.[88] Developers of newer neurotechnological products such as implantable BMIs should similarly be prepared to comply with the FDA's post-market regulatory powers including recalls and reporting.[89] Notably, relatively few non-invasive neurotechnologies such as wearable TMS devices have been cleared through the FDA, so developers of these products may benefit from working closely with the agency to determine the most appropriate pre-market steps.[90]

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[83] *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN. (2017), https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.

[84] Premarket Approval of Medical Devices, 21 C.F.R. § 814 (2020); *see Premarket Approval (PMA)* U.S. FOOD & DRUG ADMIN. (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma; *see generally* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 82.

[85] *See generally Regulatory Controls*, *supra* note 80.

[86] A successful PMA application to the FDA results in "approval" while a successful 510(k) results in "clearance." *See* JOHNSON, *supra* note 81, at 4.

[87] *See, e.g.*, *Boston Scientific Spinal Cord Stimulation System – P030017/S275*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/recently-approved-devices/boston-scientific-spinal-cord-stimulation-system-p030017s275 (last visited Oct. 5, 2020) (providing examples of a spinal cord stimulator device approved by FDA through the premarket approval pathway); *Medtronic DBS System for Epilepsy – P960009/S219*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/recently-approved-devices/medtronic-dbs-system-epilepsy-p960009s219 (last visited Oct. 1, 2020) (providing examples of a DBS device approved by FDA through the premarket approval pathway).

[88] *Medical Device Recalls: Advanced Bionics Corporation*, U.S. FOOD & DRUG ADMIN. (2006), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/resCollection_2.cfm?ID=44868&CREATE_DT=2006-04-1 (last visited Oct. 1, 2020); *see generally Postmarket Requirements (Devices)*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/postmarket-requirements-devices.

[89] *See generally Postmarket Requirements (Devices)*, *supra* note 88.

[90] *See* Tournas & Johnson, *supra* note 16 (arguing neurotechnology developers should work closely with the FDA to anticipate potential risks and determine the most appropriate review mechanisms).

The most complex neurotechnologies, including BMIs, present greater challenges to both the FDA and the industry. These devices contain hardware and software components, both of which require separate safety and effectiveness reviews, and can create cybersecurity vulnerabilities for patients relying on these devices when connected to the internet that might change the device's safety or performance.[91] These devices will likely require extensive pre-market approval applications if intended to be implanted in a patient's body.[92] Non-invasive BMI devices hold lower safety risks than implantable BMI devices, but may be less effective if the skull and skin dull neural signals read by the BMI.[93] The FDA has already begun considering how to regulate BMIs with a draft guidance in 2019 and has solicited comments from stakeholders on the document.[94] This draft guidance would clarify what types of data the FDA would want to review when considering BMIs, such as information on how BMI software and electrodes functions,[95] although a finalized guidance may take time to issue depending on the volume and character of comments submitted to the agency.

Notably, the FDA does not regulate products which do not make health claims, even if they appear to be medical devices at first glance.[96] A number of direct-to-consumer ("DTC") neurotechnological products have already appeared on the market without going through the FDA due to this gap in FDA authority, since such products typically make "wellness" claims rather than express health claims.[97] Such non-invasive DTC products claiming to assist users with sleep, focus, or meditation can already be found on the market in multiple countries.[98] These could also include non-invasive, wearable BMIs such as those under development by Facebook, advertising the ability to type and send text by using only brain signals.[99]

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[91] *See id.* (noting some upcoming regulatory challenges in managing risk in BMI hardware and software).
[92] *Id*.
[93] *See* Baldwin, *supra* note 3, at 29–30 (discussing the trade-offs between invasive and noninvasive BMIs).
[94] *See generally* U.S. Food & Drug Admin., Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations: Draft Guidance for Industry and Food and Drug Administration Staff 1 (2019) (reviewing draft guidance for BMIs).
[95] *Id*.
[96] Dasgupta, *supra* note 18, at 200.
[97] *Id*.
[98] *See* Ienca et al., *supra* note 12, at 805–07 (highlighting certain direct-to-consumer neurotechnologies available in different countries).
[99] *See* Perry, *supra* note 13 (indicating Facebook has announced efforts towards developing a BMI).

B. FTC Adjudication

The Federal Trade Commission Act grants the FTC authority to oversee consumer protection issues in the United States.[100] In comparison to the FDA, the FTC adopts a regulatory strategy primarily defined by adjudication rather than rulemaking.[101] The FTC wields the broad standard of "unfair or deceptive acts or practices,"[102] which it applies to actions by industry in a case-by-case basis through adjudication. This flexibility in enforcement provides the FTC with notable discretion and, along with a handful of new statutory authorities, has allowed it to expand its jurisdiction to include data privacy.[103] However, the agency has limited resources to use in pursuing consumer protection violations, restricting the practical scope of its oversight.[104] Over time, the FTC, through its adjudication and settlement activities, has incorporated data privacy and security within the scope of consumer protection issues that it regulates, and has built a healthy log of adjudicative "precedents" to draw from in addressing data protection violations.[105] Notably, the FTC has begun more recent efforts in enforcing companies' commitments to voluntary self-regulation in the area of data protection, expanding the agency's reach into privacy and consumer protection.[106] As such, the FTC's previously existing authorizations grant it the ability to adjudicate claims made by BMI developers, evaluating industry claims for "unfair or deceptive acts or practices."[107]

The FTC can review claims which may be false, incomplete, or misleading, including claims about the degree and type of data privacy and cybersecurity protections offered by a product or service.[108] This authority

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[100] Federal Trade Commission Act, 15 U.S.C. §§ 41–58 (2020).
[101] Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583, 620–21 (2014).
[102] Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (2020) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.").
[103] *See* Solove & Hartzog, *supra* note 100, at 598–606 (depicting how the FTC has come to regulate privacy in the U.S.).
[104] *Id*. at 605 (noting "the FTC lacks general authority to issue civil penalties" and more often "is limited to fining companies under a contempt action for violating a settlement order").
[105] *See generally id*. (describing the breadth of FTC's adjudicative jurisprudence and its expansion over the past 15 years).
[106] Wendell Wallach & Gary Marchant, *Towards the Agile and Comprehensive International Governance of AI and Robotics*, 107 PROC. IEEE 505, 506 (2019).
[107] Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (2020).
[108] *See* Solove & Hartzog, *supra* note 101 at 627–48 (describing the agency's "jurisprudence" on deception, unfairness, and other statutory rules, including on matters of data security and improper use or collection of consumer data).

enables the FTC to go further than the FDA by allowing it to review nonmedical claims made by neurotechnological products, including DTC products.[109] Even if such claims are related to general "wellness," rather than making express health claims subject to FDA purview, they could still fall under the FTC's wide scope of authority.[110]

C. Federal Court Deference

The federal courts play a significant role in the regulatory environment through their judicial review of administrative agency actions. In this context, judicial review includes determining whether an administrative agency acted beyond its statutory authority or complied with substantive and procedural requirements for taking regulatory action.[111] Beyond reviewing new rules, courts can also review agency efforts to extend the scope of their existing jurisdiction to new areas.[112] This can involve both reviewing new rules for products which the agency already regulates, or reviewing standards for new products that agencies have not regulated in the past. For example, in 2000 the Supreme Court reviewed and denied the FDA's moves to regulate tobacco under its authority to oversee drugs or devices.[113] The courts therefore could add to the regulatory environment for BMIs by placing an additional check on agency rulemaking authority.[114]

Over decades, the Supreme Court has established a robust doctrinal method of interpreting agency rules and conduct.[115] The *Chevron* and *Auer* doctrines generally direct federal courts to uphold agency rules or an agency's interpretation of its rules, respectively, when such rules are based on a reasonable interpretation of the underlying, but ambiguous, legal

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[109] *See* Dasgupta, *supra* note 18, at 200–01 (highlighting the differences between FDA and FTC jurisdiction and noting two cases of the FTC taking enforcement action against neurotechnology developers).
[110] *Id.*
[111] Kent Barnett & Christopher J. Walker, *Chevron in the Circuit Courts*, 116 MICH. L. REV. 1, 1 (2017).
[112] *See, e.g.*, City of Arlington v. FCC, 133 S. Ct. 1863 (2013).
[113] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 1294 (2000).
[114] Further, regulatory policymakers are generally aware of judicial deference doctrines, which affects how new rules are constructed; *see generally* Christopher J. Walker, *Chevron Inside the Regulatory State: An Empirical Assessment*, 83 FORDHAM L. REV. 703, 703–04 (2014).
[115] Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837, 843 (1984); United States v. Mead Corp., 533 U.S. 218, 234 (2001); City of Arlington v. FCC, 569 U.S. 1863, 1874–75 (2013).

authority.[116] Judicial deference enables agencies such as the FDA to create new rules for novel and emerging issues or products without needing to receive additional delegations from Congress to handle them.[117] In the case of neurotechnological products, the FDA must interpret its existing medical device authority to justify oversight of both hardware and software, including cybersecurity issues.[118] The agency has already issued repeated guidance on software,[119] based on their medical device rules, yet these standards have not undergone rigorous judicial review and could be subject to *Auer* scrutiny in the future.[120] The FTC relies primarily on adjudication, which remains susceptible to judicial review.[121] However, empirical studies have shown that adjudications fare better in *Chevron* suits than notice and comment rulemaking,[122] suggesting that the FTC's regulatory decisions on neurotechnological products will be less contestable.

Given that the integrity of some of the FDA's standards on BMI products may rely on federal courts applying some form of *Auer* deference, as those standards have largely been issued as guidance rather than through classic rulemaking, the fate of the *Auer* doctrine becomes critical.[123] Both *Auer* and *Chevron* have faced increasing criticism from scholars and decisionmakers in the past decade, which has placed their durability on uncertain ground.[124] In *Kisor v. Wilke*, the Supreme Court recently left the *Auer* doctrine intact by a slim 5-4 majority, though qualified existing guardrails on the doctrine and affirmed that agencies should consider whether and how much stakeholders have relied on a particular interpretation of a rule.[125] Four justices would have formally overruled *Auer*, even though the Court unanimously supported the outcome in this particular case, because of the perceived bias in favor of

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[116] *See generally Chevron*, 467 U.S. at 843 (giving deference to agency interpretation of ambiguous laws); Auer v. Robbins, 519 U.S. 452, 461 (1997) (giving agencies a high level of deference in interpreting their own regulations).
[117] *Id*.
[118] *See generally* U.S. FOOD & DRUG ADMIN., *supra* note 94 (describing the FDA's current stance on and efforts at interpreting how it will aim to apply its statutory authority to BMIs).
[119] *Guidances with Digital Health Content,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/digital-health/guidances-digital-health-content (last visited Oct. 1, 2020).
[120] *Auer*, 519 U.S. at 461 (federal courts generally recognize an agency's interpretation of its own rules as "controlling unless plainly erroneous or inconsistent with the regulation").
[121] *See* Solove & Hartzog, *supra* note 101, at 613.
[122] Barnett & Walker, *supra* note 111, at 7.
[123] *See Auer*, 519 U.S. at 461.
[124] *See generally, e.g.*, Christopher J. Walker, *Attacking Auer and Chevron Deference: A Literature Review*, GEO. J.L. & PUB. POL'Y 103, 104–20 (2018).
[125] Kisor v. Wilke, 139 S. Ct. 2400, 2416–18, 2424 (2019).

regulatory agencies that the doctrine creates.[126] Chief Justice Roberts was the swing vote in upholding the *Auer* doctrine, though he emphasized the doctrine's limitations, suggesting an openness to upend *Auer* in the future.[127]

Efforts by the FDA to extend its medical device authority to BMIs with new rules and guidance will be reviewable by courts, but whether courts become involved will ultimately depend on whether litigants such as industry members challenge these efforts. Politically, the FDA enjoys relatively stable public support, though its reputation still fluctuates across constituencies and time.[128] Recently, however, the agency has come under fire for both overburdensome and lax responses to diagnostic testing and therapeutics during the COVID-19 pandemic.[129] Should public support for the FDA collapse, neurotechnology developers could become more prone to litigate FDA efforts to increase regulation of their industry. Unfavorable judicial review of the agency's decisions to increase regulatory scrutiny on emerging BMIs could then become more likely and lead to further destabilization of the regulatory environment for these innovative products.[130] Should courts limit the FDA's oversight of BMIs, the FTC could only fill in a small fraction of the gap left regarding medical devices, given the broad differences in the scope of the two agencies' respective authorities.[131] Instead, absent further legislation, this situation could see some safety and effectiveness regulation consigned to market forces and voluntary obligations, potentially jeopardizing the effectiveness of oversight.[132]

D. Fragmented Regulatory Governance for BMIs

The presence of multiple administrative agencies and types of substantive regulation for BMIs creates the risk of fragmented and duplicative regulation,

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[126] *See id*. (Gorsuch, J., concurring; Kavanaugh, J., concurring).
[127] *Id*. at 2024 (Roberts, J., concurrence).
[128] *See* CARPENTER, *supra* note 77, at 11–15 (illustrating how the FDA relies on pharmaceutical companies and physicians for support).
[129] The Editorial Board, *The Epic Failure of Coronavirus Testing in America*, N.Y. TIMES (Mar. 19, 2020), https://www.nytimes.com/2020/03/19/opinion/coronavirus-testing.html; Laurie McGinley, *FDA Steps Up Scrutiny of Coronavirus Antibody Tests to Ensure Accuracy*, WASH. POST. (May 4, 2020), https://www.washingtonpost.com/health/2020/05/04/fda-steps-up-scrutiny-coronavirus-antibody-tests-ensure-accuracy/.
[130] James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 939–40 (2008).
[131] This FDA-FTC overlap may include, for instance, cybersecurity; *see*, *Cybersecurity*, U.S. FOOD & DRUG ADMIN. (Oct. 13, 2020), https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity.
[132] *See* O'Reilly, *supra* note 130, at 940.

if not properly coordinated.[133] Not only are administrative agencies such as the FDA and FTC involved, but also state and federal courts and lawmakers.[134] Other public entities, including the U.S. Patent and Trademark Office ("USPTO") or Consumer Products Safety Commission ("CPSC"), could contribute to this fragmentation in the future as well, although USPTO oversight may be less direct and CPSC regulation appears unlikely to trigger.[135] Fragmentation results from the involvement of multiple decisionmakers with each having only partial authority, expertise, and information to address a regulatory problem, rather than one centralized decisionmaker with a comprehensive mandate and high capacity.[136]

The resulting fragmentation from these gaps could create three types of problems in the regulatory governance of neurotechnologies like BMIs. First, overlap between agencies reviewing the same products could create additional costs on industry actors from inconsistent or duplicative norms, increasing both the financial costs and amount of time required for private actors to pass regulatory approval and remain on the market.[137] The FDA and FTC both have authority over health- and safety-related claims of BMIs and will both have capacity to review the cybersecurity protections, creating potentially costly regulatory overlap.[138] Second, and similarly, bifurcated jurisdiction could lead to different and inconsistent regulatory standards applied to the same problem.[139] The FDA wields a standard of "safety and effectiveness" for medical device performance while the FTC applies an "unfair or deceptive acts or practices" standard to business activities such as communication and marketing,[140] which could create two different sets of regulatory norms that must be met. Not only can this place costs on

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[133] Scott, *supra* note 76, at 330–31.

[134] Of course, lawmakers and courts at the state level cannot create rules conflicting with federal ones, such as FDA regulations, although defining the scope of federal preemption can be contentious. *See generally* Catherine M. Sharkey, *Federalism in Action: FDA Regulation Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013 (2007).

[135] *See* Dasgupta, *supra* note 74, at 249–50; Christi J. Guerrini et al., *The Rise of the Ethical License*, 35 NATURE BIOTECHNOLOGY 22, 22–23 (2017) (discussing how and why the U.S. Patent and Trademark Office is getting involved in the oversight of emerging neurological products).

[136] Julia Black, *Critical Reflections on Regulation*, 27 AUSTL. J.L. PHIL. 1, 5 (2002).

[137] Jason Marisam, *Duplicative Delegations*, 63 ADMIN. L. REV. 181, 182–84 (2014).

[138] *See generally* Dasgupta, *supra* note 18 (describing the regulatory approaches and providing examples of how the FDA and FTC could each regulate neurotechnologies like BMIs).

[139] Marisam, *supra* note 137.

[140] Dasgupta, *supra* note 74, at 246–47, 249.

industry,[141] but federal agencies may waste resources by developing similar expertise independent from each other, rather than by collaboratively sharing experiences. Third, the partial authority of each regulator in the neurotechnological landscape will likely result in governance gaps, as some risks and problems may fall outside of each entity's perceived or actual scope of authority.[142] In particular, using BMIs to enhance cognitive or physical performance presents novel regulatory challenges which neither the FDA nor the FTC have meaningfully addressed in the past and may lack authority over entirely.[143]

Significant fragmentation risks raising the costs of regulation for public and private actors, lowering the effectiveness of oversight, and losing public legitimacy by presenting duplicative requirements and slowing access to potentially valuable innovation.[144] Resolving or mitigating fragmentation of oversight for BMIs will require strategies to bring regulators together, potentially alongside private and civil society actors, to ensure that regulation can achieve its goals to protect the public without imposing unacceptable costs.

III. STRATEGIES FOR MANAGING FRAGMENTATION FROM CONVERGENCE

The fragmented regulatory governance scheme for BMIs in the United States could result in both inhibiting innovation or market access for these promising new products and overlooking critical risks, while using scarce regulatory resources inefficiently. Alleviating these oversight issues will require thoughtfully engaging legal and political tools to stimulate and coordinate activity by the FDA, FTC, and other public bodies without rendering judicial resolution necessary. Successful coordination will be critical to generating robust, responsive, and efficient regulation for this site of technological convergence. Part III will proceed by considering tools and institutions that can be leveraged to promote greater regulatory effectiveness and efficiency through early action and collaboration.

A. Interagency Coordination: Tools and Institutions

Multiple federal agencies can hold regulatory authority which overlaps, creating potential inefficiencies and gaps in the governance of a shared

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[141] *Id*. at 252.
[142] *See generally* Marisam, *supra* note 137 (discussing the problems of duplicative delegation).
[143] *See* Wexler & Reiner, *supra* note 5, at 235.
[144] *See* Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1209–10 (2012).

regulatory space.[145] Consolidating different agencies or subagencies into a larger department or other administrative unit provides one way to address fragmentation issues.[146] Perhaps the most notable recent example is the Bush Administration crafting the Department of Homeland Security in 2002 by fusing multiple agencies that were previously housed in other departments.[147] However, legal and social scholars have illustrated how consolidation cannot guarantee that fragmentation will not continue within the new agency, undermining the rationale for consolidation.[148] Instead, recent literature suggests that coordinating various federal agencies with similar jurisdiction offers the most effective solution to fragmentation.[149]

Coordinating agencies requires understanding the "toolbox" of available coordination solutions and which particular institutions can most effectively wield those tools.[150] These tools can involve (1) interagency consultation, whether voluntarily initiated by agencies or externally required, (2) memoranda of understanding ("MOU") or other agreements between agencies on how to manage a shared space, and (3) joint policymaking, such as co-creating and issuing rules.[151] For BMIs, each of these tools could provide value in coordinating the FDA and FTC in their endeavors. First, interagency consultation should provide opportunities for regulators at each agency to communicate with each other about their priorities, data collected,

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[145] *See generally* Gersen, *supra* note 20 (discussing problems that arise with overlapping and underlapping authority).

[146] For example, Congress has previously requested reports illustrating where federal programs overlap and recommendations on whether and how to consolidate those programs. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-318SP, OPPORTUNITIES TO REDUCE POTENTIAL DUPLICATION IN GOVERNMENT PROGRAMS, SAVE TAX DOLLARS, AND ENHANCE REVENUE (2011), https://www.gao.gov/assets/320/315920.pdf.

[147] *See Who Joined DHS*, DEP'T HOMELAND SEC. (Sept. 15, 2015), https://www.dhs.gov/who-joined-dhs (outlining the history of the DHS and why it was created).

[148] *See* Freeman & Rossi, *supra* note 144, at 1133, 1151–55 (reviewing legal and political barriers to consolidation and arguing that consolidation can "convert an *inter*agency coordination problem into an *intra*-agency problem."); *see generally* Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421, 424–27 (2015) (illustrating how coordination issues can arise even within a single agency).

[149] *See generally, e.g.*, Keith Bradley, *The Design of Agency Interactions*, 111 COLUM. L. REV. 745, 745 (2011) (exploring how interagency cooperation can lead to positive policy outcomes, especially in the context of complex "orthogonal-interests" problems); Freeman & Rossi, *supra* note 144 at 1133 (arguing the strengths of coordination outweigh those of consolidation and providing a set of tools for effective coordination); Marisam, *supra* note 137 (discussing duplicative delegation and how to leverage it towards beneficial policy outcomes).

[150] Freeman & Rossi, *supra* note 144, at 1209–11.

[151] *See id*. at 1155–73 (taxonomizing and describing several legal and organizational instruments available to coordinate multiple agencies within a shared regulatory space).

and lessons learned to form a more robust and coordinated agenda.[152] Simply by consulting each other, the FDA and FTC could share experiences and technical expertise in regulating BMIs, especially on the most complex issues arising from technological convergence. By discussing successes and failures in handling BMIs, the two agencies could collaboratively develop regulatory capacity for BMIs rather than each independently spending their own resources, and taxpayer dollars, to develop similar expertise.

Second, interagency agreements such as MOUs can bring agencies together to negotiate the scope of each of their authorities and activities in a shared regulatory space, which can reduce overlapping activity and administrative costs.[153] Agreements between the FDA and FTC on how to collectively regulate BMIs could provide significant clarity and predictability, both to regulators and to private industry, leading to a more stable environment for innovation and well-balanced oversight.[154] Such MOUs would not be unprecedented.[155] The FDA's subunit for drugs and the FTC have an existing MOU on prescription drug labeling oversight,[156] so creating another specialized agreement between the FDA's medical device authority and the FTC has clear precedent. The existing, working MOU between the agencies could lower transaction costs in establishing a new one,[157] as some of the same staff may be involved in establishing a new MOU over BMIs, particularly on the FTC side.

Third, joint policymaking sees agencies come together to collectively issue rules or guidance to assist regulated entities with compliance in a complex area.[158] Agencies may organically decide to make policy together or Congress may require this through legislation.[159] However, joint rulemaking may prove less effective in the particular case of regulating BMIs, because the FDA generally favors rulemaking while the FTC generally prefers adjudication in policymaking.[160] Yet, providing predictable and effective BMI regulation could still involve the FDA closely consulting

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[152] *Id.* at 1157, 1184, 1192.
[153] *Id.* at 1161–65.
[154] *See, e.g.*, Marisam *supra* note 137, at 212–13.
[155] *Id.*
[156] Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration Concerning Exchange of Information, U.S. FOOD & DRUG ADMIN. (Dec. 15, 2017) https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.
[157] *See* Freeman & Rossi, *supra* note 144, at 1192 ("MOUs are easier to negotiate, and more likely to be implemented, in situations where the agencies recognize the need for coordination and possess the resources to devote to it").
[158] *Id.* at 1165–69.
[159] *Id.*
[160] *See* Solove & Hartzog, *supra* note 101, at 620–21.

with the FTC before issuing rules or guidance and the FTC closely consulting the FDA during or prior to adjudication.

To be sure, interagency coordination and collaboration efforts can pose normative and statutory overreach issues when these activities empower agencies beyond what Congress may have intended when delegating power to individual agencies.[161] However, adopting a functionalist point of view, agencies "pooling powers" may be effective and normatively desirable for responding to emerging technologies, such as BMIs, when Congress fails to appropriately direct regulatory policy.[162] This strategy can even include agencies transferring their authority to adjudicate certain subject matters between each other.[163] Technological convergence will spark issues that no one agency can oversee with their current jurisdiction and expertise, such as cognitive enhancement or sensitive neuroprivacy matters.[164] Accordingly, the FDA and FTC working to expand their collective regulatory power may be desirable in both resolving fragmented governance for BMIs and working to close governance gaps to protect the public health and wellbeing.[165]

Different government institutions can apply these coordination tools, including the agencies themselves, Congress using their political or lawmaking power to facilitate coordination, or the Executive Office of the President ("EOP") convening different federal agencies.[166] Each institution has strengths and weaknesses in how well and when they can perform coordination functions.[167] In resolving fragmented regulatory governance of BMIs, however, Congress and interagency engagements have significant advantages over the EOP.[168] The Office of Budget and Management ("OMB"), an EOP subagency, has made efforts to encourage agency coordination in the governance of AI,[169] which neurotechnologies including

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[161] Daphna Renan, *Pooling Powers*, 115 COLUM. L. REV. 211, 275–85 (2015).
[162] *Id*.
[163] *See generally* Bijal Shah, *Interagency Transfers of Adjudicative Authority*, 34 YALE J. REG. 279, 281–91 (2017) (describing how, at times, "agencies make agreements in order to transfer their entire jurisdiction to adjudicate administrative decisions to other agencies").
[164] *See generally* Garden et al., *supra* note 8, at 18–19 (identifying multiple risks and regulatory concerns raised by BMIs).
[165] *See* Renan, *supra* note 161, at 239–40.
[166] *See* Walter G. Johnson, *Conflict Over Cell-Based Meat: Who Should Coordinate Agencies in U.S. Biotechnology Regulation?*, 74 FOOD & DRUG L.J. 478, 489–92, 499–500 (2019) (analyzing "the strengths and weaknesses of varying public institutions in resolving jurisdictional disputes over novel biotechnologies").
[167] *Id*.
[168] *Id*.
[169] *Technology & Science*, OFF. BUDGET & MGMT. (2020), https://www.gao.gov/technology_and_science [hereinafter *Technology*].

