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TABLE OF CONTENTS

ARTICLES

- 1 The Regulatory Shifting Baseline Syndrome: Vaccines, Generational Amnesia, and the Shifting Perception of Risk in Public Law Regimes**
Robin Kundis Craig
- 61 Advancing Harm Reduction Services in the United States: The Untapped Role of the Americans with Disabilities Act**
Abigail Fletes, Maria Katherine Delos Reyes, John C Messinger, Valarie Blake & Leo Beletsky
- 90 Reconceptualizing the International Health Regulations in the Wake of COVID-19: An Analysis of Formal Dispute Settlement Mechanisms and Global Health Diplomacy**
Celestina Radogno
- 152 Data Privacy in the Time of Plague**
Cason Schmit, Brian N. Larson & Hye-Chung Kum

The Regulatory Shifting Baseline Syndrome: Vaccines, Generational Amnesia, and the Shifting Perception of Risk in Public Law Regimes

Robin Kundis Craig*

Abstract:

Vaccination mandates have been controversial since governments first imposed them. Nevertheless, the intense politicization surrounding the COVID-19 pandemic obscures a more pervasive problem for U.S. public health laws and vaccine-preventable diseases. Until the late twentieth century, the risk of various dread diseases was sufficiently high for most people that they embraced new vaccines. The intentional result of federal and state vaccination policies was that fewer people got these diseases. The perverse result was that perceptions of disease risk shifted, making the vaccines themselves seem like the far riskier option to many people, generating pressure to eliminate or mitigate vaccination mandates. Perhaps most importantly, in the early twenty-first century, state legislatures enacted exemptions from school vaccination requirements, setting the stage for measles resurgences in 2015 and 2019.

Focusing primarily on measles vaccination, this Article argues that, while not the only factor, a regulatory shifting baseline syndrome fueled the pre-COVID-19 resistance to vaccination. In 1995, Dr. Daniel Pauly described the “shifting baseline syndrome” and its problems for fisheries management. Pauly posited that each generation forgets what the ocean and its fisheries used to contain, leading successive generations to accept the current impoverished state of marine fisheries as normal. This generational amnesia makes opaque what the goals of fisheries regulation should, or even could, be.

This Article brings the shifting baseline concept into public law, identifying for the first time a regulatory shifting baseline syndrome that can undermine the law’s ability to protect society. This syndrome arises when a public legal regime, like a school vaccination mandate, so successfully eliminates a societal problem, like dread diseases, that citizens, politicians, and lawmakers forget that the regime is, in fact, still working to keep that problem at bay. This generational amnesia can lead to changes in law and policy that allow the prior problem to re-

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emerge in society, as occurred with measles outbreaks. While COVID-19 vaccination mandates are almost uniquely politicized and too new to reflect this syndrome, decisions in the COVID-19 context may nevertheless give the regulatory shifting baseline syndrome more room to operate, potentially threatening public health gains made with respect to other vaccine-preventable diseases in the United States.

INTRODUCTION 5

**I. FROM THE SHIFTING BASELINE SYNDROME TO THE REGULATORY
SHIFTING BASELINE SYNDROME 9**

A. DANIEL PAULY’S INSIGHT: THE ORIGIN OF THE SHIFTING BASELINE
SYNDROME 9

B. USE OF THE SHIFTING BASELINE SYNDROME IN FISHERIES
MANAGEMENT AND OTHER ECOLOGICAL CONTEXTS 10

C. FROM ECOLOGY TO REGULATORY REGIMES: THE REGULATORY
SHIFTING BASELINE SYNDROME 13

 1. GENERATIONAL AMNESIA 13

 2. PUBLIC LAW AS A CULTURAL MEMORY INSTITUTION 14

 3. THE EMERGENCE OF THE REGULATORY SHIFTING BASELINE
 SYNDROME 17

D. HOW ACKNOWLEDGING THE REGULATORY SHIFTING BASELINE
SYNDROME IMPROVES REGULATORY REGIME EVALUATION 22

**II. A BRIEF HISTORY OF VACCINES, VACCINE REGULATION IN THE
UNITED STATES, AND VACCINES’ ABILITY TO AFFECT THE
DISEASE RISK BASELINE 26**

A. THE DEVELOPMENT OF VACCINES 26

B. FEDERAL REGULATION OF VACCINES IN THE UNITED STATES 26

 1. VACCINE SAFETY AND THE FDA 26

 2. FEDERAL IMMUNIZATION PROGRAMS 28

C. STATE VACCINATION REQUIREMENTS FOR SCHOOL ATTENDANCE 28

 1. STATE AUTHORITY TO REQUIRE VACCINES 28

 2. SCHOOL VACCINATION MANDATES 30

D. REAL SHIFTS IN BASELINE DISEASE RISK FROM VACCINATION:
SMALLPOX AND POLIO 30

**III. THE VACCINATION REGULATORY SHIFTING BASELINE SYNDROME
IN THE UNITED STATES 33**

A. INITIAL SIGNALS OF A VACCINATION REGULATORY SHIFTING
BASELINE SYNDROME: VACCINE LAWSUITS AND THE CHILDHOOD
VACCINE INJURY ACT OF 1986 34

 1. VACCINE LITIGATION 34



2. DEALING WITH THE VACCINE SUPPLY CRISIS: THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986	36
B. VACCINE RESISTANCE, ANTI-VAXXERS, AND THE EMERGENCE OF THE VACCINATION REGULATORY SHIFTING BASELINE SYNDROME.....	37
1. VACCINE HESITANCY IN THE UNITED STATES	37
2. VACCINE HESITANCY AND MEASLES	39
C. THE VACCINATION REGULATORY SHIFTING BASELINE SYNDROME TAKES LEGAL SHAPE: EXEMPTIONS FROM STATE VACCINATION MANDATES	40
1. INCREASING NUMBERS OF STATE EXEMPTIONS FROM SCHOOL VACCINATION REQUIREMENTS	40
2. PERSONAL PHILOSOPHICAL EXEMPTIONS FROM VACCINE REQUIREMENTS	41
3. RELIGIOUS EXEMPTIONS FROM VACCINE REQUIREMENTS	43
4. CORRELATIONS BETWEEN EXEMPTIONS AND REDUCED VACCINATION RATES	46
IV. VACCINES AND THE REGULATORY SHIFTING BASELINE SYNDROME IN A COVID-19 WORLD	47
A. COVID-19 AND TRADITIONAL VACCINE-PREVENTABLE DISEASES.....	47
B. RESPONSE #1: REACTIONS TO THE RESURGENCE OF MEASLES	50
1. THE FEDERAL GOVERNMENT’S RESPONSE TO MEASLES RESURGENCE	50
2. THE STATES’ RESPONSES TO MEASLES RESURGENCE	51
C. RESPONSE #2: THE POLITICIZATION OF THE CORONAVIRUS PANDEMIC AND THE FUTURE OF VACCINATION MANDATES	52
D. CAN AWARENESS OF THE REGULATORY SHIFTING BASELINE SYNDROME HELP?	56
V. CONCLUSION.....	58

And you, of tender years,
Can't know the fears,
That your elders grew by.
—Crosby, Stills, Nash & Young, “Teach Your Children”¹

Those who cannot remember the past are condemned to repeat it.
—George Santayana²

INTRODUCTION

In the middle of the ongoing COVID-19 pandemic, it has been easy to forget that other vaccine-preventable diseases remain public health issues. Measles, for example, is far more contagious than most strains of COVID-19,³ and measles outbreaks are expensive. When seventy-one people in Clark County, Washington, caught measles in 2019, the relatively small outbreak cost the county \$3.4 million and probably spread to other places, like Oregon and Georgia.⁴ Tragically, most of the victims were “children younger than 10 who hadn’t received the measles-mumps-rubella (MMR) vaccine.”⁵ At least part of the cause of this and similar outbreaks, this paper will argue, was generational amnesia induced by the regulatory shifting baseline syndrome. The fact that several generations of Americans never experienced the nineteenth and twentieth centuries’ dread diseases, particularly measles, has improperly devalued vaccination mandates such as school vaccination requirements and contributed to a heightened perception of risk from the vaccines themselves.

In 1995, Dr. Daniel Pauly described the “shifting baseline syndrome” and the problems it causes for fisheries management.⁶ Pauly argued that each generation of fishers and fisheries managers forgets what the ocean used to produce, instead viewing the current abundance and size of desired fish—however demonstrably impoverished those might be from a historical perspective—as normal.⁷ As a result, fisheries management, laws, and policies

1 CROSBY, STILLS, NASH & YOUNG, *Teach Your Children*, on DÉJÀ VU (Atlantic Records, 1970).

2 GEORGE SANTAYANA, *THE LIFE OF REASON* (1905).

3 Amy Norton, *Driven by Anti-Vaxxers, Measles Outbreaks Cost Everyone Money*, U.S. NEWS & WORLD REP. (Mar. 12, 2021, 8:25 AM), <https://www.usnews.com/news/health-news/articles/2021-03-12/driven-by-anti-vaxxers-measles-outbreaks-cost-everyone-money> [<https://perma.cc/5WMH-JR6J>].

4 *Id.*

5 *Id.*

6 Daniel Pauly, *Anecdotes and the Shifting Baseline Syndrome in Fisheries*, 10 TRENDS IN ECOLOGY & EVOLUTION 430, 430 (1995).

7 *Id.*

never seek to restore fisheries and marine ecosystems to true health but instead accept and adjust to progressively worsening ecological conditions.⁸ Generational amnesia, in other words, makes opaque what the goals of regulation should be, or even *could* be. Therefore, in fisheries regulation and other forms of species and ecosystem management, reconstructing historical ecological conditions has become the primary means of correcting the shifting baseline syndrome and implementing more aggressive recovery goals.⁹

This Article moves the shifting baseline syndrome into public law,¹⁰ arguing that successful public regulatory regimes can *cause* a shifting baseline syndrome—a *regulatory shifting baseline syndrome*. This syndrome arises when the laws created to correct a particular societal problem are so successful that, after some time passes, citizens, politicians, courts, administrative agencies, and legislatures forget that the regulatory regime is, in fact, still functioning—that is, that dismantling the existing regulatory requirements will cause the original problem to recur. The syndrome thus distorts public estimation of the regulatory regime’s continuing existential value.

The United States now has a large collection of generation-spanning regulatory regimes. However, the success of a public law regime can become so (apparently) complete that the relevant policymakers come to believe (or at least

⁸ *Id.*

⁹ See discussion *infra* Part I.

¹⁰ “Public law,” for purposes of this discussion, refers to the statutes, regulations, and policies that both regulate government itself and operate to protect society as a whole from problems that arise at scales too large to deal with effectively through private law mechanisms, such as contracting, insurance, or tort liability. Scholars generally distinguish “public law” from “private law” in two ways. The first approach defines public law as the law that involves and regulates the government itself. See, e.g., David Sloss, *Polymorphic Public Law Litigation: The Forgotten History of Nineteenth Century Public Law Litigation*, 71 WASH. & LEE L. REV. 1757, 1767-68 (2014) (applying a functional test to conclude that “[i]n public law cases, private actors ask courts to apply their judicial power to regulate the conduct of government actors” and defining “public law cases to comprise litigated cases involving a dispute between a private party and a government actor in which the private party alleges that the government actor committed, or threatened to commit, a violation of some established legal norm”); Ryan J. Cassidy, *Prefatory Remarks: Administrative Law and the First Annual Survey*, 5 WIDENER J. PUB. L. 617, 621-22 (1996) (defining “public law” to be “the law relating to the interaction between the state as a sovereign entity, its political subdivisions, and its citizens”). The second approach distinguishes public law from private law on the basis of the law’s subject matter. See, e.g., Philip J. McConaughay, *Reviving the “Public Law Taboo” in International Conflict of Laws*, 35 STAN. J. INT’L L. 255, 261, 300-304 (1999) (noting that “private law and public law are defined according to the categories or types of law traditionally within each: private law traditionally includes contracts, torts, property, and family law, while public law traditionally includes antitrust, securities, exchange controls, and most economic regulation”). This Article embraces both inflections of “public law” but relies more heavily on the latter, extending McConaughay’s emphasis on “public law’s focus on the public interest and preventing public harm,” *id.* at 302, to public health law and environmental and natural resources law.

argue) that its restrictions are no longer necessary. Under the influence of the regulatory shifting baseline syndrome, the (apparent) disappearance of the problem transforms initial respect for the regulatory regime (“it worked!”) into a psychological resetting of the regulatory baseline—essentially, “we no longer have to worry about *that* problem, and these laws are now an impediment to other things we want to do.” In particular, the disappearance of a specific problem can allow interest groups to re-frame the corrective regulatory regime as unnecessary, burdensome, expensive, or an infringement of private or states’ rights, lobbying the relevant decisionmakers to get rid of it. In short, once the perceived regulatory baseline shifts, policymakers may come to view the existing legal regime as no longer necessary and perhaps even harmful, opening those legal protections to re-evaluation. At the extreme, decisionmakers dismantle or weaken the now-devalued regimes—and history repeats itself.

Applying a regulatory shifting baseline syndrome analysis to evolving and often contentious public debates, therefore, has the potential to reveal an essential cultural component to the evolution of public law and policy: new generations forget the past, which can change the contours of the relevant political and legal debate over regulatory requirements and restrictions by altering perceptions of risk. This Article argues that identifying and resisting the regulatory shifting baseline syndrome offers one means of keeping needed public protections in place, avoiding the re-emergence of public commons problems that momentarily appear to have been “solved.” Specifically, awareness of the regulatory shifting baseline syndrome should prompt policymakers to reframe the status of the public problem under consideration from its objective manifestation (or lack thereof) to the human impulses driving the problem and its potential to recur. The relevant question for evaluating the regime’s continued existential value becomes: *What is likely to happen after removing the regime’s protections?*

Vaccine mandates provide a particularly timely, scientifically interesting, and complicated focus for studying the regulatory shifting baseline syndrome. The highly politicized controversy over vaccination mandates to combat the COVID-19 pandemic¹¹—a resistance to vaccination *not* grounded in the regulatory shifting baseline syndrome—has obscured the syndrome’s operation in the United States concerning the more traditional suite of non-eradicated but vaccinatable diseases, such as measles and whooping cough. All vaccines come with risks,¹² but when the risk of dying from the vaccine-preventable disease is

11 Toby Bolsen & Risa Palm, *Politicization and COVID-19 Vaccine Resistance in the U.S.*, 188 PROGRESS MOLECULAR BIOLOGY & TRANSLATIONAL SCI. 81, 81-84 (2022).

12 For example, “[a]ny vaccine can cause side effects. For the most part these are minor (for example, a sore arm or low-grade fever) and go away within a few days.” *Possible Side Effects from Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/vacc-gen/side-effects.htm> [<https://perma.cc/34KF-CC97>] (last visited Apr. 2, 2020).

high, even crude risk-risk analyses favor vaccination at societal and individual levels. As a disease disappears, however, it becomes easy for individuals to subjectively perceive the most salient threat to be the vaccine itself, even if the societal public health need for vaccination programs has not changed.¹³ Complicating regulatory decision-making, however, is the potential for successful vaccination programs to eradicate certain diseases,¹⁴ actually changing the objective risk-risk calculus—that is, *actually* shifting the regulatory baseline. As a result, decisionmakers—from legislators to individual patients—need to understand whether the risk-risk analysis has really changed, as with smallpox, or only *appears* to have changed because vaccines effectively keep people from getting the disease.¹⁵ Finally, vaccination programs require individuals to accept a (usually small) personal risk from the vaccine to eliminate disease risks both to themselves *and society as a whole*, in the form of herd immunity.¹⁶ Therefore, distorted perceptions of risk from the vaccine perpetuate disease vulnerabilities not just for the individual making the vaccination decision but also for the community.

This Article proceeds in four parts. Part I introduces the shifting baseline syndrome in its original context, then transitions the psychology of fisheries regulation into the regulatory shifting baseline syndrome. Part II provides a brief

13 Compare S. Krugman, *Measles and Mumps Immunization: Benefit Versus Risk Factors*, 43 DEV. BIOLOGICAL STANDARDIZATION 253 (1979) (concluding that the risks of measles and mumps outweigh the risks of the relatively new vaccines to prevent these diseases, which were reducing the disease incidence in the United States by 90 percent), with *Measles Vaccination: Myths and Facts*, INFECTIOUS DISEASES SOC. AM., <https://www.idsociety.org/public-health/measles/myths-and-facts/> [<https://perma.cc/CV5H-GABJ>] (last visited Apr. 12, 2022) (needing to dispel perceptions that the MMR vaccine causes autism or the measles disease in children).

14 Only smallpox has been declared eradicated *globally* as a result of vaccination. *Smallpox*, WORLD HEALTH ORG., https://www.who.int/health-topics/smallpox#tab=tab_1 [<https://perma.cc/VS8V-NKSF>] (last visited Apr. 12, 2022). However, vaccines can also eradicate diseases from particular geographic regions. For example, polio, rubella, and, until recently, measles have all been considered eradicated from the United States. Caroline Praderio, *4 Diseases that Have Been Eliminated in the United States in the Last 100 Years*, INSIDER.COM (Jan. 25, 2019, 12:13 PM), <https://www.insider.com/diseases-eliminated-united-states-vaccines-2019-1> [<https://perma.cc/MM9Y-5WDS>].

15 See, e.g., *14 Diseases You Almost Forgot About (Thanks to Vaccines)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/parents/diseases/forgot-14-diseases.html> [<https://perma.cc/C7KQ-8BR7>] (last visited May 8, 2020) (listing fourteen diseases such as polio, measles, whooping cough, mumps, and diphtheria that Americans forget about but still require vaccination for).

16 “Herd immunity occurs when a large portion of a community (the herd) becomes immune to a disease, making the spread of disease from person to person unlikely. As a result, the whole community becomes protected—not just those who are immune.” *Herd Immunity and COVID-19 (Coronavirus): What You Need to Know*, MAYO CLINIC (Dec. 17, 2021), <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808> [<https://perma.cc/M4AM-YSRD>].

history of vaccines and the changes to disease risk that vaccines have accomplished, noting that public health is a form of a commons resource where individual choices can affect the well-being of society at large. In Part III, this Article examines the vaccination regulatory shifting baseline syndrome in the United States. Part IV explores legal reactions to drops in vaccination rates for traditional vaccine-preventable diseases and new COVID-19 vaccination mandates. It suggests that the U.S. Supreme Court's COVID-19 decisions may be opening a path that privileges the individual concerns surrounding vaccination over the larger public health goals of vaccination mandates—a legal path that, if taken fully, could allow the vaccination regulatory shifting baseline syndrome to operate with impunity. More generally, like the fisheries scientists who discovered the shifting baseline syndrome, this Article concludes that the re-animation of historical knowledge and cultural memory is an important corrective to the regulatory shifting baseline syndrome's contribution to vaccination resistance—and its operation in other regulatory regimes.

I. FROM THE SHIFTING BASELINE SYNDROME TO THE REGULATORY SHIFTING BASELINE SYNDROME

Humans forget things, both individually and in societal groups. Such forgettings can have significant consequences regarding when, how, and to what extent societies regulate to protect the general public good. For example, in natural resource management, one of the most well-studied and consequential phenomena resulting from this generational, cultural amnesia has been the shifting baseline syndrome. First identified in marine fisheries management, the shifting baseline syndrome results from a society's collective inability to remember historical ecological conditions accurately and compare them to existing conditions, skewing the focus and goals of natural resource management from what might be considered optimal.

This Part explores the origins of the shifting baseline syndrome in natural resource management to highlight the solutions identified to counteract it. Specifically, biologists and ecologists of all specialties have increasingly embraced the need to reconstruct historical states to recapture forgotten understandings of what is “natural.” These recaptured cultural memories can then inform contemporary regulation by, at the very least, identifying a wider range of potential management goals.

A. Daniel Pauly's Insight: The Origin of the Shifting Baseline Syndrome

In 1995, marine biologist Daniel Pauly coined the term “shifting baseline syndrome” to identify a key problem in fisheries management and modeling:

fisheries scientists were becoming separated “from the biologists studying marine or freshwater organisms and/or communities,” leading those scientists “to factor out ecological and evolutionary considerations from [their] models.”¹⁷ The resulting myopic focus on fishers, fishing fleets, and catch numbers induced the syndrome, which

has arisen because each generation of fisheries scientists accepts as a baseline the stock size and species composition that occurred at the beginning of their careers, and uses this to evaluate changes. When the next generation starts its career, the stocks have further declined, but it is the stocks at that time that serve as a new baseline. The result obviously is a gradual shift of the baseline, a gradual accommodation of the creeping disappearance of resource species, and inappropriate reference points for evaluating economic losses resulting from overfishing, or for identifying targets for rehabilitation measures.¹⁸

What fisheries scientists needed, Pauly continued, was a method for incorporating historical observations of fisheries abundance and species diversity—generally dismissed as “anecdotes”—into contemporary fishery management policy, much as modern astronomers incorporate ancient observations “of sunspots, comets, supernovae, and other phenomena” and oceanographers continue to make use of physical data collected by mariners from at least the nineteenth century.¹⁹ Citing two such historical looks at fishing impacts with approval, Pauly concluded that “[f]rameworks that maximize the use of fisheries history would help us to understand and to overcome—in part at least—the shifting baseline syndrome, and hence to evaluate the true social and ecological costs of fisheries.”²⁰

B. Use of the Shifting Baseline Syndrome in Fisheries Management and Other Ecological Contexts

Pauly and other marine scientists have now documented the shifting baseline

¹⁷ Pauly, *supra* note 6, at 430.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* In the first study, a scientist “compiled scattered observations of (male) anthropologists reporting on fishing in the South Pacific” to argue that women’s gleaning of food from coral reefs was more important than previously acknowledged. *Id.* (citation omitted). “The authors of the second study used the anecdotes in Farley Mowat’s *Sea of Slaughter* to infer that the biomass of fish and other exploitable organisms along the North Atlantic coast of Canada now represents less than 10% of that two centuries ago.” *Id.* (citations omitted).

syndrome in fisheries worldwide.²¹ Moreover, these scientists have institutionalized the collection of historical fisheries data as one means of counteracting the syndrome,²² essentially arguing that the more they can document the actual historical state of fisheries and marine ecosystems, the greater the chance that fisheries policies and catch limits will reflect both the true historical abundance of targeted fish species and the complexity of marine ecosystems.

As a concept, the shifting baseline syndrome has also moved beyond fisheries. In particular, researchers have acknowledged the importance of this syndrome in other areas of ecological regulation, such as endangered species protection,²³ ecological restoration,²⁴ and ecosystem management more generally.²⁵ Under this more generalized conception of “environmental generational amnesia,”²⁶ “each generation grows up being accustomed to the way

21 E.g., Fiona T. Francis et al., *Shifting Headlines? Size Trends of Newsworthy Fishes*, 7 PEERJ e6395 (2019), <https://peerj.com/articles/6395/> [<https://perma.cc/S2KK-6FEB>]; H.A. Maia et al., *Shifting Baselines Among Traditional Fishers in São Tomé and Príncipe Islands, Gulf of Guinea*, 154 OCEAN & COASTAL MGMT. 133 (2018); Sean Berger, *Historical Ecology and Shifting Baseline Syndrome in the Kawartha Lakes, Ontario* (M.A. Thesis, Trent University, 2018), <https://search.proquest.com/docview/2042371835?pq-origsite=primo> [<https://perma.cc/SL7U7K5M>]; Maite Erauskin-Extramiana et al., *An Interdisciplinary Approach to Evaluate the Status of Large-Bodied Serranid Fisheries: The Case of Magdalena-Almejas Bay Lagoon Complex, Baja California Sur, Mexico*, 145 OCEAN & COASTAL MGMT. 21 (2017); Annabel A. Plummeridge & Callum M. Roberts, *Conservation Targets in Marine Protected Area Management Suffer from Shifting Baseline Syndrome: A Case Study on the Dogger Bank*, 116 MARINE POLLUTION BULL. 395 (2017); Tomaso Fortibuoni et al., *Common, Rare or Extirpated? Shifting Baselines for Common Angelshark, Squatina Squatina (Elasmobranchii: Squatinidae), in the Northern Adriatic Sea (Mediterranean Sea)*, 772 HYDROBIOLOGIA 247 (2016); A. J. Venkatachalam et al., *Changes in Frigate Tuna Populations on the South Coast of Sri Lanka: Evidence of the Shifting Baseline Syndrome from Analysis of Fisher Observations*, 20 MARINE & FRESHWATER ECOSYSTEMS 167 (2010); Samuel T. Turvey et al., *Rapidly Shifting Baselines in Yangtze Fishing Communities and Local Memory of Extinct Species*, 24 CONSERVATION BIOLOGY 778 (2010); Cameron H. Ainsworth et al., *Evidence of Fishery Depletion and Shifting Cognitive Baselines in Eastern Indonesia*, 141 BIOLOGICAL CONSERVATION 848 (2008).

22 E.g., Dirk Zeller et al., *On Losing and Recovering Fisheries and Marine Science Data*, 29 MARINE POL’Y 69 (2005); Jeremy B.C. Jackson et al., *Historical Overfishing and the Recent Collapse of Coastal Ecosystems*, 293 SCI. 629 (2001).

23 E.g., Frank Sturges, *Humane Society of the United States v. Zinke* (D.C. Cir. 2017): *Shifting Baselines in the Endangered Species Act*, 43 HARV. ENV’T L. REV. 225 (2019).

24 Matias Guerrero-Gatica, Enrique Aliste & Javier Simonetti, *Shifting Gears for the Use of the Shifting Baseline Syndrome in Ecological Restoration*, 11 SUSTAINABILITY 1458 (2019).

25 Masashi Soga & Kevin J. Gaston, *Shifting Baseline Syndrome: Causes, Consequences, and Implications*, 16 FRONTIERS ECOLOGY & ENV’T 222 (2018).

26 P.H. Kahn, Jr., *Children’s Affiliations with Nature: Structure, Development, and the Problem of Environmental Generational Amnesia*, in CHILDREN AND NATURE: PSYCHOLOGICAL, SOCIOCULTURAL, AND EVOLUTIONARY INVESTIGATIONS 93, 93-94 (P.H. Kahn, Jr. & S.R. Kellert eds., 2002).

their environment looks and feels, and so, in a system experiencing progressive impoverishment, they do not recognize how degraded it has become over the course of previous generations.”²⁷ Multiple studies outside of fisheries have empirically demonstrated intergenerational differences in resource perception, from bird species in Yorkshire, to deforestation in the Beni, Bolivia, to water availability and quality in Alaska.²⁸ These studies indicate that the shifting baseline syndrome operates in regulatory regimes to keep ecosystems in impoverished states.²⁹ However, they also suggest that when historical reconstructions can take hold and correct those shifted perceptions, more productive management decisions and even, in some cases, restoration become possible. Arguably, therefore, “the fundamental driver of [the shifting baseline syndrome] is the lack, or paucity, of relevant historical data on the natural environment.”³⁰ “Without reliable historical environmental data, people cannot infer whether long-term environmental changes have occurred, nor to what extent, and so they have little choice but to define baselines according to their own knowledge and experiences”³¹

Finally, legal scholars have argued that emerging historical insights into ecosystem change from these biological and ecological reconstructions should broadly inform current marine management policy and law.³² Moreover, historical reflection on the law’s influence on a particular fishing industry over time can suggest improvements to the regulation of that industry.³³ Even Pauly himself published in a law review to argue that the historical evidence of dramatic reductions in marine fish stocks necessitates the legal creation of marine reserves and the elimination of subsidies to fishers.³⁴ However, those perceptions have not yet been translated to the workings of law itself.

27 Soga & Gaston, *supra* note 25, at 222.

28 *Id.* at 223.

29 Guerrero-Gatica et al., *supra* note 24, at 1460; Soga & Gaston, *supra* note 25, at 222.

30 Soga & Gaston, *supra* note 25, at 224.

31 *Id.*

32 *E.g.*, Eric A. Bilsky, *Conserving Marine Wildlife Through World Trade Law*, 30 MICH. J. INT’L L. 599, 602-03 (2009); Robin Kundis Craig, *Taking Steps Toward Marine Wilderness Protection? Fishing and Coral Reef Marine Reserves in Florida and Hawaii*, 34 MCGEORGE L. REV. 155, 157 (2003); Robin Kundis Craig, *Taking the Long View of Ocean Ecosystems: Historical Science, Marine Restoration, and the Oceans Act of 2000*, 29 ECOLOGY L. Q. 649, 697-702 (2002).

33 Danielle Ringer et al., *For Generations to Come? The Privatization Paradigm and Shifting Social Baselines in Kodiak, Alaska’s Commercial Fisheries*, 98 MARINE POL’Y 97 (2018).

34 Daniel Pauly, *Unsustainable Marine Fisheries*, 7 SUSTAINABLE DEV. L. & POL’Y 10, 10-11 (2006).

C. *From Ecology to Regulatory Regimes: The Regulatory Shifting Baseline Syndrome*

In the regulatory shifting baseline syndrome, a longstanding regulatory regime is so successful that its success makes its existence appear unnecessary (i.e., the regulatory baseline appears to have shifted because the problem the regime addressed has apparently gone away). Like the fisheries shifting baseline syndrome, therefore, the regulatory shifting baseline syndrome induces lawmakers and the general public to wrongly evaluate the value and accomplishments of the current measures. In the regulatory shifting baseline syndrome, however, generational amnesia allows the original problem to re-emerge, harming overall public welfare.

The complications come in identifying exactly when the syndrome is operating because some regulatory regimes do become outdated and need to change. This section elucidates the three elements of the regulatory shifting baseline syndrome, which include: (1) generational amnesia; and (2) a longstanding regulatory regime focused on curbing individual human behaviors or impulses that collectively are likely to undermine the public good; (3) that is so successful that it renders the original problem non-salient, or at least considerably less salient, to both politicians and lawmakers. It also argues that identifying the syndrome in operation requires a greater appreciation of public law regimes as cultural memory institutions.

1. *Generational Amnesia*

The shifting baseline syndrome has always been a product of subjective human perception and psychology rather than objective reality; in fact, the syndrome is what allows humans to ignore that changing reality. However, the syndrome's grounding in psychology means that there is no reason that various forms of time-lapsed amnesia would not be an important factor in managing human behavior in areas besides fisheries and ecological conservation. Indeed, commenters have concluded that the syndrome has been at work in everything from personal weight gain³⁵ to government and business leadership³⁶ to perceptions of well-being in old age.³⁷

35 Randy Olson, *Slow Motion Disaster Below the Waves*, L.A. TIMES (Nov. 17, 2002 12:00 AM PT), <https://www.latimes.com/archives/la-xpm-2002-nov-17-op-olson17-story.html> [<https://perma.cc/P4HM-PZSS>] ("If your ideal weight used to be 150 pounds and now it's 160, your baseline—as well as your waistline—has shifted.").

36 Art Petty, *Leadership and Shifting Baseline Syndrome*, GOV'T EXEC. (Apr. 28, 2017), <https://www.govexec.com/management/2017/04/leadership-and-shifting-baseline-syndrome/137276/> [<https://perma.cc/T32N-Z2DH>].

37 Jiska Cohen-Mansfield, *The Shifting Baseline Theory of Well-Being: Lessons from Across*

To deal with these multiplying applications of “shifting baseline syndrome,” conservation biologists helpfully have identified two forms of the syndrome: generational amnesia and personal amnesia.³⁸ Like Pauly’s original characterization of the shifting baseline syndrome in fisheries, this Article is more interested in generational amnesia, which “describes individuals setting their perceptions from their own experience and failing to pass their experience on to future generations. Thus, as observers leave a system, the population’s perception of normality up-dates and past conditions are forgotten.”³⁹ This form of the shifting baseline syndrome “is a cautionary tale referring to changing human perceptions of biological systems due to loss of experience about past conditions.”⁴⁰

2. Public Law as a Cultural Memory Institution

In ecology, one prominent proffered solution to the shifting baseline syndrome is to reconstruct historical conditions with greater accuracy. Nevertheless, one should always be cautious in hoping that more information will change people’s minds about public policy.⁴¹ Even in ecological studies, scientists recognize that “the availability of (even very good) empirical evidence has not always been sufficient to convince people of historical trends in environmental conditions.”⁴²

Nevertheless, legal regimes can also benefit from historical reconstruction; moreover, efforts to identify and correct the *regulatory* shifting baseline syndrome may have an advantage over efforts to correct *ecological* shifting baseline syndromes. While ecological change might have many causes,⁴³ and historical accounts of prior bounty might be dismissed as exaggerated tall tales,⁴⁴

the Aging Spectrum, in UNDERSTANDING WELL-BEING IN THE OLDEST OLD 46, 46-64 (Leonard W. Poon & Jiska Cohen-Mansfield eds., Cambridge Univ. Press 2011), <https://doi.org/10.1017/CBO9780511920974.005> [<https://perma.cc/2SRP-PMNE>].

38 S.K. Papworth et al., *Evidence for Shifting Baseline Syndrome in Conservation*, 2 CONSERVATION LETTERS 93, 93 (2009).

39 *Id.* (citations omitted). In contrast, “Personal amnesia describes individuals updating their own perception of normality; so that even those who experienced different previous conditions believe that current conditions are the same as past conditions.” *Id.*

40 *Id.*

41 E.g., Elizabeth Kolbert, *Why Facts Don’t Change Our Minds*, THE NEW YORKER (Feb. 19, 2017), <https://www.newyorker.com/magazine/2017/02/27/why-facts-dont-change-our-minds> [<https://perma.cc/U7LJ-4X9B>]; Timothy D. Hanks & Christopher Summerfield, *Perceptual Decision Making in Rodents, Monkeys, and Humans*, 93 NEURON 15, 22 (2017).

42 Soga & Gaston, *supra* note 25, at 224.

43 Katharina E. Fabricius & Glenn De’ath, *Identifying Ecological Change and Its Causes: A Case Study on Coral Reefs*, 14 ECOLOGICAL APPLICATIONS 1448, 1448 (2004).

44 Loren McClenachan et al., *The Importance of Surprising Results and Best Practices in Historical Ecology*, 65 BIOSCI. 932, 932-33, 938 (2015),

there is no escaping that *humans* alone create regulatory regimes. Therefore, the fact that past legislatures, regulatory agencies, and other policymakers bothered to engage in this labor is inescapable evidence that they thought something was wrong.

In this very real sense, public law *is* historical knowledge. Its persistence over time renders it a cultural memory institution—a record of *why* a community has legally protected itself in the ways it has. “Memory institutions are social entities that select, document, contextualize, preserve, index, and thus canonize elements of humanity’s culture, historical narratives, [and] individual[] and collective memories.”⁴⁵ Traditional and paradigmatic memory institutions include archives, museums, and libraries; more contemporary additions include the various “networked memory institutions” of the internet and social media.⁴⁶ However, statutes and regulatory regimes, together with the histories of their creation, are also memory institutions.⁴⁷

Unfortunately, the status of public legal regimes as memory institutions is underappreciated, particularly within the law itself.⁴⁸ To be sure, the examination of statutory purpose remains a bedrock touchstone of statutory interpretation, and courts continue to examine statutory history⁴⁹ and even legislative history⁵⁰ in the

<https://academic.oup.com/bioscience/article/65/9/932/237568> [<https://perma.cc/R5KF-CEKR>].

45 Guy Pessach, *[Networked] Memory Institutions: Social Remembering, Privatization and Its Discontents*, 26 CARDOZO ARTS & ENT. L.J. 71, 73 (2008) (citing ARCHIVES, DOCUMENTS AND INSTITUTIONS OF SOCIAL MEMORY: ESSAYS FROM THE SAWYER SEMINAR (Francis X. Blouin, Jr. & William G. Rosenberg eds., 2006); REPRESENTING THE NATION: A READER—HISTORIES, HERITAGE AND MUSEUMS (David Boswell & Jessica Evans eds., 1999)).

46 *Id.*

47 Notably, the European Union is dealing with the opposite problem in the form of so-called “memory laws,” which seek to reify a particular interpretation or perspective on history. Thus, “[m]emory laws’ enshrine state-approved interpretations of crucial historical events and promote certain narratives about the past, by banning, for example, the propagation of totalitarian ideologies or criminalising expressions which deny, grossly minimize, approve, or justify acts constituting genocide or crimes against humanity, as defined by international law.” Council of Europe, ‘Memory Laws’ and Freedom of Expression 1 (July 2018), <https://rm.coe.int/factsheet-on-memory-laws-july2018-docx/16808c1690> [<https://perma.cc/2GZ2-WXCC>]. However, the use of law to actively *construct* cultural memory, as Europe justly worries about, is a different enterprise than the one advocated in this Article: the recognition that statutes and regulations created to address public problems constitute contextually situated records of cultural memory.

48 In contrast, historians often find the laws of earlier times to be valuable resources in reconstructing historical cultural norms or in establishing the bases of later reform and evolution. E.g., Michael M. Sheehan, *Marriage Theory and Practice in the Conciliar Legislation and Diocesan Statutes of Medieval England*, 40 MEDIEVAL STUD. 408, 408-60 (1978).

49 Anita S. Krishnakumar, *Statutory History*, 108 VA. L. REV. 263, 265-68 (2022).

50 E.g., *Cnty. of Maui v. Haw. Wildlife Fund*, 140 S. Ct. 1462, 1468-69, 1471-72, 1476 (2020) (emphasizing Congress’s purposes in interpreting the Clean Water Act and including an examination of legislative history); *Gundy v. United States*, 139 S. Ct. 2116, 2126 (2019) (noting that “beyond context and structure, the Court often looks to ‘history [and] purpose’ to divine the

process. However, the process of statutory construction occurs *within* the regulatory regime itself and assumes its continued legitimacy. This assumption is evident in many canons of statutory construction, but it becomes an interpretive *goal* in the canon of constitutional avoidance. The “principle of constitutional avoidance is focused on statutory interpretation, calling for statutes to be interpreted to avoid constitutional problems.”⁵¹ According to the U.S. Supreme Court, this canon “is a tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that Congress did not intend the alternative which raises serious constitutional doubts.”⁵² When limited, as the Court mandates, to interpretations of the statute that are objectively reasonable, the canon thus operates to keep the statute from being declared unconstitutional⁵³—that is, to legitimate its continuing existence.

The cultural memory at issue in this Article, in contrast, operates at a higher scale, focusing not (or not just) on what the particular legal instruments (statutes, regulations) *mean* but instead on actually assessing their continuing value to society. When that assessment occurs under the influence of the regulatory shifting baseline syndrome, rather than with full appreciation of the cultural memory embedded in the regulatory regime, the syndrome can induce a distorted cost-benefit analysis based on its ability to warp perceptions of risk. Victims of the syndrome compare the continuing costs of the regulatory regime to apparently disappearing benefits—benefits that have become invisible because

meaning of language”) (quoting *Maracich v. Spears*, 570 U.S. 48, 76 (2013)) (internal quotation marks omitted); *Environmental Defense v. Duke Energy Corp.*, 549 U.S. 561, 576 (2007) (relying on legislative history); *McCreary Cnty. v. ACLU of Ky.*, 545 U.S. 844, 861-63 (2005) (discussing the importance of legislative purpose in statutory interpretation).

51 Kate Aschenbrenner Rodríguez, *Immigration Detention: Erosion or Reinforcement of a Theory of Immigration Exceptionalism?*, 57 IDAHO L. REV. 719, 724 (2021).

52 *Clark v. Martinez*, 543 U.S. 371, 381-82 (2005) (citations omitted).

53 *Id.* at 381. Of course, if a court chooses to focus on an implausible or objectively unreasonable interpretation, that focus could become the basis for operationalizing the regulatory shifting baseline syndrome. One example was the Supreme Court’s use of the constitutional avoidance canon to arguably narrow the scope of the Clean Water Act’s jurisdiction contrary to congressional intent, precipitating an ongoing controversy over “waters of the United States” that is now moving into its third decade. See *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng’rs*, 531 U.S. 159, 172-73 (2001) (overturning the Migratory Bird Rule’s extension of Clean Water Act jurisdiction on the grounds that “[w]here an administrative interpretation of a statute invokes the outer limits of Congress’ power, we expect a clear indication that Congress intended that result This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power”) (citation omitted); *Rapanos v. United States*, 547 U.S. 715, 732-39 (plurality), 782-83 (Kennedy, J., concurring in the judgment), 810 (Stevens, J., dissenting) (2006) (fracturing the Justices over the proper test for Clean Water Act jurisdiction); *Sackett v. U.S. Env’t Prot. Agency*, 8 F.4th 1075 (9th Cir. 2021), *cert. granted in part sub nom.*, 142 S. Ct. 896, 896 (2022) (granting certiorari to decide the question of “[w]hether the Ninth Circuit set forth the proper test for determining whether wetlands is ‘waters of the United States’ under the Clean Water Act, 33 U.S.C. § 1362(7)”).

no one has seen the complete problem in quite a while. Instead of acknowledging that the regime is what keeps the problem at bay, victims of the syndrome tend to proclaim “Problem solved!” and dismantle the very regulatory machinery that makes that perception possible—completely ignoring the cultural memory function of law in the process.

3. *The Emergence of the Regulatory Shifting Baseline Syndrome*

The regulatory shifting baseline syndrome often emerges in debates over whether a regulatory regime that is at least partially controversial still serves its original (or any desirable) function. The syndrome allows the relevant decisionmakers⁵⁴ to evaluate that regime—rhetorically, economically, and politically—through an assumption (admittedly itself often politicized) of changed conditions. The resulting distorted evaluation creates a persuasive, if inaccurate, narrative of why the regime is no longer necessary. Importantly, the persuasive force of a syndrome-based argument often derives at least in part from a subtle shift in focus, moving from an analysis of the regulatory regime’s effect on human behavior to an emphasis on the changes that have occurred in objective reality. Victims of the regulatory shifting baseline, therefore, ignore the fact that changing human behavior is what caused the change in lived experience.

The U.S. Supreme Court’s 2013 Voting Rights Act decision *Shelby County v. Holder*⁵⁵ provides a significant example of a syndrome-based argument, including this analytical shift in focus. In this 5-4 decision, the majority held unconstitutional the Act’s coverage formula and preclearance requirements.⁵⁶ As it explained, “Section 5 of the Act required States to obtain federal permission before enacting any law related to voting—a drastic departure from basic principles of federalism. And § 4 of the Act applied that requirement only to some States—an equally dramatic departure from the principle that all States enjoy equal sovereignty.”⁵⁷ The question, as the majority framed it, was whether the Act remained constitutional despite changed conditions:

Nearly 50 years later, [the Voting Rights Act’s requirements] are still in effect; indeed, they have been made more stringent, and are now scheduled to last until 2031. There is no denying,

54 Who holds the relevant decisionmaking power, and hence the operative realm of the regulatory shifting baseline syndrome, can vary by regime and the relevant legal authorities that surround it. For voting rights, the relevant sphere of the syndrome is often five Justices of the U.S. Supreme Court. For vaccines, it is often state legislatures, local public health departments, and individual members of the general public.

55 570 U.S. 529 (2013).

56 *Id.* at 556-57.

57 *Id.* at 534-35.

however, that the conditions that originally justified these measures no longer characterize voting in the covered jurisdictions. By 2009, “the racial gap in voter registration and turnout [was] lower in the States originally covered by § 5 than it [was] nationwide.” Since that time, Census Bureau data indicate that African–American voter turnout has come to exceed white voter turnout in five of the six States originally covered by § 5, with a gap in the sixth State of less than one half of one percent. See Dept. of Commerce, Census Bureau, Reported Voting and Registration, by Sex, Race and Hispanic Origin, for States (Nov. 2012) (Table 4b).

At the same time, voting discrimination still exists; no one doubts that. The question is whether the Act’s extraordinary measures, including its disparate treatment of the States, continue to satisfy constitutional requirements. As we put it a short time ago, “the Act imposes current burdens and must be justified by current needs.”⁵⁸

This emphasis on changed circumstances, therefore, provided a perfect context in which the regulatory shifting baseline could emerge.

Contrary to some characterizations,⁵⁹ the *Shelby County* majority did not forget why Congress enacted the Voting Rights Act in the first place. It acknowledged, for example, why Congress had singled out certain states for special treatment: “In the 1890s, Alabama, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Virginia, began to enact literacy tests for voter registration and to employ other methods designed to prevent African-Americans from voting,” and as courts struck down these measures, “[s]tates came up with new ways to discriminate,” effectively preventing registration of Black voters.⁶⁰ Instead, the majority shifted the focus from the Act’s ability to curb legislatures’ impulses to discriminate to changes in objective reality (i.e., higher rates of African American voters). With this shift in focus, it concluded that the Act’s distinctions among states based on historic practices had served their purposes—specifically, that the states whose voting laws were still subject to federal approval had come into line with, or even improved upon, the rest of

⁵⁸ *Id.* at 535–36 (quoting *Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 203–04 (2009)).

⁵⁹ *E.g.*, Joel Heller, *Shelby County and the End of History*, 44 U. MEMPHIS L. REV. 357, 357–59, 385 (2013).

⁶⁰ *Shelby County*, 570 U.S. at 536 (citing *South Carolina v. Katzenbach*, 383 U.S. 301, 310 (1966)).

the country in terms of Black voter registration.⁶¹ In the majority's view, "things have changed dramatically."⁶² The Act had done—emphasis on the past tense—its job,⁶³ and the objective regulatory baseline had, according to the majority, (permanently) moved in constitutionally significant ways.⁶⁴

In contrast, the dissenters (and, in their view, Congress) appreciated the fact that the Voting Rights Act's preclearance requirements *were still doing* their job—that is, that objective reality was as good as it was exactly because the Act "facilitate[s] completion of the impressive gains thus far made" and, hinting at the human impulse problem, "guard[s] against backsliding."⁶⁵ The decision's

61 *Id.* at 547-49.

62 *Id.* at 547.

63 Specifically, according to the Court:

Coverage today is based on decades-old data and eradicated practices. The formula captures States by reference to literacy tests and low voter registration and turnout in the 1960s and early 1970s. But such tests have been banned nationwide for over 40 years. And voter registration and turnout numbers in the covered States have risen dramatically in the years since. Racial disparity in those numbers was compelling evidence justifying the preclearance remedy and the coverage formula. There is no longer such a disparity.

In 1965, the States could be divided into two groups: those with a recent history of voting tests and low voter registration and turnout, and those without those characteristics. Congress based its coverage formula on that distinction. Today the Nation is no longer divided along those lines, yet the Voting Rights Act continues to treat it as if it were.

Id. at 551. See also K. Sabeel Rahman, *Domination, Democracy, and Constitutional Political Economy in the New Gilded Age: Toward a Fourth Wave of Legal Realism?*, 94 TEX. L. REV. 1329, 1335 (2016) ("The Court's dismantling of the Voting Rights Act in *Shelby County* can be understood as an argument that underlying structural political inequalities that may have justified preclearance are no longer present, and thus ordinary political competition, like market competition, is sufficient to ensure freedom of choice and basic political equality.").

64 Other scholars have also explicitly characterized the *Shelby County* majority's opinion as reflecting the Justices' perception of an objectively shifted baseline. See Diane S. Sykes, *Minimalism and Its Limits*, 2015 CATO SUP. CT. REV. 17, 32 (noting that "the Court had transparently signaled its discomfort with the coverage formula, which was based on a decades-old baseline that did not reflect changes in voting and discriminatory election practices when Congress reauthorized the Act in 2006").

65 *Shelby County*, 570 U.S. at 559-60 (Ginsburg, J., dissenting). As Joel Heller has more extensively described the survival of this impulse in areas still suffering from the burdensome memory of past discrimination:

An awareness of the long history of voting discrimination on account of race in a jurisdiction may affect the attitudes of present-day policymakers towards race and the right to vote, and thus may influence the types of voting policies that they enact. One possibility is that local or state officials charged with setting

aftermath supports their conclusion that the most important regulatory baseline at issue—the impulses of the designated state legislatures to discriminate—had *not* changed significantly. The Brennan Center for Justice notes that “[w]ithin 24 hours of the ruling, Texas announced that it would implement a strict photo ID law. Two other states, Mississippi and Alabama, also began to enforce photo ID laws that had previously been barred because of federal preclearance.”⁶⁶ In a 2018 report, the Center further concluded that “the Supreme Court’s 2013 *Shelby County v. Holder* ruling, which neutered the strongest legal protection against voting discrimination, *changed the landscape*. A flood of new barriers to voting that would have otherwise been blocked were implemented, and newly unfettered legislatures were incentivized to press forward with additional restrictions.”⁶⁷

In the terms of this Article, the *Shelby County* majority justified its constitutional conclusion under the influence of a regulatory shifting baseline syndrome. Of course, it is possible—perhaps even probable—that the Justices in the majority did not sincerely believe that the Voting Rights Act was no longer necessary. However, whether the majority Justices actually believed that the Voting Rights Act no longer helped to keep voting discrimination in check, or

voting policies and election procedures will ignore any burden that a policy has on minority voters as simply a natural or unavoidable phenomenon. Centuries of precedent exist for inequality in this area of civic life, and these policymakers know that their not-too-distant predecessors in office enacted and administered such policies with a large degree of indifference, or even support, in their communities.

Heller, *supra* note 59, at 385-86.

66 *The Effects of Shelby County v. Holder*, BRENNAN CTR. FOR JUSTICE (Aug. 6, 2018), <https://www.brennancenter.org/our-work/policy-solutions/effects-shelby-county-v-holder> [<https://perma.cc/5R75-YMJ8>].

67 Wendy Weise & Max Feldman, *The State of Voting 2018*, BRENNAN CENTER FOR JUSTICE, at 5 (2018) (emphasis added), https://www.brennancenter.org/sites/default/files/2019-08/Report_State_of_Voting_2018.pdf [<https://perma.cc/4HGH-FE36>]. The fact that, by 2018, a total of twenty-three states had enacted more restrictive voting laws that disparately impacted people of color and other vulnerable populations arguably suggests that federal preclearance requirements should apply to *more* states rather than none. *See id.* at 5-7; *see also* Franita Tolson, *The Law of Democracy at a Crossroads: Reflecting on Fifty Years of Voting Rights and Judicial Regulation of the Political Thicket*, 43 FLA. STATE U. L. REV. 345, 350 (2016) (“[M]ost states have used their power over voter qualifications, which is significantly broader in the wake of *Shelby County*, to sharply define and limit who can participate in elections. In the last few years alone, states have enacted dozens of laws that make it considerably harder to vote . . .”). Notably, the *Shelby County* decision also shifted the burden of proving the discriminatory impacts of voting laws from the covered governments (who had to show nondiscrimination) to disenfranchised voters, and it effectively shielded municipal ordinances related to voting from much scrutiny at all. Sam Levine & Ankita Rao, *In 2013 the Supreme Court Guttled Voting Rights—How Has it Changed the US?*, THE GUARDIAN (June 25, 2020, 13:14 EDT), <https://www.theguardian.com/us-news/2020/jun/25/shelby-county-anniversary-voting-rights-act-consequences> [<https://perma.cc/CD3H-PSEK>].

whether instead they were rhetorically deploying the syndrome to ground their legal argument, is largely irrelevant: the syndrome's general existence made the logic of their decision possible, regardless of whether this particular argument was the result of honest belief or dishonest rhetoric in pursuit of a particular political outcome. Generational amnesia, in other words, can run the gamut from actual forgetfulness to willful burying of a particular cultural memory. The result remains the same: by refusing to acknowledge the deeper cultural memory embedded in the statute—in the case of the Voting Rights Act, the knowledge that, in the absence of federal oversight, many state legislatures will discriminate against minorities trying to exercise their rights to vote—decisionmakers can release the human impulse that the statute formerly constrained, allowing it full license once again.

Shelby County thus also illustrates the importance of the cultural memory function of public laws. Indeed, the very existence of public laws on a particular subject should remind those empowered to change them—politicians, judges, legislators, and occasionally the broader citizenship—that there was, in fact, a historical problem that might recur if the correcting regulatory regime does not remain in place.

This unfortunate outcome is particularly likely if the regulatory regime targets basic human impulses that collectively undermine the public good. These regimes embed cultural memories of important lessons that we have learned ourselves. Some of the most important of these lessons are that individual behaviors can cumulatively damage society as a whole. Whether multitudinous (e.g., polluters) or domineering (e.g., nineteenth-century monopolists), individual behavioral impulses playing out on a national stage can destabilize or otherwise deleteriously affecting various aspects of the public commons.⁶⁸ These

68 While the fit is not always exact, this Article refers to many of the public goods (however aspirational some of them remain) of U.S. society—equal access to voting and other aspects of political processes, a stable economy, public health, a clean environment—as commons resources or common-pool resources in the sense that Elinor Ostrom and her co-authors defined it: “natural and human-constructed resources in which (i) exclusion of beneficiaries through physical and institutional means is especially costly, and (ii) exploitation by one user reduces resource availability for others.” Elinor Ostrom et al., *Revisiting the Commons: Local Lessons, Global Challenges*, 284 SCI. 278, 278 (1999). Public law often operates as an exclusion by limiting how individual entities (persons, corporations, political parties, even in some circumstances governments) can affect or operate with the relevant commons and often is quite costly (economically and politically) to enact, promulgate, build capacity for implementing, and enforce. Nevertheless, in the absence of those regimes, exploitation for the benefit of those individual entities can put the entire public good at risk for everyone. “Commons” terminology then aptly undergirds a discussion of the regulatory shifting baseline syndrome because it describes situations in which governance is an important option for mediating the oft-occurring tensions between the drives and motivations of individual entities and the best interests of the public as a whole. As Garrett Hardin famously recognized in 1968, the unrestrained drives of individuals can lead to

experiential lessons, memorialized in regulatory regimes, are unlikely to lose their value unless and until human nature fundamentally transforms. Acknowledging the regulatory shifting baseline syndrome can thus illuminate and inform discussions of whether and how to reform public law regimes.

D. How Acknowledging the Regulatory Shifting Baseline Syndrome Improves Regulatory Regime Evaluation

There are, of course, excellent reasons to change established regulatory regimes. For example, evolving conceptions of ethics and morality may undermine past legal regimes; in the United States, the abolition of slavery⁶⁹ and the progressive elimination of the death penalty⁷⁰ are two prominent examples of this motivation for legal change.

Acknowledging the cultural memory embedded in public laws aids in the evaluation of whether a regulatory regime *should* change. Indeed, that acknowledgment serves two different governance goals. First, as memory institutions, laws and regulations are reminders of how their drafters understood the world and the problem at hand, allowing would-be reformers to assess whether those understandings remain objectively valid. Thus, when social ethics, norms, and standards of morality change from those embedded in earlier laws, the reconstruction of that evolution provides one principled basis for changing the law.

Changes in embedded scientific understanding or technological capacity can provide another principled basis for evolving a legal regime. As one contemporary example, environmental and natural resources scholars have argued extensively that the increasing impacts of climate change demand a re-evaluation and replacement of regulatory regimes that assume the stationarity of ecological and social-ecological systems,⁷¹ including new approaches to climate

tragedies for the larger society. Garrett Hardin, *The Tragedy of the Commons*, 162 Sci. 1243, 1243-45 (1968). However, “tragedies of the commons are real, but not inevitable”—although the governance challenges multiply as the scale of the commons increases. Ostrom et al., *supra*, at 281-82.

69 U.S. CONST., amend XIII, § 1.

70 *E.g.*, *Kennedy v. Louisiana*, 554 U.S. 407, 413 (2008) (holding that the Eighth Amendment bars Louisiana from imposing the death penalty as a sanction for the rape of a child when the crime did not result, and was not intended to result, in the death of the child); *Atkins v. Virginia*, 536 U.S. 304, 321 (2002) (holding unconstitutional Virginia’s application of the death penalty to the mentally disabled); *Thompson v. Oklahoma*, 487 U.S. 815, 838 (1988) (holding that imposition of the death penalty is unconstitutional when the defendant committed the murder at age fifteen); *Woodson v. North Carolina*, 428 U.S. 280, 286-305 (1976) (holding that North Carolina’s mandatory death penalty for first-degree murder is unconstitutional).

71 *See, e.g.*, Karrigan Börk, *Guest Species: Rethinking Our Approach to Biodiversity in the Anthropocene*, 2018 UTAH L. REV. 169; MELINDA HARM BENSON & ROBIN KUNDIS CRAIG, *THE END OF SUSTAINABILITY: RESILIENCE AND THE FUTURE OF ENVIRONMENTAL GOVERNANCE IN THE*

change adaptation.⁷² The regimes in need of significant amendment to acknowledge these evolved scientific understandings include most of the natural resources, public lands, and environmental statutes adopted throughout the twentieth century.⁷³ The crucial cultural memory embedded in these public laws is the outdated model of ecosystems prevalent in scientific discourse when Congress and state legislatures adopted them.⁷⁴ Recovering that cultural memory illuminates both that our understanding of how complex systems behave has changed significantly since the 1970s, undermining these statutes' regulatory premises,⁷⁵ and that climate change is accelerating systemic change, undermining these statutes' continuing abilities to function productively.⁷⁶ In other words, acknowledging this first cultural memory function of law helps law- and policymakers evaluate when legal regimes need to change.

More unusually, this Article explores the *second* governance function served by acknowledging that public law is a form of cultural memory: improved evaluation of whether apparently outdated legal regimes should remain in place.

ANTHROPOCENE (2017); Kalyani Robbins, *The Biodiversity Paradigm Shift: Adapting the Endangered Species Act to Climate Change*, 27 FORDHAM ENV'T L. REV. 57 (2015); Lance H. Gunderson et al., *Escaping a Rigidity Trap: Governance and Adaptive Capacity to Climate Change in the Everglades Social Ecological System*, 51 IDAHO L. REV. 127 (2014); ROBIN KUNDIS CRAIG, COMPARATIVE OCEAN GOVERNANCE: PLACE-BASED PROTECTIONS IN AN ERA OF CLIMATE CHANGE (2012); Victor B. Platt, *Adapting Laws to a Changing World: A Systemic Approach to Climate Change Adaptation*, 64 FLA. L. REV. 269 (2012); Robin Kundis Craig, "Stationarity Is Dead"—Long Live Transformation: Five Principles for Climate Change Adaptation Law, 34 HARV. ENV'T L. REV. 9 (2010); Alejandro E. Camacho, *Assisted Migration: Redefining Nature and Natural Resource Law under Climate Change*, 27 YALE J. REGUL. 171 (2010); J.B. Ruhl, *Climate Change Adaptation and the Structural Transformation of Environmental Law*, 40 ENV'T L. 363 (2010); Robert L. Glicksman, *Ecosystem Resilience to Disruptions Linked to Global Climate Change: An Adaptive Approach to Federal Land Management*, 87 NEB. L. REV. 833 (2009); J.B. Ruhl, *Climate Change and the Endangered Species Act: Building Bridges to the No-Analog Future*, 88 B.U. L. REV. 1 (2008).

⁷² See generally J.B. Ruhl & Robin Kundis Craig, *4°C*, 106 MINN. L. REV. 191 (2021) (exploring the massive governance dislocations that will most likely occur as a result of the need to adapt to the currently most likely trajectories of climate change).

⁷³ Alejandro E. Camacho & Robert L. Glicksman, *Legal Adaptive Capacity: How Program Goals and Processes Shape Federal Land Adaptation to Climate Change*, 87 U. COLO. L. REV. 711, 743-806 (2016) (assessing the federal public lands statutes); CRAIG, *supra* note 71, at 47-65, 91-169 (assessing current legal approaches to marine protected areas); Craig, *supra* note 71, at 31-40 (assessing pollution control and natural resources statutes); Camacho, *supra* note 71, at 188-210 (assessing species-related and public lands statutes); Ruhl, *Structural Transformation*, *supra* note 71, at 391-433 (assessing a broad swath of environmental and natural resources statutes).

⁷⁴ Melinda H. Benson, *New Materialism: An Ontology for the Anthropocene*, 59 NAT. RES. J. 251, 261 (2019); BENSON & CRAIG, *supra* note 71, at 31, 57, 165-66; Craig, *supra* note 71, at 32.

⁷⁵ BENSON & CRAIG, *supra* note 71, at 56-70; Craig, *supra* note 71, at 39-40; Camacho, *supra* note 71, at 179-88.

⁷⁶ Craig, *supra* note 71, at 46-48; Camacho, *supra* note 71, at 188-210; Ruhl, *Structural Transformation*, *supra* note 71, at 391-433; Glicksman, *supra* note 71, at 839-51.

Specifically, when legal regimes exist to curb human impulses and behaviors that cumulatively damage society, those regimes serve as important reminders that removing existing restraints is likely to re-create old problems. Thus, even in the environmental context, an evolved understanding of system dynamics and climate change impacts does not change the fact that pollution control regimes—that is, restraints on historically demonstrated human tendencies to contaminate commons resources (air, rivers, lakes, land, the ocean) with toxins and other damaging pollutants—remain critical protections for human health and environmental quality in the twenty-first century.⁷⁷ Failure to heed these reminders that humans often misbehave if left to their own devices allows the regulatory regime to fall victim to the regulatory shifting baseline syndrome.

Notably, whether the generational amnesia that allows the regulatory shifting baseline to emerge will occur varies by regulatory context—and, as the Voting Rights Act example suggests, some generational amnesia is more likely to be politically induced than naturally emerging. Long-existing regulatory regimes that seem equally incorporated into societal norms differentially fall victim to the regulatory shifting baseline syndrome, often because of differences in the continuing saliency of the original problems. For example, despite their eighty-year existence, child labor laws remain socially and politically salient. Until the early twentieth century, most children in working-class families worked long hours, often under dangerous conditions, and from very young ages.⁷⁸ Congress began to intervene as early as 1906,⁷⁹ culminating in the passage of the Fair Labor Standards Act in 1938.⁸⁰ As is true for many new regulatory regimes affecting business, employers initially resisted the restrictions on child labor, necessitating additional restrictions and improved enforcement.⁸¹ However, “since roughly the late 1980s, child labor in its various aspects has largely

⁷⁷ Craig, *supra* note 71, at 45-46.

⁷⁸ CONG. RSCH. SERV., CHILD LABOR IN AMERICA: HISTORY, POLICY, AND LEGISLATIVE ISSUES

1 (updated 2013),

https://www.everycrsreport.com/files/20131118_RL31501_008741c7351fd72ae2a262198ba9c0e44921a60a.pdf [<https://perma.cc/69JM-6XNF>]. See also Joanna Grisinger, *Book Review*, 28 L. & HIST. REV. 649, 649-50 (2011) (reviewing JAMES D. SCHMIDT, *INDUSTRIAL VIOLENCE AND THE LEGAL ORIGINS OF CHILD LABOR* (2010)) (describing “nineteenth-century producerist ideology, which valued individuals as workers. For Appalachian working families, clear lines between childhood and adulthood were absent. Instead, children were brought into the workplace to perform tasks appropriate to their size and skill level, growing into their roles as workers as they became adults”).

⁷⁹ However, its early efforts were often unsuccessful. See, e.g., *Constitutional Law—Federal Child Labor Law Invalid*, 27 YALE L.J. 1092, 1092-93 (1918) (summarizing the then-recent Supreme Court decision).

⁸⁰ CONG. RSCH. SERV., *supra* note 78, at 2-5. The Fair Labor Standards Act is codified at 29 U.S.C. §§ 201-219, and the child labor prohibitions are found in Section 212.

⁸¹ *Id.* at 5 (citation omitted).

disappeared from the policy scene; the issue is often viewed as a remnant of an earlier period in American history.”⁸²

Nevertheless, despite the apparent normification of child labor prohibitions and restrictions, no group strongly advocates that these restrictions have become unnecessary. In the terms of this Article, successive generations of U.S. society have not forgotten that child labor restrictions continue to provide important protections to children. That memory remains accessible partly because evidence indicates that many employers still violate regulations on child labor, especially for adolescents and immigrant children;⁸³ in other words, the impulse to exploit children and their labor has never been completely controlled. Moreover, advocates for children often view these public law protections as incomplete,⁸⁴ with organizations like the American Federation of Teachers seeking to extend existing restrictions to agriculture, which the Fair Labor Standards Act largely exempts from child labor restrictions.⁸⁵

In contrast, the non-COVID-19 diseases for which many vaccination mandates exist in the United States have lost their cultural and political salience

⁸² *Id.* at 1.

⁸³ Priyanka Boghani, *Q&A: America's "Invisible" Child Labor Problem*, PBS FRONTLINE (April 24, 2018), <https://www.pbs.org/wgbh/frontline/article/qa-americas-invisible-child-labor-problem/> [https://perma.cc/CLW2-HSE6]; Alana Semuels, *How Common Is Child Labor in the U.S.?*, THE ATLANTIC (Dec. 15, 2014), <https://www.theatlantic.com/business/archive/2014/12/how-common-is-child-labor-in-the-us/383687/> [https://perma.cc/P9HM-VRPW]; Kimberly J. Rauscher et al., *US Child Labor Violations in the Retail and Service Industries: Findings From a National Survey of Working Adolescents*, 98 AM. J. PUB. HEALTH 1693, 1693-98 (2008), <https://ajph.aphapublications.org/doi/10.2105/AJPH.2007.122853> [https://perma.cc/8BV2-X3LW]; Ana Maria Echiburu, *Immigration Raid Results in Charges Filed Against Iowa Slaughterhouse for Child Labor Violations*, 14 PUB. INT. L. REP. 93, 94 (2008) (“Child labor laws in Iowa prohibit children below the age of eighteen from working in a meatpacking plant. Employees in meat packing plants are exposed to dangerous machines and chemicals and often have to make thousands of cuts every day with sharp knives, risking lacerations, nerve damage, or muscle damage. The brutal environment of a meatpacking plant is not an appropriate place for children. Yet, the May 12 immigration raid of Agriprocessors in Iowa, uncovered underage employees working in such conditions, which is something Americans are unaccustomed to hearing about in the United States.”); Susan Makdisi, *Child Labor*, 4 LOY. POVERTY L.J. 281, 281 (1998) (“Imagine a place where children go to work on farms, in factories, on the streets, or in an industry, working five to sixteen hours a day, five to seven days a week . . . This happens all over the world, including America and other developed countries.”).

⁸⁴ *E.g.*, Meret Thali, *Missing Childhood: How Cultural Norms and Government Systems Continue to Support Child Labor in Agriculture*, 20 DRAKE J. AGRIC. L. 453, 454-55 (2015) (“This widespread general acceptance and promotion of children working in agriculture in the United States has led to federal legislation that has failed to protect these children, even though they are working in what is considered one of the three most dangerous sectors of labor.”).

⁸⁵ *Child Labor in the United States*, AM. FED. TEACHERS, <https://www.aft.org/community/child-labor-united-states> [https://perma.cc/T5X5-UZ9C] (last visited Jan. 23, 2021).

precisely because vaccination programs in the twentieth century were so successful: it is a rare person in the United States who has watched a family member die of measles, whooping cough, tetanus, polio, or smallpox. Before exploring the erosion of these traditional vaccination mandates as a regulatory shifting baseline syndrome problem, however, this Article first provides some background on vaccine development, vaccine regulation, and vaccination mandates.

II. A BRIEF HISTORY OF VACCINES, VACCINE REGULATION IN THE UNITED STATES, AND VACCINES' ABILITY TO AFFECT THE DISEASE RISK BASELINE

A. *The Development of Vaccines*

Immunization practices have existed since the eighteenth century, when English physician Edward Jenner used cowpox to inoculate patients against smallpox.⁸⁶ Louis Pasteur added the human rabies vaccine in 1885, along with the concept of virus attenuation,⁸⁷ which allows humans to develop an effective immune response to the disease without contracting it. Polio, diphtheria, tetanus, and pertussis (whooping cough) vaccines followed by 1946, but injectable vaccines were not invented until 1955.⁸⁸

With this last invention, vaccination programs backed by public health regulatory regimes became important public health initiatives in the United States.⁸⁹ Since the inception of these vaccination programs, “scientists [have] widely consider[ed] immunization to be one of the greatest public health achievements of the 20th century, and experts in medical science and research agree that timely immunization is vital to staying healthy.”⁹⁰

B. *Federal Regulation of Vaccines in the United States*

1. *Vaccine Safety and the FDA*

No vaccine is risk-free,⁹¹ even when properly manufactured and

86 Stephanie F. Cave, *The History of Vaccinations in the Light of the Autism Epidemic*, 14 ALT. THERAPIES HEALTH & MED. 54, 54 (2008), https://www.researchgate.net/publication/23556900_The_history_of_vaccinations_in_the_light_of_the_autism_epidemic [<https://perma.cc/JG89-DBYT>].

87 *Id.*

88 *Id.*

89 *Id.*

90 *My Child's Risk*, IVACCINATE (2019), <https://ivaccinate.org/child-safety/> [<https://perma.cc/478Y-7Y9S>].

91 Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in LAW IN PUBLIC HEALTH PRACTICE 262, 273 (Richard A. Goodman et al. eds., 2007) (citing Hardin, *supra* note 68, at 1243-48).

administered.⁹² For example, the oral polio vaccine can cause paralysis.⁹³ More commonly, the person getting vaccinated faces risks of an immune reaction, ranging from redness and soreness at the vaccine site to a severe allergic reaction that leads to anaphylactic shock and death.⁹⁴

In the United States currently, the regulatory regime that balances the risks of personal harm against a new vaccine's effectiveness in protecting public health is the Food & Drug Administration's (FDA's) evaluation under the drug provisions of the federal Food, Drug, and Cosmetic Act (FDCA).⁹⁵ The federal government has been regulating vaccines since the passage of the 1902 Biologics Control Act,⁹⁶ which gave the Marine Health Service's Laboratory of Hygiene (transformed in 1930 into the National Institutes of Health) authority to regulate vaccines for safety, purity, and potency.⁹⁷ "The Laboratory established standards and licensed smallpox and rabies vaccines," then in 1934 added standards for efficacy.⁹⁸

Congress enacted the Food, Drug, and Cosmetic Act in 1938.⁹⁹ Under the Act, a "drug" includes any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" in humans.¹⁰⁰ Since 1962, the FDCA has prevented the introduction of any new drug in the United States without the FDA's approval.¹⁰¹ However, this regime did not include vaccines until 1972,¹⁰² when "the Division of Biologics Standards was moved from the National Institutes of Health to the FDA."¹⁰³ To get the FDA's approval to market a new vaccine, the manufacturer must prove that it is both safe and effective.¹⁰⁴

92 Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 149 (1988) (citations omitted).

93 *Id.* at 150.

94 National Vaccine Injury Compensation Program, HEALTH RESOURCES & SERVS. ADMIN., <https://www.hrsa.gov/vaccine-compensation/index.html> [<https://perma.cc/HH8R-WAT6>] (last visited Jan. 2021).

95 21 U.S.C. §§301-399a.

96 Linda Bren, *The Road to the Biotech Revolution—Highlights from 100 Years of Biologics Regulation*, FDA CONSUMER 1, 1 (2006), <https://www.fda.gov/files/about%20fda/published/The-Road-to-the-Biotech-Revolution--Highlights-of-100-Years-of-Biologics-Regulation.pdf> [<https://perma.cc/6WKU-W6AA>]; Julie B. Milstein, *Regulation of Vaccines: Strengthening the Science Base*, 25 J. PUB. HEALTH POL'Y 173, 174 (2004).

97 Milstein, *supra* note 96, at 174, 176.

98 *Id.* at 176.

99 Act of June 25, 1938, 52 Stat. 1040, *codified at* 21 U.S.C. §§ 301-399gg.

100 21 U.S.C. § 321(g)(1) (emphasis added).

101 *Id.* § 355(a).

102 Milstein, *supra* note 96, at 177.

103 *Id.*

104 21 U.S.C. § 355(b).

2. *Federal Immunization Programs*

The federal contribution to immunization most often consists of financing programs that make widespread vaccination cheap or free. For example, the first federal vaccination program targeted polio,¹⁰⁵ and the Poliomyelitis Vaccination Assistance Act of 1955¹⁰⁶ spurred free mass vaccination by providing federal funds to states to pay for the vaccines.¹⁰⁷ The Act also allowed the Surgeon General to initiate federal polio vaccination delivery.¹⁰⁸

The federal government continues to financially support vaccination programs, especially childhood vaccination programs, on a significant scale. Most notably: “Since 1962, the federal government has supported childhood vaccination programs through a grant program administered by the CDC. These ‘317’ grants, named for the authorizing statute, support purchase of vaccine for free administration at local health departments and support immunization delivery, surveillance, and communication and education.”¹⁰⁹ Between these 317 grants and the 1994 Vaccines for Children program (discussed below), “[a]s of 2000, the CDC purchased over half the childhood vaccine administered in the United States”¹¹⁰

C. *State Vaccination Requirements for School Attendance*

1. *State Authority to Require Vaccines*

The key regulatory components of vaccine program efficacy in the United States are state requirements that children be vaccinated before they can attend public schools, and often private schools and daycare facilities as well.¹¹¹ Massachusetts enacted the first U.S. law mandating vaccination in 1809, then passed the first school vaccination requirement in 1855 “to prevent smallpox transmission in schools.”¹¹² In 1905, in *Jacobson v. Massachusetts*,¹¹³ the U.S.