BMIs use.[170] However, the federal regulation of BMIs involves an independent agency, the FTC, which may limit the utility and legitimacy of the EOP and the President to coordinate oversight here.[171] Instead, voluntary FDA-FTC engagement or Congressional nudges or mandates to collaborate may instead provide more pragmatic and less politically fraught institutions for coordination, as Presidential attempts to direct an independent agency could generate controversy.[172]

B. Technology Assessment for Policymakers

A second and complementary strategy for managing the fragmentation from convergent BMI technologies involves equipping policymakers with the information and tools to understand and respond to BMIs. Technology assessment ("TA") programs are designed to inform policymakers about various dimensions of technology policy issues by synthesizing research in social science, policy, natural science, and engineering.[173] Both interagency and Congressionally led coordination will require policymakers to anticipate the potential value of BMIs and the hazards of fragmented regulation and take proactive measures to use coordination tools described above. Given that BMIs are still emerging, and that agencies and Congress have finite time and resources when setting an agenda, successful coordination may necessitate conveying the urgency of early action to policymakers.

The first step toward policymakers having the information they need is providing expert advice directly to political decisionmakers in Congress

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[170] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 49 (discussing the advantages AI may bring to neurotechnologies).

[171] *See* Bijal Shah, *Executive (Agency) Administration*, 72 STAN. L. REV. 641, 685–89 (2020) (explaining the Trump Administration has indicated some interest in attempting to extend OMB oversight of agency rulemaking to independent agencies, though independent agency adjudication, favored by the FTC, has received relatively little attention); *see also* OFF. BUDGET & MGMT., *supra* note 169 (describing the guidance to all federal agencies to inform and coordinate the development of regulatory approaches to artificial intelligence).

[172] *See, e.g.*, Elena Kagan, *Presidential Administration*, 114 Harv. L. Rev. 2245, 2327–28 (2001) ("In then delegating power to [an independent] agency (rather than to a counterpart in the executive branch), Congress must be thought to intend the exercise of that power to be independent [from the Executive].").

[173] *See* David H. Guston & Daniel Sarewitz, *Real-Time Technology Assessment*, 24 TECH. SOC. 93, 93–95 (2002) (proposing a research program integrating science and policy research utilizing real-time technology assessment ("TA") For the purpose of this article, TA is used as a general term also incorporating newer frameworks for assessing technologies and policy options such as ethical, social, and legal implications (ELSI) or, more recently, responsible innovation); *see, e.g.*, Daniel Sarewitz et al., *This Won't Hurt a Bit: Assessing and Governing Rapidly Advancing Technologies in a Democracy*, WOODROW WILSON INT'L CTR. SCHOLARS (Dec. 2005).

through dedicated Congressional agencies, whether providing services to specific committees or the full body of Congress. Unfortunately, Congress has limited its own TA resources in past decades.[174] The Office of Technology Assessment ("OTA") was a Congressional agency that sought to provide unbiased reviews of how novel technologies function and the social and economic policy issues they might trigger.[175] Beginning in 1972,[176] the OTA produced forward-looking TA reports for Congress on issues ranging from genetic testing to the value of nurse practitioners,[177] long before these issues became significant policy concerns in the Genetic Information Nondiscrimination Act ("GINA") or Affordable Care Act ("ACA"). Though the OTA provides one model for building lawmakers' technical capacity, the agency was defunded in 1995 when Congressional leaders sought to limit their budget.[178] Since the mid-1990s, Congressional technical expertise has consolidated in the offices of individual leaders in Congress, rather than being readily accessible to Congress as a whole.[179] The lack of reliable and authoritative technical policy resources to most lawmakers has undermined Congress' knowledge of and capacity to address issues of science and technology, including BMIs, and likely weakened Congress' role in responding to COVID-19.[180] While many proposals to create a new OTA

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[174] *See* Grant Tudor & Justin Warner, *Congress Should Revive the Office of Technology Assessment. Here's How to Do It*, BROOKINGS (Dec. 18, 2019), https://www.brookings.edu/blog/fixgov/2019/12/18/congress-should-revive-the-office-of-technology-assessment-heres-how-to-do-it/.

[175] Technology Assessment Act, Pub. L. No. 92-484, 86 Stat. 797 (1972).

[176] *Id.*

[177] *See Office of Technology Assessment Reports Collection*, GEORGETOWN UNIV., https://repository.library.georgetown.edu/handle/10822/707927 (last visited Oct. 1, 2020) (containing a repository of these works).

[178] Tudor & Warner, *supra* note 174.

[179] *See* M. Anthony Mills & Robert Cook-Deegan, *Where's Congress? Don't Just Blame Trump for the Coronavirus Catastrophe*, ISSUES SCI. & TECH. (Apr. 16, 2020), https://issues.org/congress-pandemic-response/ (noting the "staff reductions—especially in [Congressional] agencies and committees with science and technology jurisdiction" as well as that "staffing has increased elsewhere, including the 'leadership' offices of the House." Instead Congress receives much information on scientific and technical issues "exactly the same way it gets all its information: from a cacophony of competing voices in the forms of lobbyists, think tanks, policy shops, advocacy groups, media reports, agency officials, interested parties and even, from time to time, the public"); Michael Rodemeyer, *Back to the Future: Revisiting OTA Ten Years Later*, WOODROW WILSON INT'L CTR. FOR SCHOLARS (Dec. 2005).

[180] *See id.* (depicting some shortcomings of the current state of technical expertise of Congress).

have surfaced since its demise, opinions diverge on how to reconstruct the institution.[181]

By informing lawmakers of the different issues and interests at stake with an emerging technology, Congress may become more involved in proactively taking steps to resolve potential issues. In BMIs, timely and nonpartisan TA could enable and empower Congress to make decisions about the fragmentation in BMI regulatory governance, thereby striking a democratically backed balance between innovation and risk management. Instead of aiming to reconstruct an old Congressional agency or create a new one for TA services, an existing Congressional agency could be used to provide reliable and authoritative TA to lawmakers. In recent years, the Government Accountability Office ("GAO") has begun to build their TA capacity and resources to fill the void of nonpartisan technical advice for policymakers.[182] The GAO has offered TA services on a range of timely issues from "deepfakes" to COVID-19.[183]

The Congressional Research Service ("CRS") also holds significant technical expertise and provides brief or in-depth reports to lawmakers upon their request.[184] Only two CRS reports to date mention BMIs, and this merely occurs within broader reports on export controls.[185] While the CRS contains significant technical expertise and access to the resources of the Library of Congress, lawmakers must request reports from the agency.[186] The potential for the CRS to successfully advise Congress on matters of BMI regulation and governance therefore depends on lawmakers' own interests in learning about new neurotechnologies and their policy dimensions as CRS only researches as directed by members of Congress.

Similarly, the National Academies of Sciences, Engineering, and Medicine ("NASEM") represents a quasi-government institution of technical experts from whom Congress or agencies can request reports on emerging

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[181] *See, e.g.*, Tudor & Warner, *supra* note 174 (recounting the defunding of the OTA).
[182] *Technology*, *supra* note 169.
[183] *Id*.
[184] *See About CRS*, U.S. CONG., RES. SERV. (Apr. 16, 2019), https://www.loc.gov/crsinfo/about/ (describing the services offered by CRS to Congress).
[185] *Export Controls: Key Challenges*, U.S. CONG. RES. SERV. (Jan. 14, 2021), https://crsreports.congress.gov/product/pdf/IF/IF11154; *Export Controls: New Challenges*, U.S. CONG. RES. SERV., (Mar. 22, 2019), https://crsreports.congress.gov/product/pdf/IF/IF11154 (listing "brain-computer interfaces," a virtually synonymous term for BMIs, as one of several emerging technologies "essential to U.S. national security").
[186] *About CRS*, *supra* note 184.

issues.[187] While NASEM has some capacity to set its own agenda, producing a report on BMIs and the issues of fragmented regulation may gain the most traction with lawmakers if they themselves prioritized this policy challenge and responded by requesting the report from NASEM.

Attracting the attention of political actors may in turn require public awareness or advocacy about the importance of striking the right balance in BMI regulation. Political science scholar John Kingdon's theory of "policy windows" argues that political interest in any given policy issue waxes and wanes, and meaningful legislative action on an issue often requires an event or significant effort to open a window of opportunity.[188] However, waiting until a notable event such as a regulatory failure or national security concern arises would not provide ideal conditions for resolving the complex fragmented regulatory environment surrounding BMIs.[189] Enacting statutes in the wake of a crisis may present risks such as overreacting to the event or drafting regulation which does not adequately balance the complex interests and issues involved.[190]

In the absence of a scandal or government failure, gaining the attention of political decisionmakers will require other strategies, potentially including building a more general public awareness of the important benefits and risks of BMIs through science communication. The field of science communication aims to provide the public with easily digestible information, consistent with their values, to inform individual decision-making and political stances.[191] Research and policy initiatives on how to propel accessible information on BMIs and how its governance aligns with public values may inspire public support for resolving fragmented regulatory issues early.[192] Efforts at public engagement, which educate lay members of the public about a technical policy issue and then solicit their opinions and

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[187] *About Us*, U.S. NAT'L ACAD. SCI. ENG'G & MED., https://www.nationalacademies.org/about (last visited Oct. 1, 2020) ("many of our activities are requested and funded by Congress and federal agencies").

[188] JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES 166–94 (2d ed. 1995).

[189] *See* Walter G. Johnson & Gary E. Marchant, *Legislating in the Time of a Pandemic: Window of Opportunity or Invitation for Recklessness?*, 7 J.L. & BIOSCIENCES at 1, 2 (2020) (outlining the U.S. regulatory failure in the COVID-19 pandemic over diagnostic testing to show the challenges of enacting regulatory reform during times of crisis).

[190] *Id*.

[191] *See* U.S. NAT'L ACAD. OF SCI. ENG'G & MED., COMMUNICATING SCIENCE EFFECTIVELY: A RESEARCH AGENDA 1, 3, 5–7 (2017) (exploring issues in communicating science effectively).

[192] *Id*.

stances,[193] could assist in both communicating BMI related-issues to the public and in bringing public interest on BMIs to the attention of policymakers in Congress and administrative agencies.[194]

Civil society and interest groups can also play a role in educating the public and in bringing public concerns to lawmakers.[195] Interest groups striving to advance BMI policy, such as patient advocacy organizations, will benefit from calling both lawmakers and regulators' attention to statements from authoritative national or global institutions which have called for policy action on BMIs. Notably, the OECD issued a recommendation to its member states, which includes the Unites States, to take proactive steps toward ensuring that neurotechnologies such as BMIs have appropriate governance.[196] The OECD recommendation and any similar statements may help in legitimizing civil society organizations' calls to lawmakers to address the fragmentation in BMI regulatory governance.[197] Further, while regulatory agencies typically have internal capacity to build expertise on new technologies such as BMIs, they still might choose not to prioritize BMIs or interagency coordination for more comprehensive, effective policy. Especially with the potential coordination challenges the FDA and FTC may face given their overlapping mandates and divergent expertise, action from nonstate actors could help place coordination activities for BMIs on regulatory and legislative agendas. Both civil society organizations and the neurotechnology industry could play a role in advocating for the importance of addressing BMIs as a collective priority to the FDA and FTC.

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[193] See Lisa M. PytlikZillig & Alan J. Tomkins, *Public Engagement for Informing Science and Technology Policy: What Do We Know, What Do We Need to Know, and How Will We Get There?*, 28 REV. PUB. POL'Y RES. 197, 197–201 (2011) (describing how public engagement can be critical for general education and knowledge about impacts of scientific research and technological development).

[194] *Id.*

[195] *Id.*

[196] *See* ORG. FOR ECON. CO-OPERATION & DEV., *supra* note 70, at 6–9 (recommending "Members and non-Members . . . promote and implement . . . principles for responsible innovation in neurotechnology," including by promoting safety in, privacy around, and access to innovation in neurotechnologies).

[197] *See, e.g.*, Kenneth W. Abbott et al., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS J. 279, 290 (2012) (describing how civil society activities have influenced government approaches to other emerging technologies, such as with nanotechnologies); *see also* BRIDGET M. HUTTER & JOAN O'MAHONY, THE ROLE OF CIVIL SOCIETY ORGANIZATIONS IN REGULATING BUSINESS 8, 12 (Ctr. Analysis Risk & Reg. London Sch. Econ. & Pol. Sci. 2006) (discussing the role of civil society organizations as regulators).

CONCLUSION

The realities of technological convergence, and the new risks it can create, challenge the notion that policymakers and regulatory frameworks can treat convergent emerging technologies in isolation.[198] This article anticipates the ways in which combining the power and potential of neuroscience, big data, AI, and engineering to create BMIs can have a multiplicative effect on both social benefits and risks, ultimately compounding the "pacing problem."[199] Furthermore, convergence can create or exacerbate already existing regulatory fragmentation problems by forcing two or more agencies into a novel, shared regulatory space.

The complexities of convergence in BMIs will require a policy response defined by collaboration and early action. Lawmakers and regulators will need to coordinate activities at the FDA and FTC to expedite expertise building by both agencies, prevent the creation of duplicative standards hostile to responsible BMI development, and manage novel risks that neither agency could address alone. Successful coordination will rely not only on favorable political conditions and support from the judiciary, but also on policymaker and public awareness of the importance of neurotechnological governance. Efforts to provide TA to decisionmakers and communicate science and risk to a diverse public will, in turn, bolster Congressional efforts to take early and informed action on coordinated BMI policy. Although fragmented regulatory governance in the United States may initially struggle to manage convergence in BMIs, these strategies offer a first step towards constructing a more robust policy approach to promote responsible development and use of BMIs.

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[198] *See* Park, *supra* note 34, at 1 (describing how regulation of converging technologies can be difficult because "delineating which policy authorizes which government agency to apply which standards to regulate which industry is no longer simple and straightforward."); *see also* MAYNARD, *supra* note 9 (arguing that converging technologies can lead to unanticipated problems and unintended consequences).

[199] *See* MARCHANT, *supra* note 63 (defining "the pacing problem").

Global Health Law & Governance Amidst the Pandemic
Evidence, Lessons, and Reforms

Julien Chaisse and Nilanjan Banik[*]

INTRODUCTION

During the past year, countries across the globe have reacted against the unprecedented circumstances caused by COVID-19 with incredulity and an "all hands on deck" approach.[1] COVID-19 is a special case which has attracted renewed attention to health systems' abilities to tackle an emergency of such magnitude.[2] The virus has also generated growing interest in the capacity of countries internationally to effectively test large groups of a population and successfully enforce lockdowns and quarantines.[3] International media carried sensational headlines warning of the impending disaster that will ensue if any country fails to conduct testing, implement contact tracing, quarantine residents, and treat those who are infected.[4] Amid

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[1] *See* Lawrence O. Gostin et al., *Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically*, 50 HASTINGS CTR. REP. 8, 9 (2020) (describing ways that states could best mobilize by working together); Jean Tirole, *Rebuilding the World After COVID-19*, TOULOUSE SCH. ECON. (Apr. 3, 2020), https://www.tse-fr.eu/rebuilding-world-after-covid-19 (emphasizing the need for solidarity in approaching the global pandemic).

[2] *See* COVID-19, LAW AND HUMAN RIGHTS: ESSEX DIALOGUES 29 (Carla Ferstman & Andrew Fagan eds. Univ. of Essex, 2020) (examining that like other epidemics and pandemics that have occurred, such as Ebola, new precautions in public are needed in order to tackle COVID-19).

[3] Wendy E. Parmet & Michael S. Sinha, *COVID-19: The Law and Limits of Quarantine*, 382 NEW ENG. J. MED., e28(1), e28(3) (2020).

[4] *See e.g.*, Faheem Aslam et al., *Sentiments and Emotions Evoked by News Headlines of Coronavirus Disease (COVID-19) Outbreak*, 7 HUMANS. SOC. SCI. COMMC'N 1, 3–4 (2020);

this media focus, developing and less developed countries were the most likely to receive scrutiny because—even before COVID-19 struck—they lacked the healthcare infrastructure such as number of hospital beds, doctors and paramedic staffs to react to a health emergency.[5]

Although governments are committed to the health of their citizens, capabilities to protect health of citizens and to impact health outcome vary.[6] This ultimately questions the extent governments are responsibility for ensuring a basic "right to health" for their citizens.[7] While every country must confront this question, it is a particularly important consideration for developing countries because their citizens lack health insurance and adequate purchasing power, making them more vulnerable to health hazards.[8] For those countries that have determined citizens have a "right to health," their governments must make available sufficient quantities of functioning public health and healthcare facilities, goods and services, as well as access for all. Healthcare infrastructure, for example, N95 masks, ventilators, etc., are needed to control the spread of pandemics.[9]

Additionally, one must assess the current state of a country's health infrastructure from the perspective of international aid and coordination of public policies worldwide. An audit of public provision of health

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see also COLLEEN M. FLOOD ET AL., VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19 15, (Univ. of Ottawa Press, 2020) (explaining that the pandemic has been used by some countries to seize control); *see also* COVID-19, LAW & HUMAN RIGHTS: ESSEX DIALOGUES, *supra* note 2 (examining the issues with contact tracing).

[5] *See* NORMAN V. LOAYZA & STEVEN PENNINGS, MACROECONOMIC POLICY IN THE TIME OF COVID-19: A PRIMER FOR DEVELOPING COUNTRIES 4 (Mar. 26, 2020) (providing an example where middle and low income countries lack capacity to treat COVID-19 due to lack of resources).

[6] *See generally* WHO, MONITORING THE BUILDING BLOCKS OF HEALTH SYSTEMS: A HANDBOOK OF INDICATORS AND THEIR MEASUREMENT STRATEGIES, vii–viii (2010), (explaining that sacrifice is necessary to protect public health during the pandemic, but governments must ensure that their needs are met).

[7] *See* Gunilla Backman et al., *Health Systems and the Right to Health: An Assessment of 194 Countries*, 372 LANCET 2047, 2047 (2008), (discussing the obligation of governments to protect citizen health as a matter of human rights law).

[8] *See* Abdulrahman M. El-Sayed, *Ineffective Insurance in Lower and Middle Income Countries is an Obstacle to Universal Health Coverage*, 8 J. GLOBE HEALTH 1, 1 (demonstrating that vulnerability is tied to lack of health insurance.); s*ee generally* WORLD ECONOMIC FORUM, COVID-19 RISKS OUTLOOK: A PRELIMINARY MAPPING AND ITS IMPLICATIONS 32 (May 2020) (stating that there is evidence that a sudden halt in the economy effects the poor disproportionately, leaving that population at risk to not being able to stay healthy during the pandemic).

[9] Off. of Disease Prevention & Health Promotion, *Public Health Infrastructure*, HEALTHYPEOPLE.GOV, https://www.healthypeople.gov/2020/topics-objectives/topic/public-health-infrastructure (last visited Jan. 1, 2021) (listing some of the items including, but not limited to, monitoring, diagnosing, and researching).

infrastructure provides a measure for the extent of accessibility to healthcare-related services for their citizenry.[10] For example, during COVID-19 there were an inadequate number of hospital beds in certain countries, which forced many governments to convert stadiums and other athletic centers into makeshift hospitals.[11] In the same vein, some political leaders are suggesting that residents stay that at home to contain the spread of the virus.[12] This is largely a result of their poorly-funded health systems and inadequate healthcare infrastructure that would be overburdened by an outbreak.[13] Despite these extraordinary efforts, many countries are still not able to respond to COVD-19 patients.[14] Accordingly, during COVID-19, countries' health infrastructure capabilities need to be analyzed to determine how more people can be admitted to a hospital.

This article proposes an approach to identifying the deficiencies of health care infrastructure for any given country. We created a health infrastructure index ("HII") which considers the availability of physicians, dentists, nursing and midwifery personnel, pharmacists, hospital beds, number of hospitals, and skilled health care professionals—such as anaesthesiologist, radiologists, etc.—all of which are normalized with respect to the population.[15] Additionally, HII accounts for variables such as money spent on account of healthcare activities by the governments as it affects the supply of health care-related infrastructure and affect the health outcomes. By taking all of

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[10] *See* WHO, *supra* note 6.

[11] Sean Gregory, *The World's Sports Stadiums are Being Converted into Hospitals to Fight the Coronavirus Outbreak*, TIME, (Apr. 1, 2020), https://time.com/5813442/coronavirus-stadiums-hospitals/ (explaining that many countries are dependent on China to accommodate COVID-19).

[12] ANI, *COVID-19 Patients' Contacts can go for Home-Quarantine as Govt Unable to Provide Isolation Facilities to Lakhs: Mamata Banerjee*, NEW INDIAN EXPRESS, (April 27, 2020), https://www.newindianexpress.com/nation/2020/apr/27/covid-19-patients-can-go-for-homequarantine-as-govt-unable-to-provide-isolation-facilities-to-lakhs-2136078.html.

[13] Banyan, *India's Government is Better at Curbing Critics than COVID-19*, ECONOMIST, (May 9, 2020), https://www.economist.com/asia/2020/05/09/indias-government-is-better-at-curbing-critics-than-covid-19; *See also* Anulekha Ray, *Indian Railways Coaches are Now Used for Treating Coronavirus Patients*, MINT (June 23, 2020) https://www.livemint.com/news/india/covid-19-treatment-indian-railways-coaches-are-now-used-for-treating-coronavirus-patients-11592907307991.html.

[14] *See generally* Lalit K. Jha, *Failure to Stop Coronavirus at Source Led to 184 Countries 'Going Through Hell': Trump*, ECONOMIC TIMES (Apr. 29, 2020), https://health.economictimes.indiatimes.com/news/industry/failure-to-stop-coronavirus-at-source-led-to-184-countries-going-through-hell-trump/75441030 (explaining that many countries are upset by Chinas lack of transparency regarding COVID-19).

[15] Normalized with respect to population is done to change the numeric value of different variables in the dataset to a common scale, without distorting the difference in the range of values.

these factors into account, HII is able to demonstrate the vulnerability of a country's health infrastructure.

HII ranking also allows international funding to make targeted health interventions to lower ranking countries.[16] The policy suggestions that we make is that ranking of countries on the basis of HII will help in international coordination of health-related policies and encourage towards participatory development by empowering the non-governmental organizations and other groups working in the healthcare sector. This index showcases the areas where governments, or multilateral organizations, should intervene and how they prioritize such interventions. Beyond national boundaries, international cooperation is required for an effective strategy to fight COVID-19.[17] International funding can be used to augment already precarious healthcare infrastructures that may exist in certain countries, and for the development and distribution of new vaccines.[18] As HII suggests, many countries do not have an adequate number of doctors, nurses, paramedic workers, or other skilled health professionals. To resolve this deficiency, it is important to liberalize (remove restrictions) the services sector and allow movement of skilled healthcare professionals.[19]

Due to greater interactions among humans and animals over the last few decades,[20] there is a greater chance of viral outbreaks (for example, a mutated version of COVID-19). Consequently there is an increased need for accountability, transparency, enforcement, and better surveillance of healthcare infrastructure, worldwide.[21] There are already a variety of legal courses of action available to individuals at the domestic level to challenge

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[16] MCDONNEL ET AL., REVIEW OF THE DEVELOPMENT COOPERATION POLICIES AND PROGRAMMES OF SWITZERLAND 9 (OECD (Dec. 2013) (explaining that domestic policies support or do not harm developing countries with lower life indexes).

[17] Yern Fai Lee & Wenyan Yang, *Recovering from COVID-19: The Importance of Investing in Global Public Goods for Health*, UNITED NATIONS (July 27, 2020), https://www.un.org/development/desa/dspd/2020/07/recovering-from-covid19/ (providing an example on how international cooperation can facilitate access to research COVID-19).

[18] Jon Kim Andrus et al., *Introduction of Human Papillomavirus Vaccines into Developing Countries: International Strategies for Funding and Procurement*, 26 VACCINE, K87, K89 (2008) (exploring how international financing strategies can help develop vaccines).

[19] *See generally* LINDSAY B. LOWELL & ALLAN FINDLAY, DRAFT SYNTHESIS REPORT: MIGRATION OF HIGHLY SKILLED PERSONS FROM DEVELOPING COUNTRIES: IMPACT AND POLICY RESPONSES 17 (Int'l Lab. Off. Dep't for Int'l Dev., UK, 2001) (describing strategies for managing migration of skilled workers from developing countries).

[20] Peter Daszak et al., *Emerging Infectious Diseases of Wildlife: Threats to Biodiversity and Human Health*, 287 SCIENCE 443–44 (2008) (discussing the causal themes between emerging infectious diseases and human population encroachment into animal habitats).

[21] Renaud Seligman, *COVID-19 (Coronavirus) Policy Response to Enhancing Institutions for Effective and Transparent Management*, WORLD BANK (June 5, 2020), https://www.worldbank.org/en/country/russia/brief/covid-19-response-enhancing-institutions-russia.

state responsibility.[22] The lack of response by the global community on the international health obligation will likely lead to complex disputes.[23] Furthermore, countries withdrawing within their borders will not eliminate their international law obligations as such obligations are of paramount importance.[24] The objective of analyzing non-compliance to such obligations is not only justified by the need to design immediate sanctions but also to induce greater international cooperation—which is the only way to mitigate the risk of future pandemics.[25]

Part I of this article analyses the measures undertaken by governments in different countries and private sector responses toward the ongoing international health crisis. Part II discusses the international legal regime surrounding potential international law violation claims before the world court and possible challenges of domestic measures before the trade court and investment tribunals. Part III considers the limitations of conventional indices such as the Human Development Index (HDI) and the Healthcare Access and Quality (HAQ) on account of accessibility of health services and proposes the formation of HII which takes into account the health infrastructure of the countries to ascertain the capacity to combat pandemics like COVID-19. Part IV details conventional and unconventional covariates like income, age profile, tropical climate, dietary habits, associated living conditions, and health policy. As with the case with healthcare infrastructure, these factors may also impact COVID-19 fatality rates. Finally, reporting of such international health emergencies is a pivotal concern, and against this backdrop, Part V explores the international health reporting mechanism envisioned under the World Health Organization (WHO) Constitution.

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[22] *See Lawsuits about State Actions and Policies in Response to the Coronavirus (COVID-19) Pandemic*, BALLOTPEDIA, (last accessed Oct. 28, 2020), https://ballotpedia.org/Lawsuits_about_state_actions_and_policies_in_response_to_the_coronavirus_(COVID-19)_pandemic,_2020 (Listing US lawsuits concerning state actions and policies in response to the coronavirus (COVID-19) pandemic, 2020); *see also* Lara Marlowe, *Coronavirus: Lawsuits Fly in France as Blame Game Begins*, IRISH TIMES (Mar. 26, 2020), https://www.irishtimes.com/news/world/europe/coronavirus-lawsuits-fly-in-france-as-blame-game-begins-1.4213267 (noting six lawsuits filed against the prime minister and current and previous health ministers on charges from unwilful harm to involuntary manslaughter).

[23] *See* discussion *infra* Part II.

[24] *See* David P. Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 CHINESE J. INT'L L. 325, 378 (2005).

[25] *Id*. at 362, 390.

I. THE GOVERNING FRAMEWORK FOR GLOBAL HEALTH SECURITY BEFORE COVID-19

This section first discusses the concept of transnational public policy and analyses the cross-country measures implemented by countries for global health pandemics. Next this section studies the role of the International Health Regulations and epidemic control.[26]

A. Global Health Security & Transnational Governance

As this article centers around the theme of global health law and governance, it is important to clarify the role played by individual nations (which might be the target of investment claims) in light of the WHO laws and recommendations. The goal of these laws and recommendations is to organize countries' responses to the pandemic.[27] Most states, like New Zealand, are using the WHO guidelines, however, other nations have been lagging behind.[28]

The WHO has been a target of criticism by the former United States' President Trump for its delayed response to the COVID-19 outbreak.[29] The criticism stems from the WHO's reliance on statistics reported by China in January 2020.[30] The WHO first received an alert from China on December 31, 2019,[31] reporting several unusual cases of pneumonia in Wuhan, followed by a report of the first human-to-human transmission of the virus on January 21, 2020.[32] However, the WHO did not declare a "public health emergency

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[26] *See generally* Ching-Fu Lin, *COVID-19 and the Institutional Resilience of the IHR (2005): Time for a Dispute Settlement Redesign?*, 13 CONTEMP. ASIA ARBITER. J. 269 (2020).

[27] Hans Henri P. Kluge, *Statement: Novel Coronavirus Outbreak: Preparing Now as One*, WHO (Jan. 25, 2020), https://www.euro.who.int/en/media-centre/sections/statements/2020/statement-novel-coronavirus-outbreak-preparing-now-as-one.

[28] *See* Adam Ferhani & Simon Rushton, *The International Health Regulations, COVID-19, and Bordering Practices: Who Gets in, What Gets out, and Who Gets Rescued?*, 41 CONTEMP. SEC. POL'Y 458, 465–66 (2020) (noting that Taiwan, as an example, has contained its response to Taiwanese citizens, against the advice of the WHO to extend the response beyond borders).

[29] Emma Farge, *WHO Rejects 'China-Centric' Charge After Trump Criticism*, REUTERS (Apr. 8, 2020), https://in.reuters.com/article/health-coronavirus-who-europe/who-rejects-china-centric-charge-after-trump-criticism-idINKBN21Q182.

[30] Jordan Fabian & Lisa Du, *Trump Halts U.S. Payments to WHO, Citing Reliance on China*, BLOOMBERG (Apr. 15, 2020, 5:24 PM), https://www.bloomberg.com/news/articles/2020-04-14/trump-says-he-s-halting-payments-to-who-for-data-sharing-failure.

[31] *Pneumonia of Unknown Cause: China*, WHO (Jan. 5, 2020), https://www.who.int/csr/don/05-january-2020-pneumonia-of-unkown-cause-china/en/.

[32] *Timeline of WHO's Response to COVID-19*, WHO (Sept. 9, 2020), https://www.who.int/news-room/detail/29-06-2020-covidtimeline.

of international concern" ("PHEIC") until January 30, 2020,[33] by which time it was too late to stop the spread of virus as Wuhan and most areas in Hubei province were already under lockdown.[34] Additionally, five million residents of Wuhan were evacuated out of the city to other parts of Mainland China and elsewhere in the world.[35] However, over a billion trips were still made into and out of China as people celebrated the Spring Festival.[36]

Preventive measures might have been implemented globally more rapidly had the WHO declared a PHEIC before China announced its province-wide lockdown.[37] For example, similar measures as the WHO Emergency Committee's travel advisories and trade restrictions that responded to the 2003 SARS epidemic in Hong Kong, would have encouraged countries to implement and follow consistent travel and/or trade restrictions for COVID-19.[38] Additionally, declaring a PHEIC would have sent a cautionary signal to more countries at the initial stage of COVID-19 outbreak, paving the way for collaborative initiatives and plans with other foreign nations, strengthening each countries' response.[39]

New Zealand's Prime Minister, Jacinda Ardern, has provided model strategies and was one of the first few developed countries affected by the

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[33] *Id.*

[34] James Griffiths & Paul Murphy, *Millions are Living in Isolation in Hubei Province*, CNN (Jan. 31, 2020, 1:53 PM), https://edition.cnn.com/asia/live-news/coronavirus-outbreak-01-30-20-intl-hnk/h_634c8fc851ff0ed4d5ed576f8e7dd6ac.

[35] Josephine Ma & Zhuang Pinghui, *5 Million Left Wuhan Before Lockdown, 1,000 New Coronavirus Cases Expected in City*, S. CHINA MORNING POST (Jan. 26, 2020, 10:23 PM), https://www.scmp.com/news/china/society/article/3047720/chinese-premier-li-keqiang-head-coronavirus-crisis-team-outbreak.

[36] *See* Cui Xingyu, *2020 Spring Festival Travel Rush in Numbers*, CHINA GLOBAL TELEVISION NETWORK (Feb. 21, 2020), https://news.cgtn.com/news/2020-02-20/2020-Spring-Festival-travel-rush-in-numbers-OeD3cMHa6Y/index.html (showing travel in and out of China).

[37] Rich Lowly, *Blaming China and WHO Over Coronavirus Isn't Scapegoating*, BOS. HERALD (Apr. 11, 2020), https://www.bostonherald.com/2020/04/11/blaming-china-and-who-over-coronavirus-isnt-scapegoating/ (describing deception by China and lack of independent action by the WHO as worsening the global spread of COVID-19).

[38] *See World Health Organization Issues Emergency Travel Advisory*, WHO (Mar. 15, 2003), https://www.who.int/mediacentre/news/releases/2003/pr23/en (outlining guidelines for travelers and airlines due to the spread of SARS).

[39] *See* Lin, *supra* note 26, at 275 (detailing the effect a declaration of a PHEIC has on State Parties).

virus.[40] After its first confirmed case on February 28, 2020,[41] and reported at total of twenty COVID-19 confirmed cases by March 18, 2020.[42] Just one week after the observed number of cases increased, New Zealand unveiled a four-level alert system to combat the pandemic.[43] Subsequently, the country changed the alert from a level two to a level three and then to a level four in just four days' time.[44] After establishing the level four alert on March 25, 2020, the country immediately declared a state of emergency and implemented a month-long lockdown.[45] The level four alert implemented a mandatory stay-at-home order, closed all non-essential services (excluding essential services like supermarkets, pharmacies and medical clinics), and closed all public areas.[46] Some critics attribute the success of the containment of the pandemic by categorizing the alert level system as a snug propaganda by the government to instill fear and concern amongst citizens and propel them into abiding by the government's order.[47]

New Zealand's process for contact tracing efforts was incredibly effective. Contact tracers start with an "index" person, track everyone exposed to that individual, and then limits future transmission of the virus by isolating the

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[40] Uri Friedman, *New Zealand's Prime Minister May Be the Most Effective Leader on the Planet*, ATLANTIC (Apr. 19, 2020), https://www.theatlantic.com/politics/archive/2020/04/jacinda-ardern-new-zealand-leadership-coronavirus/610237 (detailing policies and approaches taken by the Prime Minister from the onset of the virus outbreak).

[41] *New Zealand Confirms First Case of Coronavirus: Health Ministry*, HEALTHWORLD.COM (Feb. 28, 2020, 12:15 PM), https://health.economictimes.indiatimes.com/news/diagnostics/new-zealand-confirms-first-case-of-coronavirus-health-ministry/74377332.

[42] Media Release, N.Z. Ministry of Health, COVID-19: Eight new cases linked to overseas travel (Mar. 18, 2020) https://www.health.govt.nz/news-media-releases/covid-19-eight-new-cases-linked-overseas-travel.

[43] Derek Cheng, *Coronavirus: PM Jacinda Ardern Outlines NZ's New Alert System, Over-70s Should Stay at Home*, N.Z. HERALD (Mar. 21, 2020 8:45 PM), https://www.nzherald.co.nz/nz/coronavirus-pm-jacinda-ardern-outlines-nzs-new-alert-system-over-70s-should-stay-athome/NKTHAAX6D5JET6DIBEMLDZ2FSU/; New Zealand Government, *History of the COVID-19 Alert System*, UNITE AGAINST COVID-19, https://covid19.govt.nz/alert-system/history-of-the-covid-19-alert-system/#timeline-of-key-events (last visited Jan. 28, 2021).

[44] New Zealand Government, *supra* note 43.

[45] *Id*.

[46] Susan Strongman, *COVID-19 Pandemic Timeline*, RADIO N.Z., https://shorthand.radionz.co.nz/coronavirus-timeline/ (last visited Jan. 28, 2021).

[47] *See* Bryce Edwards, *New Zealand's Covid-19 Strategy Looks Successful, But We Must Safeguard Democracy*, GUARDIAN (Apr. 15, 2020), https://www.theguardian.com/commentisfree/2020/apr/16/new-zealands-fight-against-covid-19-looks-successful-but-democracy-is-under-threat (discussing New Zealand's response to COVID-19 as exacerbating undemocratic principles); *see generally* Michael G. Baker et al., *New Zealand's Elimination Strategy for the COVID-19 Pandemic and What is Required to Make it Work*, 133 N.Z. MED. J., 10, 10–12 (2020) (discussing benefits and risks of New Zealand's 4-tier system).

contacts.[48] This strategy, when used with public health measures, had a ninety percent efficacy rate in containing COVID-19 at the population level which is a success in comparison to the previous contact tracing methods.[49] New Zealand supplemented contacted tracing by introducing "FluTracking," an online surveillance system designed to monitor community spread of the virus by allowing all citizens to fill out a short weekly survey reporting any presence of typical flu-like symptoms and face-to-face interactions with others in the community.[50]

In comparison, Italy's response to the pandemic, led by Former prime minister, Matteo Renzi, also offers valuable lessons on inadequate responses.[51] Italy was described as the "guinea pig" of Europe in combatting COVID-19 because it was the first country in Europe to be affected by COVID-19.[52] Italian authorities were uncertain regarding the proper protocols for testing after the first two cases were discovered on January 31, 2020,[53] despite Italy being the first country in Europe to cut all transportation from China and declare a state of emergency.[54] Some critics of the response attributed Italy's high infection and fatality rates to the large elderly population, population density, and its citizens' close interaction level which results from Italian culture.[55]

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[48] *Interim Guidance: Contact Tracing in the Context of COVID-19*, WHO (May 10, 2020) https://apps.who.int/iris/bitstream/handle/10665/332049/WHO-2019-nCoV-Contact_Tracing-2020.1-eng.pdf?sequence=1&isAllowed=y.

[49] AYESHA VERRALL, RAPID AUDIT OF CONTACT TRACING FOR COVID-19 IN NEW ZEALAND 4 (New Zealand Ministry Health, May 2020), https://www.health.govt.nz/system/files/documents/publications/contact_tracing_report_verrall.pdf.

[50] AMANDA KVALSVIG ET AL., *SUPPORTING THE COVID-19 PANDEMIC RESPONSE: SURVEILLANCE AND OUTBREAK ANALYTICS* 22 (MINISTRY HEALTH 2020), https://www.health.govt.nz/system/files/documents/publications/report_for_moh_covid-19_surveillance_outbreak_analytics_final.pdf.

[51] Julien Chaisse, *Both Possible and Improbable: Could COVID-19 Measures Give Rise to Investor-State Disputes?*, 13 CONTEMP. ASIA ARB. J. 99, 108 (2020).

[52] *Id.*

[53] *Italy's Coronavirus Epidemic Began in January, Study Shows*, REUTERS (Apr. 24, 2020, 9:38 AM) https://www.reuters.com/article/us-health-coronavirus-italy-study/italys-coronavirus-epidemic-began-in-january-study-shows-idUSKCN2262B1; *see e.g.* Jason Horowitz, *Italy, Mired in Politics Over Virus, Asks How Much Testing is Too Much*, N.Y. TIMES (updated Mar. 2, 2020), https://www.nytimes.com/2020/02/27/world/europe/italy-coronavirus.html (discussing how Italian officials were uncertain of the correct response).

[54] Dave Keating, *Italy Banned Flights from China Before America: It Didn't Work*, FORBES (Mar. 12, 2020), https://www.forbes.com/sites/davekeating/2020/03/12/italy-banned-flights-from-china-before-americait-didnt-work/-499725d7481b.

[55] *See generally* Marina Goumenou et al., *COVID-19 in Northern Italy: An Integrative Overview of Factors Possibly Influencing the Sharp Increase of the Outbreak (Review)*, 22 MOLECULAR MED. REP. 20 (2020).

The Italian leadership made several mistakes that are apparent when compared New Zealand's responses.[56] Even with a timely declaration of a state emergency made January 31, 2020,[57] the Italian government failed to convey the urgency to its populace.[58] Conversely, the New Zealand alert level system introduced by New Zealand, which was criticized as propaganda that instilled fear and concern amongst citizens and propelled them into abiding by the government's order.[59] Even in late February, Italian officials were actively downplaying the seriousness of the virus by publicly shaking hands with supporters to reassure citizens that panic was unnecessary and that it was imprudent to halt economic activities.[60] Building onto that, the Italian government ordered decrees laying down practices to be undertaken by the citizens which further increased the pre-existing restrictions within red zones of the lockdown areas.[61] Over time, these restrictions were expanded and finally culminated in a country-wide lockdown.[62] Additionally, Italy has inconsistent regional responses as evidenced by the slower approach in testing taken by Italy's Lombardy's regional government that resulted in a heavy burden on the hospitals.[63] Conversely, Veneto, a neighboring region, focused on a more proactive testing tactic.[64] This tactic covered symptomatic

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[56] Jason Horowitz et al., *Italy, Pandemic's New Epicenter, Has Lessons for the World*, N.Y. TIMES (Mar. 21, 2020), https://www.nytimes.com/2020/03/21/world/europe/italy-coronavirus-center-lessons.html.
[57] *Italy Declares State of Emergency Over Coronavirus*, FRANCE 24 (Jan. 31, 2020), https://www.france24.com/en/20200131-italy-declares-state-of-emergency-over-coronavirus.
[58] Jason Horowitz, *Italy Announces Restrictions Over Entire Country in Attempt to Halt Coronavirus*, N.Y. TIMES (Mar. 9, 2020), https://www.nytimes.com/2020/03/09/world/europe/italy-lockdown-coronavirus.html (reporting how former Italian prime minister criticized the current government's failure in communicating the importance of the restrictions).
[59] Glen Johnson, *How New Zealand's Media Endangered Public Health*, ALJAZEERA (July 8, 2020), https://www.aljazeera.com/opinions/2020/7/8/how-new-zealands-media-endangered-public-health.
[60] Gary P. Pisano et al., *Lessons from Italy's Response to Coronavirus,* HAR. BUS. REV. (Mar. 27, 2020), https://hbr.org/2020/03/lessons-from-italys-response-to-coronavirus.
[61] *Coronavirus: Italy Extends 'Red Zones' as Infections Soar*, BBC (Dec. 13, 2020), https://www.bbc.com/news/world-europe-54937699.
[62] Michele Bertelli, *Italy Quarantines 16 Million People Over Coronavirus Fears*, ALJAZEERA (July 27, 2020), https://www.aljazeera.com/news/2020/03/italy-quarantines-quarter-population-fight-coronavirus-200308071832617.html.
[63] *Id.*
[64] *Id.*

and asymptomatic patients early on, ordered self-quarantine to any individual residing in proximity to patients, and engaged in home diagnosis and care.[65]

In preparation for a foreseeable COVID-19 outbreak in Taiwan, the Central Epidemic Command Center ("CECC") was set up on January 20, 2020.[66] At this point, Taiwan had prepared an intensive inspection and quarantine strategy to be enforced by border control in response to frequent cross-strait travels during the Lunar New Year holiday.[67] Additionally, Taiwan was prepared with an ample stock of surgical masks and N95 masks that was sufficient for its population.[68]Furthermore, Taiwan implemented a ban on mask exports.[69] Taiwan also adopted an alert level system like New Zealand's, enforcing a mandatory surveillance for both individuals in close proximity to patients and those who travelled to Hubei province through a mobile phone app.[70] Beginning in early February 2020, Taiwan implemented tentative guidelines citizens and owners of local businesses about maintaining operations.[71] Taiwan further proactively researched more efficient testing methods and imposed stricter border control and restrictions upon travelers.[72] On the technological front, in March 2020, Taiwan developed a successful data model computed from mobile phone tracking data.[73] As such, a "protean network of databases was initiated by the

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[65] Alaae Sbai, *Two COVID-19 Testing Strategies for Two Italian Regions: A History of Success and Failure*, INFOMINEO.COM (May 22, 2020), https://infomineo.com/covid-two-regions-history-success-failure/.

[66] Press Release, Ministry of Health & Welfare, Taiwan Established a Level 3 "Central Epidemic Command Center for Severe Pneumonia with Novel Pathogens*"* (updated June 2, 2020), https://covid19.mohw.gov.tw/en/cp-4868-53714-206.html.

[67] *See Timeline: COVID-19 in Taiwan*, FOCUS TAIWAN (Apr. 18, 2020), https://focus taiwan.tw/society/202004185001 (discussing entry restrictions).

[68] *Id.*

[69] *Taiwan Ups Chinese Visitor Curbs, to Stop Mask Exports*, REUTERS (Jan. 27, 2020, 6:43 AM), https://www.reuters.com/article/us-china-health-taiwan/taiwan-ups-chinese-visitor-curbs-to-stop-mask-exports-idUSKBN1ZQ1C6.

[70] *Taiwan to Electronically Monitor Potential Coronavirus Patients*, TAIWAN NEWS (Jan. 29, 2020), https://www.taiwannews.com.tw/en/news/3866302.

[71] Cho-Hung Chiang et al., *Maintaining Mask Stockpiles in the COVID-19 Pandemic: Taiwan as a Learning Model*, INFECTION CONTROL & HOSP. EPIDEMIOLOGY 1, 2 (2020).

[72] *See generally* Sheng-Chia Chung et al., A Rapid Systematic Review and Case Study on Test, Contact Tracing, Testing, and Isolation Policies for Covid-19 Prevention and Control, (June 17, 2020), (awaiting peer reviewed, MEDRXIV), https://www.medrxiv.org/content/10.1101/2020.06.04.20122614v2.full; Benjamin J. Cowling & Wey Wen Lim, *They've Contained the Coronavirus. Here's How*, N.Y. TIMES: OPINION (Mar. 13, 2020), https://www.nytimes.com/2020/03/13/opinion/coronavirus-best-response.html.

[73] Heather Yourex-West, *Taiwan Used Cellphone Tracking, Big Data to Contain Spread of COVID-19 - Should Canada Do The Same?*, GLOBAL NEWS (Mar. 6, 2020), https://global news.ca/news/6642722/taiwan-cellphone-tracking-data-contain-covid-19/.

government,[74] however, all response (from mask distribution to residence of confirmed cases) flowed bottom-up and top-down. This approached operated like an "online town hall" where online tool developers and citizens collaborated with the government to discover issues and develop solutions in response to the rapidly changing dynamic of the pandemic.[75]

B. The Private Sector Responses to the COVID-19

The transnational analysis requires an understanding of the private sector's role as it, in addition to governments and international organizations, plays an important role in the governance of the COVID-19 crisis.

In the United States, the demand for disposable N95 respirators skyrocketed.[76] To address this rapidly growing demand, some private companies increased their production of such products, shifting to manufacturing masks or donating them.[77] Namely, in March 2020, Honeywell hired 500 new employees to ramp up the production for N95s in the United States and other parts of the world.[78] It is also been reported that many companies helped by providing necessary materials, for example clothing manufacturer, Hanes Brands Inc., shifted its focus to cotton masks approved for the public to wear as a protective measure.[79] Apple has reported donating millions of masks.[80] To cater to the demand of local hospitals, small

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[74] Julien Chaisse, *Both Possible and Improbable—Could COVID-19 Measures Give Rise to Investor-State Disputes?*, 13 CONTEMP. ASIA ARB. J. 99, 109 (2020); Andreas Kluth, *If We Must Build a Surveillance State, Let's Do It Properly*, BLOOMBERG (Apr. 22, 2020), https://www.bloomberg.com/opinion/articles/2020-04-22/taiwan-offers-the-best-model-for-coronavirus-data-tracking.

[75] *Id.*

[76] Neil Vigdor, *Home Depot Halts Sale of N95 Masks Amid Shortage, Company Says*, N. Y. TIMES (July 27, 2020), https://www.nytimes.com/2020/04/01/business/n95-face-masks-home-depot-virus.html.

[77] Lena H. Sun & Rachel Siegel, *As Demand Spikes for Medical Equipment, Texas Manufacturer is Caught up in Coronavirus's Supply Chain Panic*, WASH. POST (July 26, 2020), https://www.washingtonpost.com/business/2020/02/15/coronavirus-mask-shortage-texas-manufacturing/.

[78] Press Release, Honeywell, Honeywell further expands N95 Face Mask Production by Adding Manufacturing Capabilities in Phoenix (Mar. 30, 2020), https://www.honeywell.com/en-us/newsroom/pressreleases/2020/03/honeywell-further-expands-n95-face-mask-production-by-adding-manufacturing-capabilities-in-phoenix.

[79] Daniel Finnegan, *HanesBrands to Produce Masks to Help Combat Shortage*, TRIAD BUS. J. (Mar. 22, 2020), https://www.bizjournals.com/triad/news/2020/03/22/hanesbrands-to-produce-masks-to-help-combat.html.

[80] Rachel Sandler, *Tim Cook says Apple is Sourcing 10 Million Masks From its Supply Chain*, FORBES (Mar. 25, 2020), https://www.forbes.com/sites/rachelsandler/2020/03/25/tim-cook-says-apple-is-sourcing-10-million-masks-from-its-supply-chain/#367b15191c15.

regional companies were dedicating their efforts to produce cotton masks.[81] For example, AST Sportswear in Orange County, California and MyPillow in Minnesota were some of the notable mask producers.[82] Furthermore, some automobile and electronics manufacturers are producing ventilators in their factories.[83] Additionally, Amazon has pledged to provide $5 million of aid to local businesses near its Seattle, Washington headquarters which are likely to suffer losses due to Amazon's work from home policy.[84] Tech giants like Microsoft and Amazon have created a COVID-19 response fund to support Washington State, which has been badly hit by the virus.[85] In addition to these, big businesses like "Alaska Airlines and the Starbucks Foundation have donated $2.5 million."[86] Whereas, Facebook and Apple have announced donations of $20 million and $15 million, respectively.[87]

Meanwhile, in other parts of the world, like in Britain, "aerospace multinational Airbus has led the Ventilator Challenge UK Consortium."[88] This was a "unified national effort" that seems to have brought "rival manufacturers from a range of industries" together in an attempt to "increase

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[81] *See* Rachel Abrams et al., *Governments and Companies Race to Make Masks Vital to Virus Fight*, N.Y. TIMES (updated Apr. 3, 2020), https://www.nytimes.com/2020/03/21/business/coronavirus-masks-hanes-trump.html (discussing the efforts being made by companies to shift production to help with mask shortages).

[82] Mark Reilly, *They Made Pillows. Cubicles, Gin and Kayaks. Now They're All Making COVID-19 Gear*, MINNEAPOLIS / ST. PAUL BUS. J. (Mar. 30, 2020), https://www.bizjournals.com/twincities/news/2020/03/30/they-made-pillows-and-cubicles-and-gin-and-kayaks.html; Mindy Schauer, *Brea Apparel Maker Donates Thousands of Masks in Drive-Through Giveaway*, ORANGE CTY. REG. (Apr. 18, 2020, 8:27 PM) https://www.ocregister.com/2020/04/18/brea-apparel-maker-donates-30000-face-masks-in-drive-through-giveaway/.

[83] *See* Kristin Korosec, *Tesla CEO Elon Musk: New York Gigafactory Will Reopen for Ventilator Production*, TECH CRUNCH (Mar. 25, 2020), https://techcrunch.com/2020/03/25/tesla-ceo-elon-musk-new-york-gigafactory-will-reopen-for-ventilator-production/ ("Stating that Tesla is one of several automakers, including GM, Ford and FCA that has pledged support to either donate supplies or offer resources to make more ventilators. Earlier this week, Ford said it is working with GE Healthcare to expand production capacity of ventilators.").

[84] Sean Fleming, *How Big Business is Joining the Fight Against COVID-19*, WORLD ECON. FORUM (Mar. 23, 2020), https://www.weforum.org/agenda/2020/03/big-business-joining-fight-against-coronavirus/.