105 *Id.*

106 Act of August 12, 1955, Pub. L. No. 377, 69 Stat. 704.

107 *Id.* §§ 3-6.

108 *Id.* § 7.

109 Malone & Hinman, *supra* note 91, at 268.

110 *Id.*

111 *State Vaccination Requirements*, CTRS. FOR DISEASE CONTROL & PREVENTION (updated Nov. 15, 2016), <https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html> [<https://perma.cc/T8GF-EA2R>]; see also Malone & Hinman, *supra* note 91, at 269 (“School vaccination laws have played a key role in the control of vaccine-preventable diseases in the United States.”).

112 Malone & Hinman, *supra* note 91, at 269, 271 (citation omitted).

113 197 U.S. 11 (1905). For the story of how resistance to smallpox vaccine mandates and the five-year stretch of smallpox epidemics that started in 1900 led to this Supreme Court case, see generally MICHAEL WILLRICH, *POX: AN AMERICAN STORY* (2012).

Supreme Court upheld Massachusetts' (and other states') authority to mandate vaccinations, removing federal constitutional Due Process obstacles to state vaccination laws. Specifically, the Court acknowledged that states have broad police power to protect public health¹¹⁴ and that Jacobson's Fourteenth Amendment liberty protections did not insulate him from those requirements:

the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.¹¹⁵

Moreover, "[u]pon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members."¹¹⁶

Seventeen years later, the U.S. Supreme Court explicitly addressed the City of San Antonio, Texas's school vaccination mandate in *Zucht v. King*.¹¹⁷ Unlike in *Jacobson*, there was no imminent threat of contagious disease in San Antonio; nevertheless, public officials barred Rosalyn Zucht from attending public and private schools because she did not have the required vaccination certificate and refused to get vaccinated.¹¹⁸ Relying on *Jacobson*, the Court found against Zucht, concluding that "it is within the police power of a state to provide for compulsory vaccination" and "that a state may, consistently with the federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative."¹¹⁹

114 *Jacobson*, 197 U.S. at 24-25.

115 *Id.* at 26.

116 *Id.* at 27.

117 260 U.S. 174 (1922).

118 *Id.* at 175.

119 *Id.* at 176 (citations omitted).

2. *School Vaccination Mandates*

By the beginning of the twentieth century, when the Court considered *Jacobson*, “nearly half the states had requirements for children to be vaccinated before they entered school. By 1963, when the measles vaccine became available, 20 states, the District of Columbia, and Puerto Rico had such laws, with a variety of vaccines being mandated.”¹²⁰

Measles became a critical focus in expanding state vaccination mandates in the later 1960s, as the United States sought to eradicate that disease, and “[t]hese experiences demonstrated that mandatory vaccination could be enforced and was effective.”¹²¹ In 1977, public health officials pursued a nationwide Childhood Immunization Initiative to increase measles vaccination levels in children to 90 percent by 1979, an effort that induced even more states to enact and enforce school vaccination requirements.¹²²

School vaccination requirements, when strictly enforced, are quite effective in preventing disease and creating herd immunity.¹²³ As a result, “[b]y the 1980-1981 school year, all 50 states had laws covering students first entering school”¹²⁴—that is, when they first enrolled in kindergarten or first grade. By 1983, all fifty states required measles vaccinations,¹²⁵ and “[a]s of the 1998-1999 school year, all states but four (Louisiana, Michigan, South Carolina, and West Virginia) had requirements covering all grades from kindergarten through 12th grade.”¹²⁶ By that point, “[t]he requirements covered diphtheria toxoid and polio, measles, and rubella vaccines in all 50 states; 49 states required tetanus toxoid, 46 required mumps vaccine, 44 required pertussis vaccine, and 28 required hepatitis B vaccine.”¹²⁷ In 2000, the Task Force on Community Preventive Services, an independent body that evaluates the effectiveness of public health preventive interventions, recommended mandatory vaccination requirements to reduce drastically the incidence of vaccine-preventable diseases.¹²⁸

D. Real Shifts in Baseline Disease Risk from Vaccination: Smallpox and Polio

Public health professionals recognize that vaccination programs like school

120 Malone & Hinman, *supra* note 91, at 269 (citation omitted).

121 *Id.* at 269 (citations omitted).

122 *Id.* (citations omitted).

123 *Id.* at 270 (citation omitted).

124 *Id.* at 270 (citation omitted).

125 *Id.* at 271 (citation omitted).

126 *Id.* (citations omitted).

127 *Id.* (citations omitted).

128 *Id.* (citing Task Force on Community Preventive Services, *Recommendations Regarding Interventions to Improve Vaccination Coverage in Children, Adolescents, and Adults*, 18 AM. J. PREVENTIVE MED. 92, 92-96 (2000)).

vaccination mandates can shift both the objective societal disease regulatory baseline and the subjective individual risk-risk calculation in getting vaccinated.¹²⁹ Vaccines thus present an interesting case study of the regulatory shifting baseline syndrome because successful vaccination programs create *both* legitimate and illegitimate shifts in the regulatory baseline. Legitimate shifts in disease baselines result after vaccines eradicate or radically attenuate a disease risk at a societal level. More commonly, however, successful vaccination programs simply prevent people from getting a disease that nevertheless remains a societal risk. The *perception* that the disease has “gone away” illegitimately distorts individual evaluations of risk from the vaccine itself, promoting individual propensities to avoid vaccination.

Smallpox is the most famous example of a legitimately shifted vaccination baseline. This disease killed about 30 percent of the roughly 50 million people globally who contracted the disease each year before vaccination programs began in earnest in the 1950s.¹³⁰ However, as a result of these vaccination efforts, the last natural case of smallpox occurred in 1977.¹³¹ The variola virus that causes smallpox now exists only in laboratories, and “[r]outine smallpox vaccination among the American public stopped in 1972 after the disease was eradicated in the United States.”¹³²

A less dramatic example of a legitimate regulatory baseline shift occurred with polio. The polio vaccine exists in two primary forms. The oral polio vaccine is more effective at preventing polio but carries a risk of paralysis, which occurs at a rate of about 1 in every 2.4 million doses of the vaccine.¹³³ The inactivated polio vaccine, in contrast, is less effective at preventing polio but carries *no* risk of paralysis.¹³⁴ Of course, polio itself can also cause paralysis and death, and so long as poliovirus circulated in the United States, the risk of paralysis from the oral vaccine “was certainly outweighed by the much larger risk for paralysis from wild polioviruses”¹³⁵ However, by 1991, successful vaccination programs eradicated wild poliovirus from the Western Hemisphere.¹³⁶ As a result, given the greatly reduced risk of contracting polio from wild poliovirus, in 2000, the CDC’s Advisory Committee on Immunization Practices recommended that

129 *Id.* at 263.

130 WORLD HEALTH ORG., BUGS, DRUGS, AND SMOKE: STORIES FROM PUBLIC HEALTH 3-5 (2011), <https://apps.who.int/iris/handle/10665/44700> [<https://perma.cc/5UXA-H8X4>].

131 *Id.* at 3.

132 *Vaccine Basics*, CTRS. FOR DISEASE CONTROL & PREVENTION (updated July 12, 2017), <https://www.cdc.gov/smallpox/vaccine-basics/index.html> [<https://perma.cc/P8MP-GXEC>].

133 Malone & Hinman, *supra* note 91, at 264.

134 *Id.*

135 *Id.*

136 *Id.*

public health officials eliminate the risk of *vaccination-caused* paralysis by switching from the oral vaccine to the inactivated polio vaccine.¹³⁷ Reduced risks of getting the disease justified switching to the safer but less effective vaccine.

More commonly, however, vaccination programs do *not* eradicate a disease, even within a geographically restricted area like the United States. Instead, successful vaccination programs achieve herd immunity. Specifically, when a sufficiently large number of individuals choose to get vaccinated against a particular disease, herd immunity emerges.¹³⁸ Herd immunity, in turn, protects those individuals who either cannot be vaccinated or who fall within the small percentage of vaccinated individuals who do not develop a strong enough immune response to keep them from getting the disease.¹³⁹

However, herd immunity lasts only so long as the relevant population remains vaccinated at sufficiently high percentages.¹⁴⁰ The exact percentage varies from disease to disease:

Measles, for example, spreads so easily that an estimated 95% of a population needs to be vaccinated to achieve herd immunity. In turn, the remaining 5% have protection because, at 95% coverage, measles will no longer spread. For polio, the threshold is about 80%.

...

Viruses like the flu, however, are different from measles in that they mutate over time, meaning antibodies from a previous infection won't provide protection for long. That's why the flu vaccine is reformulated each year to match what is expected to be the dominant strain in the coming season.¹⁴¹

The coronavirus also mutates, complicating the achievement of herd immunity, but experts still hope that an 85 percent vaccination rate could result

¹³⁷ *Id.*

¹³⁸ Katie M. Palmer, *Why Did Vaccinated People Get Measles at Disneyland? Blame the Unvaccinated*, WIRED (Jan. 8, 2015, 6:08 AM), <https://www.wired.com/2015/01/vaccinated-people-get-measles-disneyland-blame-unvaccinated/> [<https://perma.cc/7E4W-2A5H>]; Malone & Hinman, *supra* note 91, at 264 (describing herd immunity and how the percentage of the vaccinated population required varies by disease).

¹³⁹ Palmer, *supra* note 138; *Herd Immunity and COVID-19 (Coronavirus): What You Need to Know*, MAYO CLINIC (Dec. 17, 2021), <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808> [<https://perma.cc/4S7C-7V75>].

¹⁴⁰ *Herd Immunity: An Explanation*, YALEMED. (updated May 21, 2021), <https://www.yalemedicine.org/news/herd-immunity> [<https://perma.cc/6XPY-ZRET>].

¹⁴¹ *Id.*

in herd immunity.¹⁴²

The continuing need to keep vaccination rates high for most vaccine-preventable diseases is the critical medical fact that allows the illegitimate versions of the vaccination regulatory shifting baseline syndrome to emerge. Specifically, the achievement of herd immunity and a low incidence of disease can shift the public's perception of risk from the disease to the vaccine itself. The next Part explores the emergence of this syndrome in the United States regarding traditional vaccine-preventable diseases, especially measles.

III. THE VACCINATION REGULATORY SHIFTING BASELINE SYNDROME IN THE UNITED STATES

The United States declared measles eliminated within its borders in 2000.¹⁴³ Nevertheless, between mid-December 2014 and mid-February 2015, the Disney theme parks in Anaheim, California, appeared to be ground zero of a new measles outbreak. The Centers for Disease Control and Prevention (CDC) documented at least 125 measles cases in the United States that winter, 110 of which involved California residents.¹⁴⁴ Of the California residents, forty-nine were unvaccinated, including twelve infants too young to be vaccinated; another forty-seven patients' vaccination status was unknown or undocumented; and a handful of others were undervaccinated (i.e., lacking the full course of shots).¹⁴⁵ Notably, of the thirty-seven vaccine-eligible patients who definitely were not vaccinated, twenty-eight had purposely chosen to remain unvaccinated "because of personal beliefs."¹⁴⁶

Measles outbreaks in the United States spiked again in 2019, with the CDC confirming 1,282 cases in thirty-one states.¹⁴⁷ Noting that "[t]his is the greatest number of cases reported in the U.S. since 1992," it emphasized again that "[t]he majority of cases were among people who were not vaccinated against

¹⁴² *Id.*

¹⁴³ Morgan Krakow, *A Tourist Infected with Measles Visited Disneyland and Other Southern California Hot Spots in Mid-August*, WASH. POST (Aug. 24, 2019, 10:36 AM MDT), <https://www.washingtonpost.com/health/2019/08/24/tourist-infected-with-measles-visited-disneyland-other-southern-california-hotspots-mid-august/> [https://perma.cc/4HDA-3N7R].

¹⁴⁴ Jennifer Zipprich et al., *Measles Outbreak—California, December 2014–February 2015*, CTRS. FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WEEKLY REP. (Feb. 20, 2015), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a5.htm> [https://perma.cc/64GP-NVV9].

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Measles Cases and Outbreaks*, CTRS. FOR DISEASE CONTROL & PREVENTION (updated Dec. 2, 2020), <https://www.cdc.gov/measles/cases-outbreaks.html> [https://perma.cc/6BA8-9L9B].

measles.”¹⁴⁸ Vaccination is a particularly important protection for measles because, in part because it spreads through the air, “[m]easles is one of the most contagious viruses in the world. Around 90 percent of unvaccinated people exposed to the virus will contract the disease within seven to 21 days,” with death as one potential outcome.¹⁴⁹

Measles has made a comeback in the United States and other countries because of “mistrust and misinformation campaigns about vaccine safety,”¹⁵⁰ a phenomenon known more colloquially as the Anti-Vaxxer Movement.¹⁵¹ This Part examines the twentieth-century emergence of a vaccination regulatory shifting baseline syndrome in the United States.

A. Initial Signals of a Vaccination Regulatory Shifting Baseline Syndrome: Vaccine Lawsuits and the Childhood Vaccine Injury Act of 1986

1. Vaccine Litigation

As noted, vaccine “safety” is not absolute but instead requires the FDA to assess whether the vaccine’s benefits outweigh its risks. This calculus depends on many factors. The FDA might be willing to tolerate more individual risks and side effects if the vaccine prevents a particularly deadly or novel disease.¹⁵² Any patient who has received warnings about contraindications and side effects from their doctor or pharmacy in connection with a prescription, flu vaccine, or now the new coronavirus vaccines has experienced firsthand the practical results of FDA risk-benefit balancing.

As a result of this balancing, individual risks usually remain for even the most important and effective vaccines: in any large population, a few people will have an adverse reaction to the vaccine. One of the first signs that members of the U.S. public were beginning to reject the public-oriented focus of vaccination programs¹⁵³ were the products liability torts lawsuits against vaccine

148 *Id.*

149 Krakow, *supra* note 143.

150 *Id.*

151 See, e.g., Palmer, *supra* note 138 (noting that “most of the people stricken with Mickey Mouse measles do not understand how vaccines work, because they didn’t get them. The vast majority of the infected were unvaccinated against the disease, including kids who were too young for the shots and anti-vaxxers who chose against them. That’s how you get an outbreak”).

152 See 21 U.S.C. § 355-1(a)(1) (laying out the risk-benefit analysis and many of the factors to consider).

153 Miles E. Coleman, *An Overview of the National Childhood Vaccination Act*, 21 S.C. LAWYER 40, 40 (2010) (“Throughout the 20th century, as vaccination schedules prescribed more and earlier immunizations, there was a growing awareness of the potential dangers of vaccinations and an accompanying resistance to immunization. In response, Congress passed the National Childhood Vaccine Injury Act of 1986 . . .”).

manufacturers starting in the 1950s and escalating through the 1980s,¹⁵⁴ seeking personal injury damages for those individuals that vaccines harmed. These lawsuits began with the Cutter Incident, when Cutter Laboratories released a vaccine in which the virus had not been properly inactivated, despite following federally mandated manufacturing procedures.¹⁵⁵ Nearly 200 people were paralyzed, and ten people died after contracting polio from vaccines from these lots.¹⁵⁶ In 1955, the California Court of Appeals upheld a jury verdict that Cutter Laboratories was liable in tort for these injuries under implied warranty theories, even though the jury found that Cutter had not been negligent in producing the vaccine.¹⁵⁷ The proverbial tort floodgates had been opened, and vaccine litigation threatened to leave the United States without vaccine manufacturers.¹⁵⁸

The *Cutter Laboratories* case was one of the most important cases creating strict products liability, and other vaccines soon became targets of tort litigation.¹⁵⁹ In particular, a 1974 medical research paper claimed that the pertussis (whooping cough) vaccine caused brain damage, changing vaccination policies worldwide.¹⁶⁰ In the United States, plaintiffs' attorneys "attacked vaccine makers, claiming that the pertussis vaccine caused epilepsy, mental retardation, learning disorders, unexplained coma, Reye's syndrome . . . , and sudden infant death syndrome."¹⁶¹ By the late 1980s, hundreds of lawsuits had been filed seeking more than \$21 million in damages, and the cost of a single pertussis vaccine dose had increased from 17 cents to \$11.00.¹⁶² Although researchers later proved the claims wrong, "the damage was done," and the number of manufacturers producing pertussis vaccine for children in the United States dropped from four to one—with that one subject to continuing million-dollar tort liability.¹⁶³

154 Neraas, *supra* note 92, at 151 ("Lawsuits against manufacturers rose from 24 in 1980 to approximately 150 in 1985.").

155 For an insightful history of the polio vaccines' development and the *Cutter Laboratories* litigation, see generally PAUL A. OFFIT, *THE CUTTER INCIDENT: HOW AMERICA'S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS* (2005).

156 *Id.* at 89.

157 *Gottsdanker v. Cutter Laboratories*, 6 Cal. Rptr. 320, 322-24 (Cal. App. 1st Dist. 1955).

158 Vaccine Injury Compensation Programs, COLL. PHYSICIANS PHILA. (updated Jan. 17, 2018), <https://www.historyofvaccines.org/content/articles/vaccine-injury-compensation-programs> [<https://perma.cc/W3V9-6AEU>]; see also Neraas, *supra* note 92, at 152 ("Between 1966 and 1977, half the nation's vaccine manufacturers stopped producing and distributing vaccines. By 1985, only four commercial firms produced and distributed the primary vaccines used in compulsory vaccination programs.").

159 OFFIT, *supra* note 155, at 179-81.

160 *Id.* at 179-80.

161 *Id.* at 180-81.

162 *Id.* at 181.

163 *Id.* at 181-82.

2. *Dealing with the Vaccine Supply Crisis: The National Childhood Vaccine Injury Act of 1986*

As a result of vaccine injury litigation, the United States faced the distinct possibility that it would return to a non-vaccine state of public health, where “hundreds of thousands of children were routinely hospitalized, permanently harmed, or killed by vaccine-preventable diseases” each year.¹⁶⁴ Responding to this “vaccine liability crisis that has threatened the nation’s supply of childhood vaccines,”¹⁶⁵ Congress intervened with the National Childhood Vaccine Injury Act of 1986 (NCVIA), which established the National Vaccine Injury Compensation Program (VICP).¹⁶⁶ This program provides compensation to patients who are injured by listed vaccines¹⁶⁷ while insulating vaccine manufacturers from tort liability,¹⁶⁸ ensuring that vaccines remain available to the population at large. A person who receives a covered vaccine and suffers a recognized injury therefrom¹⁶⁹ can file a petition for recovery in the U.S. Court of Federal Claims,¹⁷⁰ receiving compensation as the Act allows.¹⁷¹ According to the U.S. Department of Justice,

[o]ver the past 30 years, the VICP has succeeded in providing a less adversarial, less expensive, and less time-consuming system of recovery than the traditional tort system that governs medical malpractice, personal injury, and product liability cases. More than 6,000 people have been paid in excess of \$3.9 billion (combined) since the Program’s 1988 inception . . . [and] costly litigation against drug manufacturers and health care professionals who administer vaccines has virtually ceased.¹⁷²

164 *Id.* at 182.

165 Neraas, *supra* note 92, at 149.

166 42 U.S.C. §§ 300aa-10 to 300aa-23.

167 *Id.* §§ 300aa-10(a), 300aa-11(c), 300aa-13(a).

168 *Id.* § 300aa-22(b)(1); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 232-33 (2011) (holding that the NCVIA preempts state tort law design defect claims).

169 42 U.S.C. § 300aa-14.

170 *Id.* § 300aa-11.

171 *Id.* § 300aa-15.

172 *Vaccine Injury Compensation Program*, U.S. DEPT. OF JUSTICE (updated Sept. 24, 2018), <https://www.justice.gov/civil/vicp> [<https://perma.cc/FZ4D-BUDZ>].

B. Vaccine Resistance, Anti-Vaxxers, and the Emergence of the Vaccination Regulatory Shifting Baseline Syndrome

1. Vaccine Hesitancy in the United States

Resistance to vaccination has existed since inoculations were first invented. Indeed, skepticism regarding the efficacy and safety of the earliest inoculation practices was often fully justified, given the state of medical science and rather loose oversight of practitioners at the time.¹⁷³ For example, when smallpox was the disease of most significant concern:

In the late 1800s through the early 1900s, some parents responded to school vaccination laws by refusing to send their children to school, sending their children to private schools, wiping the vaccine from their children's arms following vaccination, attempting to fake vaccine scars, and refusing to comply with vaccination requirements. This resistance was driven in part by the risks of the smallpox vaccine and the risks of inoculation, which included the transmission of other diseases, including tetanus. . . . Opposition to vaccination became stronger during the early 1900s when a milder form of smallpox, variola minor, became the dominant strain. This strain rarely caused death, leading many to conclude that the vaccine was more dangerous than the disease it prevented.¹⁷⁴

However, the United States has a long history of vaccine resistance rooted in issues other than legitimate concerns about the safety and efficacy of the vaccines themselves.¹⁷⁵ Many religions and religious leaders, for example, have actively discouraged vaccination: “fear of vaccines emerged in the 18th century. Religious figureheads often referred to them as ‘the devil’s work’ and actively spoke against them.”¹⁷⁶ Racism and racial mistrust have also played a role in

¹⁷³ *The Anti-Vaccination Movement*, MEASLES & RUBELLA INITIATIVE, <https://measlesrubellainitiative.org/anti-vaccination-movement/> [https://perma.cc/T58Q-TUH4] (last visited Jan. 27, 2021).

¹⁷⁴ Douglas S. Diekema, *Personal Belief Exemptions for School Vaccination Requirements*, 35 ANN. REV. PUB. HEALTH 275, 278 (2014) (citations omitted).

¹⁷⁵ See, e.g., MICHAEL WILLRICH, POX: AN AMERICAN STORY 12 (2012) (noting that “reasonable health concerns do not alone explain the widespread opposition to compulsory vaccination at the turn of the twentieth century”).

¹⁷⁶ Olivia Benecke & Sarah Elizabeth DeYoung, *Anti-Vaccine Decision-Making and Measles Resurgence in the United States*, 6 GLOB. PEDIATRIC HEALTH 1 (2019); see also WILLRICH, *supra* note 175, at 12 (“Christian Scientists viewed compulsory vaccination as a violation of religious freedom.”).

vaccination resistance.¹⁷⁷ Personal liberty objections have long influenced resistance to vaccination in both England and the United States. For example, when England enacted the Vaccination Act in 1853, requiring vaccination against smallpox for infants over three months old and mandating penalties for noncompliance, several organizations formed to resist the new mandate, including London's Anti-Vaccination League.¹⁷⁸ In the United States, opposition to vaccination mandates reflected uneasiness over the increasing intrusion of government into private lives, arguably constituting one of the first civil liberty struggles.¹⁷⁹ "Parents also protested on the grounds that vaccination threatened the safety of their children, usurped their parental authority, and violated the bodily integrity of their children."¹⁸⁰

Opposition to vaccines in the United States is generally categorized into two levels of severity. Some people are still resistant to vaccinating themselves and their children because of concerns about the safety of particular, or most vaccines.¹⁸¹ Vaccine hesitancy thus refers to a spectrum of resistance levels to vaccines, and "[a] vaccine-hesitant person can delay, be reluctant but still accept, or refuse some or all vaccines."¹⁸² An "anti-vaxxer," in contrast, is an individual who is opposed to *all* vaccines and vaccination requirements for reasons other than the perceived safety of the vaccine itself, including religious beliefs and assertion of personal liberty.¹⁸³ These individuals typically associate with the "anti-vaccination movement," or "anti-vaxxer movement," in an effort to prevent the use of vaccines to immunize people from certain contagious illnesses.¹⁸⁴

While the spectrum of resistance is real, people along the entire spectrum often find justification for their resistance in misleading and false information that has made the personal risks from the vaccines themselves seem unduly high. As noted, "[i]n the 1970s, concern about the possibility of pertussis vaccine causing sudden infant death syndrome or infantile spasms led to debate about pertussis vaccination requirements, even though studies showed that the vaccine caused neither event."¹⁸⁵ Nevertheless, these fears led to a substantial expansion of vaccine resistance in the United Kingdom into the 1980s, "when parents

177 WILLRICH, *supra* note 175, at 12.

178 *Id.*; *The Anti-Vaccination Movement*, *supra* note 173.

179 WILLRICH, *supra* note 175, at 13-24.

180 Diekema, *supra* note 174, at 278.

181 Ève Dubé et al., *Vaccine Hesitancy, Acceptance, and Anti-Vaccination: Trends and Future Prospects for Public Health*, 42 ANN. REV. PUB. HEALTH 175, 176-77 (2021).

182 *Id.* at 177.

183 *Id.*; Thomas Keegan & Rhiannon Edge, *It's Wrong to Assume that the Choice not to Vaccinate is Always Down to Ignorance*, THE CONVERSATION (Sept. 16, 2016), <https://theconversation.com/its-wrong-to-assume-that-the-choice-not-to-vaccinate-is-always-down-to-ignorance-123112> [<https://perma.cc/5JFP-H4TC>].

184 *The Anti-Vaccination Movement*, *supra* note 173.

185 Malone & Hinman, *supra* note 91, at 274.

increasingly refused to vaccinate their children against pertussis in response to a report that attributed 36 negative neurological reactions to the pertussis vaccine. This caused a decrease in the pertussis vaccine uptake in the United Kingdom from 81% in 1974 to 31% in 1980, eventually resulting in a pertussis outbreak”¹⁸⁶ Similarly, false connections to the onset of autism have helped to fuel the resistance to the measles vaccine, as the next section will discuss.

2. Vaccine Hesitancy and Measles

Measles is not the deadliest of infectious diseases. Even so, “[b]efore the introduction of measles vaccine in 1963 and widespread vaccination, major epidemics occurred approximately every 2–3 years and measles caused an estimated 2.6 million deaths each year.”¹⁸⁷ The world population in 1963 was a little over 3.211 billion people,¹⁸⁸ which would suggest that roughly one out of every 1,235 individuals on the planet died from measles *every year*. In contrast, the rate of severe allergic reactions to the MMR (mumps-measles-rubella) vaccine is about one in 1 million doses,¹⁸⁹ the risk of death from the vaccine in healthy people is virtually non-existent.¹⁹⁰ Getting the vaccine thus clearly reduced the risk of death. Even comparing the risk of severe allergic reaction from the vaccine to the rise of death from measles, it was still roughly 1,000 times less risky to get the vaccine than to walk around unvaccinated *even in just the year of vaccination*, let alone over a lifetime.

That calculus has changed. Even in a bad year, measles now causes only about 140,000 deaths globally,¹⁹¹ reflecting a reduction in yearly measles deaths since 1963 of over 94 percent despite a world population that has more than doubled in the interim. Nevertheless, vaccination remains necessary to protect the public commons, especially given measles’ infection rate.

186 Benecke & DeYoung, *supra* note 176.

187 *Measles*, WORLD HEALTH ORG., (Dec. 5, 2019), <https://www.who.int/news-room/fact-sheets/detail/measles> [<https://perma.cc/K9PF-VJMJ>].

188 *World Population by Year*, WORLDOMETER, <https://www.worldometers.info/world-population/world-population-by-year/> [<https://perma.cc/D8A7-DTXA>] (last visited Jan. 23, 2021).

189 Jeanne P. Spencer, Ruth H. Trondsen Pawlowski & Stephanie Thomas, *Vaccine Adverse Events: Separating Myth from Reality*, 95 AM. FAM. PHYSICIAN 786, 787 tbl. 1 (2017).

190 *Measles Vaccination: Myths and Facts*, INFECTIOUS DISEASE SOC’Y OF AM., <https://www.idsociety.org/public-health/measles/myths-and-facts/> [<https://perma.cc/7LD2-DJAG>] (last visited June 10, 2022) (“There have been no deaths shown to be related to the vaccine in healthy people. There have been rare cases of deaths from vaccine side effects among children who are immune compromised, which is why it is recommended that they don’t get the vaccine There are possible side effects from the vaccine, including sore arm (from the shot), fever, mild rash, temporary pain/stiffness in the joints, and a very small risk of febrile seizures or allergic reaction.”).

191 *Measles*, *supra* note 187.

Resistance to measles vaccines got a boost from the false linking of the MMR vaccine to autism, unfortunately given credence “by the 1998 publication of a series of articles in *The Lancet* by a former British doctor, Andrew Wakefield.”¹⁹² “Despite the small sample size ($n=12$), the uncontrolled design, and the speculative nature of the conclusions, the paper received wide publicity, and MMR vaccination rates began to drop because parents were concerned about the risk of autism after vaccination.”¹⁹³ Recent research indicates that the fraudulent research continues to influence parents’ decisions *not* to vaccinate their children, particularly as the internet and social media become increasingly popular sources of “medical” advice.¹⁹⁴

Thus, the regulatory baselines for both pertussis and MMR vaccines have illegitimately shifted, allowing individuals to exaggerate the risk to themselves or their children from the vaccine while downplaying the continuing risks of the diseases.¹⁹⁵ At the same time, expanded exemptions from state vaccination mandates played a critical role in allowing individual choices to endanger public health once again.¹⁹⁶ Children (and others) are paying the price.

C. *The Vaccination Regulatory Shifting Baseline Syndrome Takes Legal Shape: Exemptions from State Vaccination Mandates*

1. *Increasing Numbers of State Exemptions from School Vaccination Requirements*

The NCVIA ensured that childhood vaccines remained available in the United States. Nevertheless, changes to state vaccination requirements

192 Benecke & DeYoung, *supra* note 176. The critical paper was Andrew J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637, 637-41 (1998) (retracted by the journal for fraud in March 2010).

193 T. S. Sathyanarayana Rao & Chittaranjan Andrade, *The MMR Vaccine and Autism: Sensation, Refutation, Retraction, and Fraud*, 53 INDIAN J. PSYCHIATRY 95, 95 (2011).

194 Lucy E Elkin, Susan R.H. Pullon & Maria H. Stubbe, ‘*Should I Vaccinate My Child?*’ *Comparing the Displayed Stances of Vaccine Information Retrieved from Google, Facebook and YouTube*, 38 VACCINE 2772, 2771 (2020) (citations omitted); Benecke & DeYoung, *supra* note 176. For a particularly pointed internet response to anti-vaxxer rhetoric, see Rada Jones, *24 Reasons not to Vaccinate your Kid*, KEVINMD.COM (Jan. 25, 2020), <https://www.kevinmd.com/blog/2020/01/24-reasons-to-not-vaccinate-your-kid.html> [<https://perma.cc/F7WU-8DTF>].

195 While this discussion focuses on measles, pertussis outbreaks are also common in the United States. As the CDC notes, “Pertussis (whooping cough) is a common (endemic) disease in the United States. There are peaks in reported cases of pertussis every few years and frequent outbreaks. In 2012, the largest peak in recent years, states reported 48,277 cases of pertussis.” *Pertussis Outbreaks*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/pertussis/outbreaks.html> [<https://perma.cc/BB2D-7KM7>] (last visited Nov 18, 2019).

196 Benecke & DeYoung, *supra* note 176; Diekema, *supra* note 174, at 283-84.

increasingly allowed the vaccine hesitant and anti-vaxxers to pursue their personal inclinations, allowing diseases like measles to re-emerge.

Exemptions from state vaccination requirements have been part of the legal vaccination landscape almost from the beginning. For example, even in the nineteenth century, Massachusetts' vaccination laws allowed "an exception in favor of 'children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination.'"¹⁹⁷ Medical exemptions from vaccination continue to find support among public health officials because "[s]ome people have medical conditions that increase the risk for adverse effect, and therefore they should not receive vaccines. Recognizing this fact, all state vaccination laws provide for exemptions for persons with contraindicating conditions."¹⁹⁸ Utah's medical exemption is fairly typical. While Utah requires students to have a certificate of immunization to attend any "public, private, or parochial kindergarten, elementary, or secondary school through grade 12, nursery school, licensed day care center, child care facility, family care home, or head-start program,"¹⁹⁹ children can avoid this requirement if they have a physician's certification that a health condition prevents the child from receiving the vaccines.²⁰⁰

The two other exemptions that emerged in states over time—exemptions for religious reasons and exemptions based on personal philosophy—are far less well-grounded in medicine but instead seek to accommodate other, individual, values. The policy and legal issues they raise for contemporary society and the resurgence of diseases like measles are whether these personal exemptions should trump the greater public good. However, by the end of the twentieth century in the United States, they also represented the legal manifestation of the vaccination regulatory shifting baseline syndrome, undercutting the vaccination mandates that had allowed many formerly dread diseases to disappear from the average American's consciousness.²⁰¹

2. *Personal Philosophical Exemptions from Vaccine Requirements*

Personal philosophical exemptions from vaccination requirements allow parents to avoid school vaccination requirements for their children based on personal or moral beliefs.²⁰² These exemptions originated in the British

197 *Jacobson*, 197 U.S. at 12 (citing MASS. REV. L. chap. 75, § 139). Massachusetts added its medical exemption in 1894. Diekema, *supra* note 174, at 278.

198 Malone & Hinman, *supra* note 91, at 273.

199 UTAH CODE ANN. § 53A-11-301 (2020).

200 *Id.* § 53A-11-302.

201 *14 Diseases You Almost Forgot About (Thanks to Vaccines)*, *supra* note 15.

202 *States With Religious and Philosophical Exemptions From School Immunization*

Vaccination Act of 1898, which “provided a conscience clause to allow exemptions to mandatory smallpox vaccination. This clause gave rise to the term ‘conscientious objector,’ which later came to refer to those opposed to military service.”²⁰³ Philosophical objections to mandatory vaccination can hark back to Jacobson’s objection to this basic infringement on liberty, arise from a fear of an adverse reaction to or contamination from the vaccines, or reflect the parents’ conclusions that their children really are not at risk of contracting particular diseases or that the diseases for which vaccinations are required are not that bad.²⁰⁴

States actively adopted philosophical exemptions between 1970, when only “five states allowed exemption from the law if a parent simply objected in writing,”²⁰⁵ and 2014. At the beginning of the twenty-first century, fifteen states provided exemptions for personal philosophical objections—California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Utah, Vermont, Washington, and Wisconsin.²⁰⁶ By 2014, the number had risen to twenty-two, subtracting New Mexico but adding Arizona, Arkansas, Missouri (childcare facilities only), Oregon, Pennsylvania, Texas, Virginia (HPV vaccine only), and Wisconsin.²⁰⁷ More importantly, *use* of these exemptions more than doubled,²⁰⁸ indicating that ever more Americans considered the personal risks from vaccination to outweigh the risks of contracting the vaccine-preventable diseases.

States phrase these exemptions in a variety of ways. Harkening back to England, Texas allows the exemption if a parent cites “reasons of conscience.”²⁰⁹ Arizona, in turn, requires that:

The parent or guardian of the pupil submits a signed statement to the school administrator stating that the parent or guardian has received information about immunizations provided by the

Requirements, NAT’L CONF. STATE LEGISLATURES (May 25, 2022), <https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx> [<https://perma.cc/C2HN-Y7SU>].

²⁰³ *Vaccination Exemptions*, HIST. OF VACCINES (updated Jan. 7, 2018), <https://historyofvaccines.org/getting-vaccinated/vaccine-faq/vaccination-exemptions> [<https://perma.cc/2QT6-MGJQ>].

²⁰⁴ Malone & Hinman, *supra* note 91, at 273.

²⁰⁵ Diekema, *supra* note 174, at 279.

²⁰⁶ Malone & Hinman, *supra* note 91, at 273.

²⁰⁷ This list combines information from *States With Religious and Philosophical Exemptions From School Immunization Requirements*, *supra* note 202, with the legislative developments cited therein. See also *Vaccination Exemptions*, *supra* note 203 (also counting twenty states before California’s and Vermont’s changes in 2015).

²⁰⁸ *Vaccination Exemptions*, *supra* note 203.

²⁰⁹ TEX. EDUC. CODE ANN. § 38.001.

department of health services and understands the risks and benefits of immunizations and the potential risks of nonimmunization and that due to personal beliefs, the parent or guardian does not consent to the immunization of the pupil.²¹⁰

Despite their early twenty-first-century popularity, however, states can easily—at least as a matter of law—eliminate philosophical exemptions. As *Jacobson* and *Zucht* make clear, these exemptions exist purely as a matter of the state’s largesse, politically accommodating parents who prefer not to vaccinate their children, often resulting from unwarranted concerns about the vaccines.