[85] Sibahle Malinga, *Tech Giants Pledge Billions to Help Fight COVID-19*, ITWEB (Apr. 9, 2020), https://www.itweb.co.za/content/JBwEr7nBJoV76Db2.

[86] Fleming, *supra* note 84.

[87] David Hessekiel, *Companies Taking First Steps to Support COVID-19 Response Efforts*, FORBES (Mar. 11, 2020, 2:37 PM), https://www.forbes.com/sites/davidhessekiel/2020/03/11/companies-taking-first-steps-to-support-covid-19-response-efforts/#17ba64fc6f8f.

[88] Dan Robinson, *The Companies Repurposing Manufacturing to Make Key Medical Kit During Covid-19 Pandemic*, NS MED. DEVICES (Apr. 1, 2020), https://www.nsmedicaldevices.com/analysis/companies-ventilators-shortage-coronavirus/.

the number of ventilators ... from 8,175 to 30,000 within weeks."[89]A significant number of companies (such as Formula 1 team McLaren, Siemens AG, Rolls-Royce Motor Cars, GKN and Meggit, BAE Systems PLC, and Ford) have come forward to provide facilities to efficiently construct more "machines based on proven designs already used by medical device manufacturers Smiths Medical and Penlon."[90]

The AMG-Mercedes department of automotive giant Daimler-Benz strived for a target to construct about 10,000 continuous positive airway pressure machines.[91] These machines are key in facilitating the oxygen required by patients before ventilators may be needed.[92] The Daimler-Benz company has been working alongside academics and mechanical engineers at University College London and clinicians "at University College London Hospitals NHS Foundation Trust" to accomplish the process of reverse engineering (a procedure to adapt a pre-existing breathing aid for mass production).[93] To produce the first device, which was used by NHS, less than 100 hours (from the time of initial meeting) was required.[94] According to a statement given by Mercedes, in Italy, about half of the patients who were given continuous positive airway pressure machines have not required invasive mechanical ventilation.[95] It is highly problematic to observe that these continuous positive airway pressure machines have been in relatively low supply in British hospitals since the COVID-19 wave hit the UK.[96]

Ineos, the chemical giant and technically Britain's biggest company (by sales), has set up plans to start a new plant on the outskirts of Middlesbrough.[97] This plant is said to be capable of making a million bottles of hand sanitizer per month.[98] A similar strategy has been employed in Germany which established another factory for manufacturing hand

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[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id*.
[93] Fergus Walsh, *Coronavirus: Mercedes F1 to Make Breathing Aid*, BBC NEWS (Mar. 30, 2020), https://www.bbc.com/news/health-52087002.
[94] *UCL Ventura Breathing Aids for COVID-19 Patients*, UCL INST. HEALTHCARE ENG'G (July 28, 2020), https://www.ucl.ac.uk/healthcare-engineering/covid-19/ucl-ventura-breathing-aids-covid-19-patients.
[95] *Mercedes F1 Team Helps Create Breathing Aid to Keep Coronavirus Patients out of Intensive Care*, TELEGRAPH (Mar. 30, 2020, 8:21 AM), https://www.telegraph.co.uk/news/2020/03/30/mercedes-f1-team-helps-create-breathing-aid-keep-coronavirus/.
[96] *Id.*
[97] Rory Sullivan, *Coronavirus: Hand Sanitiser Plant Capable of Producing One Million Bottles a Month to Be Built in UK*, INDEPENDENT (Mar. 24, 2020, 11:12 AM), https://www.independent.co.uk/news/uk/home-news/coronavirus-ineos-hand-sanitiser-plant-middlesbrough-a9420611.html.
[98] *Id.*

sanitizer.[99] Moreover, Ineos has increased the production of isopropyl and alcohol in its factories in Scotland and Germany to aid with the production of hands sanitizers.[100] BrewDog, a Scottish craft beer brand, unfurled a new sanitizer named Brewgel Punk Sanitizer in March.[101] Brewgel Punk would be limited to giving it for charity purposes and at Aberdeen hospital.[102] Pernod Richards, the French spirits empire behind the famous Jameson Irish Whiskey and Absolut Vodka has initiated the US-based production of hand sanitizer by converting its factories to produce hand sanitizer instead of its usual line of products.[103] In the same vein, rum giant Bacardi, Anheuser-Bush InBev, and several other independent companies have significantly contributed to the effort of increased demand for hand sanitizer.[104] Three factories that are owned by luxury goods French group Moët Hennessy – Louis Vuitton SE (LVMH) that normally produce, among others, Givenchy, Dior, and Guerlain cosmetics and perfumes have also shifted its production to produce hand sanitizers, with priority for French hospitals.[105] Gucci has also pledged to make more than a million masks.[106] The joint CEOs of the Italian luxury brand Prada have offered money to help the construction of much needed intensive care units in Milan.[107] Zara has also come forward in

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[99] *Id.*

[100] Andrea D. Steffen, *Two Hand Sanitizer Factories to be Built in Ten Days by UK Chemicals Giant*, INTELLIGENT LIVING (Mar. 28, 2020), https://www.intelligentliving.co/two-hand-sanitizer-factories-built-ten-days/.

[101] Annette Cameron, *BrewDog Set to Deliver First Batch of Hand Sanitiser to Aberdeen Hospital*, EVENING EXPRESS (Mar. 22, 2020, 1:48 PM), https://www.eveningexpress.co.uk/fp/news/local/brewdog-set-to-deliver-first-batch-of-hand-sanitiser-to-aberdeen-hospital/.

[102] *Id.*

[103] Jessica Snouwaert, *The Maker of Absolut Vodka and Jameson Irish Whisky is Converting its Facilities to Produce Hand Sanitizer that it Will Donate Amid the Shortage*, BUS. INSIDER (Mar. 20, 2020, 12:07 AM), https://www.businessinsider.Nin/retail/news/the-maker-of-absolut-vodka-and-jameson-irish-whisky-is-converting-its-facilities-to-produce-hand-sanitizer-that-it-will-donate-amid-the-shortage/articleshow/74719622.cms.

[104] Chris Furnari, *With Sanitizer in Short Supply, Alcohol Producers Pivot to Battle Coronavirus Pandemic*, FORBES (Mar. 25, 2020, 5:35 PM), https://www.forbes.com/sites/chrisfurnari/2020/03/25/with-sanitizer-in-short-supply-alcohol-producers-pivot-to-battle-coronavirus-pandemic/#7242075f71f2.

[105] Richard Kestenbaum, *LVMH Converting its Perfume Factories to Make Hand Sanitizer*, FORBES (Mar. 15, 2020, 4:13 PM), https://www.forbes.com/sites/richardkestenbaum/2020/03/15/lvmh-converting-its-perfume-factories-to-make-hand-sanitizer/#6a2adcb84a9a.

[106] Ellie V. Bramley, *Prada the Latest Fashion Brand to Make Medical Face Masks*, GUARDIAN (Mar. 24, 2020, 11:00 AM), https://www.theguardian.com/fashion/2020/mar/24/prada-the-latest-fashion-brand-to-make-medical-face-masks.

[107] Giacomo Tognini, *Giorgio Armani and 22 Other Italian Billionaires Donate More than $63 Million to Fight Coronavirus in Italy*, FORBES (Mar. 19, 2020, 4:33 PM), https://www.forbes.com/sites/giacomotognini/2020/03/19/giorgio-armani-and-17-other-italian-billionaires-donate-more-than-28-million-to-fight-coronavirus-in-italy/#68cc755dadc3.

this regard and has aimed to "provide 40,000 surgical masks to hospitals.[108] H&M has pledged to provide protective equipment."[109] While questions have popped up regarding the absence of larger luxury and/or design brands in both US and Britain, smaller brands like Collina Strada, Hanes and LL Bean and many others have shown continuous support and came forward during the pandemic in to offer help in the US.[110]

C. The WHO International Health Regulations

The growing interdependence and the exponential development of international trade and tourism has transformed state isolated health risks into global risks.[111] Although it should be noted, two exceptions to this new rule aggravating risk are quarantine clauses in old trade treaties and the rules of international humanitarian law concerning the protection of the sick and wounded in situations of armed conflict since these are helpful in the present context.[112] Many actors contribute to these risks, including the states themselves, private actors, and international organizations.[113] Additionally, certain instances of action, or a lack thereof, may also contribute to causing global damage such as pandemic like poorly constructed social distancing norms or no social distancing norms at all.[114]

The internationalization of health protection has evolved as nations have been forced to face contemporary health risks together, and as a result, a purely isolated-nation framework is now impossible.[115] As such, there are three aspects of such internationalization which should be highlighted.

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[108] Dan Robinson, *The Companies Repurposing Manufacturing to Make Key Medical Kit During Covid-19 Pandemic*, NS MED. DEVICES (Apr. 1, 2020), https://www.nsmedical devices.com/analysis/companies-ventilators-shortage-coronavirus/.
[109] *Id.*
[110] *Id.*
[111] *See* Yipeng Liu et al., *The Challenges and Opportunities of a Global Health Crisis: The Management and Business Implications of COVID-19 from an Asian Perspective*, 19 ASIAN BUS. & MGMT. 277, 280 (2020), (discussing the interconnected nature of businesses in the modern world).
[112] *See* Geneva Convention Relative to the Treatment of Prisoners of War Art. 1, Aug. 12, 1949, 6 U.S.T. 3316, 75 U.N.T.S. 135.
[113] Joshua Busby, *What International Relations Tells Us About COVID-19*, E-INT'L REL. (2020), https://www.e-ir.info/2020/04/26/what-international-relations-tells-us-about-covid-19/.
[114] Timothy Bella, *Places Without Social Distancing Have 35 Times More Potential Coronavirus Spread, Study Finds*, WASH. POST (May 15, 2020 6:21 AM), https://www. washingtonpost.com/nation/2020/05/15/social-distancing-study-coronavirus-spread/.
[115] David P. Fidler, *The Globalization of Public Health: Emerging Infectious Diseases and International Relations*, 5 IND. J.L. STUD. 1, 11 (1997).

First, the revised WHO International Health Regulations in 2005 set out a series of obligations relating to health protection in response to a "health emergency of international concern."[116] The scope of these preventive obligations shows that there is a significant convergence in the declaration of a health emergency and infectious diseases. The preventive obligations rely on specific criterions including: the sharing of information in a prompt and transparent manner, the exchange of epidemiological data, the sharing of research advances, and the strengthening of national health systems.[117]

Second, the "no harm rule" developed through customary international obligations, aims to protect states from being harmed.[118] When a nation becomes aware of a risk, it has a duty to prevent by responding with due diligence and it must reasonably deploy all available resources so as to forestall the nation's acknowledgement.[119] The concept of due diligence is not limited to general obligations, but also distinct obligations, such as early caution and the sharing of information with other nations.[120]

Third, various human rights protection treaties, case law of treaty bodies, and frequent introduction into national constitutions speak to the evolving obligations pertaining to an individual's right to health.[121] Specifically, the U.N. Committee on Economic, Social and Cultural Rights (CESCR) details an individual's right to health in its general comment No. 14,[122] the International Covenant on Economic, Social and Cultural Rights (ICESCR) (to which 171 States, including China since 2001, are parties).[123] Under such obligations, one can emphasize the duty of informing the nations and persons concerned of the existence of health risks as soon as they are made

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[116] Ferhani & Rushton, *supra* note 28, at 467.
[117] David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J. L. MED. & ETHICS 85, 90–91, 93 (2006).
[118] Marte Jervan, *The Prohibition of Transboundary Environmental Harm. An Analysis of the Contribution of the International Court of Justice to the Development of the No-Harm Rule*, UNIV. OSLO 1, 5 (2014).
[119] Lucas Bastin, *State Responsibility for Omissions: Establishing a Breach of the Full Protection and Security Obligation by Omissions* 19–20 (2017) (unpublished Ph.D. thesis, Magdalen College) (on file with the University of Oxford).
[120] *Id*.
[121] *See generally The Right to Health*, WHO Fact Sheet No. 31, https://www.ohchr.org/documents/publications/factsheet31.pdf.
[122] Comm. on the Highest Attainable Standard of Health, Office of the High Commissioner for Human Rights, (Art. 12), U.N. Doc. E/C.12/2000/4 (2000).
[123] *UN Treaty Collection, Chapter IV, Human Rights*, (2020) International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 999 U.N.T.S. 3.

aware.[124]Instrumentally, such duty also includes developing an adequate health system capable of combating the exigencies.[125]

China's failure to caution the WHO and foreign nations is a blatant example of failing to apply International Health Regulations and Epidemic Control to the COVID-19 crisis.[126] The first COVID-19 case was identified in November 2019.[127] Several doctors in Wuhan voiced concerns by the end of December, but some of these were neglected and some were arrested for sharing this information.[128] This censorship led to the delayed recognition of the existence of the pandemic, which was not officially recognized by the WHO until March 12, 2020.[129] Consequently, China has yet to effectively fulfill its duties and obligations under international legislation.[130]

II. INSTABILITY AT THE GATE: COVID-19 IMPLICATIONS FOR DISPUTE RESOLUTION

The manifest lack of countries cooperation in addressing the pandemic raises serious issues under international law in terms of the responsibility of each of them in contributing to the spread of a virus that is not just killing thousands of citizens but is also causing considerable damages to economies. The question of international responsibility is especially important as a number of countries did not comply with international rules (whether health standard, trade rules, human rights norms, etc.).

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[124] Comm. on the Highest Attainable Standard of Health, *supra* note 122, at 4.
[125] *Id.* at 6.
[126] *Statement on the First Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV*), WHO (2020), https://www.who.int/news-room/detail/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).
[127] *First COVID-19 Case Can Be Traced Back to November 17 in China's Hubei Province: Report*, ECON. TIMES (Mar. 13, 2020), https://economictimes.indiatimes.com/news/international/world-news/first-covid-19-case-can-be-traced-back-to-november-2017-in-chinas-hubei-province-report/articleshow/74608199.cms?from=mdr.
[128] Gerry Shih & Hannah Knowles, *A Chinese Doctor Was One of the First to Warn About Coronavirus. He got Detained and Infected*, WASH. POST (Feb. 4, 2020), https://www.washingtonpost.com/world/2020/02/04/chinese-doctor-has-coronavirus/.
[129] *See* Dawn Kopecki et al., *World Health Organization Declares the Coronavirus Outbreak a Global Pandemic*, CNBC (Mar. 11, 2020), https://www.cnbc.com/2020/03/11/who-declares-the-coronavirus-outbreak-a-global-pandemic.html (stating that miscommunication between governments and their citizens created confusion in the wake of the epidemic).
[130] Steven Lee Myers, *China Created a Fail-Safe System to Track Contagions. It Failed*, N.Y. TIMES (Apr. 17, 2020), https://www.nytimes.com/2020/03/29/world/asia/coronavirus-china.html (discussing China's internal failings amid the outbreak).

In fact, multiple measures sanctioned by the governments worldwide have already raised concerns in the context of an erupting a wave of foreign investment claims. For example, in April 2020, threatened by an investment claim, the elected Congress of Peru adopted a law suspending the collection of toll fees on major highways as a measure to mitigate the ramifications caused by COVID-19 throughout the country.[131] Legal discussions by scholars to review the circumstances are necessary, as not all measures were successful, taken at the same time and/or with the same reliance on scientific evidence.[132] The time delay will lead to further complications with the assessment of investors' operations (and possibly bankruptcies).[133] Axiomatically, the pandemic cannot act as a façade for all recent laws and rules enacted in several countries.[134] Given the global reach of the pandemic, it is conceivable that the crisis led multiple governments to embrace such contentious measures; however, such multiplicity of actions to address the health crisis will inevitably usher a host of complex issues, peculiarly in the arena of investment treaties.[135]

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[131] Cosmo Sanderson, *Peru Warned of Potential ICSID Claims over Covid-19 Measures*, GLOB. ARB. REV. (Apr. 9, 2020), https://globalarbitrationreview.com/article/1225319/peru-warned-of-potential-icsid-claims-over-covid-19-measures.

[132] *See, e.g.*, German Lopez, *America's Coronavirus Testing Failure has Forced Us to Rely More on Painful Social Distancing*, VOX (Mar. 20, 2020), https://www.vox.com/policy-and-politics/2020/3/20/21183696/coronavirus-social-distancing-testing-covid-19-trump (describing failures to implement social distancing measures); Kyle Ferrier, *South Korea Ramps-up Exports of COVID-19 Testing Kits*, DIPLOMAT (Apr. 9, 2020), https://the diplomat.com/2020/04/south-korea-ramps-up-exports-of-covid-19-testing-kits/ (describing how South Korea's mass testing helped keep its outbreak under control); *but see, Lockdowns, Immunity, 'Test, Test, Test': Searching for the Right Virus Strategy*, FRANCE 24 (Apr. 23, 2020, 6:30 PM), https://www.france24.com/en/20200423-lockdowns-immunity-test-test-test-searching-for-the-right-virus-strategy (listing COVID-19 safety measures that countries around the world have enacted with varying success).

[133] *See generally*, CTR. FOR ECON. POL'Y RES., ECON. IN THE TIME OF COVID-19 39 (Richard Baldwin & Beatrice Weder di Mauro eds., 2020), https://voxeu.org/content/economics-time-covid-19.

[134] Pavol Blahusiak & Boris Brhlovic, *Legislative Changes in View of the Covid-19 Pandemic (In Some Countries There are Changes to Insolvency Law, Tenancy Law, Law on Consumer Contracts and Corporate Law)*, LEGALINK (Apr. 4, 2020), https://www.legal ink.ch/covid-19/europe/legislative-changes-in-view-of-the-covid-19-pandemic-in-some-countries-there-are-changes-to/1595/.

[135] *COVID-19 and Investment Treaties: Balancing the Protection of Public Health and Economic Interests*, JONESDAY: INSIGHTS (May 2020), https://www.jonesday.com/en/ insights/2020/05/covid19-and-investment-treaties.

A. State Responsibility and COVID-19: The Role of Public International Law

Several scholars have argued that China's actions while combating COVID-19 are in violation of the IHR.[136] In light of these allegations, China was believed to have breached its obligations under Article 6 and 7 of IHR.[137]

For any party attempting to sue China for its conduct, the major challenge is identifying the jurisdictional basis for such action.[138] Article 56 of the IHR provides for such a mechanism, however, by asking parties to identify the jurisdictional basis the form of arbitration, which under any event, can only be executed upon China's consent, which inherently is very unlikely.[139] Another basis to continue with such a claim is through Article 75 of the WHO Constitution, which provides that "any question or dispute concerning the interpretation or application of this Constitution which is not settled by negotiation or by the Health Assembly shall be referred to the International Court of Justice …".[140] In a nutshell, either Article 56 of the IHR or Article 75 of the WHO Constitution would constitute a solid legal basis to trigger the ICJ's jurisdiction.[141]

Furthermore, another basis could be breach of Article 63, which provides: "Each Member shall communicate promptly to the Organization important laws, regulations, official reports and statistics pertaining to health which have been published in the State concerned."[142] China was alleged to withhold crucial documents such as reports of medical staff infections[143] and data regarding the number of the asymptomatic persons ("classified Chinese government data"), which are important in determining the contagiousness

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[136] David Fidler, *COVID-19 & International Law: Must China Compensate Countries for the Damage?*, JUST SECURITY (Mar. 27, 2020), https://www.justsecurity.org/69394/covid-19-and-international-law-must-china-compensate-countries-for-the-damage-international-health-regulations.

[137] WHO, International Health Regulations (3rd. ed. 2005).

[138] Peter Tzeng, *Taking China to the International Court of Justice over COVID-19*, EJIL: TALK! (Apr. 2, 2020), https://www.ejiltalk.org/taking-china-to-the-international-court-of-justice-over-covid-19.

[139] *Id.*

[140] *Id.*

[141] *See Armed Activities on the Territory of the Congo (New Application: 2002) (Democratic Republic of Congo v. Rwanda)*, INT'L CT. JUST. (May 28, 2002), https://www.icj-cij.org/en/case/126. (In the DR Congo v. Rwanda case, the ICJ found that "[t]he jurisdiction of the Court comprises all cases which the parties refer to it and all matters specially provided for in the Charter of the United Nations or in treaties and conventions in force." In this respect, one can derive that the WHO Constitution is an acceptable legal basis.).

[142] WHO CONSTITUTION, Oct. 2006, Art. 63, 45th ed.

[143] Nick Givas, *WHO Haunted by January Tweet Saying China Found No Human Transmission of Coronavirus*, FOX NEWS (Mar. 18, 2020), https://www.foxnews.com/world/world-health-organization-january-tweet-china-human-transmission-coronavirus.

of COVID-19.[144] Although China was obligated to notify and alert WHO within twenty-four hours of such assessment,[145] the WHO was alerted by its own office in China and not by the Chinese authorities.[146] Further, the Chinese government has censored various posts on social media by Chinese doctors,[147] which reinforces the allegations of withholding crucial documents. However, whether these documents can fall within the ambit of 'published' sources under Article 63 is still a matter under deliberation.[148]

Finally, a purpose and objective of the WHO Constitution—specifically "the attainment by all peoples of the highest possible level of health"—was defeated by China,[149] despite international law aimed at avoiding this precise outcome.[150]

B. Are COVID-19 Related Domestic Trade Measures WTO-Consistent?

Turkey, Indonesia, Myanmar, Russia, and the Philippines and, in fact, most governments tend to under-report outbreaks to protect their economic and tourist activities; [151] a major reason behind WHO's advice on trade and travel restrictions throughout the pandemic.[152] Therefore, implementation of punitive travel and trade restrictions may hinder the promise of mutual transparency by nations necessary to combat the pandemic.[153]

According to an official WTO report published in April 2020, "80 countries and separate customs territories have introduced export prohibitions or restrictions as a

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[144] Josephine Ma et al., *A Third of Coronavirus Cases May be 'Silent Carriers'*, CHINA MORNING POST (Mar. 22, 2020, 06:00 PM), https://www.scmp.com/news/china/society/article/3076323/third-coronavirus-cases-may-be-silent-carriers-classified.
[145] WHO Guidance for the Use of Annex 2 of the International Health Regulations (2005).
[146] *WHO Says it was Alerted About Virus by its Own Office in China, Not the Government*, DECCAN CHRON. (July 4, 2020, 08:54 AM), https://www.deccanchronicle.com/world/neighbours/040720/who-says-it-was-alerted-about-virus-by-its-own-office-in-china-not-th.html.
[147] Reuters Staff, *China's Online Censors Tighten Grip After Brief Coronavirus Respite*, REUTERS (Feb. 11, 2020, 5:23 AM), https://www.reuters.com/article/uk-china-health-censorship-idUKKBN2051BV?edition-redirect=uk.
[148] Tzeng, *supra* note 138.
[149] WHO Constitution, *supra* note 142, at 187.
[150] Vienna Convention on the Law of Treaties, art. 18, May 23, 1969, 1155 U.N.T.S. 331, 336.
[151] *See Tourism Flows and Death Rates Suggest Covid-19 is Being Under-reported*, ECONOMIST (Mar. 7, 2020), https://www.economist.com/graphic-detail/2020/03/07/tourism-flows-and-death-rates-suggest-covid-19-is-being-under-reported; *see also* Laura Pitel & Funja Guler, *Turkey Admits Publishing Incomplete Coronavirus Tally*, FIN. TIMES (Oct. 1, 2020), https://www.ft.com/content/5307a438-f083-4f7f-a1da-5b0a0eaa6047.
[152] Ruud Koopmans, *A Virus that Knows no Borders?* (WZB Berlin Soc. Sci. Ctr. Discussion Paper No. SP VI 2020-103, 2020) at 4.
[153] Ferhani & Rushton, *supra* note 28, at 458, 460.

result of the COVID-19 pandemic."[154] The COVID-19 pandemic is major challenge to international trade law rules which also means that many lawsuits could be launched at WTO. The General Agreement on Tariffs and Trade (GATT) Article XI:1 generally eliminates quantitative restrictions on trade in goods (including any medical products need to treat the virus), stating "no prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses [sic] or other measures, shall be instituted . . . ."[155]. However, such restriction can also be challenged by a WHO member nation if it fulfils the criterion established.[156]

In spite of the quantitative export restriction imposed by WTO, a broad range of carve-outs have been provided, like export restrictions to address "critical shortages" (GATT Article XI:2(a)), health protection (GATT Article XX(b)), products in "general or local short supply" (GATT Article XX(j)), and certain export restrictions on raw materials to supply a domestic processing industry (GATT Article XX(i)) and national security (GATT Article XXI).[157]

Under European Union ("EU") law, a principle of strict proportionality applies in the sense that for a WTO Member to rely on the carve-out or any of the exceptions, a series of conditions must be met. These conditions range from the type of products covered (foodstuffs or other "essential" products" under Article XI:2(a))[158] and "necessity" (for health measures under Article XX(b))[159] to "equitable" distribution of supplies (under Article XX(j)).[160] Herein, it is pertinent to note that during a pandemic, time is of the essence when discussing legal actions which move at a delayed pace. WTO dispute settlement delays are so significant that filing a standard case to enforce

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[154] Information Note, *Export Prohibitions and Restrictions*, ¶4.3, WTO (Apr. 23, 2020), https://www.wto.org/english/tratop_e/covid19_e/export_prohibitions_report_e.pdf.
[155] General Agreement on Tariffs and Trade, art. XI, July 1, 1986, 101 Stat. 2067, U.N.T.S. 17–18 [hereinafter GATT].
[156] *Id*.
[157] Joost Pauwelyn, Export Restrictions in Times of Pandemic: Options and Limits under International Trade Agreements 6–13 (Apr. 30, 2020) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3579965; *see also* Chaisse J., *Exploring the Confines of International Investment and Domestic Health Protections: General Exceptions Clause as a Forced Perspective*, 39 AM. J.L. & MED. 332, 344–46 (2013) (noting the deviations from key trade principles and from all provisions of the GATT that WTO employs).
[158] GATT, *supra* note 156, at 1.
[159] *Id.*
[160] *Id.* at 263.

WTO limits on export restrictions is hardly an option.[161] Adding to the current hinderances, the WTO's Appellate Body is currently out of service[162] but a sub-group of WTO Members set up an interim appeal arbitration arrangement.[163] If both the parties agree, Article 25 of the Dispute Settlements Understanding ("DSU") can be invoked to envisaged expedited arbitration.[164] Even in the heat of the crisis, one can expect transparency, notifications and consultations.[165]

C. COVID-19 & International Investment Protection: Could Investment Arbitration Play a Role?

The effects of COVID-19 are not only restricted to the health sphere but also extend to the political arena. This is especially difficult for already struggling regimes like Iran—a country which has been exposed to many social and economic crises.[166] For the first time during the COVID crisis, Tehran requested assistance from the International Monetary Fund (IMF).[167] While addressing matters related to Mr. Vladimir Putin, it becomes difficult to evaluate whether the pandemic will guide him towards passing aside from Iran, whether he will further complicate the oil battle against Saudi Arabia and indirectly, the United States or make a reform in the constitution to extend his power in light of the pandemic. In fact, foreign investors, via legal claims, are only escalating pressure under such political environment.

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[161] *See* Joost Pauwelyn & Weiwei Zhang, *Busier than Ever? A Data-Driven Assessment and Forecast of WTO Caseload*, 21 J. INT'L ECON. L. 461, 476 (2018) (discussing the reasons behind the WTO caseload as that of pending past cases); *see also* Joost Pauwelyn, *The Real Rot in the System: Delays are Making WTO Dispute Settlement Irrelevant, Especially During a Pandemic*, IELP BLOG (Mar. 27, 2020), https://ielp.worldtradelaw.net/2020/03/the-real-rot-in-the-system-delays-are-making-wto-dispute-settlement-irrelevant-especially-during-a-p.html.

[162] Joost Pauwelyn, *WTO Dispute Settlement Post 2019: What to Expect?*, 22 J. INT'L ECON. L. 297, 297 (2019).

[163] Multi-Party Interim Appeal, *Statement on a Mechanisms for Developing, Documenting and Sharing Practicing and Procedures in the Conduct of TWO Disputes*, WTO Doc. 20-3358, at 1 (Apr. 30, 2020).

[164] *See* CUTS Int'l, COVID-19 and a Global Call to the WTO Members, Pledge for Trade as a Global Public Good, at 2 (2020) (urging WTO Members to "avoid raising trade disputes at the WTO as under the existing mechanisms").

[165] WTO SECRETARIAT, TRANSPARENCY: WHY IT MATTERS AT TIMES OF CRISIS 1 (Apr. 7, 2020), https://www.wto.org/english/tratop_e/covid19_e/transparency_report_e.pdf.

[166] Amirhossein Takian et al., *COVID-19 Battle During the Toughest Sanctions Against Iran*, 395 LANCET 1035, 1035–36 (2020).

[167] Roland Oliphant, *Iran Requests $5 Billion Emergency Loan from International Monetary Fund to Fight Coronavirus Pandemic*, TELEGRAPH (July 28, 2020), https://www.telegraph.co.uk/news/2020/03/12/iran-request-5-billion-emergency-loan-international-monetary/.

Foreign firms operating in host countries with lockdowns and a wide range of other measures might economically suffer from the situation.[168] Directly or indirectly countries responses will negatively affect the management of many businesses.[169] It is clear that some measures undertaken by states to mitigate the risk of the pandemic might have been more effective than others. This difference can also be inferred by comparing the results of South Korea or Singapore from that of say Italy and Spain.[170] A substantial number of these measure have the potential to negatively affect many businesses and cause harm to companies.[171] Lockdowns and side measures, by definition, restrict business, and for that reason foreign investors may decide to sue host states (see example of Peru).[172] For that reason, those actions can be challenged by foreign investors under relevant investment treaties.[173]

International Investment Tribunals and other tribunals might well once again be entrusted with the role of reviewing States' measures to tackle the COVID-19 pandemic.[174] Among these businesses the foreign investor stands out because they can claim a number of rights under investment treaties.[175]

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[168] Turgut Aycan Özcan et al., *Turkey: Assessment of the State Measures in Response to Covid-19 Outbreak in Terms of International Investment Arbitration*, MONDAQ (Dec. 17, 2020), https://www.mondaq.com/turkey/operational-impacts-and-strategy/1016990/assessment-of-the-state-measures-in-response-to-covid-19-outbreak-in-terms-of-international-investment-arbitration (concluding that Turkey's measures have directly and indirectly caused economic harms to many businesses).

[169] Richard Smith-Bingham & Kavitha Hariharan, *This is the Impact of the Coronavirus on Business*, WORLD ECON. F. (Feb. 21, 2020), https://www.weforum.org/agenda/2020/02/why-is-coronavirus-a-global-business-risk/ (explaining that the impact of COVID-related measures can take different form).

[170] G. Seetharaman, *How Countries are Using Technology to Fight Coronavirus*, ECONOMIC TIMES (Mar. 29, 2020), https://economictimes.indiatimes.com/tech/software/how-countries-are-using-technology-to-fight-coronavirus/articleshow/74867177.cms?from=mdr.

[171] *The Biggest Business Impacts of the Coronavirus Pandemic*, EMARKETER (Mar. 14, 2020), https://www.emarketer.com/content/the-biggest-business-impacts-of-the-coronavirus-pandemic-according-to-business-insider-intelligence.

[172] *See generally***,** Pierina Pighi Bel & Jake Horton, *Coronavirus: What's Happening in Peru?*, BBC NEWS (July 9, 2020), https://www.bbc.com/news/world-latin-america-53150808 (demonstrating that lockdowns and side measures, by definition, restrict business, and for that reason foreign investors may decide to sue host states).

[173] Joshua Paffery et al., *Investor-State Disputes Arising from COVID-19: Balancing Public Health and Corporate Wealth*, LEXOLOGY (Aug. 27, 2020), https://www.lexology.com/library/detail.aspx?g=89234581-29f2-4284-97e5-47a98010b3ca.

[174] Lucas Bento & Jingtian Chen, *Investment Treaty Claims in Pandemic Times: Potential Claims and Defenses*, KLUWER ARB. BLOG (Apr. 8, 2020), http://arbitrationblog.kluwerarbitration.com/2020/04/08/investment-treaty-claims-in-pandemic-times-potential-claims-and-defenses/.

[175] Ozcan, *supra* note 168; *see generally* Xu Qian , *Challenges of Water Governance (and Privatization) in China-Traps, Gaps, and Law*, 47 GA. J. INT'L COMP. L. 49 (2018); *see also*

Indirectly, investment claims will contribute assessing the legality of many countries COVID responses.[176]

Additionally, under the general international law on foreign investment, the sovereign states have the autonomy to decide whether to welcome foreign investors into their economies and to determine their subsequent admission and establishment.[177] The global investment regime has been gradually developed through a myriad of fragmented and bilateral negotiations, as opposed to multilateral negotiations, which is precisely why no multilateral international organization supports the international investment regime.[178] Due to the fact that treaty models prepared by the capital-exporting countries are the genesis for the proceedings of individual negotiations, structures, principles and purposes of the investment treaties are similar.[179]

As a consequence of the current legal environment, many disputes related to COVID-19 measures will be addressed by the states in front of an investment tribunal. In order to resolve investment claims effectively, it is necessary for every International Investment Agreement ("IIA") to have a provision for dispute settlements, arbitration.[180] Investment arbitration is flexible since parties have the option to choose either the International Centre for the Settlement of Investment Disputes ("ICSID") or other arbitration

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XU QIAN,'WATER DISPUTES IN INTERNATIONAL ARBITRATION: RECONSIDERING THE NEXUS OF INVESTMENT PROTECTION, ENVIRONMENT, AND HUMAN RIGHTS' 415 (Kluwer L. Int'l, Int'l Arb. L. Libr. Series Stavros Brekoulakis & Julian D. Lew eds., 2020 (discussing the application of investment treaties to water-related rights).

[176] *COVID-19: Pressure Points: A Balance of Obligations: The Response to the Pandemic and Investment Treaty Protections (Global)*, HERBERT SMITH FREEHILLS (Apr. 8, 2020), https://www.herbertsmithfreehills.com/latest-thinking/covid-19-pressure-points-a-balance-of-obligations-the-response-to-the-pandemic-and.

[177] U.N. Conference on Trade & Development, Admission and Establishment, *a part of* UNCTAD Series on issues in international investment agreements, at 7 (2002), https://unctad.org/system/files/official-document/iteiit10v2_en.pdf.

[178] Guiguo Wang, *International Investment Law: An Appraisal from the Perspective of the New Haven School of International Law*, 18 ASIA PAC. L. REV. 19, 22 (2010); *see also* Julien Chaisse & Can Eken, *The Monetization of Investment Claims: Promises and Pitfalls of Third-Party Funding in Investor-State Arbitration*, 44 DE. J. CORP. L. 463 (2020); *see also* FLAVIA MARISI, ENVIRONMENTAL INTERESTS IN INVESTMENT ARBITRATION: CHALLENGES & DIRECTIONS 252 (2020).

[179] JULIEN CHAISSE, ET AL., ASIA'S CHANGING INTERNATIONAL INVESTMENT REGIME: SUSTAINABILITY, REGIONALIZATION, AND ARBITRATION 5–7 (2017).

[180] Tsai-fang Chen, *Foreword to the Special Issue on "COVID-19 and International Dispute Settlement"*, 13 CONTEMP. ASIA ARB. J. 1, 4 (2020); *see also generally*, A. Reinisch, *The Scope of Investor-State Dispute Settlement in International Investment Agreements*, 21 ASIA PAC. L. REV. 3 (2013).

types, such as ad hoc or institutional arbitration to settle disputes.[181] Rules of the arbitration depend on the choice of the type of arbitration, for example, if parties have chosen to resolve their disputes by ICSID, the parties must follow the applicable rules of the convention.[182] Apart from it, as per Article 25(1)[183] of the ICSID Convention, they are required to give irrevocable consent for the arbitration.[184] Whereas other rules such as UNCITRAL rules or the New York Convention shall be applied if any other type of arbitration is used by the parties to resolve the dispute.[185] However, in IIA most of the arbitration is governed by ICSID, where both the capital exporting countries and host countries have signed the ICSID convention.[186]

Especially, bilateral investment treaties ("BIT") within IIA, which are more within popular between the countries. These BITs have some basic characteristics, which include definition and scope of application, admission of the investment, national treatment, most favored nation, fair and equitable treatment, expropriation and dispute settlement.[187] The details regarding the level of protection afforded to investment, such as national standard of treatment, most-favored-nation treatment, full protection and security, and the so-called umbrella clause, are directly influenced by the "additions"

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[181] Susan D. Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1541 (2005) (discussing that there is a trend to provide options and, thus can be interpreted as flexible).

[182] A SIMPLE GUIDE TO ARBITRATION IN HONG KONG, DEACONS 4 (2014), https://www.deacons.com/assets/Images/News%20and%20Insights/Publication/2014/201405_GuidetoArbitrationInHK_newVI.pdf (explaining that if the arbitration agreement sets out the applicable rules, the arbitrator must follow them).

[183] INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES, ICSID CONVENTION, REGULATIONS AND RULES 18–19 (April 2006).

[184] Jaemin Lee, *The Coronavirus Pandemic and International Investment Arbitration—Application of "Security Exceptions" Clauses in Investment Agreements*, 13 CONTEMP. ASIA ARB. J. 185, 185 (2020); *see also* XU QIAN, WATER DISPUTES IN INTERNATIONAL ARBITRATION: RECONSIDERING THE NEXUS OF INVESTMENT PROTECTION, ENVIRONMENT, AND HUMAN RIGHTS 415 (2020) (discussing the consent in advance that is given by States at the time investment treaties are signed); *see also* Julien Chaisse, *Both Possible and Improbable—Could COVID-19 Measures Give Rise to Investor-State Disputes?*, 13 CONTEMP. ASIA ARB. J. 99, 141 (2020) (mentioning the requirement of irrevocable consent in the ICSID rules).

[185] Stephan Wilske, *The Impact of COVID-19 on International Arbitration: Hiccup or Turning Point?*, 13 CONTEMP. ASIA ARB. J. 7, 17 (2020); *see also* Julien Chaisse & Rahul Donde, *The State of Investor-State Arbitration: A Reality Check of the Issues, Trends, and Directions in Asia-Pacific*, 51 INT'L. L. 47, 51 (2018) (discussing the UNCITRAL rules).

[186] OECD, INTERNATIONAL INVESTMENT LAW: UNDERSTANDING CONCEPTS AND TRACKING INNOVATIONS 8 (2008).

[187] OECD, NOVEL FEATURES IN RECENT OECD BILATERAL INVESTMENT TREATIES 5 (2006).

provisions of IIAs.[188] Clauses referring to the standard of protection accorded in situations of emergency, necessity, armed conflicts, and force majeure; guarantees of access to justice, fair procedure, and protection against denial of justice; and clauses covering the import and repatriation of funds, capital and profits are some common additional clauses.[189]

Exceptions, though not central, are useful accessories of law existing in every aspect. The existence of exceptional circumstances and occurrences inclusive of the pandemic in this ever-evolving global precipice strengthens the need for such exceptions.[190] Sometimes harsh and unfair measures like imposing a heavy penalty for citizens not abiding by the established social distancing norms need to be adopted for the benefit of the masses which may fall under the domain of exceptions. More importantly, however, in practice, exceptions have only been invoked in a limited number of investment disputes as a result of which limited case laws prevail leaving much room for speculations.[191] Even though, under the general conception, most potential breaches of investment treaties could be justified by some of these exceptions, specifically given the sudden emergency caused by COVID-19, some actions of the states have stretched too far even from the context of mitigating the risk of the pandemic, triggering non application of such exceptions.[192]

WHO has imposed a number of duties (e.g. declaration of a health emergency and infectious diseases, sharing of information in a prompt and transparent manner, the exchange of epidemiological data, the sharing of research advances, and the strengthening of national health systems) in order to respond to a "health emergency of international interest".[193]The liability

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[188] Yas Banifatemi, *The Emerging Jurisprudence on the Most Favored Nation Treatment in Investment Arbitration*, *in* INVESTMENT TREATY LAW: CURRENT ISSUES III 241, 247 (Andrea Bjorklund et al. eds., 2009).

[189] OECD, *Fair and Equitable Treatment Standard in International Investment Law* 2 (OECD Working Papers on Int'l. Inv. 2004/03, 2004).

[190] WHO, IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005) 134 (2011).

[191] KATHERINE V.W STONE & ALEXANDER J.S. COLVIN, THE ARBITRATION EPIDEMIC: MANDATORY ARBITRATION DEPRIVES WORKERS AND CONSUMERS OF THEIR RIGHTS 9 (2015).

[192] Alexandre Dayant, *Europe, United in Recovery- For Now*, INTERPRETER (July 29, 2020), https://www.lowyinstitute.org/the-interpreter/europe-united-recovery-now.

[193] WHO, *COVID-19 Public Health Emergency of International Concern (PHEIC) Global Research and Innovation Forum* 1–7 (Feb. 11, 2020), https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum; WHO, *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV*) (Jan. 30, 2020), https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

of the nations under the investment treaties will be affected based on their level of transparency vis-á-vis the pandemic.[194] While reviewing such measures, the tribunal will have to consider international health regulations and epidemic control measures, nations' practices, and limited (or, more precisely, fast-evolving) scientific evidence, in addition to the parties' arguments.[195] The breaches of IIAs are probable and this article highlights that nations will however be able to defend themselves using a wide range of exceptions.[196] In the, specific context of a health crisis of the magnitude of COVID-19, exceptions invoked by countries might be able to cover a wide range of problematic measures. However, a number of potential innovations have already emerged, which suggest that tribunals could further define the scope and regime of applications of many exceptions.[197] Additionally, policymakers are encouraged to articulate better connections between IIAs and WHO regulations.[198]

III. BENCHMARKING HEALTH SYSTEMS PERFORMANCES

In the words of Professor Amartya Sen, development is synonymous with freedom.[199] Freedom from poverty, illiteracy, infant mortality, and freedom to participate in political processes are all good things and characterizes any developed society.[200] Health is an important component of development.[201] Countries investing in health are likely to have a stronger and more productive workforce, and hence grow faster than countries with a less healthy workforce.[202] Citizens living in developed nations live almost

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[194] Federica Paddeu & Kate Parlett, *COVID-19 and Investment Treaty Claims*, KLUWER ARB. BLOG (Mar. 30, 2020), http://arbitrationblog.kluwerarbitration.com/ 2020/03/30/covid-19-and-investment-treaty-claims/.

[195] Matiangai Sirleaf, *Responsibility for Epidemics*, 97 TEX. L. REV. 285, 336 (2020).

[196] *See generally* Matiangai Sirleaf, *Responsibility for Epidemics*, 97 TEX L. REV. 285 (2020).

[197] OECD, COVID-19: FROM A HEALTH TO A JOBS CRISIS (2020), https://www.oecd-ilibrary.org/sites/1686c758-en/1/3/1/index.html?itemId=/content/publication/1686c758-en&_csp_=fc80786ea6a3a7b4628d3f05b1e2e5d7&itemIGO=oecd&itemContentType=book.

[198] *See, e.g.*, Tsung-Ling Lee, *Global Health in a Turbulence Time: A Commentary*, 15 ASIAN J. WTO & INT'L. HEALTH L. & POL'Y. 27, 38 (2020) (discussing an example of communicating WHO regulations through a U.N. resolution); *see also* KATHARINA PISTOR, LAW IN THE TIME OF COVID-19 174 (Columbia Law School Faculty Publications, 2020).

[199] AMARTYA SEN, DEVELOPMENT AS FREEDOM 1 (Oxford University Press, 1999).

[200] *Id*.

[201] Max Roser, *Human Development Index (HDI)*, OUR WORLD IN DATA (Nov. 2019), https://ourworldindata.org/human-development-index.

[202] WHO, WORKING FOR HEALTH AND GROWTH: INVESTING IN THE HEALTH WORKFORCE 9–10 (2016).

nineteen years longer in comparison to their counterparts in less developed countries.[203]

United Nations Development Program ("UNDP") has a way of examining the development of a country through the HDI.[204] The HDI is calculated as the average of life expectancy (a proxy for health), education (a proxy for literacy), and the per-capita GDP (a proxy for income) of a country.[205] These variables are considered as "output" or "outcome" variables because they estimate how long a person is likely to live, education attainment, and income level. HDI does not consider the "input" variables such as the factors which determine outcome variables. For example, longevity is an outcome variable. It is result of input variables such as healthy diet, or having access to healthcare infrastructure[206].

Similar to HDI index is the HAQ index. The HAQ index is more specific and only considers variables related to health.[207] That is, unlike the HDI, the HAQ does not include the income and education variables.[208] The HAQ index is based on thirty-two preventable causes of death.[209] Drawing from the *Global Burden of Diseases, Injuries, and Risk Factors Study 2015*, the HAQ index ranks countries based on the causes of death, controlling for terminal illness or end-stage disease such as cancer. That is, HAQ does not consider death of people from terminal-illness but because of lack of access to adequate healthcare services. While ranking countries based on HAQ index, adequate attention is paid to the fact that the cause of death is lack of effective healthcare services, with countries ranked higher implying access to better

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[203] UN DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2019: BEYOND INCOME, BEYOND AVERAGES, BEYOND TODAY 7 (2019).

[204] Izete Pengo Bagolin & Flavio Comim, *Human Development Index (HDI) and its Family of Indexes: An Evolving Critical Review*, 34 REVISTA DE ECONOMIA 7, 18 (2008).

[205] UN Dev. Programme, *Human Development Index (HDI)*, UNITED NATIONS DEV. PROGRAMME, http://hdr.undp.org/en/content/human-development-index-hdi (last visited Jan. 28, 2021).

[206] *See* WHO, GLOBAL REFERENCE LIST OF 100 CORE HEALTH INDICATORS (PLUS HEALTH-RELATED SDGS) 16 (2018) ("The *Global Reference List of 100 Core Health Indicators* is a standard set of *core indicators* prioritized by the *global* community to provide concise information on the *health* situation and trends, including responses at national and *global* levels."); Peter J. Kpolovie et al., *Continental Comparison of Human Development Index (HDI)*, 4 INT'L. J. HUMAN. SOC. SCI. & EDUC. 9, 27 (2017).

[207] *See* GBD 2015 Healthcare Access and Quality Collaborators, *Healthcare Access and Quality Index Based on Mortality from Causes Amenable to Personal Health Care in 195 Countries and Territories, 1990–2015: A Novel Analysis from the Global Burden of Disease Study 2015*, 390 LANCET 231, 231–34 (2017) ("The HAQ Index showed strong convergence validity as compared with other health-system indicators.").

[208] *Id*.

[209] *Id.*; Rafael Lozano, *Measuring Performance on the Healthcare Access and Quality Index for 195 Countries and Territories and Selected Subnational Locations: A Systematic Analysis from the Global Burden of Diseases Study 2016*, 391 LANCET 2236, 2238 (2018).

healthcare services.[210] This study primarily uses Mortality-to-Incidence ratios ("MIRs") data for cancer patients.[211] One drawback of the HAQ measures is its dependence on the cause of death due to the fact that deaths cannot be self-reported.[212] For evidence of this issue, data collected from a sample of fourteen countries reveals that countries under-reported the number of COVID-19 related deaths, and the actual number of deaths are sixty percent higher than the official count.[213] Under reporting the number of deaths is a limitation for calculating HAQ because relative performance of countries may change - with countries under reporting number of deaths getting a higher rank, when ranked on the basis of health indicators. Likewise, this index does not account for living conditions such as a person living in a slum with congested spaces, polluted air and water, and poor access to healthcare infrastructure.[214] Notwithstanding these limitations, the HAQ measure works under the assumption that any country can make effective use of its health care services.[215]

A. Methodology: Constructing HII

We use Principal Component Analysis to construct HII. The number of principal components ("PC") will be equal to the number of variables we consider to form an Index, thus if there are N numbers of variables, there will be N principal components. *PC analysis* is a dimensionality-reduction method that is often used to reduce the dimensionality of large data sets, by transforming a large set of variables into a smaller one that still contains most of the information that are there in the large data set. For example, to comment on the level of healthcare infrastructure in any country, researchers may choose variables like the availability of doctors, nurses, and paramedic staffs. Alternatively, using PCA we can arrive at an index, which is a single variable and yet contains information about each one of these three different variables, namely, doctors, nurses, and paramedic staffs.

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[210] GBD 2015 Healthcare Access and Quality Collaborators, *supra* note 207.
[211] *Id.*
[212] Bonnie Bruce & James F. Fries, *The Stanford Health Assessment Questionnaire: Dimensions and Practical Applications*, 1 HEALTH & QUALITY LIFE OUTCOMES 1, 3 (2003).
[213] John Burn-Murdoch et al., *Global Coronavirus Death Toll Could be 60% Higher than Reported*, FIN. TIMES (Apr. 26, 2020), https://www.ft.com/content/6bd88b7d-3386-4543-b2e9-0d5c6fac846c.
[214] Carolina Sanchez-Paramo, *COVID-19 Will Hit the Poor the Hardest. Here's What We Can Do About It*, WORLD BANK BLOGS (Apr. 23, 2020), https://blogs.worldbank.org/voices/covid-19-will-hit-poor-hardest-heres-what-we-can-do-about-it.
[215] *See* WHO, *supra* note 206 (showing HAQ measures considers the input variables and the resulting output variables, while it does not consider is how effectively the input variables are used to achieve certain output variables).

Thus, for constructing HII, we consider the following variables – physicians per 1000 population (X_1), nursing and midwifery personnel per 10000 populations (X_2), dentists per 10000 populations (X_3), pharmacists per 10000 populations (X_4), hospital beds per 10000 populations (X_5), skilled health professionals (such as anesthesiologist, radiologist, etc.) per 10000 populations (X_6), number of hospitals per 10000 populations (X_7), and government expenditure on health as a percentage of GDP (X_8). These eight variables encapsulate the health infrastructure of any country. Corresponding to these eight variables are eight such principal component indexes, each uncorrelated to the others. However, we consider only the first principal component index as a proxy for the HII. The first principal component index represents the linear combination of the constituent health indexes with maximal variance. The objective is to create the HII which separate out or characterize different countries according to the chosen measures of health infrastructure. Maximizing the variance of the linear combination of the constituent health index is equivalent to maximizing information content in the subsequent information index ranking. Rather than giving equal weight (which is 1/8) to each one of the constituent elements of the health infrastructure, the weights are derived using principal component methodology. The constituent element among the chosen eight elements of the health the infrastructure, with highest variance, gets the maximum weight. The linear combination of the constituent variables with maximum variance accounts for interdependence among component indexes, thus ensuring full use of the available information.