3. *Religious Exemptions from Vaccine Requirements*

State exemptions from vaccine requirements for religious reasons are both more pervasive and potentially more legally and politically difficult to remove, given the Free Exercise Clause in the First Amendment to the U.S. Constitution.²¹¹ The Christian Science Church was particularly active in lobbying for religious exemptions in the twentieth century, and by 1970 “most states allowed exemption from school vaccine requirements . . . if the parents could demonstrate that the vaccination would violate the teachings of a recognized religious organization to which they belonged”²¹²

The U.S. Supreme Court has never squarely addressed whether the First Amendment—or, since 1993, the Religious Freedom Restoration Act²¹³—requires a religious exemption from mandatory vaccination laws. Nevertheless, it has signaled just the opposite: when offered the opportunity, the Court has gone out of its way to suggest that vaccine mandates are insulated from claims of religious freedom. For example, its 1944 case of *Prince v. Massachusetts* addressed the issue of whether a Jehovah’s Witness could violate child labor laws on religious grounds.²¹⁴ Along the way to upholding Massachusetts’ conviction of the parent, the Court emphasized that:

neither rights of religion nor rights of parenthood are beyond limitation. Acting to guard the general interest in youth’s well being, the state as *parens patriae* may restrict the parent’s control by requiring school attendance, regulating or prohibiting the child’s labor, and in many other ways *Thus, he cannot*

210 ARIZ. REV. STAT. ANN. § 15-873(A)(1).

211 U.S. CONST., amend. I.

212 Dickema, *supra* note 174, at 279.

213 42 U.S.C. § 2000bb et seq.

214 321 U.S. 158, 159-60 (1944).

*claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.*²¹⁵

Seventy years later, in 2014, a very different Court displayed the same reluctance to subject vaccination mandates (or, more technically, requirements that medical insurance cover the vaccinations) to the vagaries of individual religious beliefs. In *Burwell v. Hobby Lobby Stores, Inc.*, the Court determined that federal mandates in the Affordable Care Act requiring that employers provide health insurance that covers contraception, to which the employers involved objected on religious grounds, violate the Religious Freedom Restoration Act.²¹⁶ While the case had nothing directly to do with vaccination, along the way to its decision (prompted by the Department of Health and Human Services), the Court majority made clear that its decision did not necessarily extend to vaccines:

Our decision should not be understood to hold that an insurance-coverage mandate must necessarily fall if it conflicts with an employer's religious beliefs. *Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them.*²¹⁷

215 *Id.* at 166-67 (citations omitted; emphasis added). Indeed, even in 1972 in one of the most important cases upholding religious freedom against state schooling requirements, the Supreme Court still emphasized that the case was “not one in which any harm to the physical or mental health of the child or to the public safety, peace, order, or welfare has been demonstrated or may be properly inferred,” again insulating the decision from directly intruding into public health mandates. *Wisconsin v. Yoder*, 406 U.S. 205, 230 (1972). Moreover, the U.S. Courts of Appeals recently have nearly uniformly upheld vaccine mandates against religious freedom claims. *See, e.g., Fallon v. Mercy Cath. Med. Ctr. of Se. Pa.*, 877 F.3d 487, 492-93 (3d Cir. 2017) (holding that a hospital worker's refusal to comply with a flu vaccination requirement did not give rise to a religious discrimination claim and noting that “that we are not the only court to come to the conclusion that certain anti-vaccination beliefs are not religious”); *Phillips v. City of New York*, 775 F.3d 538, 542-44 (2d Cir. 2015) (upholding New York's application of its religious exemption against challenges from parents seeking exemptions on non-religious grounds); *Caviezel v. Great Neck Pub. Sch.*, 500 Fed. Appx. 16, 18-19 (2d Cir. 2012) (upholding a New York denial of a religious exemption); *Workman v. Mingo Co. Bd. of Educ.*, 419 Fed. Appx. 348, 354-56 (4th Cir. 2011) (upholding West Virginia's lack of a religious exemption).

216 573 U.S. 682, 736 (2014).

217 *Hobby Lobby*, 573 U.S. at 733 (emphasis added). In addition, as the Court explained at length, the application of the Religious Freedom Restoration Act to *state* mandates created a

Even the Supreme Court's most recent coronavirus-related religious freedom case, *Roman Catholic Diocese of Brooklyn v. Cuomo*,²¹⁸ does not necessarily subject vaccination requirements to constitutional or statutory claims of religious freedom. The case upheld a religious freedom First Amendment challenge to the New York Governor's executive order limiting religious services in "red" and "orange" zones to ten and twenty-five attendees, respectively.²¹⁹ The Court emphasized that the executive order imposed no such crowding limitations on "essential" businesses like liquor and hardware stores, nor did it tailor attendance limitations to the size of the church or synagogue,²²⁰ constitutionally suspect differentiations that a vaccination mandate is unlikely to make. In addition, Justices Breyer, Sotomayor, and Kagan dissented on the merits regardless,²²¹ and both Justices Gorsuch and Kavanaugh, who voted in the majority, wrote concurring opinions that suggest that they might see a vaccination case differently. Justice Gorsuch explicitly suggested that the vaccine requirement in *Jacobson* might survive strict scrutiny,²²² while Justice Kavanaugh emphasized the "substantial deference" owed to state policy choices during pandemics.²²³

In the few cases that exist, state supreme courts explicitly ruled against religious freedom claims and upheld vaccine mandates.²²⁴ Indeed, in 1979 the Mississippi Supreme Court went so far as to strike down the legislature's attempted religious exemption on grounds that it violated the Fourteenth Amendment's Equal Protection Clause.²²⁵ Tipping its hand, it first asked, "Is it mandated by the First Amendment to the United States Constitution that innocent children, too young to decide for themselves, are to be denied the protection against crippling and death that immunization provides because of a religious belief adhered to by a parent or parents?"²²⁶ The specter of children suffering "the horrors of crippling and death resulting from poliomyelitis or smallpox or from one of the other diseases against which means of immunization are known and have long been practiced successfully" haunts the rest of the opinion.²²⁷

separate set of constitutional issues, leading to the Court invalidating Congress's original attempt to do so pursuant to the Fourteenth Amendment. *Id.* at 693-96 (explaining *City of Boerne v. Flores*, 521 U.S. 507 (1997)).

218 114 S. Ct. 63 (2020).

219 *Id.* at 66.

220 *Id.* at 66-67.

221 *Id.* at 76-78 (Breyer, J., dissenting). Chief Justice Roberts dissented on grounds of mootness. *Id.* at 75-76 (Roberts, C.J., dissenting).

222 *Id.* at 71 (Gorsuch, J., concurring).

223 *Id.* at 73-74 (Kavanaugh, J., concurring).

224 *E.g.*, *Wright v. DeWitt Sch. Dist.*, 385 S.W.2d 644, 648 (Ark. 1965).

225 *Brown v. Stone*, 378 So. 2d 218, 233 (Miss. 1979).

226 *Id.* at 221.

227 *Id.* at 222-23. *See also* *Dalli v. Bd. of Ed.*, 267 N.E.2d 219, 223 (Mass. 1971) (striking

Nevertheless, despite the apparent lack of constitutional or statutory requirements, the vast majority of states avoided Mississippi's haunting. By the beginning of the twenty-first century, forty-eight states—all but Mississippi and West Virginia—allowed exemptions from mandatory school vaccination requirements on religious grounds.²²⁸

4. *Correlations Between Exemptions and Reduced Vaccination Rates*

The non-medical exemptions from state school vaccination requirements allowed the vaccine hesitant and anti-vaxxers considerable latitude to exercise their individual choices—with consequences to public health. To be sure, into the twenty-first century nationwide vaccination rates remained high.²²⁹ Nevertheless, of the seven states where more than 1 percent of students used exemptions in the 1997-1998 school year, four—Colorado, Michigan, Utah, and Washington—had philosophical exemptions.²³⁰ Moreover, pockets of non-vaccination began to emerge at the community scale, and “in some communities, the levels of exemptors may be as high as 5%. In 1995, 84% of California schools had fewer than 1% of students with exemptions, but 4% of schools had 5% or more with exemptions”²³¹—meaning that student vaccination rates in those schools were approaching the rate (95 percent) that signals the loss of herd immunity for measles. The State of Washington, which allows all three kinds of exemptions, had an overall “exemption rate of 5.2% in the 2014-15 school year.”²³² Overall, between the 2011-2012 school year and the 2017-2018 school year, use of non-medical exemptions for school vaccination requirements continued to increase, with some states seeing the vaccination rates for kindergartners entering school in Fall 2017 as low as 81.3 percent.²³³

Starting in the late 1980s, exemptions from vaccination also increasingly correlated to increased risk of measles, particularly in religious communities such as the Amish.

Salmon et al. found that persons with documented religious or philosophic exemptions were 35 times more likely to contract measles than were vaccinated persons during 1985-1992. *They*

down Massachusetts' religious exemption on Equal Protection grounds because it favored some religions over others).

228 Malone & Hinman, *supra* note 91, at 273.

229 *Id.* at 274 (citation omitted).

230 *Id.*

231 *Id.* (citation omitted).

232 *Vaccination Exemptions*, *supra* note 203.

233 Robert A. Bednarczyk et al., *Current Landscape of Nonmedical Vaccination Exemptions in the United States: Impact of Policy Changes*, 18 EXPERT REV. VACCINES 175, 178 (2019).

*also found that persons living in communities with high concentrations of exemptors were themselves at increased risk for measles because of increased risk for exposure.*²³⁴

Thus, individual choices to seek exemptions from state vaccination mandates quickly began to impact both community health and the exemptors themselves. It also became clear that legal design was an important factor in individuals' decisions to exploit an exemption: states with complicated processes for obtaining their religious and philosophical exemptions maintained high rates (over 99 percent) of student vaccination, while one-third of the states with simple procedures had their exemption rates exceed 1 percent of students.²³⁵

Exemptions from school vaccination mandates and the increasing willingness of parents to use them thus undercut—especially for measles—the herd immunity that seemed well established by the turn of the twenty-first century. In the terms of this Article, the problem—vaccine-preventable diseases—will re-emerge if vaccination programs do not remain robust, as the measles outbreaks in 2015 and 2019 amply demonstrated.

Increasing rejection of childhood vaccinations before COVID-19 arose, particularly for measles, thus represents an illegitimate shift in risk perception and hence an example of the regulatory shifting baseline *syndrome*. This syndrome manifests in personal decisions not to vaccinate based on incorrect or exaggerated perceptions of risk from the vaccines themselves, often coupled with assertions of individual liberty or religious rights. However, this shift in risk perception and personal unwillingness to participate in vaccination programs has been possible on a large scale only because of the very success of twentieth-century vaccination programs and requirements—that is, because at least two generations of Americans had the luxury of forgetting what it is like to live with the constant threat of contracting and dying from last century's dread diseases. However, as a result of that generational amnesia, the diseases in question—especially measles—are starting to return.

IV. VACCINES AND THE REGULATORY SHIFTING BASELINE SYNDROME IN A COVID-19 WORLD

A. COVID-19 and Traditional Vaccine-Preventable Diseases

Although not as intuitively obvious as air or water, public health is a commons resource,²³⁶ where the well-being of society as a whole depends

²³⁴ *Id.* (citations omitted; emphasis added).

²³⁵ *Id.*

²³⁶ Malone & Hinman, *supra* note 91, at 263 (2007) (citing Hardin, *supra* note 68, at 1243-).

upon—and can be destroyed by—the cumulative effects of individual choices. For the first time in many decades, all Americans have been experiencing this reality firsthand in the COVID-19 pandemic. That experience should have revived cultural memories about the importance of vaccines and vaccination mandates in reducing the risks of dying from dread diseases. Instead, hyperpoliticization regarding the risks of both COVID-19 and its vaccines during the Trump Administration and the perceived infringements on personal liberty have led significant segments of the U.S. population to reject masks, social distancing, and vaccines,²³⁷ brightly illuminating the public-private interplay inherent in promoting public health.

Resistance to COVID-19 vaccines is obviously *not* a case of generational amnesia or the vaccination regulatory shifting baseline syndrome. Nevertheless, the traditional vaccine-preventable diseases and the threat posed by the pre-COVID-19 vaccination shifting baseline syndrome have not disappeared during the pandemic, a fact that the controversies over COVID-19 have fairly effectively obscured.

But those threats remain, and COVID-19 may have exacerbated them globally—making it all the more important to resist exacerbating vulnerability to the traditional vaccine-preventable diseases through the regulatory shifting baseline syndrome. At the start of the pandemic, the World Health Organization (WHO) issued guidelines aimed primarily at resource-strapped countries. These guidelines added a new risk-risk calculus to vaccination programs, recommending that

governments temporarily pause preventive immunization campaigns where there is no active outbreak of a vaccine-preventable disease The recommendations also ask governments to undertake a careful risk-benefit analysis when deciding whether to delay vaccination campaigns in response to outbreaks, with the possibility of postponement where risks of COVID-19 transmission are deemed unacceptably high.²³⁸

Governments followed these recommendations, and in November 2021, WHO and the U.S. CDC reported that “[t]he risk of outbreaks of measles across the world is mounting because the covid-19 pandemic caused millions of

48); see also Hardin, *supra* note 68 (defining a commons resource).

237 Wolfgang Stroebe et al., *Politicization of COVID-19 Health-Protective Behaviors in the United States: Longitudinal and Cross-National Evidence*, 17 PLOS ONE 1, 3-4 (Oct. 2021); Bolsen & Palm, *supra* note 11.

238 *COVID-19’s Impact on Measles Vaccination Coverage*, CTRS. FOR DISEASE CONTROL & PREVENTION (updated Nov. 11, 2020), <https://www.cdc.gov/globalhealth/measles/news/covid-impact-on-measles-vaccination.html> [https://perma.cc/7TSD-G9EP].

children to miss out on essential vaccinations and has severely affected disease surveillance systems”²³⁹ Across the globe, “[i]n 2020 around 22.3 million children missed their first dose of the measles vaccine, three million more than in 2019 and representing the largest increase in the number of unvaccinated children since 2000, at the height of unfounded safety concerns over the measles, mumps, and rubella vaccine”²⁴⁰ Thus, globally, resurgences of these vaccine-preventable diseases may be on the horizon. From the point of view of combatting the pandemic, this advice may have been a misstep, because new research indicates that receiving other vaccines, including the flu vaccine, helps the vaccinated person to resist COVID-19.²⁴¹

However, in light of resuming international travel, the potential for measles outbreaks elsewhere only underscores the need to resist the vaccination regulatory shifting baseline in the United States and to keep school vaccination mandates strong. While the public health measures established to slow the spread of COVID-19 also worked to prevent the spread of measles during the pandemic, public health officials fear increased outbreaks as the pandemic restrictions ease.²⁴² Pakistan, for example, has been experiencing an “unprecedented rise in measles outbreaks across the country” in 2021.²⁴³ As a good first step, the United States avoided the global trend of reduced childhood immunizations, with first-dose coverage increasing slightly from 90.4 percent in 2019 to 90.7 percent in 2020²⁴⁴—although this vaccination rate is still below the 95 percent rate needed for full herd immunity to measles.

As the United States faces this intensified potential threat of measles resurgence and the transportation of measles and other vaccine-preventable diseases into its territory, two sets of potentially opposing legal responses to disease threats are occurring simultaneously. One set, which began to take shape before the COVID-19 pandemic, provides regulatory correctives to the vaccination regulatory shifting baseline syndrome for traditional diseases like measles. However, the other set consists of the judicial responses to COVID-19 mandates, which may end up undermining vaccination mandates more generally.

239 Ingrid Torjesen, *Measles Outbreaks Likely as Covid Pandemic Leaves Millions of World's Children Unvaccinated*, *WHO Warns*, *BMJ* (Nov. 11, 2021), <https://www.bmj.com/content/375/bmj.n2755> [<https://perma.cc/Z9E4-FCEP>].

240 *Id.*

241 Nathaniel Hupert et al., *Heterologous Vaccination Interventions to Reduce Pandemic Morbidity and Mortality: Modeling the US Winter 2020 COVID-19 Wave*, 119 *PROC. NAT'L ACAD. SCI. (PNAS)* 1, 1 (2022).

242 Torjesen, *supra* note 239.

243 Muhammad Suleman Rana et al., *Emergence of Measles During the COVID-19 Pandemic Threatens Pakistan's Children and the Wider Region*, 27 *NATURE MED.* 1127, 1127 (2021).

244 Torjesen, *supra* note 239.

B. Response #1: Reactions to the Resurgence of Measles

Incidents like the *Lancet* fraud and the low vaccination rates in some states in 2017 illuminate how far the public's risk perception baseline has shifted from the vaccine-preventable diseases to the vaccines themselves, warranting restoration of regulatory regimes' full strength. Fortunately, resurgences of diseases thought long vanquished, like measles, have inspired governments to strengthen their vaccine programs and requirements once again, suggesting that disease resurgence is reactivating cultural memory and partially correcting this regulatory shifting baseline syndrome—at least for the traditional diseases.

1. The Federal Government's Response to Measles Resurgence

Although vaccination levels in schoolchildren during the 1980s were 90 percent or higher as a result of the new school vaccination requirements, rates among preschool children were significantly lower,²⁴⁵ correlating with the increasing availability of exemptions from school vaccination mandates. The result was a measles resurgence in 1989-1991, "primarily affecting unvaccinated preschool-aged children,"²⁴⁶ which resulted in 55,000 reported cases. In response, Congress created the Vaccines for Children Program²⁴⁷ through the Omnibus Budget Reconciliation Act of 1993.²⁴⁸ The program originally lasted two decades, between 1994 and 2013. Under it, "all Medicaid-eligible children, all children who are uninsured, all American Indian and Alaska Native children, and insured children whose coverage does not include vaccinations (with limitations on the locations where this last group can receive VFC vaccine) qualify to receive routine childhood vaccines at no cost for the vaccine."²⁴⁹

In 2014, the CDC analyzed this program and concluded that it was a rousing success.²⁵⁰ Thus, the Vaccines for Children Program indicates that stepped-up federal financing of vaccination can be one effective corrective to the vaccination regulatory shifting baseline syndrome. Notably, however, once vaccine rates increased, the government stoppoed providing free vaccines, helping to set the stage for another measles resurgence and perhaps reflecting a small instance of the vaccination regulatory shifting baseline syndrome.

²⁴⁵ Malone & Hinman, *supra* note 91, at 270.

²⁴⁶ *Id.*

²⁴⁷ Cynthia G. Whitney et al., *Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013*, CTRS. FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WEEKLY REP. (Apr. 25, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm> [<https://perma.cc/HQ2F-R2N8>].

²⁴⁸ Pub. L. No. 103–66, § 13631, 107 Stat. 312 (Aug. 10, 1993), *codified at* 42 U.S.C. § 1396v.

²⁴⁹ Malone & Hinman, *supra* note 91, at 268.

²⁵⁰ Whitney et al., *supra* note 247.

2. *The States' Responses to Measles Resurgence*

Resurgences of diseases like measles have also led some states to re-think their exemptions from school vaccination requirements. In response to the 2014-2015 measles outbreak, for example, several states revisited their vaccination laws. In 2015, “Vermont became the first state to repeal its personal belief exemption,” followed by California, which “removed exemptions based on personal beliefs, which are defined in that state as also including religious objections.”²⁵¹ Other states made it more difficult to claim an exemption from the vaccine requirements—a procedural modification that, as noted above, has been correlated with significantly lower rates of exemption use. For example, Connecticut “require[d] an annual, notarized, statement from parents or guardians specifying religious objection to required vaccinations.”²⁵² At the same time, West Virginia amended its vaccine legislation to “require[] certification by a licensed physician for medical exemption requests,” and Illinois “require[d] parents or guardians who claim a religious exemption to detail their objections for specific immunizations, obtain a health care provider’s signature, and submit an exemption certificate for each child before kindergarten, sixth and ninth grade.”²⁵³

State amendments to vaccine exemptions have continued. In 2016, both Michigan and Delaware revisited their school vaccine mandates, and Delaware weakened its religious exemption.²⁵⁴ In 2017, Utah potentially eviscerated parental control by allowing minors to consent to their own vaccinations.²⁵⁵

The 2019 measles outbreak again inspired states to strengthen their vaccine requirements, especially New York. As noted above, measles cases in 2019 occurred in thirty-one states, but “75% of cases were linked to outbreaks in New York City and New York state, most of which were among unvaccinated children in Orthodox Jewish communities.”²⁵⁶ In response to these measles outbreaks, New York ended its religious exemption and other exemptions from school

251 *States With Religious and Philosophical Exemptions From School Immunization Requirements*, *supra* note 202 and legal developments cited therein. *See also Vaccination Exemptions*, *supra* note 203 (noting Vermont’s and California’s 2015 laws eliminating all non-medical exemptions).

252 *States With Religious and Philosophical Exemptions From School Immunization Requirements*, *supra* note 202.

253 *Id.*

254 *Id.*

255 *Id.*

256 News Staff, *In Wake of Measles Outbreaks, CDC Updates 2019 Case Totals*, AAFP (Oct. 9, 2019), <https://www.aafp.org/news/health-of-the-public/20191009measlesupdt.html> [<https://perma.cc/PG5L-MFT6>].

vaccine requirements.²⁵⁷

State legislatures in Arkansas, Maine, Washington, Colorado, and Virginia also responded to the 2019 measles outbreaks. In fairly targeted legislation, Washington removed “the personal belief exemption for the measles, mumps and rubella vaccine requirement for public schools, private schools and day care centers.”²⁵⁸ Maine, in contrast, eliminated both its religious and personal belief exemptions,²⁵⁹ although these changes did not take effect until September 2021.²⁶⁰ As of 2019, Arkansas required public and private schools to maintain records regarding vaccination exemption use; in 2020, Colorado established similar requirements and required parents claiming a personal or religious exemption to complete an online education program first.²⁶¹ In 2020, Virginia required its school vaccination requirements to “be consistent with the Immunization Schedule developed and published by the Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians.”²⁶² In 2021, Connecticut removed its religious exemption entirely, becoming the sixth state to remove all non-medical exemptions from school vaccination requirements.²⁶³

Thus, over the course of seven years, state legislatures significantly shifted the vaccine regulatory baseline back toward public protection. By January 2021, the number of states with a personal philosophy exemption dropped back to fifteen.²⁶⁴ A record six states now have no non-medical exemptions, while several others have made use of their exemptions more difficult, including through education requirements.²⁶⁵ The cultural memory that school vaccination requirements curb personal impulses that put the public health at risk appears to be, for the moment, at least partially re-activated.

C. Response #2: The Politicization of the Coronavirus Pandemic and the

257 Bobby Allyn, *New York Ends Religious Exemptions for Required Vaccines*, NPR (June 13, 2019), <https://www.npr.org/2019/06/13/732501865/new-york-advances-bill-ending-religious-exemptions-for-vaccines-amid-health-cris> [https://perma.cc/5G7X-7TBA].

258 *States With Religious and Philosophical Exemptions From School Immunization Requirements*, *supra* note 202.

259 *Id.*

260 *State Vaccination Exemptions for Children Entering Public Schools*, BRITANNICA PROCON.ORG (updated Mar. 4, 2020), <https://vaccines.procon.org/state-vaccination-exemptions-for-children-entering-public-schools/> [https://perma.cc/3LKS-A5XG].

261 *Id.*; *States With Religious and Philosophical Exemptions From School Immunization Requirements*, *supra* note 202 (providing the same information).

262 *State Vaccination Exemptions for Children Entering Public Schools*, *supra* note 260.

263 *Id.*

264 *Id.*

265 *Id.*

Future of Vaccination Mandates

While the state's legal responses to resurgences of traditional vaccine-preventable diseases—strengthening their school vaccination mandates—are positive steps toward countering the vaccination regulatory shifting baseline syndrome in the United States, law deriving from pandemic-based litigation is more worrisome. In particular, the U.S. Supreme Court's responses to challenges to COVID-19 vaccination mandates suggest that the legalities of vaccination mandates going forward may be more complex than in the past.

Before COVID-19 locked down the United States in March 2020, the last true pandemic in this country was the 1918 H1N1 flu ("Spanish flu") pandemic—although the 2009 H1N1 flu ("swine flu") outbreak did considerable damage.²⁶⁶ In the thirteen months between January 21, 2020, and February 20, 2021, the coronavirus pandemic killed over 495,000 people in the United States and over 2.45 million worldwide²⁶⁷—levels approaching pre-vaccine death rates from measles. By February 2021, mass vaccination against the new disease was in its early stages, even as public health workers were discovering more virulent mutations of the virus.²⁶⁸

Politicization of the pandemic and resistance to vaccination, much of it growing from skepticism that the FDA had properly vetted the COVID-19 vaccines, means that vaccination rates remain too low to achieve herd immunity,²⁶⁹ even in the absence of new variants. One response has been federal vaccination mandates, which have in turn inspired new litigation.

The U.S. Supreme Court issued two COVID-19 vaccination mandate decisions on January 13, 2022, upholding one federal vaccination mandate and overturning the other. In *Biden v. Missouri*, a narrow (5-4) majority of Justices lifted lower court injunctions against the Secretary of Health and Human Services' vaccination mandate for health care professionals, upholding the

266 *Worst Outbreaks in U.S. History*, HEALTHLINE, <https://www.healthline.com/health/worst-disease-outbreaks-history> [<https://perma.cc/FW6Y-W7AN>] (last visited Jan. 27, 2021). "The CDC estimates that there were 60.8 million cases, 274,304 hospitalizations, and 12,469 deaths in the United States" from the 2009 flu outbreak. *Id.*

267 *United States COVID-19 Cases and Deaths by State*, CTRS. FOR DISEASE CONTROL & PREVENTION (updated Jan. 26, 2021), https://covid.cdc.gov/covid-data-tracker/#cases_totaldeaths [<https://perma.cc/M86J-R5VQ>]. The exact count as of January 26, 2021, was 419,827 deaths, reflecting 1,891 new deaths from the previous day. *Id.*

268 *COVID-19: Emerging SARS-CoV-2 Variants*, CTRS. FOR DISEASE CONTROL & PREVENTION (updated Jan. 28, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html> [<https://perma.cc/ZKK2-B5S3>].

269 Giovanni Russonello, *The Rising Politicization of Covid Vaccines*, N.Y. TIMES (updated Apr. 30, 2021), <https://www.nytimes.com/2021/04/06/us/politics/covid-vaccine-skepticism.html> [<https://perma.cc/48EN-8JTL>]

agency's authority to impose such mandates.²⁷⁰ "In November 2021, the Secretary announced that, in order to receive Medicare and Medicaid funding, participating facilities must ensure that their staff—unless exempt for medical or religious reasons—are vaccinated against COVID-19."²⁷¹ The Secretary issued the rule after finding that "35% or more of staff remain unvaccinated" and that those staff "pose a serious threat to the health and safety of patients. That determination was based on data showing that the COVID-19 virus can spread rapidly among healthcare workers and from them to patients, and that such spread is more likely when healthcare workers are unvaccinated."²⁷² Noting that "COVID-19 is a highly contagious, dangerous, and—especially for Medicare and Medicaid patients—deadly disease" and that "[t]he Secretary of Health and Human Services determined that a COVID-19 vaccine mandate will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients," the Court majority had no trouble concluding that the vaccination mandate fit within the Secretary's statutory authority "to impose conditions on the receipt of Medicaid and Medicare funds that 'the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services.'"²⁷³ Moreover, "[v]accination requirements are a common feature of the provision of healthcare in America: Healthcare workers around the country are ordinarily required to be vaccinated for diseases such as hepatitis B, influenza, and measles, mumps, and rubella."²⁷⁴ The majority concluded, "The challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred upon it. At the same time, such unprecedented circumstances provide no grounds for limiting the exercise of authorities the agency has long been recognized to have."²⁷⁵

In contrast, in *National Federation of Independent Businesses v. Secretary of Labor, Occupational Safety & Health Administration*, a 6-3 majority of the Court stayed the Occupational Safety and Health Administration's (OSHA's) emergency temporary standard (ETS) mandating that employers with more than 100 employees require employees to be vaccinated against COVID-19 or take weekly COVID-19 tests at their own expense and wear a mask in the workplace.²⁷⁶ The majority concluded that the Occupational Safety and Health Act did not authorize any such regulation because "[t]he Act empowers the

270 Biden v. Missouri, 142 S. Ct. 647, 650 (2022) (*per curiam*).

271 *Id.* (citing 86 Fed. Reg. 61555 (2021)).

272 *Id.* at 651 (citing 56 Fed. Reg. at 61559).

273 *Id.* at 652 (quoting 42 U. S. C. § 1395x(e)(9)).

274 *Id.* at 653.

275 *Id.* at 654.

276 Nat'l Fed. of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin., 142 S. Ct. 661, 662 (2022) (*per curiam*).

Secretary to set workplace safety standards, not broad public health measures.”²⁷⁷

Both of these decisions most obviously turn on administrative law questions regarding the scope of federal agency regulatory authority under particular statutes. As such, the fact that the Court reached opposite conclusions regarding the propriety of vaccination mandates within two different regulatory regime need not necessarily raise alarm bells. However, within these differing administrative law contexts, *both* cases acknowledged the rights of individuals *not* to get vaccinated, regardless of what low vaccination rates might do to public health. For example, the majority in *National Federation of Independent Businesses* emphasized that OSHA’s standard “ordered 84 million Americans to either obtain a COVID–19 vaccine or undergo weekly medical testing at their own expense. This is no ‘everyday exercise of federal power.’ . . . It is instead a significant encroachment into the lives—and health—of a vast number of employees.”²⁷⁸

While the rights of individuals not to become vaccinated was necessarily more attenuated in *Biden v. Missouri*, Justice Thomas clearly raised the issue in dissent, while the majority emphasized the special positionality of the medical profession vis-à-vis the pandemic. For example, the majority involved “the fundamental principle of the medical profession: first, do no harm” to help to justify the necessity of a vaccination mandate: “COVID–19 is a highly contagious, dangerous, and—especially for Medicare and Medicaid patients—deadly disease. The Secretary of Health and Human Services determined that a COVID–19 vaccine mandate will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients.”²⁷⁹ Thus, this healthcare-centered justification based on the special obligations of the medical profession could, perversely, undermine support for more general vaccination mandates. Indeed, Justice Thomas’s dissent did not find even this medical context sufficient to override the the individual rights of medical workers, emphasizing that “[c]overed employers must fire noncompliant workers or risk fines and termination of their Medicare and Medicaid provider agreements. As a result, the Government has effectively mandated vaccination for 10 million healthcare workers.”²⁸⁰ This “omnibus rule,” Justice Thomas noted, “compels millions of healthcare workers to undergo an unwanted medical procedure that ‘cannot be removed at the end of the shift’”²⁸¹

Moreover, both the *National Federation of Independent Businesses* majority

²⁷⁷ *Id.* at 665 (citing 29 U.S.C. §§ 655(b), 655(c)(1)).

²⁷⁸ *Id.* (citation omitted).

²⁷⁹ *Biden v. Missouri*, 142 S. Ct. at 652.

²⁸⁰ *Biden v. Missouri*, 142 S. Ct. at 655 (Thomas, J., dissenting).

²⁸¹ *Id.* at 656 (Thomas, J., dissenting) (citation omitted).

and the dissents in *Biden v. Missouri* undermine the normal flexibility accorded governments during emergencies, and are more attuned to protecting individual liberties than protecting the public health commons. More importantly for the long term, and at both the federal and state levels, they hint at potential Due Process limitations, both procedural and substantive, on vaccination mandates that could have broad applicability if ever clearly recognized. Thus, even as states are reinvigorating their school vaccination mandates for both the traditional vaccine-preventable diseases and, in some cases, COVID-19—"California and the District of Columbia will require children to receive an FDA-approved COVID-19 vaccine for school entry in 2022"²⁸²—judges and Justices appear to be beginning to question the general legitimacy of vaccination mandates.

D. Can Awareness of the Regulatory Shifting Baseline Syndrome Help?

It is understandably easy for all decisionmakers, from parents to Supreme Court Justices, to forget about other diseases during a deadly pandemic. Given this reality, the fact that childhood vaccination rates actually increased slightly in the United States in 2020 may be a positive sign that the pandemic revitalized a more general cultural memory regarding the value of vaccines and the true risk-risk analysis they embody.

Nevertheless, the COVID-19 pandemic has also given the vaccine-resistant members of the U.S. population multiple opportunities, from social media to courtrooms, to demand control over their own bodies. The perverse result may be that the immediacy of the coronavirus pandemic and its public health and legal challenges—and particularly given the politicization of COVID-19 vaccination in the United States—may further obscure the workings of the vaccination regulatory shifting baseline syndrome with respect to other diseases. One must wonder: if push comes to shove, will there be another Mississippi Supreme Court to voice an Equal Protection rebuttal to an assertion of individual rights, acknowledging "the horrors of crippling and death . . . from . . . the diseases against which means of immunization are known and have long been practiced successfully"?

Vaccination mandates require a communitarian perspective on the functions of law and government because herd immunity requires that most individual choices give way to the community's needs as a whole. Were the result as simple as leaving those who refuse to get vaccinated to take on the risks of dying from the disease, vaccination mandates would be a far easier legal issue. However, an individual's refusal to get vaccinated imposes costs on others—on the individuals who need herd immunity to be protected because they *cannot* be vaccinated, on

282 *States With Religious and Philosophical Exemptions From School Immunization Requirements*, *supra* note 202.

the individuals whose *other* healthcare needs cannot be properly attended to during an outbreak, and—as the pandemic has made clear—potentially on the healthcare system itself. Assertions of individual rights *not* to vaccinate, in other words, impose externalities on the public health commons. And the resulting disease outbreaks are the kind of collective tragedy of the commons that has long been acknowledged as a legitimate reason to regulate individual behavior.²⁸³

Notably, healthcare workers are colloquially aware of the vaccination regulatory shifting baseline syndrome, which they often summarize as vaccines being a victim of their own success.²⁸⁴ For example, in 2019, before the pandemic, Dr. Seth Berkley, chief executive of the GAVI global vaccine alliance, told an international audience that the vaccination challenge has changed from achieving the maximum level of vaccination coverage to getting parents to have their children vaccinated at all, and “that this trend was, ironically, caused by the fact that vaccines have eradicated the most lethal diseases.”²⁸⁵ To circle back to Daniel Pauly, what is needed is a way to operationalize these anecdotal observations and to make the fact of generational amnesia regarding vaccine-preventable diseases legally cognizable.

Awareness of the regulatory shifting baseline syndrome prompts revitalization of our cultural memories of the original drivers of vaccination mandates—high risks of dying from or being disfigured by the early twentieth century’s dread diseases (minus smallpox and polio). It reminds decisionmakers why vaccine manufacturers once were—and arguably still should be—broadly protected under state tort law²⁸⁶ and why Congress enacted the NCVIA.

283 Hardin, *supra* note 68, at 1243-46. Notably, Elinor Ostrom and others have done considerable work to show that other solutions are possible to commons management, challenging the inevitability of Hardin’s tragedy. *See generally*, e.g., ELINOR OSTROM, GOVERNING THE COMMONS: THE EVOLUTIONS OF INSTITUTIONS FOR COLLECTIVE ACTION (1990). However, public health on a global or even national scale, particularly when mediated by vaccines, is unlikely to be amenable to other governance approaches given the high percentage of individuals who must participate.

284 Matthew Janko, *Vaccination: A Victim of Its Own Success*, 14 VIRTUAL MENTOR 3, 3-4 (2012); Gerardo Fortuna, *Vaccines Are Victim of Their Own Success*, *Global Health Expert Says*, EURACTIV (updated July 2, 2019), <https://www.euractiv.com/section/health-consumers/interview/vaccines-are-victim-of-their-own-success-global-health-expert-says/> [<https://perma.cc/VHE5-EZK5>]; Adriana Belmonte, ‘A Victim of Their Own Success’: How Vaccines Became A Casualty of Misinformation in the U.S., YAHOO! FINANCE (Oct. 19, 2019), <https://finance.yahoo.com/news/vaccines-anti-vax-debate-135125026.html> [<https://perma.cc/UP2F-CHFG>]; Amy Prideaux, *Vaccines—A Victim of Their Own Success*, MEDICS ACAD. (Apr. 1, 2021), <https://blog.medics.academy/vaccines-a-victim-of-their-own-success/> [<https://perma.cc/27YW-FN4Q>].

285 Fortuna, *supra* note 284.

286 *See* OFFIT, *supra* note 155, at 154-59 (recounting the progressive changes in U.S. tort law that allowed vaccine manufacturers to be held strictly liable for the individual injuries their vaccines caused).