Data:

All health-related data used in this study was collected from the WHO, 2020.[216] WHO categorizes all available information related to health data into four buckets. The first bucket relates to *Inputs and Process*, and cover data related to health financing, health workforce, health infrastructure, health information and governance. The second bucket relates to *Output*, and captures data related to service access and availability (inpatient admissions and surgical volume), service quality and safety, and health security (international health regulations). The third bucket relates to *Outcome*, and captures data related to outcome variables such as coverage of interventions (antenatal care coverage, antiretroviral therapy coverage, coverage of essential health services, etc.), and risk factors and behaviors (air pollution, accessibility to safe drinking water, etc.). And, the fourth basket relates to *Impact*, and covers data related to health status (life expectancy at birth,

[216] *Indicators*, WHO, https://www.who.int/data/gho/ data/ indicators? (last visited Jan. 28, 2021).

infant mortality rate, etc.).[217] The data sets refer to the categories, *Output*, *Outcome*, and *Impact*, and the categories are used by UNDP and Lancet to create indexes such as HDI, HAQ, and to monitor sustainable development goals (SDGs).[218] Data on income and Gini coefficients (measuring income inequality) are collected from World Development Indicators (WDI), World Bank, 2020.[219] To maintain uniformity we consider data related to health, income and "Gini" coefficients for the latest available year for each country as reported in WDI, 2020 and WHO, 2020.[220] The number of persons affected and the number of deaths from COVID-19 are collected from Our World in Data,[221] and report data as of July 2, 2020.

B. Results

Identification of the largest characteristic root (eigenvalue) from (4) gives 8 optimal weights, one for each one of the constituent elements of HII. The first principal component has a variance (characteristic root or eigenvalue) of 4.02 and accounts for 50.30% variation in all the regressors. The second principal component has a variance of 1.01, however, accounting for only 12.63% of the total variation. For the purpose of ranking, we therefore only considered the first principal component. Considering the first principal component, the weights for physicians per 1000 population (X_1), nursing and midwifery personnel per 10000 populations (X_2), dentists per 10000 populations (X_3), pharmacists per 10000 populations (X_4), hospital beds per 10000 populations (X_5), skilled health professionals per 10000 populations (X_6), number of hospitals per 10000 populations (X_7), and government expenditure on health as a percentage of GDP (X_8) are 0.44, 0.43, 0.39, 0.37, 0.25, 0.44, 0.02, and 0.23, respectively. The principal component weights are different than assigning equal weights for each one of these variables. We observe, considering first principal component, number of physicians, skilled

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[217] WHO, *supra* note 206 at 14–16.
[218] UNDP (2020), https://www.undp.org/content/undp/en/home/sustainable-development-goals/goal-3-good-health-and-well-being.htm.
[219] *Indicators*, WORLD BANK, https://data.worldbank.org/indicator (last visited Jan. 28, 2021).
[220] *See id.* (showing some of the data, for instance, the ones on Gini coefficients do not change within a span of few years. For instance, the National Sample Survey Organization, Government of India conducts a consumption expenditure survey (an instrument used for income variable) at an interval of every 5 years to report Gini coefficient data for India. World Bank 2020 reports data on Gini coefficients, the latest available for each country).
[221] *Cumulative Confirmed COVID-19 Cases*, OUR WORLD DATA, https://ourworldindata.org/coronavirus-data-explorer?zoomToSelection=true&time=earliest..2020-07-02&country=~USA&region=World&casesMetric=true&interval=total&smoothing=0&pickerMetric=total_cases&pickerSort=desc (last visited Jan. 28, 2021).

healthcare professional, and nursing and midwifery personnel, loading heavily on this principal component, implying they are important component of healthcare infrastructure. On the other hand, number of hospitals are weighted the least, implying merely having bricks and mortar hospital will be of little use without healthcare professionals.

Figure 1: Cumulative Proportions of Eigen values

Source: Authors' Calculation, Eviews 11.

Weighting with first principal component and ranking all 186 countries in terms of health infrastructure yields the following results. A higher HII score means that there is a better healthcare infrastructure available. Monaco tops the list with the best available health infrastructure, conversely, Somalia is found to have the least available health infrastructure (see the Appendix for the ranking of countries on the basis of HII scores).

IV. Enhancing Health Systems Performances

The HII framework considers variables related to health infrastructure. However, there can be other variables such as income, age profile, tropical climate, dietary habits, and health policy, which may impact COVID-19 fatality rate. Below we discuss these factors and also their relationships with HII.

A. HII and Income

There is a statistically significant positive relationship between HII and income. (Figure 2). This relationship is not surprising because high income countries are likely to spend more and have a more developed or robust health infrastructure. However, as the U.S. suggests, spending more does not always guarantee that an effective health care system is in place.[222] For instance in 2016, data reveals that the U.S. government spent almost double the amount on medical care in comparison to eleven other wealthier nations.[223] The higher amount spent by the United States (and this exclude money spent by the private insurers) was mostly on account of high costs of labor, pharmaceuticals, and administrative costs, and this did not translate to having better health outcomes.[224] Life expectancy was still lowest and infant mortality rates still the highest in the United States., in comparison to the eleven developed countries in the OECD group.[225] Even in the case of COVID-19, the U.S. has had the highest number of infected persons with 22,761,269 affected and 382,105 deaths as of January, 10 2021.[226] As the case with the U.S. suggests, developed infrastructure set-up for any high-income country does not necessarily translate into a better health outcomes.[227]

Plotting HII against the number of COVID-19 deaths (Figure 3), reveals a horizontal trend suggesting that COVID-19 is equally likely to affect countries irrespective of their level of per-capita income. The result is not surprising, as a vaccine has not been widely distributed, thus both the rich and the poor income countries are equally like to get impacted.[228] Yet, we find some difference in terms of overall fatality rates, which may be due to other factors that will be discussed next.

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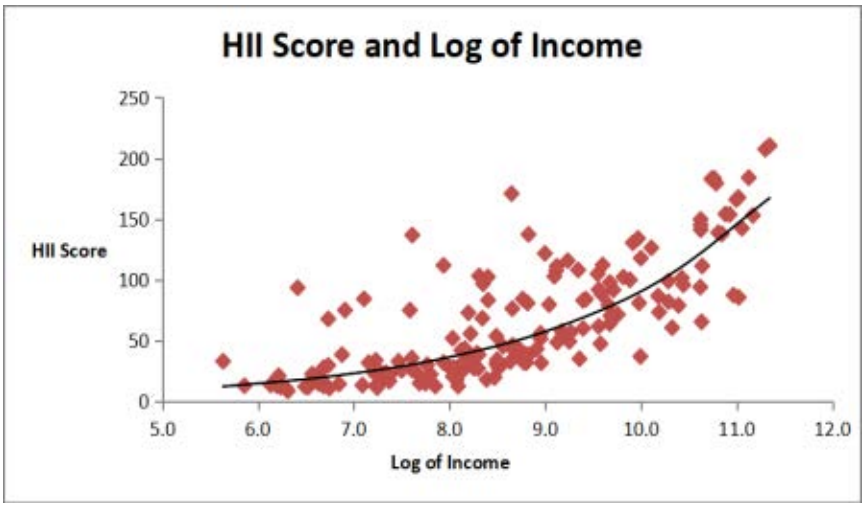
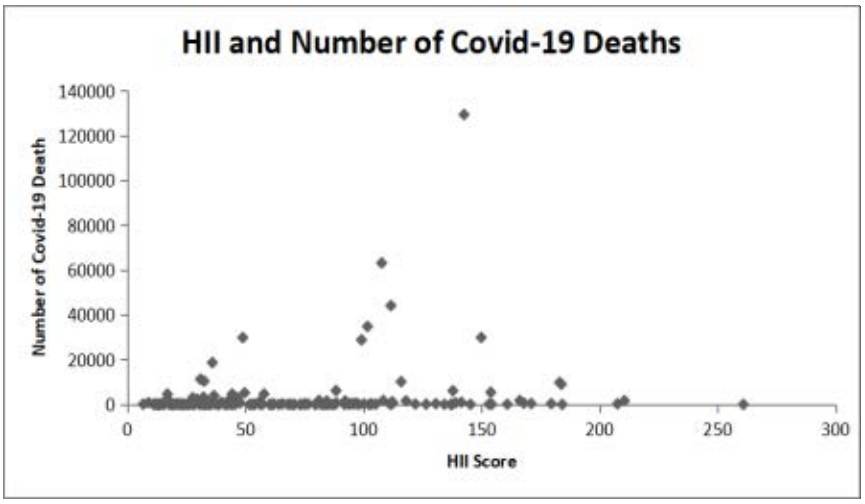
[222] Harris Meyer, *Why Does the U.S. Spend So Much More on Healthcare? It's the Prices*, MODERN HEALTHCARE (Apr. 7, 2018), https://www.modernhealthcare.com/article/20180407/NEWS/180409939/why-does-the-u-s-spend-so-much-more-on-healthcare-it-s-the-prices.
[223] Irene Papanicolas et al., *Health Care Spending in the United States and Other High-Income Countries*, 319 J. AM. MED. ASS'N 1024, 1027 (2018).
[224] *Id*. at 1038.
[225] *Id*. at 1028.
[226] *COVID-19 Coronavirus Pandemic*, WORLDOMETER, https://www.worldometers.info/coronavirus/country/us/ (last visited on Jan. 28, 2021).
[227] Don E. Detmer, *Building the National Health Information Infrastructure for Personal Health, Health Care Services, Public Health, and Research*, 3 BMC MED. INFORMATICS & DECISION MAKING 1, 4–5 (2003) (discussing the variance of Medicare spending and lack of correlation to better health care updates).
[228] At the time of writing this paper, vaccination administration program for COVID-19 has not started.

Figure 2. HII score and Log on Income



Source: compiled by the authors

Figure 3. HII and number of COVID-19 deaths



Source: compiled by the authors

B. HII and Income distribution

Plotting HII against the Gini coefficient for the sample countries gives a negative relationship, and this is statistically significant at five percent level. (Figure 4). Although, COVID-19 is equally likely to affect all the low, middle, and high-income countries, lower-income households, however as

other study shows, within a given country are more to be severally affected thus far (studying the first wave).[229] Evidence suggests five percent of the poor income-households residing in the low and middle income countries, spend disproportionately more than the rich as a percentage of household income on health care.[230] To top it all, governments in less developed economies spend less on public healthcare infrastructure, which generally comes free of charge.[231] In India, for instance, the government spends less than seventy-five dollars per person per year towards provision of public healthcare.[232] The corresponding figures for the United States and the United Kingdom are $9,536 and $4,396, respectively.[233] The Indian government spends less on healthcare and as a result 63.21% of healthcare expenses are "out-of-pocket" expenses for Indian citizens.[234] For the poor residing in high-income countries with larger income inequalities (that is higher gini coefficients), they are also deprived of the healthcare services. As the case with the United States suggests life expectancy for the bottom five percent of poor people did not change between 2001 and 2014.[235] However, during the same period, the life expectancy of people in the high-income bracket showed improvement.[236] Poor health outcomes for individuals with lower-income directly result from exposure to harmful environments.[237] In Europe, it was found foregone medical care (that is, self-reported unmet need for medical care) has increased between 2008 and 2013 in the majority of the 30 countries, especially among the disadvantaged part of the population.[238] The results show that HII and Gini Coefficient are negatively related, that is, countries scoring high HII are the ones with lower income inequalities. However, there can be

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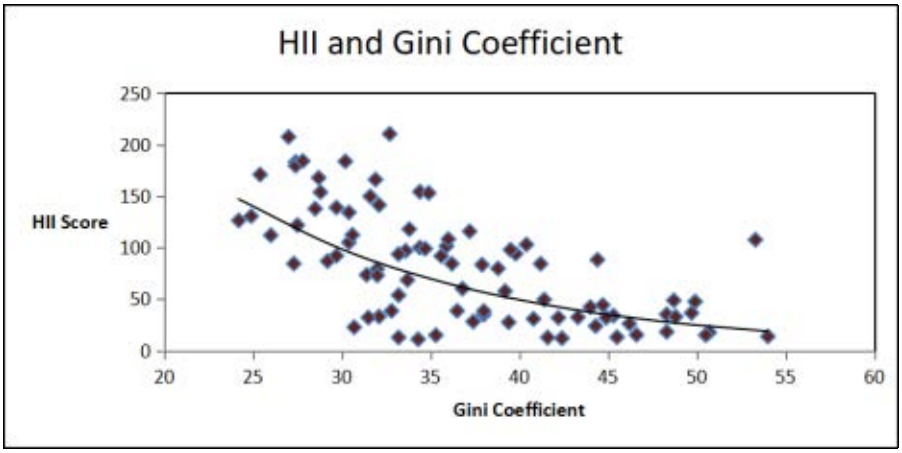
[229] DHRUV KHULLAR & DAVE A. CHOKSHI, HEALTH AFF., HEALTH, INCOME, & POVERTY: WHERE WE ARE & WHAT COULD HELP 2 (Oct. 4, 2018).
[230] *Id.*
[231] *Current Healthcare Expenditure Per Capita*, WORLD BANK, https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?view=map (last visited Jan. 28, 2021).
[232] Nilanjan Banik, *Dealing with a Health Catastrophe*, TIMES INDIA BLOG (Jan. 26, 2020), https://timesofindia.indiatimes.com/blogs/info-nomics/dealing-with-a-health-catastrophe/.
[233] *Id.*
[234] NAT'L HEALTH ACCOUNTS TECH. SECRETARIAT, GOV'T OF INDIA, NATIONAL HEALTH ACCOUNTS ESTIMATES FOR INDIA 2016-17, at 13, 1035 (2019) (see table 3).
[235] Raj Chetty et al., *The Association Between Income and Life Expectancy in the United States*, 315 J. AM. MED. ASS'N. 1750, 1751 (2016).
[236] *Id.*
[237] Ernie Hood, *Dwelling Disparities: How Poor Housing Leads to Poor Health*, 113 ENV'T HEALTH PERSPS. 310, 312 (2005).
[238] Jon Ivar Elstad, *Income Inequality and Foregone Medical Care in Europe during the Great Recession: Multilevel Analyses of EU-SILC surveys 2008-2013,* 15 INT'L J. EQUITY HEALTH 101, 3-4 (2016) (generally noting for the low-income group, unmet need for medical care tended to be higher in countries with larger income inequalities, regardless of the average economic standard in terms of GDP per capita).

exceptions. As noted above for the high-income countries with large income inequalities, there is a need for targeted healthcare intervention designed for the low-income households.

Figure 4. HII and Gini Coefficient



Source: compiled by the authors

C. Additional Covariates outside the purview of HII that may affect COVID-19 fatality rates

Vaccine for COVID-19 has not yet arrived, and therefore both the rich and the poor-income households are equally like to get affected by this disease.[239] As discussed in the previous section, in terms of accessibility, the rich-income households have better access to healthcare infrastructure in comparison to the poor-income households. A better HII may help the rich with better access to healthcare. However, in addition to the variables that we used for constructing HII, there can be other exogenous factors (that is, outside ambit of any government policy) that may impact COVID-19 fatality rate. In this section we consider these other exogenous variables, such as age profile, comorbidity, climatic conditions, clean air quality, and dietary habits (culture). We consider India as a special case - a country which has second highest COVID-19 caseload, after the

[239] At the time of writing this paper, vaccination administration program for COVID-19 has not started for the majority of the world.

United States.[240] However, COVID-19 fatality rate is less for India. This may be because of these exogenous variables which we discuss below.

1. Age Profile and Comorbidity

The global evidence thus far indicates that the severity of COVID-19 is directly correlated with old age,[241] this is because the elderly are usually comorbid, meaning that they are suffering from more than one disease at a time.[242] The prevalence of medical conditions such as hypertension, diabetes, and heart disease, increases rapidly with age.[243] The increased risk of becoming severely ill due to COVID-19 may either be due to increased age, comorbidity, inadequate treatment or a combination of these factors.[244] For the elderly group, there is considerable likelihood of hospitalization and intensive care once infected.[245] For example, a report of 72,314 cases from mainland China shows that the overall fatality rate increased from 2.3% to 8.0% for those aged between 70 and 79 and for those above 80 years, the fatality rate was at 14.8%.[246] Similarly, for Italy, the fatality rates the 70–79-year category was 12.8% and 20.2% for those above 80 years.[247] In the United States, according to the CDC, people suffering from other diseases like heart disease and diabetes were twelve times more likely to die and six times more likely to be hospitalized because of COVID-19 in comparison to the younger healthy populations.[248] India may have a lower COVID-19-

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[240] See generally, *Live: Delhi Records 125 New Cases of COVID-19, 3 Deaths*, HINDUSTAN TIMES (Feb. 13, 2021), https://www.hindustantimes.com/india-news/coronavirus-india-world-latest-news-covid-19-death-toll-february-8-2021-101612748889531.html (explaining a lower COVID-19 fatality rate in India).

[241] Wang et al., *Epidemiological and Clinical Features of 125 Hospitalized Patients with COVID-19 in Fuyang, Anhui, China*, 95 INT'L J. INFECTIOUS DISEASES 421, 421 (2020).

[242] Seung-Ji Kang & Sook In Jung, *Age-Related Morbidity and Mortality Among Patients with COVID-19*, 52 INFECTION & CHEMOTHERAPY 154, 158 (2020).

[243] James W. Davis et al., *Prevalence of Comorbid Conditions with Aging Among Patients with Diabetes and Cardiovascular Disease*, 70 HAW. MED. J. 209, 210 (2010).

[244] KJETIL BRURBERG & ATLE FRETHEIM, COVID-19: THE RELATIONSHIP BETWEEN AGE, COMORBIDITY AND DISEASE SEVERITY: A RAPID REVIEW 8–10 (Norwegian Institute of Public Health, 2020).

[245] *Id.*

[246] Graziano Onder et al., *Case-Fatality Rate and Characteristics of Patients Dying Relation to COVID-19 in Italy*, 323 J. AM. MED. ASS'N. 1775, 1776 (2020).

[247] *Id.*

[248] Sanchita Sharma, *People with Co-Morbidities 12 Times More Likely to Die of Covid: US Study*, HINDUSTAN TIMES (June 17, 2020), https://www.hindustantimes.com/india-news/people-with-co-morbidities-12-times-more-likely-to-die-of-covid-us-study/story-MjafvURM5fxc4nFxmmsmlK.html.

related mortality rate due to its relatively younger population.[249] However, as cited earlier, individual factors, such as age and underlying disease (for instance a young person may suffer from a heart disease) can be linked to the risk of a severe course of disease.[250]

2. Tropical Climate

Most viruses exhibit seasonality with peak in activity in different seasons.[251] This seasonal attribute cause differential impact on humans, depending upon the climatic conditions across geographical regions.[252] In temperate regions, upper respiratory tract infection increase in frequency in autumn, remains high through winter , and decreases in spring.[253] Human coronaviruses cause respiratory tract infections which usually peak with cold weather condition.[254] COVID-19, specifically, has been found to be less communicable in hot and humid climates.[255] A study with 166 nations confirmed for every 1°C increase in temperature, there is a daily reduction in new COVID-19 cases by 3.08%.[256] Likewise, a 1°C rise in humidity leads to a 0.85% decrease in COVID-19 cases and the resultant death rate decrease of 0.51%.[257] Conversely,, temperature below 3°C, was found to increase the COVID-19 prevalence rate by 4.8% daily.[258] These relationships reflect how the immune system does not work as effectively in cold and dry climates as it does in warm and humid climates.[259] Thus, the relatively high COVID-19 mortality rates in Western European nations and the U.S., may be largely

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[249] Soutik Biswas, *India Coronavirus: The 'Mystery' of Low Covid-19 Death Rates*, BBC NEWS (July 30, 2020), https://www.bbc.com/news/world-asia-india-52435463.
[250] BRURBERG, *supra* note 244.
[251] Rory Henry Macgregor Price et al., *Association Between Viral Seasonality and Meteorological Factors*, 9 SCI. REP. 1, 2 (2019).
[252] Micaela E. Martinez, *The Calendar of Epidemics: Seasonal Cycles of Infectious Diseases*, 14 PLOS PATHOGENS 1, 1 (2018).
[253] Terho Heikkinen & Asko Järvinen, *The Common Cold*, 361 LANCET 251, 252 (2003).
[254] Robert Kozak et al., *Severity of Coronavirus Respiratory Tract Infections in Adults Admitted to Acute Care in Toronto, Ontario,* 126 J. CLINICAL VIROLOGY 1, 1 (2020).
[255] Qasim Bukhari et al., *Effects of Weather on Coronavirus Pandemic*, 17 INT'L J. ENVTL. RES. & PUB. HEALTH 1, 5 (2020).
[256] Yu Wu et al., *Effects of Temperature and Humidity on the Daily New Cases and New Deaths of COVID-19 in 166 Countries*, 729 SCI. TOTAL ENV'T 1, 3 (2020).
[257] *Id*.
[258] Jingui Xie & Yongjian Zhu, *Association Between Ambient Temperature and COVID-19 Infection in 122 Cities from China*, 724 SCI. TOTAL ENV'T 1, 1 (2020).
[259] Mohammad Sarmadi et al., *Association of COVID-19 Global Distribution and Environmental and Demographic Factors: An Updated Three-Month Study*, 188 ENVTL. RES. 1, 2 (2020).

dependent on their cold weather conditions, as opposed to other health infrastructure factors.[260]

3. Dietary habits, clean air, and health policy

India's Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) has issued guidelines for the use of Indian Ayurvedic (traditional, plant-based) medicines with antipyretic properties as a general immunity booster.[261] In Ayurveda,[262] there is a belief that the phytocompounds found in herbs such as *andrographis paniculata*, *vetiveria zizanioides*, *Cymbopogon jwarancusa cymbopogon jwarancusa*, ginger, *cyperus rotundus cyperus rotundus*, and others can stop COVID-19 from replicating itself.[263] In addition, the guidelines further suggest that practicing yoga, in addition to maintaining a healthy diet with these herbs and spices, can develop immunity.[264] The actual efficacy of such advice, however, remains unfounded.[265]

Clean air quality may also help to reduce the impact of COVID-19 and the subsequent deaths.[266] Recent studies in the United States and northern Italy found that citizens in these countries living in densely populated, polluted regions were more likely to contract and die from COVID-19.[267] For

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[260] *Id.*; Bukari et al., *supra* note 255, at 1.
[261] MINISTRY OF AYUSH, AYURVEDA'S IMMUNITY BOOSTING MEASURES FOR SELF-CARE DURING COVID-19 CRISIS 1-2 (2020).
[262] *See, Ayurvedic Medicine: In Depth*, NAT'L. INSTS. HEALTH (Jan. 2019), https://www.nccih.nih.gov/health/ayurvedic-medicine-in-depth (stating that Ayurveda is the traditional Hindu system of medicine, which is based on the idea of balance in bodily systems and uses diet, herbal treatment, and yogic breathing).
[263] U Tejonmayam, *Ingredients in Kabasura Kudineer Can Fight Virus, Says Researchers in Chennai*, TIMES INDIA (Apr. 24, 2020 6:50 PM), https://timesofindia.indiatimes.com/city/chennai/ingredients-in-kabasura-kudineer-can-fight-covid-say-researchers/articleshow/75335027.cms.
[264] *Covid-19 Battle: Immunity Boosting Tips from the Ayush Ministry*, ECON. TIMES (Apr. 16, 2020), https://economictimes.indiatimes.com/news/politics-and-nation/covid-19-battle-immunity-boosting-tips-from-the-ayush-ministry/pm-modis-appeal/slideshow/75177676.cms.
[265] *Homoeopathy for Coronavirus: Is AYUSH Commitment to Alt Meds Healthy or Promoting Quackery?*, PRINT (Jan 29, 2020 6:12 PM), https://theprint.in/talk-point/homoeopathy-for-coronavirus-is-ayush-commitment-to-alt-meds-healthy-or-promoting-quackery/356179/.
[266] Isabelle Gerretsen, *How Air Pollution Exacerbates Covid-19*, BBC (Apr. 27, 2020), https://www.bbc.com/future/article/20200427-how-air-pollution-exacerbates-covid-19.
[267] Leaonardo Setti et al., *SARS-Cov-2RNA Found on Particulate Matter of Bergamo in Northern Italy: First Evidence*, 188 ENVTL. RES. 109754, 1–2 [online format page numbers] (2020), https://www.sciencedirect.com/science/article/abs/pii/S0013935120306472 (discussing recent studies that found a relationship between high concentration of particulate matter COVID-19 mortality rates).

example, in March 2020, deaths due to COVID-19 were more among people living in the polluted more industrialized regions of Milan, in the province of Lombardy, than in any other part of Italy.[268] A nationwide study on 3,080 counties confirmed that long-term exposure to air pollution increases vulnerability to the most severe COVDI-19 outcomes."[269]

Conversely, one of the primary reasons for low COVID-19 mortality rate in India may be due to the fact that the country saw a massive improvement in air quality during the period of lockdown.[270] The air quality in Delhi improved drastically, with micro-pollutants in air falling from 900 micrograms per cubic meter in 2019 to 2020 micrograms during the period of lockdown.[271] In fact, the COVID-19 lockdown has improved the air quality in many parts of the world in terms of reduction in pollutant elements such as particulate matter 2.5, nitrogen dioxide, and sulphur dioxide.[272] The extended period of lockdown in various parts of the world including Europe, Asia, and North America has helped to slower the spread of COVID-19.[273]

As in the case with dietary habit and clean air, another factor that may affect covid-19 fatality rate is the national health policies. health policy that encourages universal vaccination may help to explain lower covid-19 related death.[274] There is evidence that administering the Bacille Calmette-Guérin ("BCG") vaccine may have provided protection against COVID-19.[275] People residing in African and South Asian nations usually get vaccinated at

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[268] Damian Carrington, *Air Pollution Linked to Far Higher COVID-19 Death Rates, Study Finds*, GUARDIAN (Apr. 7, 2020 12:16 PM), https://www.theguardian.com/environment/2020/apr/07/air-pollution-linked-to-far-higher-covid-19-death-rates-study-finds.

[269] Xiao Wu et al., Exposure to Air Pollution and COVID-19 Mortality in the United States at 6, 8, (April 27, 2020) (unpublished manuscript) https://www.medrxiv.org/content/medrxiv/early/2020/04/27/2020.04.05.20054502.full.pdf.

[270] Hannah Ellis-Petersen et al., '*It's Positively Alpine!': Disbelief in Big Cities as Air Pollution Falls*, GUARDIAN (Apr. 11, 2020), https://www.theguardian.com/environment/2020/apr/11/positively-alpine-disbelief-air-pollution-falls-lockdown-coronavirus.

[271] *Id.*

[272] Surinder Suthar, et al., *Epidemiology and Diagnosis, Environmental Resources Quality and Socio-economic Perspectives for COVID-19 Pandemic*, 280 J. ENVTL. MGT. 111700, 4 [online format page numbers] (2021), https://www.sciencedirect.com/science/article/pii/S030147972031625X.

[273] *Id.*

[274] Kalyan Ray, *BCG Vaccination Can Reduce Covid-19 Incidence, Lower Death Rates, New Study Finds*, DECCAN HERALD (July 12, 2020), https://www.deccanherald.com/science-and-environment/bcg-vaccination-can-reduce-covid-19-incidence-lower-death-rates-new-study-finds-860335.html.

[275] Paul K. Hegarty et al., *BCG Vaccination May be Protective Against Covid–19*, UROTODAY (June 16, 2020), https://www.urotoday.com/recent-abstracts/covid-19-and-genitourinary-cancers/120589-bcg-vaccination-may-be-protective-against-covid-19.html; Nigel Curtis et al., *Considering BCG Vaccination to Reduce the Impact of COVID-19*, 395 LANCET 1545, 1545 (2020).

a young age , which may explain why the fatality rate in this part of the world is lower in comparison to countries in North America and Europe.[276] In fact, countries with higher COVID-19 fatality rates, such as the United States and Italy, do not have universal BCG vaccination policy.[277]

V. ACCOUNTABILITY FOR INTERNATIONAL HEALTH REGULATIONS REPORTING

Any government, especially the developing and less-developed countries, have limited fiscal resources to fight pandemic like COVID-19.[278] Thus, there is a need to prioritize health expenditure during health during COVID-19. Governments across the globe are resorting to policies to fight against COVID-19.[279] In the short-run, supply-side economics may not work.[280] For instance, to increase availability of skilled workers such as health care professionals (doctors, paramedic staff, nurses, etc.) is not possible in the short-run unless otherwise a favorable immigration policy helps to bridge the shortage by allowing doctors and paramedical staffs to migrate.[281] These supply-side ideas require planning over a longer period of time horizon and require investment in school, university, and education system of a country.[282] COVID-19 has also led to disruption in the supply of output. The ship lining companies, for example, Maersk had to cancel dozen of container ships, and estimate that China's factories are operating at fifty to sixty percent capacity.[283] Therefore, countries are stressing on demand-management

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[276] Aaron Miller et al., Correlation Between Universal BCG Vaccination Policy and Reduced Morbidity and Mortality for COVID–19: An Epidemiological Study (Sept. 14, 2020) (unpublished manuscript) (on file with Dep't. of Biomedical Sci., NYIT Coll. of Osteopathic Med., NY Inst. of Tech.); Luis E. Escobar et al., *BCG Vaccine Protection from Severe Coronavirus Disease 2019 (COVID-19)*, 117 PROCEEDINGS NAT'L. ACAD. SCI. 17720, 17724–25 (2020).

[277] Gil Redelman-Sidi, *Could BCG Be Used Protect Against COVID-19?*, 17 NATURE REVS. UROLOGY 316, 316 (2020).

[278] HELENE BARROY ET AL., ASSESSING FISCAL SPACE FOR HEALTH EXPANSION IN LOW-AND-MIDDLE INCOME COUNTRIES: A REVIEW OF THE EVIDENCE, at v (2016).

[279] Peter A. Diamond, *Aggregate Demand Management in Search Equilibrium*, 90 J. POL. ECON. 881, 881 (1982); CTR. FOR ECON. POL'Y. RES., *supra* note 133.

[280] Bennett T. McCallum, *The Current State of the Policy-Ineffectiveness Debate*, 69 AM. ECON. REV. 240, 242 (1979).

[281] Jan Rutkowski, From the Shortage of Jobs to the Shortage of Skilled Workers: Labor Markets in the EU New Member States 19–25 (Dec. 2007) (Inst. for the Study of Lab., discussion paper No. 3202).

[282] Gostin et al., *supra* note 1, at 10.

[283] RICHARD BALDWIN &BEATRICE WEDER DI MAURO, ECONOMICS IN THE TIME OF COVID-19, 32 (2020) (ebook); *see also* CTR. FOR ECON. POL'Y. RES., ECON. IN THE TIME OF COVID-19 (Richard Baldwin & Beatrice Weder di Mauro eds., 2020), https://voxeu.org/content/economics-time-covid-19.

policies to fight the pandemic.[284] To revive the demand, governments, particularly from the high-income countries, have already pledged more than ten trillion dollars, which is three times more than the response to 2008 financial crisis.[285] These fiscal and monetary packages are geared towards building additional hospitals, makeshift health care infrastructure (for example, converting a football stadium into a hospital), manufacturing greater number of health personal protective types of equipment and other healthcare kits.[286] As health and human rights are related, some developing countries are opting for, "cash transfer (for example, Iran and Malaysia), subsidizing utilities (Maldives), reducing or deferring social security payments (Brunei Darussalam), deferring student loans (Fiji), providing rental subsidies (Nepal) and providing free food and ration (India and Myanmar)."[287] Additionally, countries across the economic stratum are also spending on administration such as implementing travel restrictions, social distancing and enforcing lockdown measures.[288]

While most of these targeted interventions to fight COVID-19 are domestic-centric, there is a need for building an international coalition. In the COVID-19 Fund created by the WHO, countries like Australia, Azerbaijan, and New Zealand have contributed.[289] Japan is contributing to the Catastrophe Containment and Relief Trust set up by the IMF.[290] Similarly, South and South-West Asian countries are contributing to COVID-19 Fund in the South Asian Association for Regional Cooperation (SAARC) region.[291] Such funds will be of use and will save more lives in the poorer

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[284] Giovanni Dell'Ariccia et al., *Economic Policies for the COVID-19 War*, IMF BLOG (Apr. 1, 2020), https://blogs.imf.org/2020/04/01/economic-policies-for-the-covid-19-war/.
[285] ZIYAD CASSIM ET AL., THE $10 TRILLION RESCUE: HOW GOVERNMENTS CAN DELIVER IMPACT 2 (2020).
[286] *Policy Responses to COVID-19 World Health Organization*, INT'L. MONETARY FUND, https://www.imf.org/en/Topics/imf-and-covid19/Policy-Responses-to-COVID-19 (last visited Jan. 28, 2021); Srishti Choudhary, *Covid-19: India Ramps Up Manufacture of Personal Protection Kits, Devices*, MINT (Mar. 30, 2020), https://www.livemint.com/news/india/covid-19-india-ramps-up-domestic-manufacturing-of-ppes-masks-ventilators-11585580452636.html.
[287] ZHENQIAN HUANG & SWETA C. SAXENA, COMBATING COVID-19 IN ASIA AND THE PACIFIC: MEASURES, LESSONS AND THE WAY FORWARD 2–9 (2020).
[288] Matteo Chinazzi et al., *The Effect of Travel Restrictions on the Spread of the 2019 Novel Coronavirus (COVID-19) Outbreak*, 368 SCI. 395, 398 (2020).
[289] *Coronavirus Disease* (*COVID-19) Donors & Partners: WHO Says Thank You!*, WHO, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/donors-and-partners/funding (last visited Jan. 28, 2021).
[290] HUANG & SAXENA, *supra* note 287, at 3.
[291] Abhishek Trivedi, *COVID-19: Why a New Normative and Institutional Framework for SAARC Nations is Needed to Fight the Coronavirus*, LONDON SCH. ECON. & POL. SCI.:

countries. HII contains information about how vulnerable a country is when it comes to the paucity of health infrastructure. Countries with lower HII ranks are ideal candidates to get more international funding to make targeted health intervention in their domestic economies.[292]

International funding can also be used for the development of a joint research project to develop any new vaccine to fight future pandemics.[293] For this to happen, there is an added requirement to bring in extra-trade subjects into negotiations. As HII suggests, many countries do not have an adequate number of doctors, other skilled health professionals such as anesthesiologists, radiologists, nurses, and paramedic workers.[294] In this regard, it is important to liberalize the services sector and allow movement of these skilled healthcare professionals because some countries, particularly low-income countries, face a shortage in the availability of doctors and other skilled paramedical healthcare workers. Like in the case with ASEAN, EU, and NAFTA, mobility of these skilled healthcare professionals should be promoted through Mutual Recognition Arrangements ("MRA")," so that a degree granted in any country also remains valid for other countries as well.[295] For instance, India has an abundant supply of skilled healthcare professionals and is known for medical tourism. The cost of medical tourism in India and Malaysia is least in the South East Asian region.[296] Most of the patients involved in the medical tourism market in India come from Bangladesh, Afghanistan, the Gulf (Iraq and Oman), and some African countries such as Nigeria, Kenya and Tanzania.[297] During pandemics, coordination of public policies enabling cross borders movement of these health professionals will be of great help.[298]

SOUTHEAST ASIA BLOG (Apr. 2, 2020), https://blogs.lse.ac.uk/southasia/2020/04/02/covid-19-why-a-new-normative-and-institutional-framework-for-saarc-nations-is-needed-to-fight-the-coronavirus/.

[292] Susan Horton et al., *Ranking 93 Health Interventions for Low- and Middle-Income Countries by Cost-Effectiveness,*12 PLoS ONE 1, 10 (2017).

[293] Tung Thanh Le et al., *The COVID-19 Vaccine Development Landscape*, 19 NATURE REV. 305, 306 (2020).

[294] WHO, *supra* note 216.

[295] Chandra Shah & Michael Long, Global Labour Mobility and Mutual Recognition of Skills and Qualifications: European Union and Australia/New Zealand Perspectives17–20, (Monash Univ. Ctr. for the Econs. of Educ. & Training Working Paper, Paper No. 65, 2007), https://www.researchgate.net/publication/226731340.

[296] NEIL LUNT ET AL., MEDICAL TOURISM: TREATMENTS, MARKETS AND HEALTH SYSTEM IMPLICATIONS: A SCOPING REVIEW 12 (2011).

[297] Manveena Suri, *India Wants to Make Medical Tourism a $9 Billion Industry by 2020,* CNN HEALTH (Feb. 15, 2019), https://www.cnn.com/2019/02/13/health/india-medical-tourism-industry-intl/index.html.

[298] Kelley Lee et al., *Global Coordination on Cross-Border Travel and Trade Measures Crucial to COVID-19 Response*, 395 LANCET 1593, 1593–94 (2020).

Another area that requires international coordination is research collaboration in the healthcare sector. India is emerging as the hotspot for clinical contract research and knowledge process outsourcing. Foreign players are setting up their offices because of lower input costs in India.[299]Future negotiations for better health outcome should try to enable services related to delivery of online health services. For this to happen there is a need to remove restrictions on outsourcing of clinical data and patient health related information.[300] The argument for restricting outsourcing of clinical data is based on the fact that there is no guarantee to ensure safety and rights of the trial volunteers in the developing countries, as happens in high-income countries such as European and North American nations.[301] If such a concern is taken care of then coordinated activities ensuring free flow of knowledge and disease surveillance will be helpful.[302]

A. What should be obliged to communicate to the WHO?

Amidst the unprecedented circumstances caused by COVID-19, regulating nations' response to the global pandemic emerges as a pivotal concern because the IHR was created to prevent the spread of diseases globally and provide a public health response.[303] Its main function is to protect, control the spread disease in such a way that reduced the risk of public health and avoid unnecessary interference with international traffic and trade.[304]

Soon after the declaration of COVID-19 as a 'public health emergency of international concern' by the WHO through an order dated January 30, 2020,

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[299] Falguni Sen & Michael Shiel, *From Business Process Outsourcing (BPO) to Knowledge Process Outsourcing (KPO): Some Issues*, 25 HUMAN SYS. MGMT. 145, 155 (2006), https://content.iospress.com/articles/human-systems-management/hsm620.

[300] Umesh Soni & Monica Singh, *Clinical Trials Outsourcing: Good or Bad?*, 2 Drug Designing 1, 2 (2013) (Although outsourcing has several advantages, there is a need for having strong regulations in developing and less-developed countries so that human safety and human rights are not violated).

[301] James Cekola, *Outsourcing Drug Investigations to India: A Comment on U.S., Indian, and International Regulation of Clinical Trials in Cross-Border Pharmaceutical Research*, 28 NW. J. INT'L L. & BUS. 125, 145 (2007).

[302] Mary H. Stanfill & David T. Marc, *Health Information Management: Implications of Artificial Intelligence on Healthcare Data and Information Management*, 28 IMIA YEARBOOK MED. INFORMATICS 56, 64 (2019).

[303] *Alert, Response, and Capacity Building Under the International Health Regulations*, WHO, https://www.who.int/ihr/howtheywork/10things/en/#whatis (last visited Jan. 28, 2021); *see generally* Lee et al., *supra* note 298, at 1593–95 (discussing importance of border control during a pandemic).

[304] WHO, INTERNATIONAL HEALTH REGULATIONS (2005): A BRIEF INTRODUCTION TO IMPLEMENTATION IN NATIONAL LEGISLATION 2 (2009).

the global community demonstrated solidarity and cooperation[305]. However, travel and trade restrictions were excluded from the additional recommendation.[306] Notably, the WHO provides a recommendation regarding the health measures to states at the point of entry and if recommendations are further extended by the states by doing any activities such as closing their borders against the advice of the WHO, then the states as per the Article 43(5) are required to justify their actions to the WHO.[307] However, the power of the WHO as per Article 43(4) is limited to request the state party to reconsider their decision and not restrict the governments from exceeding its advised measures.[308]

In the case of SARS in China, the outbreak was covered up and, ultimately, wasted the valuable preparation and prevented countries from taking mitigation steps. To avoid such situation, all the countries need to be more transparent.[309] Common surveillance and containment strategies need to be defined, which can be done if countries work together and with the WHO with proper co-ordination.[310] The SARS pandemic demonstrated that there is a need to delegate more power to the WHO so that it can investigate the outbreaks independently rather than relying on the information provided by the government official sources.[311]

Recently, the WHO revised its account and stated that it was "alerted by its own office in China, and not by the Chinese Authorities."[312] Timely and accurate communication of information and transparency are very important to tackle the spread of disease.[313] The COVID-19 pandemic is reemphasizing the need for efficient risk communication to control the outbreak and reduce the impacts (economic, health, psychological) of infectious diseases.[314]

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[305] Yuri Bruinen de Bruin et al., *Initial Impacts of Global Risk Mitigation Measures Taken During the Combatting of the COVID-19 Pandemic*, 128 SAFETY SCI. 1, 7 (2020); WHO, *supra* note 137.
[306] Ferhani & Rushton, *supra* note 28, at 458.
[307] WHO, *supra* note 137, at 29.
[308] *Id.*
[309] Ferhani & Rushton, *supra* note 28, at 463.
[310] WHO, THE WORLD HEALTH REPORT 2003: SHAPING THE FUTURE 78–79 (2003).
[311] *See generally* WORLD HEALTH ASSEMBLY RES. 56/29, SEVERE ACUTE RESPIRATORY SYNDROME (2003).
[312] Agence France-Presse, *WHO Revises Coronavirus Timeline to Clarify its China Officer Raised Alert, Not Authorities*, S. CHINA MORNING POST (July 4, 2020), https://www.scmp.com/news/china/science/article/3091820/who-revises-coronavirus-timeline-clarify-its-china-office-raised.
[313] P. O'Malley et al., *Transparency During Public Health Emergencies: From Rhetoric to Reality*, 87 BULL. WORLD HEALTH ORG. 614, 616 (2009).
[314] *See e.g. New Study Highlights the Role of Risk Communication in Coping with COVID-19*, PREVENTION WEB (Oct. 16, 2020), https://www.preventionweb.net/news/view/74240 (reporting that early risk communication during COVID-19 mitigated damage).

B. Whether in terms of tests, patients, or even how states implement the WHO regulations

The responsibility for implementing the IHR rests jointly with WHO and its state parties.[315] IHR reporting during a state of pandemic is necessary to analyze the condition and work towards discovering ways to mitigate such risks.[316]

A state can implement regulations through varied channels, including the set-up of an adequate legal framework to support IHR.[317] It is upon the state's discretion whether or not to implement these regulations.[318] So, in order to implement regulations through diverse means, a nation might as well setup an appropriate legal framework to promote IHR. Some states have a strict requirement that in order to apply IHR within the national law or domestic jurisdiction, relevant authorities need to adopt the implementing legislation for the rights and obligations for member states that are appropriate.[319] However, if it is not conceivable for a nation's legal system to adopt the implementing legislation in order to give effect to IHR, it might as well revise some legislation, regulations, or other such instruments of the country's legal system to facilitate IHR in an efficacious and beneficial manner.[320]

One of the chief tasks while channeling the assessment of national regulations, legislations, and other instruments in order to include provisions of IHR involves determining all legislative subjects and operational functions at all governmental levels.[321] These need to be appropriate for the state party to give effect to the implementation of IHR. Identifying the instruments, legislations or regulations (if any) that has the capability to intervene with effective implementation of IHR; determining any potentially enabling or authorizing legislation which may be suitable for the State party to implement its rights or fulfill obligations, cross-referencing other the WHO guidance documents on the Regulations, maintaining a record (written) of the outcomes of the assessment, consenting on a follow-up action when adoption/revision of legislation, regulations or other instruments are deemed appropriate to implement IHR provisions.[322]

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[315] *See* Lee, *supra* note 198, (explaining that IHR implementation is however dependent on each State Party in light of relevant domestic legal and governance systems); *see also* PISTOR, *supra* note 198, (stressing that each Party must have the capacity to identify issues and needs through a well-established domestic surveillance but also response system).
[316] WHO, MANAGING EPIDEMICS, KEY FACTS ABOUT MAJOR DEADLY DISEASES 218 (2020).
[317] WHO, *supra* note 304, at 10.
[318] *Id.* at 14.
[319] *Id*. at 5.
[320] *Id.* at 2.
[321] *Id*. at 17.
[322] *Id.* at 8–9.

There are, however, other approaches that could possibly be applied for implementation. These include the incorporation of State parties and the WHO equally to report the implementation of IHR in World Assembly,[323] official communication related to events under the IHR to be undertaken and performed by National IHR Focal-point and the associated Regional the WHO IHR Contact Point, both of whom are officially appointed and need to be accessible 7 days a week on a 24 hour basis.[324] Additionally, state parties should inform and report to the WHO of all the events that are, in general, evaluated as potentially composing a PHEIC, considering the background in which an event takes place within 24 hours of assessment of such happening and a definitive assessment cannot be concluded.[325] Further, there is an explicit option available to the state parties of starting confidential consultations with the WHO and trying to get advice on the evaluation, assessment and reliable measures related to health to be taken.[326] State Parties should mandatorily notify the WHO through the National IHR Focal Point within 24 hours of receipt of evidence of any identified risk to public health risk outside the territory that may result into spreading of the disease internationally. Such is evidenced by exported or imported human cases. Vectors are responsible for transfer of infection or contamination, or by goods that are contaminated. The WHO and state parties should work together in the assessment and regulation of public health events and risks, even before the WHO has been informed about such kind of events in an official manner. All State Parties should prepare, enhance, and maintain the key public capacities for the response procedure and surveillance, while applying for the health measure procedures related to IHR. State Parties are required to treat the international travelers with respect, taking full consideration of parameters such as their socio-cultural, religious and ethnicity, gender and they must necessarily be provided with accommodation, food, water, and medical necessities and if quarantined, isolated or otherwise subject to public or medical health measures under IHR.[327] All that said, approaches may prove to be beneficial in alleviating the current risks.

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[323] *Strengthening Health Security by Implementing the International Health Regulations (2005)*, WHO, https://www.who.int/ihr/procedures/annual-reporting/en/ (last visited Jan. 28, 2021).
[324] WHO, *supra* note 304, at 7.
[325] WHO, WHO TECHNICAL CONSULTATION ON THE IMPLEMENTATION AND EVALUATION OF ANNEX 2 OF THE INTERNATIONAL HEALTH REGULATIONS (2005), at 14.
[326] WHO, International Health Regulations (3rd. ed. 2005) part VIII, Article 44, https://www.who.int/csr/ihr/WHA58-en.pdf.
[327] WHO, *supra* note 303.

C. WHO Public Health Emergency of International Concern (PHEIC) declarations

The present definition of PHEIC places emphasis on the serious nature of the situation which extends beyond the national borders of a country.[328] The term PHEIC is defined in the IHR as "an extraordinary event which is determined… to constitute a public health risk to other States through the international spread of disease; and to potentially require a coordinated international response."[329] The purpose of a PHEIC declaration is to catalyze timely evidence-based actions, to cause increased international funding and support, and to restrict the emerging and re-emerging of disease risks thereby impacting public health and society.[330]

Under the IHR, a nation is bound to report any event that may constitute a PHEIC.[331] Countries are expected to assess each event occurring within their territories within forty-eight hours by applying a specific algorithm contained in Annex 2 of the IHR.[332] The criterions upon which such assessment is based includes the following questions of consideration – (1) is the public health impact of the event serious or not, (2) is the event unusual or unexpected, (3) is there a significant risk of international spread, and (4) is there a significant risk of international travel or trade restrictions?[333] And, if two or more of the four questions are answered in the affirmative, a nation is required to notify the WHO within twenty-four hours.[334] The Director-General of the WHO (DG) carries with him the responsibility to determine whether a particular situation calls to be declared as a PHEIC or not.[335] The DG is advised in this duty by the IHR Emergency Committee.[336] Temporary recommendations, which contain all the measures that should be promulgated on an emergency basis are made on the advice of the IHR Emergency Committee.[337] The members of the IHR committee are selected by two methods - i) from the roster of experts maintained by the WHO ii)

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[328] *IHR Procedures Concerning Public Health Emergencies of International Concern* (PHEIC), WHO, https://www.who.int/ihr/procedures/pheic/en/ (last visited Jan. 28, 2021).
[329] *Id.*
[330] David N. Durrheim et al., *When Does a Major Outbreak Become a Public Health Emergency of International Concern*?, 20 LANCET 887, 889 (2020).
[331] *Reporting Events*, WHO, https://www.euro.who.int/en/health-topics/health-emergencies/international-health-regulations/event-reporting-and-review/reporting-events (last visited Jan. 28, 2021).
[332] *Id.*
[333] *Id.*
[334] WHO, *supra* note 325, at 5.
[335] WHO, *supra* note 303.
[336] *Id.*
[337] *Id.*

from the WHO expert advisory panels and committees.[338] Further, it is mandatory that at least one member be an expert nominated by a state party within whose territory the event arises.[339]

The confusion faced by COVID PHEIC dates back to January 2020 when the initial concerns surfaced, the WHO preferred to communicate about its knowledge through Twitter,[340] which was inherently contrary to the agreed communication plan as established in the IHR.[341] In addition to their website, subsequent updates were also made through other social media platforms with scattered presence culminating into unequal access of such paramount information.[342] Furthermore, WHO's failed communication strategy muddled the definition of key terms like entry/exit screening, risk assessments, travel recommendations, etc.[343]

The WHO's situation reports try to highlight the conundrum.[344] The global risk was originally stated as "moderate" under the situation Report No. 3 and No. 4.[345] Later, the error in the previous reports was corrected in situation Report No. 6 which published the global risk as "high."[346] This major error caused a lot of uncertainty over the WHO risk assessment as it came through at a critical point in time.[347] Further, when situation Report No. 9 stated that there were no particular travel recommendations yet, the situation extended automatically to the domain of travel as well.[348] Despite claiming no recommendations existed, Report No. 9 also included a separate section on travelling and traffic advice.[349] However, based on the information that is currently accessible, it would be a difficult task to ascertain whether there was an error in the risk assessment or communication.[350]

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338 *Id*.
339 *Id*.
340 WHO (@WHO), TWITTER (Jan. 23, 2020, 12:28 PM), https://twitter.com/who/status/1220413117001322497?lang=en.
341 L. O. Gostin & R. Katz, *The International Health Regulations: The Governing Framework for Global Health Security*, 94 MILBANK Q. 264, 270, 294 (2016).
342 The Editors, *WHO Failed*, NAT'L REV. (Apr. 7, 2020 9:07 PM), https://www.nationalreview.com/2020/04/coronavirus-pandemic-world-health-organization-failed/.
343 Gabriel Blouin-Genest et al., *The WHO's Risky Communication Strategy Created Confusion Around COVID-19*, CONVERSATION (July 2, 2020), https://theconversation.com/the-whos-risky-communication-strategy-created-confusion-around-covid-19-140043.
344 *Id*.
345 *Id*.
346 *Id*.
347 *Id*.
348 *Id*.
349 *Id*.
350 *Id*.

CONCLUSION

The outpour of regulatory responses aimed at mitigating the development of the COVID-19 pandemic may well be culminating into the development of new transnational health policy. States (whether federal or centralized), public and private companies, international organizations, non-governmental organizations, and individuals have cumulatively contributed to the development of such responses and all have some degree of responsibility. While many scholars are echoing a need for a globally cohesive integrated action to tackle the aftermath of COVID-19,[351] each nation is due to resolve their own predicaments. While the pandemic led governments to spend trillions of dollars in aid to mitigate the economic shock, with the goal of returning to the pre-pandemic business era, before companies go bankrupt remains high priorities.[352] With businesses shutting down, the fear is that this pandemic may lead the world to a double-recession.[353] The COVID-19 crisis is the worst healthcare crisis that the world has witnessed in a century and is affecting all the low, middle, and high-income countries.[354] However, within a given country it is the lower-income households who are most likely to be severely affected.[355] We proposed a novel approach to identify the deficiencies of health care infrastructure among countries so that the interventions by the governments and multilateral organizations can be tailored in an effective fashion. We created HII to understand how well a country is equipped to face the pandemic. Countries with lower HII ranks are ideal candidates to receive more international funding to make targeted health intervention in their domestic economies. This index shows cases the areas where governments, or multilateral organizations, should intervene.