Those revived memories, in turn, should make decisionmakers pause to consider long and hard whether individual rights should be able to undermine broader public health goals. There was a time, after all, when eight-year-old children cried when they got their sneakers wet in the course of a summertime romp along a stream, fearing that polio would strike.²⁸⁷ Living without that fear is a luxury—but a luxury, at least for diseases other than polio, that we can continue to enjoy only by resisting the vaccination regulatory shifting baseline syndrome.

V. CONCLUSION

Protecting ourselves from ourselves and squarely addressing commons abuse are two of the trickiest goals of public law because the resulting regulatory regimes tend to privilege the general public welfare over individual liberty—the communitarian perspective. When such a regulatory regime succeeds, generational amnesia can, perversely, obscure its general welfare benefits, allowing relevant interest groups and decisionmakers to question why the regime was necessary in the first place or the fact that the regime is still working to protect the public. If this cultural amnesia leads to a conclusion by the relevant decisionmakers—such as the Supreme Court majority in *Shelby County*—that the problem is no longer a problem, the regulatory shifting baseline syndrome has taken hold, and history will likely repeat itself. This Article has focused on how the success of vaccination requirements has allowed individuals to forget how harmful the dread diseases actually were, contributing to vaccination resistance in the United States. However, the regulatory shifting baseline syndrome may also help to explain recurring problems in other arenas, such as decisions to deregulate businesses and financial institutions that lead to economic downturns and crashes.

If one accepts that the shifting baseline syndrome is a real phenomenon with real consequences that generally impoverish society as a whole, the question then becomes how to prevent, or at least correct for, its emergence. The loss of intergeneration memory about historical ecological conditions—“environmental generational amnesia”²⁸⁸—may require active reconstruction of cultural memory through new sources of data and creative extrapolation. For the regulatory shifting baseline syndrome, however, the cultural memory is *right there*—embodied in the very regulatory regime whose success allows the syndrome to emerge.

More information, in other words, is unlikely to be a necessary or effective corrective to the regulatory shifting baseline syndrome. Instead, the various

287 MEREDITH WADMAN, *THE VACCINE RACE: SCIENCE, POLITICS, AND THE HUMAN COSTS OF DEFEATING DISEASE* 13 (2017).

288 Kahn, *supra* note 26, at 93-94.

regulatory decisionmakers—members of legislatures, agency personnel, presidents and governors, and judges—need institutional prods to remind them to remember and value the cultural memory they retrieve. For example, in agencies and perhaps some legislatures, procedural public participation requirements could help ensure that those who benefit from the regulatory regime’s continued existence have at least to the opportunity to speak on its behalf. In the courts, a revived and strengthened purposivist approach to statutory interpretation that considers not only the legislature’s goals but the social context of a statutory regime would be a helpful prod.²⁸⁹ For constitutional and other reasons, these institutional prods will often need to function as norms rather than as requirements. Nevertheless, institutional norms, once developed, can still be powerful. As one example, when FDR broke the two-term presidential norm that George Washington established, the result was a constitutional amendment to ensure that no President ever did it again.²⁹⁰

The first step in correcting the regulatory shifting baseline syndrome is deceptively simple: A broad swath of society must identify regulatory regimes as memory institutions. When interest groups or even a large percentage of the population challenge a longstanding public regulatory regime as outdated and obstructionist, the first response should become: “Why does it exist in the first place? What problem might we resurrect if this regime goes away?”

Again, the point is *not* that longstanding public regulatory regimes cannot outlive their usefulness; they most certainly can. The point, rather, is that legislatures and agencies created them for a reason—a reason that was worth the effort and expense of putting the new regime into place. Particularly when the industries and interest groups that propose dismantling the regime argue in favor of the *private* benefits that will result—such as, in the case of vaccines, greater individual freedom and autonomy—a high threshold of skepticism and a presumption in favor of continuing to protect the general public welfare is warranted.

The second step is to reconstitute the *full* risk-benefit balancing at issue. At the very least, regulatory gatekeepers should understand the full range of societal problems at stake before attempting to re-evaluate the regulatory regime for contemporary circumstances. The temptation in light of immediate political pressure is to discount the vanquished regulatory problem as irrelevant—to shift the regulatory baseline. Therefore, to ensure that this impulse does not allow the regulatory shifting baseline syndrome to emerge, legislatures and courts should

289 See, e.g., John David Ohlendorf, *Purposivism Outside Statutory Interpretation*, 21 TEX. REV. L. & POL. 235, 237-38 (2016) (describing purposivism and its competing school of textualism).

290 U.S. CONST., amend. XXII.

assess the extent to which the public is still benefitting from the regulatory regime—even if the problem itself has not been seen for decades. In the case of vaccine-preventable diseases, for example, they should ask: will infectious diseases return to the United States if we stop vaccinating and allow herd immunity to lapse? With the exception of completely or geographically eradicated diseases like smallpox and polio, all available evidence says *yes*. Vaccination mandates—and especially the children they protect—should not fall prey to generational amnesia.

Advancing Harm Reduction Services in the United States: The Untapped Role of the Americans with Disabilities Act

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Abstract:

Now in its third decade, the overdose crisis continues to worsen. Harm reduction strategies, such as syringe service programs (SSPs), are proven, cost-effective responses to this ongoing public health emergency. Despite extensive research demonstrating that the health and social benefits of harm reduction services far outweigh alleged negative externalities, the number and scope of these programs continue to be severely limited. Restrictive zoning and other discriminatory legal measures figure among key barriers to harm reduction service access. The Americans with Disabilities Act (ADA) and Rehabilitation Act (RA) have recently gained prominence in challenging discrimination against people who seek substance use treatment. But the instrumental potential of these landmark statutes to advance access to harm reduction services has been largely unrealized. By drawing lessons from the emerging success in using Title II of the ADA and Section 504 of the RA in the realm of substance use treatment, we call for urgent deployment of these statutes to expand access to harm reduction services in the United States. In the context of a spiraling crisis, these legal tools offer enormous promise in safeguarding the rights—and lives—of vulnerable people.

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INTRODUCTION	63
I. SYRINGE SERVICES ARE CRITICAL TO ADDRESS THE OPIOID CRISIS.....	67
A. THE IMPORTANCE OF SSPS.....	67
B. SSPS AND COVID-19	69
C. NIMBY CHALLENGES TO SSPS	70
II. THE ADA AND RA PROVIDE LEGAL REMEDIES FOR PERSONS WITH SUBSTANCE USE DISORDER TO CHALLENGE FACIALLY DISCRIMINATORY ZONING PROVISIONS.	75
III. LEGAL PRINCIPLES APPLIED IN THE LINE OF ADA SUBSTANCE USE TREATMENT CASES ARE APPLICABLE TO SYRINGE SERVICE PROGRAMS.	80
A. IS THERE A PROTECTED CLASS?	81
B. ARE COVERED ENTITIES INVOLVED?	83
C. IS THE CONDUCT COVERED BEHAVIOR?	83
D. IS THE CONDUCT DISCRIMINATORY?	84
IV. OVERCOMING DEFENSES	85
V. EXPANDING APPLICATION OF THE ADA TO COVID-19 TESTING SITES	88
VI. CONCLUSION	89



INTRODUCTION

The United States is facing an unprecedented set of public health challenges, at a time when the COVID-19 pandemic has compounded the ongoing overdose crisis. Disruption in treatment and support services, economic shocks, and social isolation wrought by coronavirus have all impeded efforts to bend the overdose curve—now surging again after a momentary deceleration prior to the onset of the pandemic. In 2021, over 107,000 overdose deaths were reported nationally, representing another double-digit increase from the previous calendar year, with disproportionate impact on Black and brown communities.¹ This means that nearly 300 people die each day from a preventable cause. Emergency department visits for non-fatal overdoses also continue to surge.² To make matters worse, there is evidence that people with substance use disorder are more susceptible to COVID-19 infection and its deadly sequelae.³

Prevention and supportive services are vital to safeguarding the health of people who use drugs. Although access to substance use treatment has received substantial attention and support, harm reduction services continue to be largely ignored by policymakers and public health officials. These vital programs include syringe service programs (SSPs), naloxone distribution, drug checking, and supervised consumption facilities. Since their community-based beginnings in the 1980s, SSPs have developed as a grass-roots movement to offer access to sterile syringes and other equipment for consuming drugs more safely. This includes access to a range of additional wrap-around services, such as substance use treatment, infectious disease testing, wound care, and other pertinent assistance. Intended to address the needs of highly stigmatized, criminalized people who use illicit drugs, SSPs have been shown especially effective as

¹ NAT'L CTR. FOR HEALTH STATS., PROVISIONAL DRUG OVERDOSE DEATH COUNTS, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#data-tables> [<https://perma.cc/K6Z9-TBFR>] (last visited Mar. 11, 2020).

² See William E. Soares III et al., *Emergency Department Visits for Nonfatal Opioid Overdose During the COVID-19 Pandemic Across Six US Health Care Systems*, 79 ANNALS EMERGENCY MED. 158, 161-163 (2022).

³ Rita Rubin, *Substance Use Disorders and COVID-19 Vaccine Response*, 326 JAMA 2000, 2000 (2020); Robert Csák et al., *Harm Reduction Must Be Recognized an Essential Public Health Intervention During Crises*, 18 HARM REDUCTION J. 1, 1 (2021).

platforms for stemming bloodborne infections, preventing overdose, and facilitating access to a broad range of supports.⁴

As the COVID-19 pandemic has made abundantly clear, public health is highly political—and as with all politics, public health politics are local. Social distancing, mask mandates, testing, and other measures to address this crisis are being met with fervent resistance in many communities, fueled by misinformation and ideological polarization. Many jurisdictions resisted the siting of critical pandemic services, including testing and supportive housing for people infected or at risk of contracting COVID-19. For those working in harm reduction, however, such local opposition is nothing new. In fact, siting of syringe services, substance use treatment facilities, and other services for people who use drugs have frequently been met with community opposition, foreshadowing many of the same challenges on stark display during the historic crisis of the COVID-19 pandemic.⁵

The justification for neighborhood opposition to public health efforts to address substance use disorder (SUD)—and COVID—is often tenuous. Concerns are loosely based on fears for the health and safety of the area’s

⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, SYRINGE SERVICE PROGRAMS (SSPs) FACT SHEET, <https://www.cdc.gov/ssp/syringe-services-programs-factsheet.html> [<https://perma.cc/T2R4-6LAK>] (last visited May 23, 2019); Sara Glick et al., *The Impact of COVID-19 on Syringe Services Programs in the United States*, 24 AIDS & BEHAV. 2466, 2466 (2020) (explaining that “SSPs stressed the importance of their connections with populations with environmental and structural risk factors for serious COVID-19 sequelae, and their commitment to continuing to serve these participants. These connections present the opportunity to offer COVID-19 screening and testing, which some programs are already doing.”).

⁵ See, e.g., Nathaniel Cline, *Neighbors Oppose Planned Residential Youth Treatment Facilities*, LOUDOUN TIMES (Dec. 29, 2021), https://www.loudountimes.com/news/neighbors-oppose-planned-residential-youth-treatment-facilities/article_39d0e1d6-6846-11ec-9523-4b3ce77e4d88.html [<https://perma.cc/AP4Q-CZM3>]; Emily Alpert Reyes & Ben Brazil, *California Backs Syringe Programs. But They’re Nowhere to Be Found in Orange County*, LA TIMES (Mar. 13, 2022), <https://www.latimes.com/california/story/2022-03-13/california-syringe-programs-needle-access-orange-county> [<https://perma.cc/J28W-5CZZ>]; *Itasca Officials Reject Drug Treatment Facility, But Proponents Say Fight May Continue*, NBC CHICAGO (Nov. 2, 2021), <https://www.nbcchicago.com/news/local/itasca-officials-reject-drug-treatment-facility-but-proponents-say-fight-may-continue/2668937/> [<https://perma.cc/GX55-CACT>].

current residents, while not grounded in any science, or sometimes have no basis at all.⁶ Colloquially referred to as not-in-my-back-yard (“NIMBY”) zoning, such tactics have significantly hindered the expansion of lifesaving health screenings, quarantine sites,⁷ housing for homeless populations amid the pandemic,⁸ and access to SSPs and drug treatment. When NIMBY challenges successfully halt or delay the necessary public health response to appropriately address COVID-19 and the drug crisis in America, it will cost many people their lives.

Despite the heightened need for SSPs in the midst of the COVID-19 pandemic, it appears that opposition to their existence has only grown stronger in recent months, as evidenced by several high-profile closures⁹ across the country. In response to these closures, activist organizations, such as the South Jersey AIDS Alliance fighting for Oasis in Atlantic City,¹⁰ have filed lawsuits to prevent policymakers from eliminating SSPs and the valuable resources they provide. However, there are few descriptions of potential legal strategies that may be employed to block shutdowns in such cases. Beyond limited mention in internal materials by

⁶ Nolan Gray, *The NIMBYs of the Coronavirus Crisis*, BLOOMBERG CITYLAB (Mar. 27, 2020), <https://www.citylab.com/perspective/2020/03/coronavirus-fear-covid-19-testing-center-nimby-community/608929/> [<https://perma.cc/8ZFV-X4Z9>].

⁷ See Ivan Pereira, *Feds Backtrack on Transfer of Quarantined Coronavirus Patients to Alabama*, ABC NEWS (Feb. 23, 2020), <https://abcnews.go.com/Health/feds-backtrack-transfer-quarantined-coronavirus-patients-alabama/story?id=69162771>

[<https://perma.cc/CR2Y-DZJG>]; Faith Pinho & Hillary Davis, *Costa Mesa’s Objection to Coronavirus Quarantine Based On Fear-Mongering, Officials Say*, L.A. TIMES (Feb. 24, 2020), <https://www.latimes.com/california/story/2020-02-24/costa-mesas-objection-to-coronavirus-quarantine-based-on-fear-mongering-officials-say> [<https://perma.cc/4CSQ-S3PQ>].

⁸ Angelica Acevedo, *Queens Councilman Calls for Closure of Glendale Homeless Shelter Amid Coronavirus Crisis*, QNS (Mar. 19, 2020), <https://qns.com/story/2020/03/19/queens-councilman-calls-for-closure-of-glendale-homeless-shelter-amid-coronavirus-crisis/> [<https://perma.cc/4DKH-SNAW>].

⁹ Jennifer D. Oliva et al., *Defending Syringe Services Programs*, HEALTH AFFS. BLOG (Aug. 23, 2021).

¹⁰ Molly Shelly, *Atlantic City Barred from Shutting Down Syringe Exchange Program Until November Court Date*, THE PRESS OF ATLANTIC CITY (Sept. 30, 2021), https://pressofatlanticcity.com/news/local/atlantic-city-barred-from-shutting-down-syringe-exchange-program-until-november-court-date/article_58469000-21f3-11ec-873d-2f9cd61e8150.html [<https://perma.cc/6Y5C-5VET>].

legal advocates,¹¹ the potential instrumentality of federal anti-discrimination legislation to safeguard harm reduction programs has not, to our knowledge, been previously explored. This is likely due to pervasive stigma and misinformation that applies to harm reduction services and measures in academic and policy circles.

To fill this gap, this Article draws on the case study of an SSP in Kennewick, Washington to advance a legal framework for using the Americans with Disabilities Act (“ADA”) and the Rehabilitation Act (“RA”), two laws that prohibit disability discrimination, to challenge discriminatory zoning practices targeting SSPs. In our analysis, we apply an evolving ADA and RA canon in an analogous, but distinct realm: NIMBY zoning challenges to deter and displace substance use treatment facilities which courts have in several cases found to be facially discriminatory under the ADA and RA. These NIMBY zoning challenges seek to discriminate against people with SUD, who have been recognized as a protected class under the ADA and RA. This Article outlines how litigants can apply this principle, building on the case law related to substance use disorders to overcome NIMBY zoning restrictions on SSPs. The rationale for invoking the ADA and RA to challenge SSP discriminatory regulations is strengthened by the reality that substance use treatment services are physically co-located in a growing number of SSPs—making these programs precisely analogous to facilities where ADA protections have already been established. These substance use treatment services administered by healthcare providers may include prescription of medications for opioid use disorder (MOUD), provision of a variety of psychotherapies, and treatment for other medical comorbidities related to drug use.

While we focus on arguments for combating discriminatory zoning against SSPs, many of our legal arguments can also be used to challenge other NIMBY restrictions on access to health services for COVID-19, drug treatment, and other issues.

¹¹ LEGAL ACTION CTR., EMERGENCY: HOSPITALS CAN VIOLATE FEDERAL LAW BY DENYING NECESSARY CARE FOR SUBSTANCE USE DISORDERS IN EMERGENCY DEPARTMENTS, <https://www.lac.org/resource/emergency-hospitals-can-violate-federal-law-by-denying-necessary-care-for-substance-use-disorders-in-emergency-departments> [<https://perma.cc/E4KD-PK48>].

I. SYRINGE SERVICES ARE CRITICAL TO ADDRESS THE OPIOID CRISIS.

A. *The Importance of SSPs*

Drug overdose is the leading cause of death in the United States for those ages eighteen to forty-five ahead of gun violence and automobile accidents.¹² This crisis is multi-faceted, but two response options offer significant promise in reducing the rate of fatal and non-fatal overdoses. The first is the distribution of naloxone, the opioid overdose antidote, which has been shown to significantly reduce community overdose rates.¹³ The second is improving access to MOUD, such as methadone and buprenorphine.¹⁴ Maintenance therapy deploying these medications slashes individual overdose risk by nearly 60 percent after a year of treatment.¹⁵ Tragically, access to naloxone and MOUD remains inadequate because of logistical, financial, and legal barriers, all propelled by stigma against drug use.¹⁶

¹² CTRS. FOR DISEASE CONTROL & PREVENTION, LEADING CAUSES OF DEATH AND INJURY, <https://cdc.gov/injury/wisqars/LeadingCauses.html/> [<https://perma.cc/XT59-5ESL>] (last visited Apr. 5, 2022).

¹³ Alexander Walley et al., *Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution In Massachusetts: Interrupted Time Series Analysis*, 346 *BMJ* 1, 4, 10-11 (2013).

¹⁴ The U.S. Department of Justice enforces the ADA to reduce opioid-related deaths by investigating treatment centers preventing access to MOUD. See The United States Attorney's Office, District of Massachusetts, *U.S. Attorney's Office Settles Disability Discrimination Allegations at Skilled Nursing Facility*, U.S. DEP'T JUST. (May 10, 2018), <https://www.justice.gov/usao-ma/pr/us-attorney-s-office-settles-disability-discrimination-allegations-skilled-nursing> [<https://perma.cc/RDR4-Y9BK>]; *Justice Department Reaches Settlement with Selma Medical Associates Inc. to Resolve ADA Violations*, U.S. DEP'T JUST.: OFF. PUB. AFFS. (Jan. 31, 2019), <https://www.justice.gov/opa/pr/justice-department-reaches-settlement-selma-medical-associates-inc-resolve-ada-violations> [<https://perma.cc/K65A-WVZT>] ("Unlawfully denying services to individuals with disabilities because of their medical conditions subjects these individuals to unwarranted stigma and harm, and will not be tolerated by the Department of Justice").

¹⁵ Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder*, JAMA NETWORK OPEN, Feb. 2020, at 1.

¹⁶ Leo Beletsky, *21st Century Cures for the Opioid Crisis: Promise, Impact, and Missed Opportunities*, 44 *AM. J. L. & MED.* 359, 363-372 (2018).

In concert with an unprecedented rise in overdose deaths, the United States is also experiencing an increase in sequelae of widespread problematic substance use, including injection-related diseases like hepatitis B, hepatitis C, and HIV.¹⁷ One in every ten new HIV infections is now among people who inject drugs, and many of these individuals are co-infected with hepatitis C.¹⁸ There have been a number of outbreaks of HIV in the wake of the overdose crisis, including in Scott County, Indiana; Lawrence, Massachusetts; and Huntington, West Virginia.¹⁹ Hundreds of additional counties are facing a high risk of outbreaks if prevention measures continue to lag behind.²⁰

The good news is that SSPs can effectively address all of these issues under one roof. SSPs have consistently been shown to be effective at saving lives and reducing the spread of infectious diseases.²¹ Almost universally, SSPs provide a variety of health and social services beyond clean and safe injection supplies. These services may include the provision of—or referrals to—substance use treatment, prevention education for sexually transmitted diseases, HIV counseling and testing, screening for tuberculosis, and primary health care.²²

¹⁷ CTRS. FOR DISEASE CONTROL & PREVENTION, ADDRESSING THE INFECTIOUS DISEASE CONSEQUENCES OF THE U.S. OPIOID CRISIS, <https://www.cdc.gov/nchhstp/budget/infographics/opioids.html> [https://perma.cc/BT2N-CYPC] (last visited Mar. 18, 2020).

¹⁸ *Id.*

¹⁹ Kevin Cranston et al., *HIV Diagnoses Among Persons Who Inject Drugs—Northeastern Massachusetts, 2015–2018*, 68 MORBIDITY & MORTALITY WKLY. REP. 253, 253 (2019); Dan Goldberg, *The Nightmare Everyone is Worried About: HIV Cases Tied to Opioids Spike in West Virginia County*, POLITICO (Sept. 2, 2019), <https://www.politico.com/story/2019/09/02/hiv-opioids-cabell-west-virginia-1668389> [https://perma.cc/RQV6-ZKDG]; Lisa Rapaport, *Indiana HIV Outbreak Among Drug Users May Have Been Avoidable*, REUTERS (Oct. 4, 2018), <https://www.reuters.com/article/us-health-hiv-indiana/indiana-hiv-outbreak-among-drug-users-may-have-been-avoidable-idUSKCN1ME2N7> [https://perma.cc/CTE9-F4PX].

²⁰ *Id.* at 1–3.

²¹ UNAIDS, DO NO HARM: HEALTH, HUMAN RIGHTS AND PEOPLE WHO USE DRUGS 15 (2016), https://www.unaids.org/sites/default/files/media_asset/donoharm_en.pdf [https://perma.cc/LH4V-S935].

²² ACLU, FACT SHEET ON NEEDLE EXCHANGE PROGRAMS, <https://www.aclu.org/fact-sheet/needle-exchange-programs-promote-public-safety> [https://perma.cc/KD23-7RR3] (last visited Mar. 12, 2020).

B. SSPs and COVID-19

Although SSPs emerged in the United States in response to the HIV epidemic, their presence has grown dramatically since the start of the ongoing overdose crisis.²³ Over the past two years, they have become a critical tool in the fight against COVID-19. As COVID-19 surges across the United States, people with substance use disorder are uniquely vulnerable to contracting the virus and becoming severely ill. Substance use disorder is strongly associated with homelessness²⁴ and major medical comorbidity²⁵, two factors that greatly increase the risk of becoming seriously ill from COVID-19.²⁶ Additionally, the COVID-19 pandemic has overwhelmed the already overburdened systems that serve this vulnerable population. Across the country, hospitals scramble to meet the demands of an influx of patients, with many lacking necessary resources to safely combat the virus. Local governments face new challenges in providing food and shelter to the homeless as shelters stop taking new entrants²⁷ and foodbanks fight to keep their doors open.²⁸ SSPs provide vital health services, including access to sterile syringes to prevent

²³ The United States is in the midst of a crisis in drug overdose, addiction, and bloodborne infectious disease linked to syringe sharing among people who inject drugs. See NAT'L CTR. FOR HEALTH STATS., *supra* note 1, at 1.

²⁴ Erin J. Stringfellow et al., *Substance Use Among Persons with Homeless Experience in Primary Care*, 37 SUBSTANCE ABUSE 534, 536 (2016).

²⁵ Eric Sarlin, *Substance Use Disorders Are Associated With Major Medical Illnesses and Mortality Risk in a Large Integrated Health Care System*, NIDA, (Oct. 24, 2017), <https://www.drugabuse.gov/news-events/nida-notes/2017/10/substance-use-disorders-are-associated-major-medical-illnesses-mortality-risk-in-large-integrated> [<https://perma.cc/E3GB-7EFX>].

²⁶ Homeless Research Institute, *Population At-Risk: Homelessness and the COVID-19 Crisis*, NAT'L ALL. TO END HOMELESSNESS (2020), <https://endhomelessness.org/wp-content/uploads/2020/03/Covid-Fact-Sheet-3.25.2020-2.pdf> [<https://perma.cc/7LFR-PK8G>].

²⁷ Samantha Melamed, *'It's Heartbreaking': Coronavirus Puts Philly Homeless Services in Survival Mode*, PHILADELPHIA INQUIRER (Mar. 19, 2020), <https://www.inquirer.com/health/coronavirus/philadelphia-coronavirus-covid-19-homeless-response-social-distancing-20200319.html> [<https://perma.cc/624L-YH2W>].

²⁸ Yelena Dzhanova, *Food Banks Are Closing and Losing Their Workforce Because of the Coronavirus*, CNBC (Apr. 28, 2020), <https://www.cnbc.com/2020/04/28/coronavirus-food-banks-are-closing-and-losing-their-workforce.html> [<https://perma.cc/BV9P-ZKYL>].

bloodborne disease, provision of naloxone to reverse overdoses, various diagnostic services, wound care, and access to substance use treatment and other supportive services. In many cities and states, SSPs have been deemed “essential” and are allowed to keep their doors open amid the pandemic, notwithstanding the forced shutdown of other businesses and nonprofits.²⁹ In the face of this crisis, SSPs are one of last places where people with substance use disorder can receive vital care.

C. NIMBY Challenges to SSPs

While there has been some recent progress as an increasing number of states pass laws permitting the formation of SSPs,³⁰ many local governments are employing a variety of legal tactics to thwart this progress. Discriminatory zoning ordinances have been one of the principal instruments in suppressing the lifesaving and cost-saving potential of SSPs. Through such tactics, numerous programs throughout the country have shut down or have been prevented from opening their doors at all.³¹

²⁹ NYC HEALTH DEP’T, COVID-19: ESSENTIAL SERVICE GUIDANCE FOR SYRINGE SERVICE PROGRAMS (May 23, 2020), <https://www1.nyc.gov/assets/doh/downloads/pdf/imm/syringe-service-programs.pdf> [https://perma.cc/XM5D-T545] (New York); Letter from North Carolina Department of Health and Human Services (Apr. 6, 2020), <https://files.nc.gov/ncdhhs/documents/files/covid-19/Safer-Syringe-Programs-are-Essential-Services-Memo.pdf> [https://perma.cc/VH7H-GRYX] (North Carolina); Jake Ellison, *Large Majority of State’s Heroin Users Want to Reduce Use; Syringe Programs Helping During COVID-19 Crisis*, UW NEWS (Apr. 10, 2020), <https://www.washington.edu/news/2020/04/10/large-majority-of-states-heroin-users-want-to-reduce-use-syringe-programs-helping-during-covid-19-crisis/> [https://perma.cc/N72L-SLXS] (Washington); Aneri Pattani, *Syringe Exchanges Deemed ‘Life-Sustaining’ During PA Coronavirus Shutdown, Raising Hopes For Eventual Legalization*, PHILADELPHIA INQUIRER (Mar. 30, 2020), <https://www.inquirer.com/news/pennsylvania/spl/pennsylvania-coronavirus-syringe-exchange-life-sustaining-legalization-20200330.html> [https://perma.cc/5X4C-6WUU] (Pennsylvania).

³⁰ Marcelo H. Fernandez-Vina et al., *State Laws Governing Syringe Services Programs and Participant Syringe Possession, 2014-2019*, 135 PUBLIC HEALTH REPS. 128S (Supp. I 2020).

³¹ Amelia Ferrell Knisely, *Hepatitis C Numbers Soar in Kanawha Following Syringe Exchange Closure*, CHARLESTON GAZETTE-MAIL (Oct. 1, 2019), <https://www.wvgazettemail.com/news/health/hepatitis-c-numbers-soar-in-kanawha->

In October 2019, SSPs in Kennewick, Washington, came under attack by local lawmakers through a seemingly benign proposal to amend local zoning laws. The Kennewick City Attorney's Office proposed amendments to designate limited zones where SSPs could operate within the municipality and to impose stringent requirements on their manner of operation, such as imposing burdensome distance restrictions from residential zones, schools, parks, and public facilities as well as limitations on time of operation and number of syringes provided to each attendant.³² In response, members of the affected community mounted a challenge to the proposed zoning provision.³³

The hearing on the proposed ordinance in Washington was a replay of analogous proceedings in Indiana, California, and a number of other jurisdictions where SSPs are up against increasingly antagonistic zoning and other ordinances. A medical student-run SSP in Claremont, New Hampshire, was forced to shut down after local officials concluded that the program was not allowed to operate within 1,000 feet of a school zone.³⁴ Commissioners in Asheville, North Carolina, have attempted to rebrand SSPs as resembling "shelters" to justify their closure by claiming

following-syringe-exchange-closure/article_0577f072-4b6e-5dc3-821f-b4d4479f4e26.html [https://perma.cc/4RR8-9V8R]; German Lopez, *An Indiana County Just Halted a Lifesaving Needle Exchange Program, citing the Bible*, VOX (Oct. 20, 2017), <https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange> [https://perma.cc/F8KV-HV3P]; Alicia Robinson, *Court Decision Means Needle Exchange Program Can't Operate in Orange County*, THE ORANGE COUNTY REGISTER (Oct. 25, 2019), <https://www.ocregister.com/2019/10/25/court-decision-means-needle-exchange-program-cant-operate-in-orange-county/> [https://perma.cc/YWF9-C99U].

³² The changes were proposed in Kennewick's Proposed Zoning Ordinance Amendment # 19-07/AMD-2019-02719. KENNEWICK CITY ATTORNEY'S OFFICE, STAFF REPORT ON SYRINGE EXCHANGE PROGRAMS: AMENDMENTS TO TITLE 18 (2019), https://www.go2kennewick.com/AgendaCenter/ViewFile/Agenda/_10212019-1198 [https://perma.cc/8PMP-RFVQ].

³³ CITY OF KENNEWICK CITY COUNCIL, REGULAR MEETING MINUTES, at 3 (2019), <https://docs.ci.kennewick.wa.us/SearchForms/CouncilMinutes.htm> [https://perma.cc/QBX6-H5ZE].

³⁴ Nora Doyle-Burr, *Claremont Needle Exchange Program Searches for a New Home*, VALLEY NEWS (Nov. 11, 2017), <https://www.vnews.com/Claremont-Officials-Seek-Legal-Exemption-to-Allow-Needle-Exchange-to-Relocate-to-Hospital-Near-School-13661092> [https://perma.cc/6N5P-NP63].

that the sites did not possess proper permits for operation.³⁵ Colloquially referred to as not-in-my-back-yard (“NIMBY”) challenges, these zoning restrictions have been used in the past to limit mental health and drug treatment facilities from being established in communities either through new construction or repurposing of older buildings.

Many of these NIMBY challenges are backed by unsupported claims regarding the potential harms of SSPs. For instance, many who oppose SSPs claim that the provision of harm reduction services will promote drug use amongst individuals who would not have used otherwise and increase crime. However, thirty years of research have found that SSPs do not increase drug use or crime in the communities they serve,³⁶ and studies have even shown a higher likelihood in treatment participation amongst attendees.³⁷ Others claim that SSPs increase discarded drug paraphernalia,³⁸ while studies show the opposite.³⁹ Finally, opponents decry worries that SSPs will attract large groups of people who use drugs to the area and subsequently drive down surrounding property values. Beyond finding these claims to be inappropriate as they are extremely stigmatizing towards people who use drugs, there are few, if any, studies that substantiate such concerns.

However, in Kennewick, the City Council faced a novel legal argument when attempting to institute NIMBY zoning laws. Its actions, the advocates asserted, would violate protections from discriminatory

³⁵ Brailey Sheridan, *City of Asheville Tries to Shut Down Syringe Exchange*, THE BLUE BANNER (Oct. 9, 2018), <https://thebluebanner.net/city-of-asheville-tries-to-shut-down-syringe-exchange/> [<https://perma.cc/57JY-TCW2>].

³⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, SUMMARY OF INFORMATION ON THE SAFETY AND EFFECTIVENESS OF SYRINGE SERVICES PROGRAMS (SSPS), <https://cdc.gov/ssp/syringe-services-programs-summary.html/> [<https://perma.cc/B7AD-LB2P>] (last visited Apr. 5, 2022).

³⁷ Hilary L. Surratt, et al., *Motivation to Change and Treatment Participation Among Syringe Service Program Utilizers in Rural Kentucky*, 36 J. RURAL HEALTH 224, 228-229 (2020).

³⁸ Danny Jones & Robin Young, *'You Don't Sacrifice a Whole City' Over Needle Exchange, West Virginia Mayor Says*, HERE AND NOW: WBUR-BOSTON (May 16, 2018), <https://www.wbur.org/hereandnow/2018/05/15/needle-exchange-charleston-west-virginia> [<https://perma.cc/KM49-YKYX>].

³⁹ Harry Levine et al., *Syringe Disposal Among People Who Inject Drugs Before and After Implementation of a Syringe Services Program*, 202 DRUG & ALCOHOL DEPENDENCE 13, 15 (2019).

practices, such as those outlined in the Title II of the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act (RA).⁴⁰ These arguments ultimately carried the day, with Kennewick City Council sending the ordinance back to the Planning Commission for further consideration.⁴¹

We focus on the use of the ADA and the RA to tackle discriminatory NIMBY zoning restrictions; however, we admit that there many other strategies to block SSPs that may fall outside of this approach. For instance, in 2017, local lawmakers in Lawrence County, Indiana, successfully halted an SSP from opening its doors despite state-level approval of the program.⁴² The blockage of the program at the local level was possible because Indiana law stringently requires county approval of SSPs on an annual basis and stipulates that SSPs may only be operated under a public health emergency, granting considerable leeway for officials in discerning the need for such services.⁴³ In the case of Lawrence County, one commissioner cited the Bible and morality as justification.⁴⁴

The following year in West Virginia, despite positive outcomes and a marked reduction of hepatitis C cases, the needle exchange portion of the Kanawha-Charleston Health Department's harm reduction program was suspended after a local police chief imposed severe regulations which, among other things, required government-issued identification to access clean syringes.⁴⁵ Similar regulations were further codified into law when West Virginia Governor Jim Justice signed a bill that created licensure requirements for the operation of SSPs. This licensure requires patrons to provide West Virginia identification, one-to-one needle exchange, provision of "unique" syringes that may be tracked to specific sites, necessitates a statement of support from city councils that may be revoked

⁴⁰ KENNEWICK CITY ATTORNEY'S OFFICE, *supra* note 32, at 3.

⁴¹ CITY OF KENNEWICK CITY COUNCIL, *supra* note 33, at 3.

⁴² Leigh Hedger, *2nd Indiana County Ends Needle Exchange, With 1 Official Citing Moral Concerns*, INDYSTAR (Oct. 23, 2017), <https://www.indystar.com/story/news/2017/10/23/2nd-indiana-county-ends-needle-exchange-one-official-citing-moral-concerns/787740001/> [<https://perma.cc/34RF-U3K2>].

⁴³ Lopez, *supra* note 31, at 1.

⁴⁴ *Id.* at 1.

⁴⁵ Knisely, *supra* note 31.

at any time, and imposes \$500 to \$10,000 fees per violation.⁴⁶ Such hefty regulations effectively eliminate the sustainability of SSPs that are already strapped for resources.

Next, in October 2019, after three counties in California sued to block an Orange County SSP from launching a mobile service that would serve four different cities, a San Diego County Superior Court Judge issued an order that required the state to rescind its approval of the SSP.⁴⁷ Local leaders in opposition to the Orange County SSP claimed that the program would be a nuisance and a public health and safety hazard, arguing that the state failed to comply with environmental laws when it approved the SSP.⁴⁸ Specifically, local officials argued that the SSP led to increases in improperly discarded syringes in the surrounding area, despite evidence⁴⁹ demonstrating the opposite. Even though such arguments lack an empirical basis, they often railroad discussions and are used to determine the fate of SSPs. This judicial rescission means that organizers will have to reapply, and the state will need to hold an environmental review before their SSP is approved.⁵⁰

The extreme limitations written into laws that guide the operation of SSPs can in part be explained by the presence of drug paraphernalia laws in most states that predated SSPs and made illegal the distribution and possession of a syringe with the intent of using drugs. In response, laws governing SSPs are forced to carve a narrow set of circumstances for their operation, which leaves them vulnerable to a variety of attacks, including zoning laws used to enact NIMBY agendas. One solution for these assaults is state legislation that bans NIMBY actions by explicitly preempting or otherwise limiting the application of other laws to the context

⁴⁶ Lauren Peace, *Judge Rules Law Restricting West Virginia Needle Exchange Programs Can Stand*, MOUNTAIN STATE SPOTLIGHT (July 15, 2021), <https://mountainstatespotlight.org/2021/07/15/law-restricting-wv-needle-exchange-programs-can-stand/> [<https://perma.cc/BL2V-CPUY>].