Economic policy in the short-run should be targeted towards providing healthcare access to the vulnerable section of the population, especially from

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[351] Patrick Brown, *Studying COVID-19 in Light of Critical Approaches to Risk and Uncertainty: Research Pathways, Conceptual Tools, and Some Magic from Mary Douglas*, 22 HEALTH RISK & SOC'Y 1, 1–14 (2020).

[352] *The Global Economic Outlook During the COVID-19 Pandemic: A Changed World*, WORLD BANK (June 8, 2020), https://www.worldbank.org/en/news/feature/2020/06/08/the-global-economic-outlook-during-the-covid-19-pandemic-a-changed-world.

[353] *See Coronavirus: World Economy 'May Face Double Recession'*, BBC NEWS (Apr. 16, 2020), https://www.bbc.com/news/business-52306001 (noting that the world economy is already facing an economic downturn, and there is a likelihood that this could be followed by another possibly much worse downturn).

[354] *See COVID-19 Position Paper: A Multidimensional Crisis that Affects Us All*, ESU (Apr. 6, 2020), https://www.esu-online.org/?policy=covid-19-position-paper-a-multidimensional-crisis-that-affects-us-all (noting that the recent outbreak of COVID-19 is the gravest health crisis that the world has faced).

[355] Univ. Coll. London, *Low-Income Workers Disproportionally Affected by COVID-19*, SCI. DAILY (May 1, 2020), www.sciencedaily.com/releases/2020/04/200430191258.htm.

the low and middle-income countries. The economic costs of lockdowns are likely to be worse for low-income countries, which generally have fragile healthcare systems.[356] Beyond national boundaries, international cooperation is required for an effective strategy to fight COVID-19. So far, individual countries experience to fight against COVID-19 differ. The U.S., for example, has four percent of the world population but is accounting for twenty-five percent of the COVID-19 cases.[357] This is in spite of the U.S. creating a two trillion dollars economic relief package.[358] In this regard, it is pertinent to learn from the experience of countries such as New Zealand or Taiwan, which have been able to successfully contain spread of COVID-19.

[356] NORMAN V. LOAYZA & STEVEN PENNINGS, MACROECONOMIC POLICY IN THE TIME OF COVID-19: A PRIMER FOR DEVELOPING COUNTRIES 1 (2020).
[357] Scottie Andrew, *The US Has 4% of the World's Population but 25% of its Coronavirus Cases*, MERCURY NEWS (June 30, 2020), https://www.mercurynews.com/2020/06/30/the-us-has-4-of-the-worlds-population-but-25-of-its-coronavirus-cases/.
[358] Stephanie Denning, *Why the $2 Trillion Stimulus Package is Putting Dollars in the Wrong Place*, FORBES (Apr. 8, 2020), https://www.forbes.com/sites/stephaniedenning/2020/04/08/why-the-2-trillion-stimulus-package-is-putting-dollars-in-the-wrong-place/#c8981b367773.

APPENDIX

THEORETICAL FRAMEWORK FOR DERIVING HEALTH INFRASTRUCTURE INDEX (HII) [359]

The healthcare infrastructure is represented by vector X $(where, X = X_1, X_2, ..., X_8)$. The first principal component, Z (also representing HII), is the weighted average of $X_1, X_2, ..., X_8$ with maximal variance. Therefore, $Z = Xw$, where, *w* represents the vector of optimal weights $w' = (w_1, w_2, ..., w_8)$.

The variance of Z is

$$Var(Z) = Var(w_1X_1 + w_2X_2 + ... + w_8X_8) \quad (1)$$

Or, $Var(Z) = w\,Sw$, subject to the normalization constraint $w\,w = 1$. Here, *S* represents variance-covariance matrix with S_{ij} is the covariance between X_i and X_j, and S_{ii} representing the variance of X_i.

To optimize in terms of weights, we use the Lagrangian Function as $L = w'Sw + \lambda(1 - w'w)$. To maximize the variance we select the weight, *w*, in accordance to the first order condition of maximization.

$$\frac{\partial L}{\partial w} = \frac{\partial[w'Sw + \lambda(1 - w'w)]}{\partial w} = 0 \quad \frac{\partial L}{\partial w} = \frac{\partial[w'Sw + \lambda(1 - w'w)]}{\partial w} = 0 \quad (2)$$

which implies, $(S - \lambda I)w = 0$ (3)

The solution to (3) is the characteristic vector, *w*. Thus, the roots are chosen such that

$$|S - \lambda I| = 0 \quad (4)$$

The solution to (4) will have multiple roots but we consider largest characteristic root of S. This will ensure all maximum possible use of available information which are there in the individual variables. Before undertaking to construct PCA, we standardize the data with respect to mean and standard deviation to ensure unit-free comparison between the data. For each country, we then compute HII using software package Eviews 11.

[359] *See generally* KANTILAL V. MARDIA ET AL., MULTIVARIATE ANALYSIS 15–17 (1979).

RANKING OF COUNTRIES

Countries	Medical doctors per 1000 popn.	Nursing and mid-wifery per 10000 popn.	Dentists per 10000 popn.	Pharmacists per 10000 popn.	Hosp. density per 10000 popn.	Hosp. beds per 10000 popn.	Skilled health professionals density per 10000 popn.	Govt. Health Spending as % of GDP	PCI
Monaco	75.1	201.6	10.2	26.3	10.6	29.0	271.6	1.8	260.9
Switzerland	42.5	173.3	5.0	7.0	1.1	47.0	223.0	12.3	210.5
Norway	29.2	182.2	8.7	8.3	1.1	39.0	222.1	10.4	207.6
Iceland	39.8	157.1	8.3	5.1	3.6	32.0	190.8	8.3	184.1
Germany	42.5	132.4	8.5	6.5	1.1	83.0	179.8	11.2	183.8
Belgium	30.7	189.7	7.5	12.3	1.1	63.0	141.7	10.3	183.1
Finland	33.9	146.8	7.3	10.9	1.4	49.0	182.3	9.2	179.5
Denmark	40.1	103.2	7.4	5.2	1.0	31.0	206.7	10.1	167.9
Ireland	32.9	161.0	6.5	11.6	1.1	28.0	152.0	7.2	166.1
Cuba	83.0	77.3	16.8	2.4	2.0	51.0	155.0	11.7	160.9
Australia	36.8	125.5	5.9	8.8	1.1	29.0	157.2	9.2	154.3
Sweden	39.8	117.6	8.2	7.7	1.1	26.0	160.6	11	153.9
Luxemburg	30.1	121.7	9.8	7.0	1.1	51.0	152.4	5.5	153.1
France	32.7	114.7	6.7	10.6	1.1	65.0	138.0	11.3	149.8
New Zealand	34.7	123.2	6.2	6.8	1.1	28.0	143.0	9.2	145.3
United States of America	26.1	145.5	5.8	9.2	1.1	29.0	117.3	17.1	142.6
Japan	24.1	119.5	8.0	18.0	1.1	29.0	136.0	10.9	141.4
Austria	51.7	70.9	5.7	7.1	1.1	76.0	135.1	10.4	138.9

Netherlands	36.1	111.8	5.1	2.1	0.8	29.0	139.8	10.1	137.8
Lithuania	48.3	79.8	10.0	9.9	2.2	73.0	124.2	6.5	137.5
Uzbekistan	23.7	112.8	1.5	0.4	1.1	40.0	149.5	6.4	137.0
Estonia	44.8	111.6	13.8	10.9	1.9	50.0	98.0	6.4	134.2
Czechia	40.7	84.0	7.4	6.9	1.3	65.0	120.9	7.2	130.6
Slovenia	30.9	99.7	7.0	6.8	1.3	46.0	116.6	8.2	126.5
Kazakhstan	39.8	72.0	3.7	8.2	3.5	67.0	116.8	3.1	121.9
Portugal	51.2	69.7	10.1	9.1	1.1	34.0	108.0	9	118.0
Russian Federation	40.1	45.3	2.8	0.5	1.1	82.0	126.6	5.3	115.9
Hungary	34.1	69.2	7.1	8.1	1.0	70.0	97.3	6.9	112.4
Ukraine	29.9	66.6	6.0	0.3	1.1	88.0	100.4	7	112.1
United Kingdom	28.1	81.7	5.2	8.9	1.1	28.0	112.5	9.6	111.6
Maldives	45.6	64.3	2.0	3.5	6.7	29.0	118.3	9	111.4
Romania	29.8	73.9	8.0	9.1	1.7	63.0	90.8	5.2	108.3
Brazil	21.7	97.4	12.5	6.8	1.1	23.0	93.0	9.5	107.7
Croatia	31.7	61.9	7.9	7.2	1.5	59.0	96.4	6.8	105.1
Azerbaijan	34.5	64.3	2.7	2.0	8.0	47.0	102.7	6.7	103.4
Bulgaria	40.3	48.2	10.5	1.7	1.1	68.0	93.2	8.1	103.1
Belize	11.2	185.1	1.5	6.8	2.1	9.0	25.8	5.6	102.6
Slovakia	34.4	60.1	4.9	4.9	1.5	58.0	94.7	6.7	102.5
Italy	39.8	57.4	8.2	10.9	2.1	29.0	97.4	8.8	101.6

Greece	54.8	36.3	12.5	10.6	1.1	29.0	96.5	8	100.1
Spain	38.7	57.3	7.9	11.5	1.6	30.0	92.0	8.9	99.1
Uruguay	39.5	58.7	7.4	2.4	3.9	25.0	97.9	9.3	98.0
Armenia	44.0	61.1	5.6	0.5	4.0	41.0	82.3	10.4	96.9
Kuwait	26.5	71.5	6.7	4.9	1.1	22.0	96.5	5.3	96.1
Republic of Korea	23.6	71.2	5.0	7.2	3.4	29.0	92.2	7.6	95.3
Israel	34.8	57.0	7.3	8.0	0.6	31.0	88.8	7.4	94.2
Libya	20.9	65.3	8.8	6.0	2.6	37.0	89.9	8.2	93.7
Poland	23.8	57.0	3.5	7.7	0.9	65.0	79.8	6.5	92.1
Latvia	31.9	47.5	7.1	8.3	1.6	58.0	81.1	6	91.9
Republic of Moldova	32.1	49.2	4.2	4.1	2.1	58.0	77.1	7	88.5
Chile	25.9	133.2	12.5	5.3	1.0	22.0	11.8	9	88.3
Singapore	22.9	61.7	3.9	5.1	0.5	21.0	94.0	4.4	87.6
Malta	28.6	83.7	4.8	12.9	0.9	48.0	40.1	9.3	87.0
Qatar	24.9	72.6	6.3	8.9	1.1	14.0	76.7	2.6	85.8
Kyrgyzstan	22.1	59.4	1.7	0.4	2.6	45.0	81.0	6.2	84.5
Serbia	31.1	60.9	2.1	8.1	1.1	29.0	71.6	8.4	84.4
Argentina	39.9	26.0	9.2	5.1	1.1	49.0	81.2	9.1	84.3
Andorra	33.3	40.1	8.2	10.1	1.1	29.0	81.3	10.3	84.3
Georgia	71.2	47.3	7.6	1.0	2.2	26.0	45.7	7.6	83.4
Nauru	13.5	67.3	1.9	1.9	10.0	29.0	83.6	11	83.2

Brunei Darussalam	17.8	66.4	2.3	1.7	1.4	29.0	82.6	2.4	82.1
Saudi Arabia	26.1	54.8	5.0	8.6	1.0	22.0	77.7	5.2	81.1
Turkmenistan	22.2	44.3	1.2	1.7	1.1	74.0	70.6	6.9	81.1
Montenegro	27.6	52.3	0.5	1.9	2.1	29.0	80.8	6.3	79.8
Seychelles	21.2	80.8	3.6	4.7	1.1	29.0	54.2	5	79.5
North Korea	36.8	44.5	2.2	4.0	6.9	29.0	75.3	4	79.2
Cook Islands	14.1	65.5	12.4	0.6	1.1	29.0	69.5	3.3	78.1
Bosnia and Herzegovina	21.6	61.8	2.4	1.3	1.0	11.0	77.6	8.9	76.5
Tajikistan	21.0	47.5	1.6	1.0	4.7	48.0	69.9	7.2	75.2
Niue	18.8	100.0	12.5	6.3	1.1	29.0	18.3	6.3	75.2
Republic of North Macedonia	28.7	37.9	8.8	2.4	1.1	44.0	66.7	6.1	75.0
Cyprus	26.2	40.3	7.5	6.5	7.5	34.0	66.1	6.7	73.6
Mongolia	28.6	40.8	2.3	5.0	2.5	29.0	72.6	4	73.1
Palau	14.2	63.1	2.6	1.1	1.1	23.0	64.5	12	71.7
Trinidad and Tobago	41.7	40.9	3.5	6.6	1.1	27.0	51.0	7	70.6
Barbados	17.7	47.4	3.0	9.1	1.1	62.0	45.7	6.8	69.9

Jordan	23.2	33.6	7.3	16.0	1.9	18.0	65.4	8.1	68.6
Mali	1.4	4.1	0.1	0.1	0.5	29.0	130.5	3.8	68.0
United Arab Emirates	25.3	57.3	6.5	8.8	1.1	12.0	46.2	3.3	65.7
Antigua and Barbuda	29.6	45.0	0.4	1.8	1.1	39.0	45.7	4.5	64.1
Oman	20.0	42.0	3.0	5.6	1.4	17.0	60.7	3.8	61.9
Saint Kitts and Nevis	26.8	42.2	3.9	2.4	7.4	29.0	45.7	5	61.1
Bahamas	20.1	32.5	2.7	2.4	1.1	29.0	62.4	5.8	60.8
Mauritius	23.1	35.2	3.2	4.2	1.0	29.0	53.5	5.7	60.2
China	19.8	26.6	4.5	3.2	1.1	29.0	59.7	5.2	57.8
Malaysia	13.3	38.1	1.6	3.3	0.5	29.0	56.6	3.9	57.2
Lebanon	21.0	16.7	10.2	12.9	3.1	29.0	49.4	8.2	56.2
Philippines	6.0	52.7	2.4	3.3	1.8	29.0	45.7	4.4	55.9
Albania	12.2	36.5	2.2	8.4	1.4	29.0	45.7	6.3	53.9
Saint Vincent and the Grenadines	9.3	46.5	1.2	3.3	0.0	25.0	45.7	4.5	53.2
Grenada	14.1	30.6	1.5	6.8	0.9	37.0	45.2	4.8	52.7
Kiribati	2.0	46.4	0.6	0.3	0.0	29.0	48.1	10.8	52.1
Dominica	5.4	44.9	0.6	2.4	5.6	29.0	45.7	5.9	51.7
Turkey	18.5	27.1	3.4	3.5	1.6	27.0	44.1	4.2	49.6
Mexico	23.8	25.1	1.4	0.5	3.5	16.0	48.8	5.5	48.8

Panama	15.7	29.9	2.8	2.4	0.9	29.0	38.5	7.3	47.6
South Africa	8.0	13.3	1.1	2.7	0.7	29.0	60.5	8.1	46.4
Suriname	7.1	30.6	0.5	0.6	0.4	29.0	45.7	6.2	45.5
Ecuador	20.6	25.1	5.3	0.4	0.3	15.0	37.5	8.3	44.3
Venezuela (Bolivarian Republic of)	19.5	11.4	5.6	2.4	1.1	29.0	45.7	1.2	44.2
Tunisia	12.8	26.6	3.1	2.3	2.3	21.0	39.6	7.2	43.5
Botswana	5.3	41.2	0.4	2.1	1.3	29.0	31.1	6.1	43.3
Bolivia (Plurinational State of)	15.9	11.2	2.2	2.2	1.1	29.0	45.7	6.4	42.4
Fiji	8.6	30.2	0.7	1.1	0.0	29.0	37.8	3.5	42.1
Syrian Arab Republic	12.9	15.4	7.2	10.7	1.1	15.0	38.5	6.3	41.2
Algeria	17.2	15.5	3.7	4.5	1.1	29.0	31.2	6.4	39.8
Thailand	8.1	27.6	2.3	5.5	1.8	29.0	27.6	3.7	38.7
Nepal	7.5	31.1	1.0	4.0	0.4	29.0	26.4	5.6	38.7
Sri Lanka	10.0	21.8	0.7	0.8	0.1	29.0	36.8	3.8	38.6
Gabon	6.8	29.5	0.2	0.6	3.5	29.0	33.0	2.8	38.5
Bahrain	9.3	24.9	1.0	1.6	1.1	21.0	34.1	4.7	37.1
Colombia	19.7	11.7	9.7	2.4	1.1	15.0	29.0	7.2	36.6

India	8.6	17.3	2.0	8.9	1.1	29.0	28.5	3.5	35.9
Costa Rica	13.8	30.1	1.4	7.3	0.8	11.0	19.5	7.3	35.2
El Salvador	15.7	18.0	7.6	6.5	0.5	11.0	24.1	7.2	35.1
Namibia	4.2	19.5	0.7	2.4	1.9	29.0	31.3	8.6	34.5
Comoros	1.7	9.2	0.2	0.2	0.7	29.0	45.7	7.4	34.0
Eswatini	3.3	37.7	0.4	0.3	0.8	29.0	15.3	6.9	33.5
Burundi	1.0	8.5	0.0	0.0	0.5	29.0	45.7	7.5	33.2
Bangladesh	5.8	4.1	0.6	1.8	0.2	29.0	45.7	2.3	33.1
Paraguay	13.5	16.6	1.6	0.3	2.4	29.0	23.3	6.7	33.0
Peru	13.0	21.8	1.8	0.5	1.1	15.0	26.1	5	32.4
Eritrea	0.8	9.2	0.1	0.1	0.4	29.0	45.7	2.9	32.4
Egypt	4.5	19.3	20.0	4.6	0.6	5.0	22.5	5.3	32.1
Equatorial Guinea	4.0	5.0	0.1	0.2	1.1	29.0	45.7	3.1	32.1
Lesotho	0.4	5.6	0.0	0.0	1.1	29.0	45.7	8.8	32.0
Dominican Republic	15.3	11.7	2.2	3.9	1.1	16.0	28.3	6.1	31.9
Micronesia (Federated States of)	6.2	1.5	1.4	2.4	4.8	29.0	38.0	12.4	31.8
Saint Lucia	6.4	31.5	1.7	4.4	1.7	13.0	19.6	4.5	31.6
Marshall Islands	4.2	33.0	0.7	0.7	3.8	29.0	7.9	16.4	31.2

Iran (Islamic Republic of)	15.8	4.4	4.5	2.9	1.1	15.0	30.4	8.7	30.9
Viet Nam	8.3	14.5	2.2	3.4	1.1	29.0	22.6	5.5	30.4
Sudan	4.1	8.2	2.1	4.4	1.4	8.0	42.2	6.3	29.8
Iraq	8.4	18.1	2.5	2.9	1.1	13.0	26.6	4.2	29.5
Bhutan	4.2	18.5	0.8	0.6	1.7	35.0	18.9	3.2	28.2
Vanuatu	1.8	18.4	0.7	1.2	2.4	29.0	24.0	3.3	28.1
Haiti	2.3	6.8	0.2	0.3	0.2	7.0	45.7	8	27.9
Indonesia	4.3	24.1	0.6	0.9	0.4	29.0	15.5	3	27.6
Jamaica	13.1	14.7	0.9	0.2	0.8	17.0	21.3	6	27.5
Samoa	4.8	17.9	0.6	0.7	4.2	29.0	18.8	5.5	27.2
Solomon Islands	1.9	19.9	0.5	1.3	1.1	29.0	19.7	4.7	27.1
Nicaragua	9.8	15.3	0.4	1.9	1.0	9.0	23.0	8.6	26.1
Timor-Leste	7.2	16.7	0.1	1.9	1.1	29.0	15.1	3.9	25.9
Cabo Verde	7.8	9.5	0.1	0.1	1.0	29.0	20.4	5.2	25.0
Zimbabwe	2.1	19.3	0.1	1.0	0.5	29.0	12.4	6.6	23.9
Zambia	11.9	13.4	0.0	0.4	0.5	29.0	9.8	4.5	23.7
Ghana	1.4	23.5	0.0	0.2	1.4	29.0	10.2	3.3	23.4
Gambia	1.0	15.4	0.1	0.0	0.7	29.0	17.3	3.3	22.8
Myanmar	6.8	10.0	0.7	0.7	0.6	29.0	15.0	4.7	22.7

Lao People's Democratic Republic	3.7	12.6	0.7	2.5	2.3	29.0	14.5	2.5	22.5
Kenya	1.6	11.7	0.2	0.2	1.5	29.0	17.8	4.8	22.1
Congo	1.6	17.9	0.3	0.6	1.1	29.0	10.5	2.9	21.3
Morocco	7.3	13.9	1.4	2.6	1.1	9.0	14.9	5.2	20.7
Guyana	8.0	10.4	0.4	0.1	3.4	29.0	7.4	4.9	19.9
Uganda	1.0	15.6	0.1	0.0	0.4	29.0	7.4	6.3	19.1
Rwanda	1.3	12.0	0.2	0.7	1.1	29.0	9.0	6.6	18.9
Guatemala	3.5	0.7	0.1	0.0	0.3	29.0	17.6	5.8	18.3
Angola	2.1	4.1	0.1	0.5	1.1	29.0	15.9	2.8	17.8
Guinea-Bissau	1.3	5.9	2.2	0.0	56.5	29.0	7.3	7.2	17.7
Pakistan	9.8	6.7	1.0	1.6	0.5	6.0	14.8	2.9	16.8
Congo	0.9	4.1	0.0	0.0	0.5	29.0	10.5	6.3	15.5
Cameroon	0.9	9.2	0.0	0.1	0.8	29.0	6.0	4.7	15.4
CÃ´te d'Ivoire	2.3	6.3	0.2	1.1	1.7	29.0	6.2	4.5	15.3
Honduras	3.1	7.4	0.3	0.5	0.4	7.0	15.2	7.9	15.1
Burkina Faso	0.6	6.6	0.0	0.1	1.1	29.0	6.8	6.9	15.0
Yemen	5.3	8.8	0.2	1.1	3.0	7.0	10.7	6.3	14.5
Mozambique	0.8	6.8	0.1	0.1	1.1	29.0	4.6	4.9	13.8
Benin	0.8	3.9	0.0	0.3	0.4	29.0	7.5	3.7	13.5

Sierra Leone	0.3	2.8	0.0	0.3	1.1	29.0	3.4	13.4	13.3
Cambodia	1.9	9.6	0.2	0.3	0.6	7.0	10.9	5.9	13.1
Malawi	0.4	4.4	0.0	0.1	0.4	29.0	3.5	9.6	13.1
Ethiopia	0.8	7.1	0.2	0.4	0.2	29.0	2.8	3.5	12.9
Papua New Guinea	0.7	4.5	0.2	0.1	1.6	29.0	5.9	2.5	12.8
Djibouti	2.2	7.3	0.2	2.3	1.1	14.0	7.9	3.3	12.8
Togo	0.8	4.1	0.0	0.3	0.6	29.0	3.6	6.2	12.5
United Republic of Tanzania	0.6	4.3	0.0	0.1	1.1	29.0	4.4	3.6	12.2
Madagascar	1.5	3.0	0.0	0.0	0.5	29.0	3.6	5.5	12.1
Chad	0.5	2.5	2.2	0.1	0.7	29.0	3.5	4.5	12.0
Senegal	0.7	3.1	0.1	0.1	0.2	29.0	3.8	4.1	11.6
Central African Republic	0.7	2.1	0.0	0.0	0.5	29.0	3.0	5.8	11.1
Guinea	0.8	1.2	0.0	0.1	0.4	29.0	4.4	4.1	11.1
Niger	0.4	2.7	0.0	0.0	0.6	29.0	1.6	7.7	11.1
Afghanistan	2.8	1.5	0.0	0.5	0.4	5.0	6.4	11.8	8.8
Somalia	0.2	1.1	2.2	2.4	1.1	9.0	1.1	6.3	6.6

Source: Authors' Calculation, Eviews 11.

The Beazley Institute for Health Law and Policy
At Loyola University Chicago School of Law

The Beazley Institute

The Beazley Institute for Health Law and Policy was created in 1984 to recognize the need for an academic forum to study the burgeoning field of health law and to foster a dialogue between the legal and health care professions. Since that time, the Beazley Institute has grown to offer one of the most comprehensive and respected health law programs in the country. The Institute today is comprised of students, faculty, researchers, practitioners, lecturers, librarians and staff working together to fulfill a common mission: **We educate the health law students of tomorrow.**

Advanced Degrees for Attorneys

The Master of Laws (LLM) in Health Law degree is a post-J.D. master's degree program for attorneys who wish to develop or enhance a special expertise in health law. This 24-credit degree program can be completed on-campus or online. All students enrolled in the LLM in Health Law degree program take courses from cutting-edge curriculum developed in conjunction with a committee of leading health lawyers, industry professionals, and national experts. Courses focus on the legal, regulators, political, ethical and economic aspects of health care delivery.

The Doctor of Juridical Sciences (SJD) in Health Law and Policy program provides qualified attorneys with the opportunity to pursue a doctoral digress, using legal research methods as the tools for analyzing key issues in health law and policy. Loyola is proud to be one of a handful of law schools across the nation to offer an SJD degree, and the first to offer such a degree in health law.

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