⁴⁷ Robinson, *supra* note 31.

⁴⁸ Luke Money & Faith E. Pinho, *Court Order All But Bans Mobile Needle Exchange Program In Costa Mesa, Other O.C. Cities*, L.A. TIMES (Oct. 25, 2019), <https://www.latimes.com/socal/daily-pilot/news/story/2019-10-25/court-order-all-but-bans-mobile-needle-exchange-program-in-costa-mesa-other-o-c-cities> [<https://perma.cc/9E49-NXRV>].

⁴⁹ CTRS. FOR DISEASE CONTROL, *supra* note 4.

⁵⁰ Robinson, *supra* note 31.

of SSPs. One recent example of this is a recent California law that will block lawsuits citing environmental regulations in order to shut down SSPs.⁵¹

II. THE ADA AND RA PROVIDE LEGAL REMEDIES FOR PERSONS WITH SUBSTANCE USE DISORDER TO CHALLENGE FACIALLY DISCRIMINATORY ZONING PROVISIONS.

Disability anti-discrimination laws are another avenue to challenge discriminatory NIMBY zoning of SSPs, given the success of these laws in striking down discriminatory zoning of substance use disorder treatment centers. This may be a particularly wise legal strategy in states and legal jurisdictions that have proven hostile to SSPs, as this is a federal approach, with relief possible through either federal courts or action from federal agencies. The current Biden Administration, in particular, has expressed support of SSPs in the form of increased funding for such programs as a means of promoting health for people with SUD and seeking to mitigate the opioid crisis.⁵² In April 2022, the Department of Justice published guidance claiming that people with opioid use disorder (OUD) are protected under the ADA and that “a town [refusing] to allow a treatment center for people with OUD to open after residents complained that they did not want ‘those kind of people’ in their area” may violate the ADA.⁵³ In this Part, we describe prior cases related to zoning for treatment center locations; in the next Part, we turn to the novel application of anti-discrimination laws to zoning ordinances for SSPs.

⁵¹ State Department of Public Health: Needle and Syringe Exchange Services, A.B. 1344, 2021–2022 Leg., Reg. Sess. (Cal. 2021), https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB1344 [<https://perma.cc/ZZ46-5AX2>].

⁵² American Rescue Plan Act of 2021, Pub. L. No 117-2 §§ 2702–2706, 135 Stat. 4, 45–47 (2021), <https://www.congress.gov/bill/117th-congress/house-bill/1319/text> [<https://perma.cc/UY9K-55YQ>].

⁵³ U.S. DEP’T JUST., THE AMERICANS WITH DISABILITIES ACT AND THE OPIOID CRISIS: COMBATING DISCRIMINATION AGAINST PEOPLE IN TREATMENT OR RECOVERY, https://www.ada.gov/opioid_guidance.pdf [<https://perma.cc/9F6R-K4RR>] (last visited Apr. 16, 2022).

Passed into law and signed in 1990, Title II of the Americans with Disabilities Act (ADA) prohibits disability discrimination by public entities, including state and local governments.⁵⁴ Likewise, Section 504 of the Rehabilitation Act of 1973 (RA) prohibits recipients of federal financial assistance from discriminating on the basis of disability in their programs and activities.⁵⁵ Both laws only protect people with qualifying disabilities, which includes people who have a physical or mental impairment that substantially limits major life activities, people who have a record of such impairment, or people who are regarded as having such an impairment.⁵⁶ Private rights of action are available to allege intentional or facial discrimination,⁵⁷ as well as disparate impact claims.⁵⁸ If a plaintiff can establish that the ordinance violates the ADA or RA, a municipality that attempts to pass a discriminatory ordinance, at minimum, may be enjoined from enforcing the wrongful ordinance and, if shown to be intentionally discriminatory, may be held liable for monetary damages including attorneys' fees.⁵⁹ Both the ADA and RA abrogate

⁵⁴ 42 U.S.C. §§ 12131–32 (2018) (“Subject to the provisions of this subchapter, no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.”).

⁵⁵ 29 U.S.C. § 794 (“No otherwise qualified individual with a disability . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”).

⁵⁶ 45 C.F.R. § 84.3(j) (2021).

⁵⁷ *Chapman v. Pier 1 Imports (U.S.) Inc.*, 631 F.3d 939, 946 (9th Cir. 2011) (citing *Trafficante v. Metro. Life Ins. Co.*, 409 U.S. 205, 209, (1972)).

⁵⁸ *Alexander v. Choate*, 469 U.S. 287 (1985). The text of the Rehabilitation Act and the ADA do not expressly state whether disparate impact claims are permitted. In *Choate*, the Supreme Court indicated a willingness to consider some disparate impact claims, however. The topic was to be revisited by the Supreme Court in *CVS Pharmacy v. Doe* but the parties settled before the case could be decided. See *CVS Pharmacy v. Doe*, 141 S. Ct. 2882 (2021). For more on the topic, see Jessica L. Roberts & Hannah Eichner, *Disability Rights in Health Care Dodge a Bullet*, 3 JAMA HEALTH FORUM e221353 (2022).

⁵⁹ This is because the only way to alter a facially discriminatory ordinance is to remove the discriminating language, which would render the ordinance a nullity. Additionally, it is worth noting that a facial challenge precludes the government from asserting a reasonable accommodation defense. See *Bay Area Addiction Research & Treatment, Inc. v. City of Antioch*, 179 F.3d 725, 735 (9th Cir. 1999) (concluding that the reasonable

sovereign immunity, clearly permitting suits against states, local governments, and their officials. Federal government agencies may also issue injunctions against violating laws.

These provisions have been successfully employed through facial challenges to discriminatory zoning ordinances targeting substance use treatment programs.

Twenty years ago, in *Bay Area Addiction Research & Treatment, Inc. v. City of Antioch*, the Ninth Circuit established that the ADA and the RA apply to zoning restrictions targeting substance use treatment facilities because “zoning is a normal function of a government entity.”⁶⁰ The court reasoned that the “sweeping language [of the ADA]—most noticeably Congress’s analogizing the plight of the disabled to that of ‘discrete and insular minorit[ies]’ like racial minorities—strongly suggests that § 12132 [the section of the ADA prohibiting discrimination by public entities] should not be construed to allow the creation of spheres in which public entities may discriminate on the basis of an individual’s disability.”⁶¹ The court then struck down an emergency moratorium prohibiting the operation of methadone clinics within 500 feet of residential areas as facially discriminatory on the basis of the plaintiff’s disability and a per se violation of Title II of the ADA.⁶² The court also stated, however, that a city might defend its ordinance with the “direct threat” test by showing that a clinic poses a significant risk to the health or safety of the community and that it is ameliorating that risk through reasonable modifications.⁶³ The court stressed, though, that there must be evidence of a real and significant risk, it “may not be based on generalizations or stereotypes about the effects of a particular disability.”⁶⁴

modifications test does not apply to facially discriminatory laws and that facially discriminatory laws present per se violations of § 12132); *MX Grp. Inc. v. City of Covington*, 293 F.3d 326, 334 (6th Cir. 2002) (holding that plaintiff not required to request reasonable accommodation because the blanket prohibition of all methadone clinics from the entire city was discriminatory on its face).

⁶⁰*Bay Area Addiction Research & Treatment, Inc.*, 179 F.3d at 731.

⁶¹ *Id.*

⁶² *Id.* at 737.

⁶³ *Id.*

⁶⁴ *Id.*

Three years later, in *MX Group, Inc. v. City of Covington*, the Sixth Circuit invalidated an ordinance limiting the number of all SUD treatment clinics to one facility for every 20,000 persons in the city, finding that “the blanket prohibition of all methadone clinics from the entire city was discriminatory on its face” in violation of the ADA.⁶⁵ In that case, the court emphasized that the zoning ordinance was clearly motivated by prejudice against people with addictions and, furthermore, that this prejudice underscored their status as people with disabilities:

Plaintiff adduced sufficient evidence to show that the reason the city denied Plaintiff the zoning permit was because the city feared that Plaintiff’s clients would continue to abuse drugs, continue in their drug activity, and attract more drug activity to the city. In other words, based on fear and stereotypes, residents believed that the drug addiction impairment of Plaintiff’s potential clients, at the very least, limited the major life activity of productive social functioning, as their status as recovering drug addicts was consistently equated with criminality. The record also supports the district court’s finding that the Board of Adjustment denied Plaintiff’s permit primarily for these reasons.⁶⁶

Similarly, the Third Circuit in *New Directions Treatment Servs. v. City of Reading* struck down a state statute imposing a ban on the establishment of SUD treatment clinics within 500 feet of schools, churches, and residential housing developments, holding that the statute “facially singles out methadone clinics, and thereby methadone patients, for different treatment, thereby rendering the statute facially discriminatory.”⁶⁷ The case of *New Directions Treatment Servs.* as well as others rely on proof of intentional discrimination under the ADA and RA. While future cases employing this strategy may be weakened significantly if intentional discrimination cannot be proven and they instead must rely on demonstrations of disparate impact, this rarely comes into play given the discriminatory language used in NIMBY zoning laws:

⁶⁵ *MX Grp., Inc. v. City of Covington*, 293 F.3d 326, 345 (6th Cir. 2002).

⁶⁶ *Id.* at 342 (citing *Ross v. Campbell Soup Co.*, 237 F.3d 701, 706 (6th Cir. 2001)).

⁶⁷ *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 304 (3d Cir. 2007).

The only way to alter a facially discriminatory ordinance is to remove the discriminating language. The Antioch ordinance could only have been “rendered facially neutral by expanding the class of entities that may not operate within 500 feet of a residential neighborhood to include all clinics at which medical services are provided, or by striking the reference to methadone clinics entirely,” and, “[either modification. would fundamentally alter the zoning ordinance, the former by expanding the covered establishments dramatically, and the latter by rendering the ordinance a nullity.”⁶⁸

Additionally, the court rejected the “direct threat” defense by the government, clarifying the standard for determining whether a clinic poses a risk: “we cannot base our decision on the subjective judgments of the people purportedly at risk, the Reading residents, City Council, or even Pennsylvania citizens, but must look to objective evidence in the record of any dangers posed by methadone clinics and patients.”⁶⁹

There are a number of other cases where the ADA and RA have been successfully invoked to strike down discriminatory zoning provisions targeting SUD treatment and rehabilitative services.⁷⁰ In White Plains, New York, an SSP was denied a permit to open an office space for counseling after vehement public opposition on the grounds that this space would fit under “hospital or sanitarium” use, despite no physicians or prescribing taking place at the location. The SSP went on to win an injunction allowing for its operation in this space on the grounds that restricting this use represented discrimination under the ADA and RA, as it was determined that allocation of zoning permits constituted a “service,

⁶⁸ *Id.* at 303.

⁶⁹ *Id.* at 306.

⁷⁰ *Innovative Health Sys., Inc. v. City of White Plains*, 117 F.3d 37 (2d Cir. 1997) (holding the ADA and RA applied to defendant city’s zoning decision); *New Directions Treatment Servs.*, 490 F.3d 293 (3d Cir. 2007) (holding restrictions on methadone clinic violative of Title II of the ADA); *New Directions in Freedom Healthcare Servs. v. Zoning Hearing Bd. of the City of New Castle*, 983 A.2d 1286 (Pa. Commw. Ct. 2009) (reversing zoning board’s denial of a special use application to run a methadone clinic); *Habit OPCO v. Borough of Dunmore*, 2011 Pa. Commw. Unpub. LEXIS 319 (Commw. Ct. Apr. 21, 2011) (denying zoning board restriction on methadone clinic).

program, or activity” as defined in Section 508 of the RA.⁷¹ In Reading, Pennsylvania, the opening of a methadone clinic was contested under a state zoning statute stipulating that “a methadone treatment facility shall not be established or operated within 500 feet of an existing school, public playground, public park, residential housing area, child-care facility, church, meetinghouse or other actual place of regularly stated religious worship established prior to the proposed methadone treatment facility”⁷²

The application of this statute was overturned by the Third Circuit which ruled that it facially discriminated against individuals with substance use disorder under Title II of the ADA and the RA.⁷³ This past litigation teaches us that zoning ordinances resulting in outright bans of facilities providing SUD treatment and rehabilitative services directly fall under the purview of the ADA and RA and ultimately do not withstand judicial scrutiny

III. LEGAL PRINCIPLES APPLIED IN THE LINE OF ADA SUBSTANCE USE TREATMENT CASES ARE APPLICABLE TO SYRINGE SERVICE PROGRAMS.

Here we propose the novel argument that discriminatory zoning ordinances targeting SSPs are facially discriminatory in violation of the ADA and the RA, much like the courts have concluded with respect to SUD treatment centers.

To demonstrate the applicability of this framework to SSPs, we use the proposed Kennewick zoning ordinance by way of example. Proposed Section 18.12.245 of the Kennewick Municipal Code bears many similarities to the ordinances that were struck down in the series of substance use treatment cases invoking the ADA and RA discussed above. Similar to the ordinances in *Bay Area* and *New Directions*, proposed Section 18.12.245(2) provides in relevant part:

No Syringe Exchange Program, shall be located (a) Within 500 feet of any residential or urban mixed use zone; (b) Within 500

⁷¹ *Innovative Health Sys.*, 117 F.3d at 37.

⁷² 53 PA. CONS. STAT. § 10621 (2021).

⁷³ *New Directions Treatment Servs.*, 490 F.3d at 293.

feet of any public or private school, or any trade or vocational school that on a regular basis has at least one student under the age of 18; (c) Within 500 feet of any park or any public facility or institution; (d) Within 1,000 feet of another syringe exchange program⁷⁴

Furthermore, this provision, in conjunction with proposed Section 18.12.245(4) (limiting business hours for SSPs to “daytime hours”),⁷⁵ Section 18.12.245(9) (the “One for One Plus” 10 requirement)⁷⁶ and Section 18.12.245(10) (the syringe marking provision)⁷⁷ amount to intentional discrimination that approach an outright ban of SSPs, as it would be practically impossible to maintain an SSP anywhere in the jurisdiction. As such, a successful legal challenge could have been mounted if the proposed ordinance had been approved.

A. Is There a Protected Class?

In 1985, the Supreme Court failed to classify disability as a protected class under the Fourteenth Amendment in *City of Cleburne, Texas v. Cleburne Living Center, Inc.*⁷⁸ Thus, the ADA represents one of the only legal mechanisms to offer protections for individuals with disabilities. In the case of SSPs, first, the plaintiffs must be persons with disabilities. Courts have recognized that persons with SUD are “disabled” within the meaning of the ADA.⁷⁹ In fact, the Department of Health and Human Services specifically provides that “drug addiction, including an addiction

⁷⁴ Beaton, *supra* note 32, at 10 (Proposed Ordinance No. 5840).

⁷⁵ Beaton, *supra* note 32, at 10 (Proposed Ordinance No. 5840).

⁷⁶ The “One for One Plus” basis provides a one for one exchange of needles. The municipality further proposed that SSPs could only provide 10 extra syringes regardless of the number of syringes brought in by a participant, and capped the total number of syringes given to each person at 100 syringes per visit. *Id.*

⁷⁷ The proposed ordinance provided: “The syringes and needles that are distributed to a program participant shall have an identifiable unified color or mark to identify the source as being the Syringe Exchange Program.” *Id.*

⁷⁸ 473 U.S. 432 (1985).

⁷⁹ *MX Grp., Inc. v. City of Covington*, 106 F. Supp. 2d 914, 918–20 (finding that recovering heroin addicts are “persons with a disability” within the meaning of the ADA).

to opioids, is a disability under Section 504 of the Rehabilitation Act [and] the Americans with Disabilities Act . . . when the drug addiction substantially limits a major life activity.”⁸⁰ The prior cases addressing zoning discrimination also dealt with people with SUDs, and the courts permitted them to proceed under claims of disability discrimination under both the ADA and RA. As one example, in *MX Group*, where plaintiffs sought access to a methadone clinic, the court viewed people with SUD as having a qualifying disability under each of the three prongs of the ADA.⁸¹ They had a physical impairment that limits a major life activity because their addiction was severe enough to require their admittance to a facility, disrupting their ability to work, parent, and live independently or with their families.⁸² The plaintiffs also had a record of a disability, as they had to show proof their addiction had lasted at least one year.⁸³ Lastly, they were regarded as having a disability, because they were denied public services because of wrongful stereotypes (for instance, assumptions the plaintiffs were associated with criminal activity).⁸⁴

With respect to SSPs, the similar or same population is seeking out the service. These are individuals with SUD who require access to a given service to maintain their health and well-being. Some may argue these individuals would not meet the first prong of a disability, as their addiction may not arguably affect a major life activity in the same ways as individuals who have demonstrated a need for institutional care. Although it is inappropriate to generalize about how severely an addiction impacts any single person’s life, people who meet the diagnostic criteria for a substance use disorder under DSM-5 have a “clinically significant impairment or distress.”⁸⁵ We might assume that these individuals may have the level of impairment needed to meet the first prong of the

⁸⁰ U.S. DEP’T HEALTH & HUMAN SERVICES OFF. FOR C.R., *Fact Sheet: Drug Addiction and Federal Disability Rights Laws* (Oct. 25, 2018), <https://www.hhs.gov/sites/default/files/drug-addiction-aand-federal-disability-rights-laws-fact-sheet.pdf> [<https://perma.cc/8PQX-MHKH>].

⁸¹ *MX Grp.*, 106 F. Supp. 2d at 918–20.

⁸² *Id.* at 918.

⁸³ *Id.* at 918–19.

⁸⁴ *Id.* at 919.

⁸⁵ AM. PSYCHIATRIC ASS’N, *DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS* (5th ed. 2013).

definition of a disability under the ADA. Moreover, these individuals would likely qualify under one of the other prongs, especially being regarded as having a disability, as they are experiencing the same stereotyping of criminality that plaintiffs experienced in treatment site cases. This stereotyping may be even more pronounced in the case of SSPs as harm reduction services are often even further stigmatized as patrons of these facilities do not have to commit to abstinence-based treatment in order to benefit from their services that reduce the negative effects of drug use.

B. Are Covered Entities Involved?

The successful zoning ordinance challenges related to SUD treatment centers involved state and local laws.⁸⁶ In the cases dealing with treatment centers, courts held states and local government to be covered entities under the ADA and RA.⁸⁷ The ADA expressly covers state and local governments under Title II, while the RA covers entities receiving federal financial assistance which includes local and state governments.

Discriminatory zoning ordinances impeding or blocking access to SSPs are also being issued by state and, more typically, local government entities. These actions are squarely covered under both the ADA and RA.

C. Is the Conduct Covered Behavior?

Courts have held discriminatory zoning decisions to be covered activity under the ADA and RA. In *Bay Area*, the court considered this as a matter of first impression and held that the ADA and RA applied to zoning decisions, noting, “Although we recognize that zoning is a traditionally local activity, Congress has spoken.”⁸⁸ The court did not believe it appropriate to apply the ADA to some activities of public officials but not

⁸⁶ See, e.g., *Bay Area Addiction Research & Treatment, Inc. v. City of Antioch*, 179 F.3d 725, 731 (9th Cir. 1999) (“[Title II of the ADA] thus constitutes a general prohibition against discrimination by public entities.”); see also *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 301 (3d Cir. 2007) (holding that the Rehabilitation Act and ADA reach actions of public officials as well as private actors).

⁸⁷ *Bay Area Addiction Rsch. & Treatment, Inc.*, 179 F.3d at 731; *New Directions Treatment Servs.*, 490 F.3d at 301.

⁸⁸ *Bay Area Addiction Rsch. & Treatment, Inc.*, 179 F.3d at 732.

others. In *MX Group*, the court agreed with this sentiment, noting that the ADA forbids discrimination by public officials, regardless of the context.⁸⁹

Just as in the discriminatory treatment center cases, the action by public officials in NIMBY zoning against SSPs is discriminatory zoning ordinances., bringing them under the ADA and RA.

D. Is the Conduct Discriminatory?

Lastly, NIMBY zoning against SSPs is arguably discriminatory in the same way as those bans against treatment sites. De facto bans such as these are simply a denial of health services to persons with SUD in contravention of the ADA and RA, and courts have repeatedly struck down closely analogous provisions in the past, as detailed above.

In *New Directions*, the court struck down a zoning restriction on a methadone clinic as a form of facial discrimination, because the ordinance “singles out methadone clinics, and thereby methadone patients, for different treatment, thereby rendering the statute facially discriminatory.”⁹⁰ In *MX Group*, under similar facts, the court likewise found the ordinance to be facially discriminatory: “The ordinance under consideration is a blanket prohibition of all methadone clinics from the entire city. It is discriminatory on its face and thus violative of the ADA and void.”⁹¹ In *Bay Area*, a NIMBY ordinance was also viewed as facially discriminatory by singling out methadone clinics. The court mused that the only way to make the ordinance not discriminatory would be to impose the same bans on all clinics of all kinds, not just methadone clinics.⁹²

The tenor of these arguments is likely to be applicable to most SSP zoning restrictions if these zoning ordinances impose restrictions on SSPs only and not other kinds of public health or health care centers. To analogize to the logic of the *New Directions* court, ordinances that single out SSPs, and therefore people who inject drugs, are being facially discriminatory based on disability.

⁸⁹ *MX Grp., Inc.*, 106 F. Supp. 2d 914 at 920.

⁹⁰ *New Directions Treatment Servs.*, 490 F.3d at 304.

⁹¹ *MX Grp., Inc.*, 106 F. Supp. 2d 914 at 920.

⁹² *Bay Area Addiction Rsch. & Treatment, Inc.*, 179 F.3d at 734.

In short, NIMBY attacks against SSPs appear to be one in the same with the earlier attacks on SUD treatment centers. Thus, courts are likely to view them similarly as intentional forms of discrimination against people with disabilities.

IV. OVERCOMING DEFENSES

While there are many possible defenses that governments may use to block claims of intentional discrimination, we advance two key defenses worth addressing: (1) that SSPs threaten their residents and (2) that individuals that use illegal drugs may not qualify as disabled.

First, jurisdictions may mount a defense on the grounds that their citizens face a direct threat from the SSPs, similar to the defenses raised in the *Bay Area* case. Such defenses failed in the past because state and local governments could not substantiate the claims that SUD treatment facilities placed their residents in harm's way. Fueled by misinformation, policymakers hypothesize that SSPs will increase rates of crime, encourage illegal drug use amongst people who would not otherwise use illegal drugs, and increase the number of improperly discarded syringes in the surrounding area.⁹³ However, no evidence exists to support such claims; to the contrary, the presence of these treatment centers does not change rates of crime nor increase enrollment in treatment for addiction, and in fact, reduces improperly discarded drug paraphernalia.⁹⁴ Though a full review of the data is beyond the scope of this Article, the opposition to SSPs appears to be akin to that of SUD treatment centers, rooted in bias

⁹³ Mitch Legan, *Indiana Needle Exchange That Helped Contain a Historic HIV Outbreak to Be Shut Down*, NPR (June 3, 2021), <https://www.npr.org/sections/health-shots/2021/06/01/1001278712/indiana-needle-exchange-that-helped-contain-an-hiv-outbreak-may-be-forced-to-clo> [https://perma.cc/6KMC-VANK]; Joe Atmonavage, *Atlantic City Votes to Close State's Largest Needle Exchange Program, Drawing Outrage*, NJ.COM (July 22, 2021), <https://www.nj.com/news/2021/07/atlantic-city-votes-to-close-states-largest-needle-exchange-program-drawing-outrage.html> [https://perma.cc/KTF2-32BT]; John C. Messinger & Leo Beletsky, *Misinformation Is Fueling the Overdose Crisis*, COMMONWEALTH MAG. (Jan. 16, 2022), <https://commonwealthmagazine.org/drug-addiction/misinformation-is-fueling-the-overdose-crisis/> [https://perma.cc/5EY5-YWRX].

⁹⁴ CTRS. FOR DISEASE CONTROL, *supra* note 4, at 1.

and stigma against people who use drugs rather than any real and objective claims that these centers generate crime or violence.⁹⁵

Second, despite recognition of SUD as a disability by the courts, a municipality may counter that protection under the ADA and the RA does not extend to clients of SSPs, as current users of illegal drugs may not be “qualified individual[s] with a disability.”⁹⁶ Both statutes contain limited carve-outs exempting discrimination protections from those who are “currently engaging in the illegal use of drugs” when the “covered entity acts on the basis of” the plaintiff’s illegal use of drugs.⁹⁷ The SUD treatment cases outlined above have not considered this defense because the patients in question were participating in rehabilitation programs and presumably no longer using illegal drugs.⁹⁸ However, with SSPs, at least some of the services provided include providing needles for safe drug use, making this a more likely defense that cities and states may try to put forth.

However, we argue that this defense would not succeed because these statutory exclusions are inapplicable in the present context. Both statutes limit their “current use” exception (excluding current users of drugs from disability anti-discrimination protections) with safe harbor provisions guaranteeing the protection of health services to individuals who currently use illegal drugs. Both the ADA and RA maintain that covered entities⁹⁹

⁹⁵ Michael Botticelli, *Stigma and Substance Use Disorder: Breaking Down Barriers to Treatment and Sound Public Policy*, HEALTH CITY (May 23, 2019), <https://healthcity.bmc.org/policy-and-industry/stigma-key-barrier-sud-treatment-and-sound-public-policy> [https://perma.cc/U6N6-S598].

⁹⁶ 42 U.S.C. § 12131 (2018); 29 U.S.C. § 794 (2018).

⁹⁷ See 42 U.S.C. § 12210(a) (2018); 29 U.S.C. § 705(20)(C)(i) (2018).

⁹⁸ See *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 309 (3d Cir. 2007) (“The ADA and Rehabilitation Act specifically provide that a person who has completed a supervised rehabilitation program or is currently participating in such a program and “is no longer engaging” in drug use shall be deemed a qualified individual”); *MX Grp. Inc. v. City of Covington*, 293 F.3d 326, 339 (6th Cir. 2002) (“Indeed, the statute itself contemplates that individuals participating in drug rehabilitation programs, who are no longer using drugs or presumably impaired by their effects, are covered by the Act”).

⁹⁹ U.S. DEP’T HEALTH & HUMAN SERVS. OFF. FOR C.R., *Fact Sheet: Drug Addiction and Federal Disability Rights Laws* (Oct. 25, 2018), <https://www.hhs.gov/sites/default/files/drug-addiction-aand-federal-disability-rights-laws-fact-sheet.pdf> [https://perma.cc/BB6U-SGQR] (“Covered entities may include, but

are prohibited from denying “health services, or services provided in connection with drug rehabilitation” to an individual on the basis of that individual’s current illegal use of drugs, if they are otherwise entitled to such services.¹⁰⁰ As discussed above, many SSPs provide, among other things, SUD treatment, wound care, infectious disease testing, and overdose prevention supplies. Therefore, SSPs are bona fide health services facilities, providing essential services to those with SUD—a recognized disability under the ADA. While courts have yet to consider the applicability of the safe harbor provision to SSPs, ample reasoning supports the contention that patients of SSPs would fall under the protections of the safe harbor provision.

An analysis of the legislative reasoning behind the adoption of the statutory carve-out supports the contention that the safe harbor provision would be applicable in the present context. The statutory exemption excluding ADA protection for individuals currently using illegal drugs was adopted to serve an employment function: the legislative purpose was focused on ensuring that employers could discharge employees who may have been under the influence or otherwise impaired while at work and that employers could not discharge employees who were recovering from SUD.¹⁰¹ The fact that Congress, through the safe harbor provision, explicitly provided for an exception for patients seeking health services, even if those individuals are currently using drugs, is important.¹⁰² As one

are not limited to: Substance Use Disorder Treatment Programs, Hospitals and Health Clinics, Pharmacies, Contracted Service Providers, Medical and Dental Providers, Nursing Homes, Child Welfare Agencies, State Court Systems. In addition, state and local governments are prohibited from discriminating on the basis of disability.”)

¹⁰⁰ 42 U.S.C. § 12210(c) (2018); 29 U.S.C. § 705(20)(C)(iii) (2018).

¹⁰¹ See *New Directions Treatment Servs.*, 490 F.3d at 309 (quoting *Brown v. Lucky Stores, Inc.*, 246 F.3d 1182, 1188 (9th Cir. 2001)); citing H.R. Rep. No. 101–596, at 62 (1990); U.S. Code Cong. & Admin. News 1990, pp. 565, 570–571 (Conf.Rep.).

¹⁰² The U.S. Department of Health and Human Services Center for Substance Abuse Treatment has provided guidance on this regulation, stating that as an example that “a hospital that specializes in treating burn victims could not refuse to treat a burn victim because he uses illegal drugs, nor could it impose a surcharge on him because of his addiction.” U.S. DEP’T HEALTH & HUMAN SERVS. CTR. FOR SUBSTANCE ABUSE TREATMENT, SUBSTANCE ABUSE TREATMENT FOR PERSONS WITH HIV/AIDS 187 (2008), https://www.ncbi.nlm.nih.gov/books/NBK64923/pdf/Bookshelf_NBK64923.pdf [<https://perma.cc/P9CW-NAX6>].

Federal District Court judge reasoned, “[i]f the [ADA] and [RA] were interpreted to exempt from its protections individuals with drug addictions seeking help . . . section (c) would be reduced to a nullity and mere surplusage . . . Whether any of the prospective patients were engaging in the use of illegal drugs is orthogonal to the question of whether the ADA or [RA] provides protection for them.”¹⁰³ Under this line of reasoning, patients of SSPs who are currently using illegal substances are still within the protection of the ADA through the application of the safe harbor provision.

In sum, zoning ordinances that approach a de facto ban on SSPs anywhere in the jurisdiction, such as the one successfully challenged in Kennewick, result in an effective denial of health services to persons with SUD in direct violation of the safe harbor provisions in both the ADA and the RA.

V. EXPANDING APPLICATION OF THE ADA TO COVID-19 TESTING SITES

Unfortunately, COVID-19 testing sites, like SSPs, have also come under attack by discriminatory zoning laws similar to those we have addressed in this Article. In late March, plans for a drive-thru COVID-19 test site in Darien, Connecticut, were canceled amid opposition from neighbors, despite a surging demand to expand the county’s testing capacities.¹⁰⁴ Just one week earlier before the closure in Connecticut, a drive-thru coronavirus test site in Ewin, New Jersey, was shut down after the building’s landlord issued a cease-and-desist letter to the operator of the test site citing complaints about “too much commotion” in the parking lot.¹⁰⁵ The Ewin drive-thru facility was one of only three coronavirus test sites in the entire state of New Jersey.¹⁰⁶ These complaints echo many of

¹⁰³ *RHJ Med. Ctr., Inc. v. City of DuBois*, 754 F. Supp. 2d 723, 750 (W.D. Pa. 2010).

¹⁰⁴ Sandra Diamond Fox & Lidia Ryan, *Twitter Slams CT Town for Cancelling Coronavirus Testing Site*, THE STANFORD ADVOCATE (Mar. 20, 2020), <https://www.stanfordadvocate.com/news/coronavirus/article/CT-cancels-coronavirus-testing-neighbor-complains-15146002.php> [<https://perma.cc/6L6F-MMM3>].

¹⁰⁵ Isaac Avilucea, *Ewing Coronavirus Drive-thru Center Shut Down Over Apparent Landlord Flap*, THE TRENTONIAN (Mar. 18, 2020), <https://www.trentonian.com/2020/03/18/ewing-coronavirus-drive-thru-center-shut-down-over-apparent-landlord-flap/> [<https://perma.cc/U3Q9-46X2>].

¹⁰⁶ *Id.*

those that have been launched against SSPs since their inception, which view these services as a threat to property values or the general quality of the neighborhood. Across the country, efforts to track and contain the spread of COVID-19 and harm reduction services aimed at reducing the burden of the overdose epidemic are met with fierce opposition by vocal community members who wish to maintain community boundaries and shift the burden of these public health crises elsewhere. While this Article focuses on ADA law as a tool to tackle zoning restrictions on SSPs, we acknowledge that restrictions on COVID-19 testing sites are also a public health crisis for people with addictions and others, and that some of our legal approaches could be used to remedy NIMBY restrictions on testing sites, too.

VI. CONCLUSION

As the overdose crisis continues to spiral, many of the legal tools deployed to address it have missed the mark by myopically focusing on supply reduction measures. Meanwhile, harm reduction strategies have remained under-utilized, under-funded, and under attack by discriminatory policies and practices. There is little doubt that expansion in the number and scope of SSPs across the United States is crucial to addressing the overdose crisis and its attendant harms. The critical role SSPs serve has become increasingly apparent as lawmakers across the country make timely decisions as to which services are absolutely essential and must remain open in the face of the pandemic. In the context of an ongoing crisis, the ADA and RA offer enormous promise in safeguarding the rights—and lives—of vulnerable people who use drugs. While their wide deployment does not offer a comprehensive political solution to this problem, it presents an important instrument for advancing public health through the law. Rights-based litigation based on these statutes also offers an opportunity to highlight the individual and community benefits of SSPs, opening the door to educating decision-makers, the public, and the press about key misconceptions and helping harm reduction win in the court of public opinion.

Reconceptualizing the International Health Regulations in the Wake of COVID-19: An Analysis of Formal Dispute Settlement Mechanisms and Global Health Diplomacy

Celestina Radogno*

Abstract:

The COVID-19 pandemic brought renewed attention to the International Health Regulations, a multilateral treaty to “prevent, protect against, control and provide a public health response to the international spread of disease.” But a historical review of the treaty reveals the true focus of the treaty has always been about avoiding economic restrictions during pandemics. This resulted in a State practice of widespread non-compliance with the treaty. Some have suggested the United States invoke the International Health Regulations’ legal dispute resolution mechanism against China in response to China’s role in the spread of COVID-19. Yet, since its inception, this mechanism has never been pursued. Why? This Article answers this question by walking through what an international lawsuit or arbitration by the United States against China would actually look like—and how it would fail. Likely appreciating this reality, State practice has made the International Health Regulations function more like a soft power tool than an instrument of hard law. This is not necessarily a bad thing, as diplomacy has upsides that formal legal settings do not. However, unchecked diplomatic tactics have increased geopolitical tensions between the United States and China at the expense of countries in the Global South’s ability to recover from the pandemic. In the conclusion of this Article, I suggest some solutions outside traditional treaty law that can help reach the ultimate goal of the International Health Regulations: an efficient global pandemic response system.

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I. INTRODUCTION 93

II. HISTORY AND OVERVIEW OF THE IHR 94

 A. THE HISTORY OF INTERNATIONAL LAW AND PUBLIC HEALTH..... 95

 B. THE CURRENT VERSION OF THE INTERNATIONAL HEALTH
 REGULATIONS..... 98

 C. THE IHR IN PRACTICE 101

 D. LEGACY AND CRITICISM..... 103

III. THE UNITED STATES VS. CHINA 105

 A. THEORY OF LIABILITY 108

 1. FAILURE TO NOTIFY..... 108

 2. FAILURE TO SHARE INFORMATION 110

 3. LIABILITY DEFENSES 112

 B. JURISDICTION AND VENUE..... 113

 1. ARBITRATION..... 115

 2. INTERNATIONAL COURT OF JUSTICE 117

 C. REMEDIES..... 119

 1. LEGAL BASIS FOR REMEDIES..... 119

 2. RESTITUTION..... 120

 3. COMPENSATION 122

 4. SATISFACTION..... 123

 D. ENFORCEMENT AND COMPLIANCE 124

IV. EFFICACY OF INFORMAL MECHANISMS 128

 A. CHINESE DIPLOMACY AND GLOBAL HEALTH—OVERVIEW..... 129

 B. CHINESE DIPLOMACY: FROM SARS TO COVID-19 130

 1. HISTORICAL BACKGROUND OF SARS 130

 2. INFORMATION CONTROL 132

 3. EXTERNAL INFLUENCE 134

 C. THE WORLD RESPONDS TO CHINA 139



1. ADDITIONAL HEALTH MEASURES	139
2. RAMPED-UP RHETORIC	142
3. “VACCINE DIPLOMACY”—THE UNITED STATES COUNTERS.....	146
V. CONCLUSION.....	149



I. INTRODUCTION

On January 30, 2020, the Director-General of the World Health Organization (WHO) declared a novel coronavirus, COVID-19, a Public Health Emergency of International Concern (PHEIC).¹ The power to do so is derived from Article 12 of the International Health Regulations (IHR), a multilateral treaty designed to regulate State behavior in the face of a disease outbreak.² The IHR was most recently revised in 2005, but the framework for the treaty stems back to the International Sanitary Conferences of the 1800s.³ The purpose of the IHR is to “prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic.”⁴ Unfortunately, noncompliance has been an issue since the first iterations of the treaty, particularly with provisions requiring States to report to WHO information regarding PHEICs as well as any related travel and trade restrictions they plan to implement.⁵ In addition, States have struggled to meet the IHR’s requirements to develop and maintain core public health capacities, which affects their ability to monitor and respond to PHEICs.⁶ The COVID-19 pandemic was no exception. From the very start of the outbreak in late 2019, many States violated the IHR.⁷ Since its onset, COVID-19 spread to 532.3 million people worldwide and caused 6.3 million deaths (as of June 2022).⁸ In 2020, the global economy contracted three-and-a-half percent.⁹

In this Article, I argue that not only is the IHR legally insufficient to tackle PHEICs but that it has consequently been turned into a tool for soft power

1 *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORG. (Jan. 30, 2020), [https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)) [<https://perma.cc/JQY9-8HN5>].

2 World Health Organization: Revision of the International Health Regulations art. 12, May 23, 2005, 44 I.L.M. 1013 [hereinafter IHR].

3 Norman Howard-Jones, *The Scientific Background of the International Sanitary Conferences 1851-1938*, 1 HIST. INT’L PUB. HEALTH 9 (1975).

4 IHR, *supra* note 2, art. 2.

5 *See infra* note 70 and accompanying text.

6 IHR, *supra* note 2, Annex 1A; Nirma Kandel, Stella Chungong, Abbas Omaar & Jun Xing, *Health Security Capacities in the Context of COVID-19 Outbreak: An Analysis of International Health Regulations Annual Report Data From 182 Countries*, 395 LANCET 1047, 1050-52 (2020).

7 *See infra* Part IV.C.

8 *COVID-19 Dashboard*, JOHNS HOPKINS U., <https://coronavirus.jhu.edu/map.html> [<https://perma.cc/66EG-Z7LT>].

9 Eduardo Levy Yeyati & Federico Filippini, *Social and Economic Impact of COVID-19*, at 1 (Brookings Inst., Working Paper No. 158, 2021).

diplomacy, which can undermine the IHR's objective. I will highlight the ineffectiveness of the IHR by exploring the multitude of barriers to successfully utilizing the legal dispute resolution mechanisms in the event of a breach of the treaty by a State. I further show how because the legal mechanisms are doomed to fail, States defer to soft power tactics instead. By juxtaposing the legal fiction with the political reality, I illustrate why the IHR needs to be reimagined. This Article will start with background information about the IHR, including the object and purpose, State practice since the adoption of the treaty, and instances where States have failed to perform their treaty duties. Second, this Article will discuss why recourse to international dispute settlement bodies is not a viable tool to increase the effectiveness of the IHR, exemplified by the hypothetical case against The People's Republic of China (China) regarding China's handling of COVID-19. I picked China as the hypothetical defendant as China is the most likely country of origin for the COVID-19 virus. In addition, China has been the central focus of international scrutiny surrounding COVID-19, especially by the United States. This Article will discuss theories of liability, and the difficulty of obtaining the appropriate venue, assessing remedies, and enforcing judgments under international law. Next, this Article will discuss the efficacy of informal dispute mechanisms such as diplomacy and how they have played out in the COVID-19 pandemic as well as in previous pandemics. I will conclude by discussing new approaches for achieving the goals of the IHR.

II. HISTORY AND OVERVIEW OF THE IHR

Globalization on the heels of the Industrial Revolution brought increased concern for transmitting diseases across borders. At the same time, international law was beginning to take the shape it has today.¹⁰ The nineteenth century brought about the beginnings of the intersection of international law and public health. Yet, another concern always loomed over this evolution of international health law and arguably had more influence on its formation than any other aspect: travel and trade. Walking through the history of the IHR, we see how economic concerns were always, at least implicitly, at the forefront of discussions. Additionally, the advent of new technologies, as well as increased international focus on the environment and human rights, led to major changes to the IHR in 2005. These changes affected the legal dispute resolution mechanisms in the treaty, rendering them less effective. But even before the 2005 changes, historical State practice in relation to the IHR showed rampant noncompliance. Fearing economic repercussions from admitting to disease outbreaks, States generally take actions

10 Malcolm Shaw, *International Law, in* ENCYC. BRITANNICA, <https://www.britannica.com/topic/international-law/Historical-development> [https://perma.cc/6AFD-VVES].

guided by economic considerations before health or legal considerations. The result is that the IHR has been treated like a guidance tool for diplomacy rather than an instrument of hard law. This is most easily exemplified by the spike in tension between the United States and China following the spread of COVID-19. In this section, I will discuss the history of the IHR and how it has come to function today.

A. The History of International Law and Public Health

In the summer of 1851, twelve States convened in Paris for the first-ever International Sanitary Conference.¹¹ Attendance was almost exclusively European, but the goal was to reach an “international” consensus on quarantine regulations following an outbreak of cholera in India.¹² The conference was unsuccessful at achieving any tangible goals.¹³ This failure was in large part due to the familiar and futile combination of politics and ignorance: diplomats and the physician-delegates that accompanied them were as strong-headed in their convictions as they were wrong.¹⁴ The Austrian and British governments refused to discuss cholera at all, focusing only on yellow fever and the plague.¹⁵ They incorrectly believed that cholera was an airborne disease originating from foul smells and filthy people, even though this theory was already debunked by England’s top doctor.¹⁶

Despite the failure of the first conference, States continued to meet on the issue of international disease control. The second through sixth International Sanitary Conferences were as unproductive as the first, with delegates continuing to contest the cause of cholera.¹⁷ But though disagreements persisted, some common themes that would carry into the twentieth and twenty-first centuries

11 Howard-Jones, *supra* note 3, at 12.

12 *Id.* at 9-11.

13 *Id.* at 12.

14 *Id.*

15 *Id.*

16 In 1849 Dr. John Snow postulated that the cholera outbreak in London originated from feces-contaminated drinking water. Snow, who at the time was the personal anesthetist to Queen Victoria, later became known as the “father of modern epidemiology.” *Id.*; Theodore H. Tulchinsky, *John Snow, Cholera, the Broad Street Pump; Waterborne Diseases Then and Now*, CASE STUDIES IN PUBLIC HEALTH 77, 80, 93 (2018).

17 Howard-Jones, *supra* note 3, at 17-57; *Contagion: International Sanitary Conferences*, HARV. LIBR. CURIOSITY COLLECTIONS [hereinafter *Contagion*], <https://curiosity.lib.harvard.edu/contagion/feature/international-sanitary-conferences> [https://perma.cc/WN5W-MQJN].

emerged: concerns about how disease control would affect trade,¹⁸ travel,¹⁹ and State sovereignty.²⁰ For example, a central issue of the second through sixth conferences was the regulation of the Suez Canal following outbreaks of cholera among Mecca pilgrims.²¹ The British government protested the proposed regulations, citing concerns that lengthy inspections of merchant ships would render the use of the canal “uneconomic.”²² Additionally, requiring entire passenger ships to quarantine when there may be only one confirmed case of cholera was too restrictive on travelers.²³ Britain’s justification for wanting an exception was that it “d[id] not demand specially favourable treatment; but it wishe[d] that each country should act as it s[aw] fit in regard to its own ship.”²⁴ Though this sovereignty argument was likely a shroud for another reason Britain wanted unrestricted access to the Suez Canal,²⁵ it still begged the question posed by medical historian Norman Howard-Jones: “if every country were left free to make its own arrangement, what was the purpose of the international conference?”²⁶

It was not until the seventh conference in 1892 that any significant result on international disease control was achieved.²⁷ States finally agreed on a treaty establishing sanitary and quarantine regulations for ships traveling westward on the Suez Canal that would later become incorporated into the International Sanitary Convention of 1903.²⁸ From a public health perspective, this treaty was a success: the signing parties unanimously agreed to include a provision that finally put to rest the persistent yet incorrect theory that cholera was an airborne disease.²⁹ But from an international relations perspective, the treaty was less laudable: it was only

18 See, e.g., Howard-Jones, *supra* note 3, at 57.

19 See, e.g., *id.* at 28-30.

20 See, e.g., *id.* at 56.

21 *Id.* at 28-57.

22 *Id.* at 56-57.

23 *Id.*

24 *Id.* at 56.

25 At the time the British delegate made this statement to the sixth conference in 1885, the British Empire was in the fledgling years of its occupation of Egypt, including control over the Suez Canal, which gave Britain an advantage in its military and trade interests, as well as its interest in colonizing Africa. *Egypt: The Period of British Domination (1882-1952)*, in ENCYC. BRITANNICA, <https://www.britannica.com/place/Egypt/Renewed-European-intervention-1879-82#ref22393> [https://perma.cc/79AN-UWX7]; Suez Canal, HIST. (Mar. 30, 2021), <https://www.history.com/topics/africa/suez-canal> [https://perma.cc/2QFA-NEQH].

26 Howard-Jones, *supra* note 3, at 56.

27 *Contagion*, *supra* note 17.

28 Howard-Jones, *supra* note 3, at 64-65, 81.

29 *Id.* at 64 (“The germ of cholera is contained in the digestive tracts of patients; its transmission is effected principally by the dejections and vomited matter and, consequently, by linen, clothing, and soiled hands.”).

made with significant arm-bending of, and concessions to, the British Empire.³⁰ Nevertheless, conferences continued to be held, and Britain continued to participate in the makings of what would eventually become the international health system as we know it today. In 1907, at the urging of the French government, delegates began drafting statutes for the first-ever permanent international health office.³¹ In 1909, the Office International d'Hygiène Publique (Office) opened its doors in France, where it remained until it was succeeded by the contemporary World Health Organization in 1948.³²

WHO is a specialized agency of the United Nations (UN) tasked with the lofty objective of “the attainment by all peoples of the highest possible level of health.”³³ WHO is organized into three branches: the Secretariat, which is responsible for technical and administrative duties; the World Health Assembly (WHA), which is the main decision- and policy-making body; and the Executive Board, which executes WHA actions, advises the WHA on WHO matters, and has authority to take measures to combat health emergencies.³⁴ The WHO Constitution confers on the WHA the authority to make regulations concerning “sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease.”³⁵

In 1951, just three years after its charter and 100 years after the first International Sanitary Conference, the WHA promulgated the International Sanitary Regulations (ISR).³⁶ The ISR revised and replaced the International Sanitary Convention of 1903 and consolidated other existing international health agreements.³⁷ Among the revisions were minor changes to definitions of relevant diseases and updated quarantine and vaccination protocols that reflected contemporary scientific consensus.³⁸ The legal changes, on the other hand, were

30 *Id.* at 62-64 (“Austria-Hungary had also taken special measures to encourage the participation of an ever-reluctant Britain; in a letter of 27 November 1891 its ambassador in London had assured the British Prime Minister, the Marquis of Salisbury, that, as promised, his Government [which had initiated the conference] ‘would endeavour to exclude from discussions at the Conference everything that might seem unacceptable to English interests.’”).

31 *Id.* at 86.

32 *Id.* at 9, 86-87.

33 U.N. Charter art. 57; WHO, Basic Documents: Constitution of the World Health Organization, 48 WHO 7 (2014), [hereinafter WHO Constitution], <http://apps.who.int/gb/bd/PDF/bd48/basic-documents-48th-edition-en.pdf#page=7> [<https://perma.cc/7CCN-75HS>].

34 WHO Constitution, *supra* note 33, arts. 18(a)-(m), 19, 21, 28(a)-(i), 30.

35 *Id.* art. 21(a).

36 World Health Organization Regulations, A4/60 (2), at 2 (May 21, 1951).

37 *Id.*; Lawrence Gostin & Rebecca Katz, *The International Health Regulations: The Governing Framework for Global Health Security*, 94 MILBANK Q. 264, 266 (2016).

38 See, e.g., *International Sanitary Regulations*, 257 LANCET 1163, 1163 (1951) (“Measures

more significant.³⁹ For one, only governments were allowed to be parties to the treaty, whereas the 1903 Convention also applied to autonomous health administrations.⁴⁰ In addition, the ISR had an eye toward flexibility and scientific advancement; it included a provision for continuous review and revision rather than repeal and replace.⁴¹ Lastly, the ISR included a dispute-settlement mechanism should “[a]ny question or dispute concerning the interpretation or application of these Regulations or of any Regulations supplementary to these Regulations” arise.⁴² In that event, the State concerned may refer the question or dispute to the Director-General of WHO.⁴³ Should the Director-General be unable to settle the dispute, it may, “by written application, be referred by any State concerned to the International Court of Justice for decision.”⁴⁴

In 1969, the International Sanitary Regulations were changed in name to the International Health Regulations, but the substance of the treaty mostly remained the same.⁴⁵ Amendments were made again in 1973 and 1981 to change the provisions regarding cholera and exclude reference to smallpox, which had by then been declared eradicated.⁴⁶

B. The Current Version of the International Health Regulations

In 1995, global events led the WHA to consider revising the IHR for the first time since 1981.⁴⁷ Among other things, WHO recognized that the emergence of new international legal regimes for trade, environmental protection, and human rights—all of which intersected with international public health—needed to be reconciled with the IHR.⁴⁸ In addition, the rising threat of bioterrorism and new epidemics such as HIV/AIDs led WHO to realize that an exhaustive list of actionable diseases was ineffective at preventing novel outbreaks.⁴⁹ Yet, it was not until the 2003 outbreak of SARS that the WHA really kicked the revision process into gear. Finally, in 2005, the WHA completed the version of the IHR that is in

against yellow fever remain largely unchanged, but there is now a clause that allows local areas which keep the aedes index below 1% to be excluded from the yellow fever endemic zone.”).

³⁹ *Id.*

⁴⁰ *Id.*; Howard-Jones, *supra* note 3, at 38 n.58, 56 (“The result of this curious provision was that Austria-Hungary had two votes—one for Austria and the other for Hungary.”).

⁴¹ *International Sanitary Regulations*, *supra* note 38.

⁴² World Health Organization Regulations, *supra* note 36, art. 112(1).

⁴³ *Id.* arts. 112(1), (3).

⁴⁴ *Id.*

⁴⁵ David P. Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 CHINESE J. INT’L L. 325, 333 (2005).

⁴⁶ Max Hardiman & Annelies Wilder-Smith, *The Revised International Health Regulations and Their Relevance to Travel Medicine*, 14 J. TRAVEL MED. 141, 141 (2007).

⁴⁷ Fidler, *supra* note 45, at 340.

⁴⁸ *Id.* at 340–41.

⁴⁹ *Id.* at 338.

use today.⁵⁰

The biggest change to the IHR was the shift from an exhaustive list of diseases to an “all-hazards” framework. An “all-hazards” approach represents a significant departure from the exhaustive list model by recognizing that though emergencies vary greatly in nature, they all put a similar strain on health systems, and thus health systems should be generally prepared for emergencies.⁵¹ This, coupled with core capacity-building requirements, opened the door to broaden the IHR’s reporting requirements to include any event that may constitute a PHEIC rather than the specifically enumerated diseases.⁵² But despite this substantive overhaul, the drafters maintained their commitment to the same concerns expressed in 1851: public health measures must be achieved in the least restrictive manner to travel and trade.⁵³ This, in turn, bore directly on the dispute resolution process.⁵⁴ With an exhaustive list of diseases, previous iterations of the treaty could include a detailed list of travel and trade restrictions States were allowed to implement in response to a disease outbreak.⁵⁵ It was therefore easy to identify when the treaty was violated in this regard. With the change to an “all-hazards” approach, however, including a detailed list of acceptable trade and travel restrictions became impractical if not impossible.⁵⁶ Thus, the drafters grappled with how to reconcile the “all-hazards” approach with the continued commitment to minimize travel and trade restrictions.⁵⁷

A provisional draft in 1998 included a compulsory arbitration clause.⁵⁸ While compulsory arbitration could be applied to any dispute arising out of the IHR, the proposal was geared primarily toward addressing unwarranted travel and trade restrictions.⁵⁹ The drafters believed “WHO’s ability to gather non-governmental sources of surveillance information,” including from unofficial sources such as social media, would remedy failures to notify.⁶⁰ This proposal, however, was

⁵⁰ *Id.* at 325-36.

⁵¹ *European Programme of Work*, WORLD HEALTH ORG. EUR., <https://www.euro.who.int/en/health-topics/health-emergencies/from-disaster-preparedness-and-response/policy> [perma.cc/47PQ-AY7G].

⁵² Gostin & Katz, *supra* note 37, at 267, 270; Fidler, *supra* note 45, at 350.

⁵³ Fidler, *supra* note 45, at 344; IHR, *supra* note 2, art. 2 (“The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”).

⁵⁴ Fidler, *supra* note 45, at 352.

⁵⁵ *Id.*

⁵⁶ *Id.* at 346, 350, 352.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 347 n.125 (“As WHO worked on and circulated the Provisional 1998 IHR Draft, the

quickly scrapped.⁶¹ Instead, the final version of the 2005 IHR provides WHO with authority to issue temporary recommendations for appropriate travel and trade measures States may take in response to a PHEIC.⁶² Compliance with these recommendations is completely voluntary and meant to be achieved by non-legal means, relying on a State's incentive to have a positive public image.⁶³ Thus, the final version of the formal dispute-settlement mechanism codifies its voluntariness and is framed as a last resort if informal means of negotiation and settlement fail.⁶⁴

Organization continued to build and use a new platform for global infectious disease surveillance and response. At the heart of this strategy was the Global Outbreak Alert and Response Network (GOARN), which WHO utilized to strengthen global surveillance of infectious disease events. Critical to the functioning of GOARN was WHO's access to sources of information beyond that received from governments. Well before the IHR's government-only information framework of the IHR had been changed, WHO started harnessing the revolution in information technologies for global public health purposes. WHO first informally established its global outbreak alert and response network in 1997 and then formalized the network in the form of GOARN in 2000.”).

61 *Id.* at 352.

62 *Id.* at 352-53.

63 *Frequently Asked Questions about the International Health Regulations (2005)*, WORLD HEALTH ORG. (2009), <https://web.archive.org/web/20220317112700/https://www.who.int/ihr/about/FAQ2009.pdf> [https://perma.cc/DBN9-T8HD] (“The IHR (2005) were agreed upon by consensus among WHO Member States as a balance between their sovereign rights and shared commitment to prevent the international spread of disease. Although the IHR (2005) do not include an enforcement mechanism per se for States which fail to comply with its provisions, the potential consequences of non-compliance are themselves a powerful compliance tool. Perhaps the best incentives for compliance are “peer pressure” and public knowledge. With today’s electronic media, nothing can be hidden for very long. States do not want to be isolated. The consequences of non-compliance may include a tarnished international image, increased morbidity/mortality of affected populations, unilateral travel and trade restrictions, economic and social disruption and public outrage. Working together with WHO to control a public health event and to accurately communicate how the problem is being addressed has helped to protect countries from unjustified measures being adopted unilaterally by other states.”).

64 IHR, *supra* note 2, art. 56(1)-(5) (“1. In the event of a dispute between two or more States Parties concerning the interpretation or application of these Regulations, the States Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it. 2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, the States Parties concerned may agree to refer the dispute to the Director-General, who shall make every effort to settle it. 3. A State Party may at any time declare in writing to the Director-General that it accepts arbitration as compulsory with regard to all disputes concerning the interpretation or application of these Regulations to which it is a party or with regard to a specific dispute in relation to any other State Party accepting the same obligation. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States applicable at the time a request for arbitration is made. The States Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final. The Director-General shall inform the Health Assembly regarding such action as appropriate. 4. Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental

C. The IHR in Practice

Since the 2005 revisions, the IHR has at various times been subject to scrutiny for its ineffectiveness, particularly regarding noncompliance.⁶⁵ But to truly evaluate the success or failure of the IHR in practice, it must first be determined what it means for the IHR to function effectively. This requires examining the fine line between plausibility and practicality in an increasingly globalized and complicated world. As leading global health law scholar David P. Fidler so aptly put it, “[w]e cannot lawyer diseases out of human societies”⁶⁶ Thus, the most practical benchmark for measuring the effectiveness of the IHR is rather simplistic: is pandemic preparedness and response bettered by the existence of the IHR?

There are many factors that fall under this holistic benchmark. From an epidemiologic perspective, one could take any disease outbreak and calculate how many incidences of disease were prevented from prompt reporting or, conversely, how many incidences of disease could have been prevented if reporting happened sooner.⁶⁷ From an economic perspective, a country’s investment in disease surveillance and emergency preparedness could be compared. One may also look at social determinants of health such as unemployment caused by a pandemic or whether outbreak response measures are discriminatory.⁶⁸ Regardless, attributing any of these outcomes to the IHR necessitates first determining whether the outcomes were caused by compliance or noncompliance with the IHR’s legal requirements. Thus, the remainder of this Article will focus on compliance.

The IHR is legally binding on 196 States, making it one of the most-signed international legal documents.⁶⁹ But noncompliance, especially with reporting

organizations or established under any international agreement. 5. In the event of a dispute between WHO and one or more States Parties concerning the interpretation or application of these Regulations, the matter shall be submitted to the Health Assembly.”).

65 See, e.g., Andrea Spagnolo, *(Non) Compliance with the International Health Regulations of the WHO from the Perspective of the Law of International Responsibility*, 18 GLOB. JURIST 20170025 (2018).

66 Fidler, *supra* note 45, at 392.

67 See generally Wayne W. LaMorte, *Measures of Association: Attributable Proportion*, BOS. U. PUB. HEALTH (Mar. 19, 2018), https://sphweb.bumc.bu.edu/otlt/mph-modules/ep/ep713_association/ep713_association6.html [<https://perma.cc/AT8J-45CL>].

68 See generally *Social Determinants of Health*, WORLD HEALTH ORG., https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1 [<https://perma.cc/K2WF-PMTS>].

69 *International Health Regulations*, WORLD HEALTH ORG., https://www.who.int/health-topics/international-health-regulations#tab=tab_1 [<https://perma.cc/H2GN-J4HC>]; see also *Most-Ratified International Treaties*, UN BLOGS (Sept. 24, 2012), <https://blogs.un.org/blog/2012/09/24/most-ratified-international-treaties> [<https://perma.cc/CAQ9-P8A5>].

duties, has been widespread since the first ISR.⁷⁰ This is largely because States appear to be more concerned with short-term economic loss than any other repercussion (including the spread of disease), and that fear has, in turn, led to increased noncompliance with obligations to report to WHO information regarding possible PHEICs within their country.⁷¹ Specifically, States are worried that once information about an outbreak or potential outbreak becomes public, WHO may recommend that other States and the private sector make travel and trade restrictions against them, which could hurt their economy.⁷²

Under Article 43 of the IHR, in the event of a disease outbreak, States may implement “additional health measures,” i.e., travel and trade restrictions, as long as these additional health measures are based on scientific principles and commensurate with WHO guidance.⁷³ Any measures that significantly interfere with international travel or trade must be reported to WHO within forty-eight hours of implementation, along with the State’s rationale for implementing such measures.⁷⁴ Historically, noncompliance with these obligations has been rampant.⁷⁵ For example, after the 1994 plague outbreak in India, unilateral travel and trade restrictions against India resulted in an estimated loss of \$2 billion USD, despite WHO advising against such restrictions.⁷⁶ During the 2009 H1N1 outbreak, twenty States adopted bans on pork imports from the United States, Canada, and Mexico despite WHO, the World Trade Organization (WTO), and other intergovernmental organizations’ advice that pork products did not transmit H1N1.⁷⁷ During the 2014-2016 Ebola outbreak, there were reports of 570 additional health measures by sixty-nine countries contrary to WHO recommendations.⁷⁸ Of these 570 additional measures, forty-one were deemed to have significantly interfered with international traffic.⁷⁹ This resulted in a combined estimated loss of \$2.8 billion to Guinea, Sierra Leone, and Liberia.⁸⁰ In all of these pandemics, a majority of the States implementing additional health measures did not comply with their IHR obligations to report such measures, nor

70 Fidler, *supra* note 45, at 335; Gostin & Katz, *supra* note 37, at 279-80.

71 Gostin & Katz, *supra* note 37, at 279-80.

72 *Id.*

73 IHR, *supra* note 2, art. 43.

74 *Id.*

75 Roojin Habibi et al., *Do Not Violate the International Health Regulations During the COVID-19 Outbreak*, 395 LANCET 664 (2020); Steven Hoffman et al., *The Stellenbosch Consensus on Legal National Responses to Public Health Risks*, INT’L ORG. L. REV. (2020), <https://brill.com/view/journals/iolr/aop/article-10.1163-15723747-2020023/article-10.1163-15723747-2020023.xml?language=en> [<https://perma.cc/4VET-V2VM>].

76 Hoffman et al., *supra* note 75, at 34.

77 *Id.* at 36.

78 *Id.*

79 *Id.*

80 *Id.* at 37; Gostin & Katz, *supra* note 37.

did they comply with the requirement to provide WHO with the scientific rationale for each measure.⁸¹

Because of these very real and very devastating economic repercussions, States are incentivized to delay or withhold reporting until they can get the situation under control and prepare for the economic impact. This incentive to delay or withhold reporting is, in turn, exacerbated by the lack of enforcement by or repercussions from WHO.⁸² In other words, since WHO has no power other than to make recommendations, offer technical and logistical assistance (which is discretionary and can easily be solicited from other sources), and shame violators in press releases, States have little if anything to lose by not complying with *any* of the regulations.⁸³ In addition, the dispute-settlement mechanism remains voluntary.⁸⁴ In fact, as of 2016, WHO reported that the Article 56 dispute-settlement mechanism had never been invoked.⁸⁵ Therefore, it can be inferred that non-compliance is, at least in part, driven by a status quo of States unwilling to hold other States accountable for violations.

D. Legacy and Criticism

In 1979, Louis Henkin asserted that “almost all nations observe almost all principles of international law and almost all of their obligations almost all of the time.”⁸⁶ More than forty years later, global health experts point out that “it appears that most states remain in compliance with the IHR most of the time,”⁸⁷ lamenting that attention is mostly paid to violators rather than to compliers.⁸⁸ But when it comes to such a fundamental part of existence as health, attention *should* be paid to non-compliance because, as we have seen, the provisions that are not complied with are severely consequential to health and well-being. The problem with the IHR, however, is that it is, as it always has been, less about health than about economics and sovereignty. Reporting on the seventh International Sanitary Conference in 1892, the *Lancet* noted that “[s]o many incidental interests are involved in anything relating to the Suez Canal that science can hardly be expected

81 *Id.*

82 Fidler, *supra* note 45, at 390.

83 IHR, *supra* note 2.

84 *Id.* art. 56.

85 WHO, Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, A69/21 (13 May 2016), 37 ¶ 83 [hereinafter WHO Report].

86 LOUIS HENKIN, *HOW NATIONS BEHAVE* 47 (2d ed. 1979) (emphasis omitted).

87 Hoffman et al., *supra* note 75.

88 *Id.*

to find itself paramount in any conclusions that may be arrived at.”⁸⁹ The same can certainly be said about the competitive medical diplomacy surrounding the Panama Canal today.

Overall, the 2005 revisions to the IHR took one step forward and two steps back. One major addition to the 2005 IHR was the requirement that States implement thirteen domestic core capacities for emergency preparedness and response, such as disease surveillance systems, risk communication, and IHR coordination.⁹⁰ As of 2018, annual scorecards show that global progress was made in all thirteen capacities, though significant disparities persist in poor countries with weak health systems.⁹¹ In addition, changing the applicability of the IHR from an exhaustive list of diseases to an all-hazards approach led six disease outbreaks that were previously not actionable to be declared as PHEICs (H1N1, poliovirus, Ebola twice, Zika, and COVID-19).⁹² Declaration of these disease outbreaks as PHEICs led to streamlined approaches for funding and “development of therapeutics, vaccines and/or diagnostics under emergency use authorization.”⁹³

However, the switch to the all-hazards approach has arguably created more harm than good. In making this landmark change, the drafters of the 2005 IHR scrapped the idea of compulsory dispute settlement because it was impossible to codify every potential instance of non-compliance for a non-exhaustive list of health hazards.⁹⁴ They also believed that the nonreporting of PHEICs took care of itself with WHO’s increased surveillance ability in light of technological advancements.⁹⁵ They believed a State’s concern for its reputation would be enough to deter it from violating the IHR.⁹⁶ Unfortunately, this turned out not to be the case. Instead, States are much more concerned with avoiding economic repercussions than anything else, which has led to delayed reporting.⁹⁷ In the case of COVID-19, this problem was not rectified by WHO’s own surveillance since it did not learn of anything going on in China until weeks after the first cluster of patients was identified.⁹⁸ In addition, WHO’s surveillance system is, at its best,

89 Howard-Jones, *supra* note 3, at 63.

90 IHR, *supra* note 2, Annex 1; *IHR Core Capacities*, WORLD HEALTH ORG., <https://www.euro.who.int/en/health-topics/health-emergencies/international-health-regulations/capacity-building/ihr-core-capacities> [<https://perma.cc/7MCE-WEV3>].

91 Director-General, *Public Health Emergencies: Preparedness and Response: Annual Report on the Implementation of the International Health Regulations (2005)*, ¶ 35, World Health Org. Doc. A72/8 (Apr. 4, 2019).

92 Annelies Wilder-Smith & Sarah Osman, *Public Health Emergencies of International Concern: A Historic Overview*, 27 J. TRAVEL MED. 1, 3 (2020).

93 *Id.* at 10.

94 *See supra* notes 53-60 and accompanying text.

95 *See supra* notes 53-60 and accompanying text.

96 *See supra* notes 53-60 and accompanying text.

97 *See supra* pp. 10-11.

98 *See supra* Section II.A.

only as good as the information available. If a State suppresses or censors official and unofficial information at the beginning of an outbreak, as it is alleged China did, then relying on WHO surveillance instead of State reporting is useless. Furthermore, even if WHO does learn of an outbreak through its surveillance system, it is still at the mercy of a State to be forthcoming with information and allow it to come into the country to investigate.

The real legacy of the 2005 IHR is not a system where reputational concern deters noncompliance but rather where noncompliance (delayed reporting) begets noncompliance (travel and trade restrictions) with impunity. This document that was meant to be hard law is instead treated like a soft law instrument where States can pick and choose which aspects they comply with and which they do not. It is clear from State practice that some, such as the United States and China, follow an “act now and apologize later” approach where they continuously violate the IHR when it is advantageous and then employ similarly advantageous damage control diplomacy tactics. The result of this is unchecked competition between the United States and China that has been likened to Cold War geopolitics.⁹⁹ The problem is that in this game, the losers are not the United States or China—they are the poor countries whose health and economic well-being are often at the mercy of and most affected by the actions of wealthier countries.

III. THE UNITED STATES VS. CHINA

The outbreak of COVID-19, which most likely originated in China, came at an interesting time for international law and policy scholars, as the United States’ approach to U.S.-China relations was undergoing one of its most drastic shifts in history.¹⁰⁰ Specifically, the Trump Administration sought to break the historically cooperative approach to U.S.-China relations in pursuit of more aggressive actions.¹⁰¹ Dubbed “America first,” the Trump Administration’s policy was particularly concerned with pushing back on problematic Chinese behavior and advancing U.S. interests in technology, investment, and trade.¹⁰²

The emergence of COVID-19 from China gave the Trump Administration a golden opportunity to criticize China in front of an international audience.¹⁰³ And

⁹⁹ See *infra* Section IV.C.3.

¹⁰⁰ David Dollar, Ryan Hess & Jeffrey A. Bader, *Assessing U.S.-China Relations 2 Years into the Trump Presidency*, BROOKINGS (Jan. 15, 2019), <https://www.brookings.edu/blog/order-from-chaos/2019/01/15/assessing-u-s-china-relations-2-years-into-the-trump-presidency> [<https://perma.cc/7DDV-XARR>].

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ See Scott Neuman, *In U.N. Speech, Trump Blasts China and WHO, Blaming Them For Spread of COVID-19*, NAT’L PUB. RADIO (Sept. 22, 2020),

though many of his speeches were mired in lies, nationalism, and racist overtones, Trump did manage to call attention to the fact that China likely did not comply with the IHR for various reasons.¹⁰⁴ For the first time ever, a State was now attempting to hold another State responsible for potential malfeasance in a pandemic.¹⁰⁵ By spring 2020, lawsuits against the Chinese government began trickling into U.S. courts.¹⁰⁶ These lawsuits included national class actions filed in U.S. district courts, state-specific class actions filed in U.S. state courts, lawsuits filed by states themselves, and lawsuits filed by individuals.¹⁰⁷ While most cases allege China failed to notify WHO of a PHEIC in a timely manner and subsequently withheld information,¹⁰⁸ only some of the lawsuits mention the IHR specifically.¹⁰⁹ Just one lawsuit (which was voluntarily dismissed) included a specific count for “negligence per se for violation of the IHR legally binding mandates.”¹¹⁰

Many of these U.S.-based lawsuits have already been dismissed, and the filing itself has been sharply criticized as political posturing by the Republican party.¹¹¹ One major problem with these suits is that China enjoys sovereign immunity in U.S. courts.¹¹² The irony, however, is that the call for lawsuits against China, heavily led by the party historically against global governance,¹¹³ brought renewed

<https://www.npr.org/sections/coronavirus-live-updates/2020/09/22/915630892/in-u-n-speech-trump-blasts-china-and-who-blaming-them-for-spread-of-covid-19> [<https://perma.cc/564B-3J5K>].

104 *Id.*; see also *China Delayed Releasing Coronavirus Info, Frustrating WHO*, AP NEWS (June 2, 2020), <https://apnews.com/article/united-nations-china-public-health-only-on-ap-virus-outbreak-fed0f89a3b46cfa401e62ce7386f0cfb> [perma.cc/8E3K-RBQ3]; STEPHEN MULLIGAN, CONG. RSCH. SERV., LSB10525, CAN THE UNITED STATES SUE CHINA OVER COVID-19 IN AN INTERNATIONAL COURT? (2020).

105 Sienho Yee, *To Deal with a New Coronavirus Pandemic: Making Sense of the Lack of Any State Practice in Pursuing State Responsibility for Alleged Malfeasances in a Pandemic-Lex Specialis or Lex Generalis at Work?*, 19 CHINESE J. INT’L L. 237 (2020).

106 Sean Mirski & Shira Anderson, *What’s in the Many Coronavirus-Related Lawsuits Against China?*, LAWFARE (June 24, 2020), <https://www.lawfareblog.com/whats-many-coronavirus-related-lawsuits-against-china> [<https://perma.cc/Z9XS-RSQQ>].

107 *Id.*

108 See, e.g., *Patella v. People’s Republic of China*, No. 1:20-cv-433 (M.D.N.C. May 15, 2020); *Missouri v. People’s Republic of China*, No. 1:20-cv-99, (E.D. Mo. Apr. 21, 2020); *Mississippi v. People’s Republic of China*, No. 1:20-cv0168 (S.D. Miss. May 12, 2020).

109 See, e.g., *Patella v. People’s Republic of China*, No. 1:20-cv-433 (M.D.N.C. May 15, 2020).

110 Amended Complaint Count IV, *Bella Vista LLC v. People’s Republic of China*, No. 2:20-cv-574 (D. Nev. June 5, 2020).

111 Jan Wolfe, *In a First, Missouri Sues China over Coronavirus Economic Losses*, REUTERS (Apr. 21, 2020), <https://www.reuters.com/article/us-health-coronavirus-china-lawsuit/in-a-first-missouri-sues-china-over-coronavirus-economic-losses-idUSKCN2232US> [<https://perma.cc/LYM4-YVMS>].

112 *Id.*

113 Colin Dueck, *Republican Party Foreign Policy: 2016 and Beyond*, FOREIGN POL’Y RSCH. INST. (July 22, 2016), <https://www.fpri.org/article/2016/07/republican-party-foreign-policy-2016-beyond> [<https://perma.cc/83YJ-PCW5>].

attention to the formal Article 56 dispute-settlement mechanisms of the IHR. Subsequently, Congressmembers, international law scholars, and practitioners alike began discussing whether there *are* viable legal options to hold China accountable for its IHR violations.¹¹⁴ While many inquiries focus solely on U.S.-based lawsuits, others have considered the international-based dispute settlement possibilities that are actually envisioned by Article 56.¹¹⁵ What would an Article 56 adjudication look like? What are plausible theories of liability? Where can the case be adjudicated? Could China *actually* be made to pay? The following section will attempt to answer these questions by walking through a hypothetical case against China by the United States.¹¹⁶ This, in turn, will help evaluate whether an Article 56 adjudication could be used in the future as an effective IHR compliance tool.

The calls for legal accountability for China's handling of COVID-19 have stirred renewed discussion about the Article 56 dispute-settlement mechanisms of the IHR as a compliance tool. But because Article 56 has never been invoked, there is no precedent for how a dispute may unfold. As such, there are several considerations involved in a State bringing an international adjudication that need to be contemplated, and each poses difficulties for the complainant. This is because an international adjudication is not just a function of pure law but of geopolitical considerations weighed by States. The first consideration is having a valid reason to sue or a theory of legal liability. In the case against China for its handling of COVID-19, this is the easiest hurdle to pass as a good argument can be made that China did not comply with its reporting duties and was not forthcoming with necessary information. From there, however, the likelihood of seeing an adjudication through to the end diminishes. The second consideration is to find a proper venue that will accept jurisdiction over the claim and the defendant (and, as will be discussed, that the defendant will accept the jurisdiction of). Here, China may easily refuse to show up to court. The next consideration is what type of remedy would achieve the goal of the lawsuit, which in this case would be to hold China fiscally accountable for potential IHR violations and ensure future compliance. However, these types of remedies are rarely awarded. Lastly, should an award be made in the complaining party's favor, the award would either need to be voluntarily complied with or enforced, neither of which is likely. The following section will address each of these considerations in more detail, starting with liability.

114 Yee, *supra* note 105, at 238.

115 MULLIGAN, *supra* note 104.

116 It is important to note that the United States's official understanding is that the IHR does not create privately enforceable judicial rights. IHR, *supra* note 2, Appendix 2.

A. *Theory of Liability*

The prevailing theory of liability is that China violated Articles 6 and 7 of the IHR in its handling of COVID-19.¹¹⁷ Articles 6 and 7 prescribe the notification and information-sharing procedures when a State suspects an event within its territory that may lead to a PHEIC.¹¹⁸ Under Article 6, a State is responsible for assessing when an event is notifiable using a decision instrument (Annex 2).¹¹⁹ In general, the decision-making criteria are broad and suggest that States should be over-inclusive in their reporting. Should an event be deemed notifiable under Annex 2 criteria, the State must then notify WHO within twenty-four hours.¹²⁰ Following notification, the State must continue to keep WHO apprised by continuing

to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential [PHEIC].¹²¹

Similarly, Article 7 requires States to notify WHO of “all relevant public health information” if the State has “evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a [PHEIC].”¹²² In the event a State is in possession of such evidence, the provisions of Article 6, including reporting within twenty-four hours, apply.¹²³

1. *Failure to Notify*

The timeline of what China knew about COVID-19 and when they knew it is complicated and, for some events, remains unclear.¹²⁴ This makes it difficult to determine the exact date China’s Article 6 or 7 notification duties would be triggered, but based on public information, a window can be determined. A conservative date to trigger Article 6 and 7 duties would be in the time range between December 27–31, 2019. On December 24, 2019, after clusters of patients

¹¹⁷ See, e.g., MULLIGAN, *supra* note 104.

¹¹⁸ IHR, *supra* note 2, arts. 6–7.

¹¹⁹ *Id.* art. 6(1), Annex 2.

¹²⁰ *Id.* art. 6(1).

¹²¹ *Id.* art. 6(2).

¹²² *Id.* art. 7.

¹²³ *Id.*

¹²⁴ SUSAN V. LAWRENCE, CONG. RSCH. SERV., R46354, COVID-19 AND CHINA: A CHRONOLOGY OF EVENTS (DECEMBER 2019–JANUARY 2020), at 13 (2020).

with pneumonia-like symptoms were identified in Wuhan, China, Wuhan Central Hospital sent a genomics company, Vision Medicals, a fluid sample from an ill patient.¹²⁵ Three days later, Vision Medicals reported back to the hospital that the sample was “a new coronavirus.”¹²⁶ That same day, Wuhan Central Hospital sent a sample from another patient with pneumonia-like symptoms to a different laboratory, CapitalBio Medlab.¹²⁷ On December 30, 2019, CapitalBio reported that the sample tested positive for Severe Acute Respiratory Disease (SARS).¹²⁸ By then, Wuhan-based doctors had already confirmed seven other local cases of SARS (which would later be re-classified as COVID-19), and the Wuhan Municipal Health Commission was made aware of these cases.¹²⁹ Annex 2 does not specifically name coronaviruses in its list of reportable diseases, but the fact that other clusters of patients were already hospitalized for similar unknown illnesses may have fallen under Annex 2’s catch-all category and triggered Article 7 duties on December 27. In addition, SARS is an immediately reportable disease under Annex 2, so it can also be argued that China’s Article 6 and 7 duties were triggered when the Wuhan Municipal Health Commission was made aware of confirmed SARS cases on December 30, 2019.¹³⁰

For its part, the Wuhan Municipal Health Commission reported these cases to China’s National Health Commission and the China CDC in Beijing within twenty-four hours.¹³¹ This is important because, under the IHR, China designated its National Health Commission as the National Focal Point in charge of communicating with WHO.¹³² Thus, it may also be argued that China’s Article 6 and 7 duties were triggered on December 31, 2019. For the sake of an actual

¹²⁵ *Id.*

¹²⁶ *Id.* at 15.

¹²⁷ *Id.*

¹²⁸ *Id.* at 16.

¹²⁹ *Id.* at 15-16.

¹³⁰ Under the IHR, China designated its “local health administrative authorities [as] the health authorities responsible for the implementation of the IHR in their respective jurisdictions.” The Wuhan Municipal Health Commission would fall under this category and thus be responsible for IHR duties. IHR, *supra* note 2, at 62, Annex 2.

¹³¹ LAWRENCE, *supra* note 124, at 17.

¹³² China’s declaration in the 2005 IHR names the Ministry of Health as its National Focal Point. In 2013, the Ministry of Health was merged into the National Health and Family Planning Commission, and in 2018 was reorganized into the National Health Commission. IHR, *supra* note 2, at 62, art. 4; Deng Shasha, *China to Merge Health Ministry, Family Planning Commission*, XINHUANET (Mar. 10, 2013), https://web.archive.org/web/20130313112946/http://news.xinhuanet.com/english/china/2013-03/10/c_132221724.htm [perma.cc/NM5K-SPLX]; Hai Fang, *China*, COMMONWEALTH FUND (June 5, 2020), <https://www.commonwealthfund.org/international-health-policy-center/countries/china> [https://perma.cc/RSY5-PK47].

adjudication, however, the difference between December 27 and December 31 is moot. The Chinese National Health Commission (or any other Chinese entity) did not alert WHO of any information it had within twenty-four hours of December 31.¹³³

2. Failure to Share Information

Another theory of liability stems from China's unwillingness to share information with WHO at the beginning of 2020. On December 31, 2019, WHO learned of the outbreak in Wuhan, China—but not from Chinese health authorities.¹³⁴ Instead, WHO picked up a post on a U.S. listserv, ProMED, which contained a translation of two “urgent notices” sent by the Wuhan Municipal Health Commission to local medical institutions “instructing them on how to manage patients with pneumonia of unknown cause and ordering them to track such cases and report them in a timely fashion to district CDCs and the Wuhan Municipal Health Commission.”¹³⁵ WHO was also notified directly of the situation in Wuhan by Taiwan's CDC, which asked WHO to share any relevant information it may have.¹³⁶

Learning this information on December 31, 2019 triggered IHR duties for WHO itself.¹³⁷ Under Article 9, WHO may take into consideration and assess evidence of PHEICs from sources other than Article 6 and 7 notifications.¹³⁸ After receiving this information, WHO may request verification from the State about which such reports are made pursuant to Article 10.¹³⁹ The requestee State must

133 LAWRENCE, *supra* note 124, at 19.

134 *Id.* at 18-19.

135 *Id.* at 16-18.

136 *Id.* at 18 (“Taiwan’s Centers for Disease Control sends an email to WHO. It reads, ‘News resources today indicate that at least seven atypical pneumonia cases were reported in Wuhan, CHINA. Their health authorities replied to the media that the cases were believed not SARS; however the samples are still under examination, and cases have been isolated for treatment. I would greatly appreciate if you have relevant information to share with us.’ Taiwan’s Central Epidemic Command Center later notes, ‘To be prudent, in the email we took pains to refer to atypical pneumonia, and specifically noted that patients had been isolated for treatment. Public health professionals could discern from this wording that there was a real possibility of human-to-human transmission of the disease.’”) (citations omitted).

137 *Id.* at 19.

138 As an aside, some Republican leaders believe WHO violated its duties under Articles 9-11 to share information with other State parties once it received information from ProMED and Taiwan. However, the legal considerations to hold WHO accountable are different than holding China accountable and are therefore outside the scope of this paper. IHR, *supra* note 2, arts. 9-11; Kevin McCarthy, *Holding China Accountable: A Republican Call to Action & Roadmap for Covid-19 Accountability*, REPUBLICAN LEADER (June 21, 2021), <https://www.republicanleader.gov/holding-china-accountable> [<https://perma.cc/4XX8-4DM9>].

139 IHR, *supra* note 2, art. 10.

respond to WHO's Article 10 request within twenty-four hours.¹⁴⁰ WHO sent their Article 10 request to the Chinese government on January 1, 2020.¹⁴¹ China, however, did not respond to WHO's request until January 3, 2020, thereby violating Article 10.¹⁴²

China not only failed to respond to WHO's Article 10 request within twenty-four hours, but whistleblowers have accused Chinese authorities of suppressing information and destroying evidence in the early stages of the outbreak.¹⁴³ Perhaps one of the most famous whistleblowers was Dr. Li Wenliang, an ophthalmologist at Wuhan Central Hospital, who, on December 30, 2019, posted on social media about "7 confirmed SARS cases from the Huanan Fruit and Seafood Market."¹⁴⁴ On January 3, 2020, Dr. Li was detained by Wuhan's Public Security Bureau and made to sign a letter of admonition saying that statements he made on social media were false.¹⁴⁵ He was also ordered to stop talking or face legal consequences.¹⁴⁶ Government-run agencies such as the Wuhan Municipal Public Security Bureau, Wuhan Municipal Health Commission, and Chinese Central Television subsequently made public statements claiming reports by whistleblowers such as Dr. Li were "inaccurate" "rumors" spread by "lawbreakers."¹⁴⁷ The agencies also made public statements that there was no evidence of human-to-human transmission or cases among health workers, both of which were later proven to be untrue at the time they were made.¹⁴⁸ This failure to share information in a timely manner, especially after specifically requested, further violates Articles 6 and 7.¹⁴⁹

140 *Id.* art. 10(2).

141 LAWRENCE, *supra* note 124, at 19.

142 *Listing of WHO's Response to COVID-19*, WORLD HEALTH ORG. (June 29, 2020), <https://www.who.int/news/item/29-06-2020-covidtimeline> [<https://perma.cc/Z5GK-VDYX>].

143 LAWRENCE, *supra* note 124, at 19, 21 (citing Gao Yu et al., *In Depth: How Early Signs of a SARS-Like Virus Were Spotted, Spread, and Throttled*, CAIXIN GLOBAL (Feb. 29, 2020), <https://caixinglobal.com/2020-02-29/in-depth-how-early-signs-of-a-sars-like-virus-were-spotted-spread-and-throttled-101521745.html> [<https://perma.cc/BL7K-JZ4P>]) ("The Hubei Provincial Health Commission reportedly orders genomics companies to stop testing samples from Wuhan and to destroy existing samples. . . . China's National Health Commission issues a directive on management of biological samples in major infectious disease outbreaks. The directive reportedly 'ordered institutions not to publish any information related to the unknown disease, and ordered labs to transfer any samples they had to designated testing institutions, or to destroy them.'"); AP NEWS, *supra* note 104 ("China in fact sat on releasing the genetic map, or genome, of the virus for more than a week after three different government labs had fully decoded the information.").

144 LAWRENCE, *supra* note 124, at 16.

145 *Id.* at 20; Andrew Green, *Li Wenliang*, 395 LANCET P682 (2020).

146 Green, *supra* note 145, at P682.

147 LAWRENCE, *supra* note 124, at 19.

148 *Id.* at 24-28.

149 MULLIGAN, *supra* note 104, at 2-3.

Finally, it has also been argued that this withholding of information violates Articles 63 and 64 of the WHO Constitution.¹⁵⁰ Article 63 states that “[e]ach Member [of WHO] shall communicate promptly to [WHO] important laws, regulations, official reports, and statistics pertaining to health which have been published in the state concerned.”¹⁵¹ Article 64 states that “[e]ach Member [of WHO] shall provide statistical and epidemiological reports in a manner to be determined by the Health Assembly [WHA].”¹⁵² Since the WHA promulgated the IHR as a manner to share statistical and epidemiological information about PHEICs, it can be argued that a violation of Articles 6 and 7 of the IHR is linked to a violation of Article 64 of the WHO Constitution.¹⁵³ In the same vein, Article 22 of the WHO Constitution enforces upon all members any regulations promulgated by the WHA, such as the IHR.¹⁵⁴

3. Liability Defenses

China denies any wrongdoing in its handling of COVID-19, calling the suggestion that it delayed information sharing “totally untrue.”¹⁵⁵ In addition, in a July 6, 2020, press conference, Chinese foreign ministry spokesperson Zhao Lijian seemed to assert that China satisfied its Article 6 reporting duties on December 31, 2019, when the Wuhan Municipal Health Commission posted on its website about its investigation into twenty-seven cases of pneumonia.¹⁵⁶ However, this defense is very clearly at odds with the text of Article 6, which specifies that WHO must be informed “by way of the National IHR Focal Point.”¹⁵⁷ Furthermore, raising this defense in an adjudication would inherently concede that WHO *should* have been notified by December 31, 2019, instead of the official notification date of January 3, 2020.

Instead, a more legitimate defense for China may be to dispute the timeline and argue that its reporting duties were not triggered until the Chinese CDC (as

150 *Id.*

151 WHO Constitution, *supra* note 33, art. 63.

152 *Id.* art. 64.

153 MULLIGAN, *supra* note 104, at 2-3.

154 WHO Constitution, *supra* note 33, art. 21-22.

155 Cate Cadell, *China Rejects Report that it Delayed COVID-19 Information Sharing with WHO*, REUTERS (June 3, 2020, 3:48 AM), <https://www.reuters.com/article/us-health-coronavirus-china-who/china-rejects-report-that-it-delayed-covid-19-information-sharing-with-who-idUSKBN23A0YM> [<https://perma.cc/YNE4-ZJ3N>].

156 See *Foreign Ministry Spokesperson Zhao Lijian's Regular Press Conference on July 6, 2020*, MINISTRY OF FOREIGN AFFS. CHINA (July 6, 2020), <https://www.mfa.gov.cn/ce/ceus/eng/fyrth/t1795337.htm> [<https://perma.cc/VY68-9MXC>]; *Timeline of China Releasing Information on COVID-19 and Advancing International Cooperation*, NAT'L HEALTH COMM'N PEOPLE'S REPUBLIC OF CHINA (Apr. 6, 2020), http://en.nhc.gov.cn/2020-04/06/c_78861_2.htm [<https://perma.cc/2R94-4BBY>].

157 IHR, *supra* note 2, art. 6.

opposed to a private lab) completed the genome sequence for COVID-19. This, in turn, would give China room to argue why, under Annex 2, it did not believe it needed to report to WHO until the genome was fully sequenced. After all, the initial lab results concluding that COVID-19 was a SARS virus and not a novel coronavirus turned out to be incorrect.¹⁵⁸ And while there are conflicting reports on whether the Chinese CDC had sequenced the virus on January 3 or January 7, that factual dispute would not need to be resolved as China did report to WHO by January 4.¹⁵⁹ The question for the adjudicators to decide then would be whether it mattered that the initial reports that concluded the outbreak was caused by SARS, and thus immediately reportable, were ultimately incorrect and not yet verified by a government lab.

Unfortunately for China, even if this defense—which is likely its best¹⁶⁰—was viable, it still does not address nor absolve liability for continuing to withhold and suppress information once WHO was involved.¹⁶¹ Thus, there is a strong incentive for China to avoid litigating these claims. Consequently, this brings up the question of jurisdiction—is there a dispute settlement body that *could* make China litigate?

B. Jurisdiction and Venue

As discussed, the IHR does not have a compulsory dispute-settlement

158 Zaheer Allam, *The First 50 Days of COVID-19: A Detailed Chronological Timeline and Extensive Review of Literature Documenting the Pandemic*, ELSEVIER PUB. HEALTH EMERGENCY COLLECTION (July 24, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7378494> [<https://perma.cc/DQ9H-RF88>].

159 Compare AP NEWS, *supra* note 104, and LAWRENCE, *supra* note 124, at 21, with Chen Wang, Peter W Horby, Frederick G Hayden & George F Gao, *A Novel Coronavirus Outbreak of Global Health Concern*, 395 LANCET P470 (2020), and *Novel Coronavirus (2019-nCov) Situation Report*, WORLD HEALTH ORG. (Jan. 21, 2020), <https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf> [<https://perma.cc/9NN9-VK5L>].

160 China could also argue that the December 31, 2019 notification to WHO by Taiwan counted as its own notification because of China's assertion that Taiwan is a part of China. However, Taiwan's status internationally is still ambiguous and China would likely not want an international tribunal to rule on territory claims after recently being dealt a blow by the Permanent Court of Arbitration regarding its maritime claims in the South China Sea, so it would not subject itself to that consideration by raising that defense. See Robert D. Williams, *Tribunal Issues Landmark Ruling in South China Sea Arbitration*, LAWFARE (July 12, 2016, 11:28 AM), <https://www.lawfareblog.com/tribunal-issues-landmark-ruling-south-china-sea-arbitration> [<https://perma.cc/TNW8-Z4VW>].

161 Emily Feng, *Critics Say China has Suppressed and Censored Information in Coronavirus Outbreak*, NAT'L PUB. RADIO (Feb. 8, 2020, 9:00 AM), <https://www.npr.org/sections/goatsandsoda/2020/02/08/803766743/critics-say-china-has-suppressed-and-censored-information-in-coronavirus-outbreak> [<https://perma.cc/3Q33-RJQV>].

mechanism.¹⁶² Instead, the current iteration contains four provisions for disputing States, though the voluntary nature of all four provisions function more like suggestions than prescriptions.¹⁶³ First, the IHR implores disputing States to settle their dispute through “negotiation or any other peaceful means of their own choice.”¹⁶⁴ This may involve informal negotiations or a formal request for a consultation by a State impacted by another State’s health measures, such as travel restrictions.¹⁶⁵ If negotiation fails, States may refer the dispute to the WHO Director General, “who shall make every effort to settle it.”¹⁶⁶ Alternatively, States may opt in to arbitration at the Permanent Court of Arbitration (PCA).¹⁶⁷ Lastly, the IHR include a provision that states, “[n]othing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.”¹⁶⁸

Assuming negotiation fails, the United States could either refer the dispute to the Director-General, attempt to arbitrate, or find another international agreement to establish jurisdiction under. Referral to the Director-General, however, would likely not satisfy those hoping for true legal recourse. First of all, it is unclear what exact authority “every effort to settle” a dispute confers on the Director-General.¹⁶⁹ Neither the IHR nor the WHO Constitution answers this question.¹⁷⁰ In addition, no State has ever even tried to refer a dispute to the Director-General, so there is no guidance by way of precedent.¹⁷¹ But considering that WHO itself has no enforcement mechanism, it would not make much sense to assume the Director-General has the power to enforce dispute resolutions single-handedly. Furthermore, what States are involved in the dispute, and what State the Director-General is a citizen of, may influence a State’s decision to go to or accept the Director-General as a conciliator due to perceived geopolitical biases. Instead, States seeking an enforceable resolution would have better luck in arbitration or another judicial body.

162 World Health Organization Regulations, *supra* note 36, art. 112(1); International Health Regulations, art. 93, Jan. 1, 1982, 1286 U.N.T.S. 390 [hereinafter, IHR 1982]; IHR, *supra* note 2, art. 56.

163 IHR, *supra* note 2, art. 56(1)-(4).

164 *Id.* art. 56(1).

165 *Id.* art. 43(7).

166 *Id.* art. 56(2).

167 *Id.* art. 56(3).

168 *Id.* art. 56(4).

169 *Id.* art. 56(2).

170 *Id.*; WHO Constitution, *supra* note 33.

171 WHO Report, *supra* note 85, at 81.

1. Arbitration

The IHR expressly gives the PCA jurisdiction to settle disputes between two States.¹⁷² Arbitration under this provision would be governed by the PCA's Optional Rules for Arbitrating Disputes between Two States.¹⁷³ To exercise this option, States must declare in writing to the Director-General that they accept compulsory arbitration either regarding *all* disputes that may arise out of the IHR, or for a specific dispute in which case the disputed State must also affirmatively accept compulsory arbitration.¹⁷⁴ To this day, there is no record that any State has accepted compulsory arbitration regarding any or all disputes.¹⁷⁵

It is unlikely that China would accept compulsory arbitration in the PCA. This is mainly because China is only recently beginning to engage in international dispute-settlement mechanisms.¹⁷⁶ When it does engage, it stays clear of arbitrating issues involving sovereignty; most cases involve commercial and trade disputes, and these cases mainly take place in the WTO's dispute-settlement body.¹⁷⁷ In fact, the public record shows that the government of China has only been a party to a PCA arbitration three times.¹⁷⁸ These three cases—*Radio Corporation of America*, *Jason Yu Song*, and *South China Sea*—highlight China's differing attitudes toward cases about commerce and trade and cases about sovereignty.¹⁷⁹ China accepted PCA jurisdiction in *Radio Corporation*—a contract dispute¹⁸⁰—and in *Yu Song*, an

172 IHR, *supra* note 2, art. 56(3).

173 In addition, in its understandings of the IHR, “the Government of the United States of America does not believe that the IHR was intended to create judicially enforceable private rights: The United States understands that the provisions of the Regulations do not create judicially enforceable private rights.” *Id.* art. 53(3), Appendix 2.

174 *Id.*

175 Yee, *supra* note 105.

176 See Harriet Moynihan, *China's Evolving Approach to International Dispute Settlement*, CHATHAM HOUSE (Mar. 2017), <https://www.chathamhouse.org/sites/default/files/publications/research/2017-03-29-chinas-evolving-approach-international-dispute-settlement-moynihan-final.pdf> [<https://perma.cc/8BJR-Q7L6>].

177 *Id.*

178 Information about cases in the Permanent Court of Arbitration (PCA) are based on agreements by the parties to release case information publicly. Thus, there may be additional cases involving the Chinese government that are not of public record. *Cases*, PERMANENT CT. ARB., <https://pca-cpa.org/en/cases/> [<https://perma.cc/2EHC-J34Z>] (last visited July 29, 2021).

179 *Radio Corporation of America v. China*, PERMANENT CT. ARB., <https://pca-cpa.org/en/cases/16> [<https://perma.cc/CBG4-WL29>]; *Yu Song (United Kingdom) v. People's Republic of China*, PERMANENT CT. ARB., <https://pca-cpa.org/en/cases/241> [<https://perma.cc/LHU7-ZPKA>]; *The South China Sea Arbitration*, PERMANENT CT. ARB., <https://pca-cpa.org/en/cases/7> [<https://perma.cc/RUM5-LNVP>].

180 Charter of the United Nations and Statute of the International Court of Justice, Oct. 15, 1946 U.N.T.S. No. 993, at Endnote 1 [hereinafter Statute of the ICJ] (“In a communication received

investment dispute.¹⁸¹ On the other hand, China vehemently opposed PCA jurisdiction in *South China Sea*, believing the claims brought against it by the Philippines were for territorial sovereignty.¹⁸² The case proceeded in the PCA without China's participation pursuant to a provision in the relevant treaty that expressly allows the PCA to do so.¹⁸³ There is no such provision in the IHR. The PCA found for the Philippines and China subsequently ignored the award.¹⁸⁴

In explaining why China is more likely to engage in international dispute-settlement for trade disputes than issues of sovereignty, observers have noted that China believes "trade issues are not that sensitive; you may gain or lose it's a balance [sic]. If you lose on territory, you do not gain something."¹⁸⁵ In other words, China has more to gain in the long run from cooperating in global trade and investment mechanisms by way of reciprocity.¹⁸⁶ The status quo ebbs and flows—in fact, "China has revised over 3,000 laws at central government level, and many more at [the] local level, in order to bring its legal system into compliance with WTO standards."¹⁸⁷

On the other hand, China has more to lose than to gain by defending itself against failure to notify and share information claims under the IHR. The interests at issue here for China are the integrity of its governmental and economic institutions.¹⁸⁸ China steadfastly maintains the narrative that it handled the pandemic exceedingly well.¹⁸⁹ Arbitrating claims for noncompliance would take a

by the Secretary-General on 5 December 1972, the Government of the People's Republic of China indicated that it does not recognize the statement made by the defunct Chinese government on 26 October 1946 in accordance with paragraph 2 of Article 36 of the Statute of the International Court of Justice concerning the acceptance of the compulsory jurisdiction of the Court."); Moynihan, *supra* note 176, at 3 ("In most cases, when China enters into a treaty, it will opt out of any provisions referring disputes under the treaty to international courts or tribunals."); *Radio Corporation*, *supra* note 179.

181 Yu Song, *supra* note 179.

182 Moynihan, *supra* note 176; *The South China Sea Arbitration*, *supra* note 179; The South China Sea Arbitration, Case No. 2013-19, Award on Jurisdiction and Admissibility (Perm. Ct. Arb. 2013).

183 The South China Sea Arbitration, Case No. 2013-19, Award on Jurisdiction and Admissibility (Perm. Ct. Arb. 2013), ¶¶ 11-12.

184 Nguyen Hong Thao & Nguyen Thi Lan Huong, *The South China Sea Arbitration Award: 5 Years and Beyond*, THE DIPLOMAT (July 12, 2021), <https://thediplomat.com/2021/07/the-south-china-sea-arbitration-award-5-years-and-beyond> [https://perma.cc/ZN4F-GKKP].

185 Moynihan, *supra* note 176.

186 *Id.*

187 *Id.*

188 Yanzhong Huang et al., *China's Approach to Global Governance*, COUNCIL ON FOREIGN RELS., <https://www.cfr.org/china-global-governance> [https://perma.cc/DS43-GGS8].

189 David Stanway, *China Doubles Down on COVID Narrative as WHO Investigation Looms*, REUTERS (Jan. 5, 2021, 1:02 AM), <https://www.reuters.com/article/health-coronavirus-china-who-int/china-doubles-down-on-covid-narrative-as-who-investigation-looms-idUSKBN29A0LX> [https://perma.cc/MY4Y-YRXN]; *China Covid-19: How State Media and Censorship Took On*

huge gamble with this narrative. If China does not arbitrate, it will not have to relinquish any control over its narrative, and it can easily defend criticism of non-cooperation by saying it is still open to settling through diplomacy. Thus, the factors weigh against China accepting compulsory arbitration.

2. *International Court of Justice*

Since the IHR does not impair a State's right to pursue dispute settlement under other international agreements or with other international bodies, some scholars have considered pursuing jurisdiction in the International Court of Justice (ICJ).¹⁹⁰ Under Article 75 of the WHO Constitution, "[a]ny question of 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 [ICJ] in conformity with the Statute of the Court."¹⁹¹ Whether a dispute concerns the interpretation or application of an instrument can be complicated. The ICJ defines such a dispute as one where the States:

'Hold clearly opposite views concerning the question of the performance or non-performance of certain' international obligations [citations omitted]. The claim of one party must be 'positively opposed' by the other [citations omitted]. In order to determine, even prima facie, whether a dispute exists, the Court 'cannot limit itself to noting that one of the Parties maintains that the Convention applies, while the other denies it' [citations omitted] [T]he Court must ascertain whether 'the acts complained of by [the Applicant] are prima facie capable of falling within the provisions of [those] instruments[s] and . . . as a consequence, the dispute is one which the Court has jurisdiction *ratione materie* to entertain [citations omitted].'¹⁹²

The ICJ has only considered Article 75 jurisdiction in a contentious case one time. In *Armed Activities on the Territory of the Congo*, the Democratic Republic of the Congo (DRC) tried to establish Article 75 jurisdiction in the ICJ because it alleged Rwanda's aggression in Congolese territory harmed the health of its

Coronavirus, BBC NEWS (Dec. 29, 2020), <https://www.bbc.com/news/world-asia-china-55355401> [<https://perma.cc/LP55-EN2C>] [hereinafter *China Covid-19*].

190 MULLIGAN, *supra* note 104, at 2-3.

191 WHO Constitution, *supra* note 33, art. 75.

192 Application of the International Convention for the Suppression of the Financing of Terrorism and of the International Convention on the Elimination of All Forms of Racial Discrimination (Ukr. v. Russ.), Order, 2017 I.C.J. Rep. 104, ¶ 22 (Apr. 19).

citizens.¹⁹³ Siding with Rwanda, the ICJ denied Article 75 jurisdiction because the DRC did not specify which WHO Constitution obligation Rwanda violated, noting that a Member State's failure to carry out the general object and purpose of WHO was not "a question concerning the interpretation or application of the WHO Constitution on which [the DRC] and Rwanda had opposing views, or that [the DRC] had a dispute with [Rwanda] in regard to this matter."¹⁹⁴

As discussed in the previous section on liability, WHO Constitution violations by China may be established through two theories: directly via Article 63 or indirectly via Articles 22 and 64's application to the IHR. Whether the ICJ would think either sufficiently concerns the interpretation and application of the WHO Constitution is unknown, but the prospect is more likely than in *Armed Territories*, especially concerning the direct violation of Article 63. Unlike the general claims of bad faith in *Armed Territories*, Articles 63 and 64 prescribe affirmative obligations on the Member Parties, and Article 22 binds Member Parties to the prescriptions in the IHR.¹⁹⁵

Whether or not the ICJ would accept jurisdiction over an IHR case is only one piece of the puzzle; China may also refute jurisdiction. The modern Chinese government has never been a party to a case in the ICJ.¹⁹⁶ In fact, the only involvement China has ever had with the ICJ was in 2009, when it submitted a statement on its position regarding the legality of Kosovo's declaration of independence.¹⁹⁷ And while ICJ jurisdiction in cases arising out of the WHO Constitution is compulsory upon China because of its WHO membership, China otherwise does not recognize compulsory jurisdiction of the ICJ.¹⁹⁸ Therefore, what China may do in response to a unilateral application against it is unprecedented. Given China's preference for diplomacy when settling disputes and general disdain for unilateral measures, it would likely have a negative reaction to being served in the ICJ, nor would it likely voluntarily accept jurisdiction for

193 Case Concerning Armed Activities on the Territory of the Congo (Dem. Rep. Congo v. Rwanda), Judgment, 2006 I.C.J. Rep. 6, ¶ 97 (Feb. 3) ("The DRC alleges that Rwanda, in resorting to the spreading of AIDS as an instrument of war and in engaging in large-scale killings on Congolese territory, has not 'in good faith carried out the Constitution of the WHO, which aims at fostering the highest possible level of health for all peoples of the world'; the DRC further claims to have made an ample showing that a number of international organizations, both governmental and other, 'have published detailed reports on the serious deterioration of the health situation in the DRC as a consequence of the war of aggression' waged by Rwanda.").

194 *Id.* ¶ 99.

195 WHO Constitution, *supra* note 33, art. 63-4.

196 Moynihan, *supra* note 176.

197 Accordance with International Law of the Unilateral Declaration of Independence in Respect of Kosovo, Written Statement by the People's Republic of China, 2009 I.C.J. II-III (Apr. 6) (invoking principles of sovereignty and limitations of self-determination, China, unsurprisingly, opposed Kosovo's "secession" from Yugoslavia).

198 WHO Constitution, *supra* note 33, app. 1; Statute of the ICJ, *supra* note 180.

reasons stated earlier.¹⁹⁹ It is quite possible that China may simply refuse to show up to court. However, as the PCA did in *South China Sea*, the ICJ can continue proceedings without the respondent party.²⁰⁰

The prospect of China willingly accepting jurisdiction and participating in adjudication is uncertain at best. Balancing the factors that China may consider when engaging in international dispute settlement mechanisms, it is unlikely that China would voluntarily accept the jurisdiction of the PCA or the ICJ when it does not have to. But what if it did? Assuming for the sake of the hypothetical that China *did* accept jurisdiction, the next step is to consider what remedy would be appropriate for the United States to ask for and conceivably be awarded.

C. Remedies

1. Legal Basis for Remedies

In 2001 the International Law Commission of the UN adopted Articles on the Responsibility of States for Internationally Wrongful Acts (ILC Articles).²⁰¹ The ILC Articles serve as a codification of previously relied-on principles of international law and have subsequently served as the theoretical basis for decisions of arbitral tribunals and the ICJ.²⁰² Chapter II lays out principles for remedies that are considered when making a judgment or award in favor of the complaining State.²⁰³ Forms of remedies fall into three categories: restitution,

199 See *supra* text accompanying notes 172-188; see also Moynihan, *supra* note 176; *The Declaration of the Russian Federation and the People's Republic of China on the Promotion of International Law*, MFA RUSSIA (June 25, 2016, 17:07), https://www.mid.ru/en/foreign_policy/position_word_order/1530748 [hereinafter *Declaration of Russia & China*]; *The Costs of International Advocacy*, HUMAN RTS. WATCH (Sept. 5, 2017), <https://www.hrw.org/report/2017/09/05/costs-international-advocacy/chinas-interference-united-nations-human-rights#> [https://perma.cc/Z329-GVSM]; *China Calls for Avoiding Unilateral Moves over Kashmir*, CGTN (Aug. 10, 2019), <https://news.cgtn.com/news/2019-08-09/China-calls-for-avoiding-unilateral-moves-over-Kashmir-J1BVPLxrq0/index.html> [https://perma.cc/YE5Y-RHYZ].

200 *How the Court Works*, INT'L CT. JUST., <https://www.icj-cij.org/en/how-the-court-works> [https://perma.cc/2MB7-GX6Q].

201 International Law Commission, *Draft Articles on Responsibility of States for Internationally Wrongful Acts*, November 2001, Supplement No. 10 (A/56/10), chp.IV.E.1, <https://www.refworld.org/docid/3ddb8f804.html> [https://perma.cc/6PH2-BLBZ] [hereinafter *ILC Articles*].

202 SIMON OLLESON, *THE IMPACT OF THE ILC'S ARTICLES ON RESPONSIBILITY OF STATES FOR INTERNATIONALLY WRONGFUL ACTS* 19 (Oct. 10, 2007), https://www.biiel.org/files/3107_impactofthearticlesonstate_responsibilitypreliminarydraftfinal.pdf [https://perma.cc/5RFV-HMW6].

203 *Id.* at 212.

compensation, or satisfaction (or a combination of the three).²⁰⁴ Restitution should be looked to first before compensation and satisfaction, though satisfaction is frequently awarded.²⁰⁵ It should also be noted that there is no precedent for damages in infectious disease cases in international law.²⁰⁶ In addition, neither the IHR nor the WHO Constitution specifically addresses remedies; however, the ICJ has maintained that “[i]t is a principle of international law that the breach of an engagement involves an obligation to make reparation in an adequate form. Reparation therefore is the indispensable complement of a failure to apply a convention, and there is no necessity for this to be stated in the convention itself.”²⁰⁷

2. Restitution

Under Article 35 of the ILC Articles, restitution is meant to “re-establish the situation which existed before the wrongful act was committed.”²⁰⁸ In drafting Article 35, the ILC considered whether its definition of restitution would be as stated or, alternatively, “the establishment or re-establishment of the situation that *would have* existed if the wrongful act had not been committed.”²⁰⁹ The ILC concluded that it would adopt the narrower definition so that courts or tribunals would not have to speculate about what might have been.²¹⁰ The ILC also noted limitations to restitution. Namely, States are not obligated to make restitution when doing so is “materially impossible” or the burden of making restitution outweighs the benefit received.²¹¹ Common awards of restitution include the return of property, persons, territory, or other assets illegally seized or detained, as well as specific performance, contract renegotiation, and juridical revision.²¹²

The situation before China’s alleged breach of the IHR was that COVID-19 existed in Wuhan and was beginning to spread. Had China performed its

204 ILC Articles, *supra* note 201, art. 34.

205 OLLESON, *supra* note 202, at 213-15; Juliette McIntyre, *The Declaratory Judgment in Recent Jurisprudence of the ICJ: Conflicting Approaches to State Responsibility?*, 29 LEIDEN J. INT’L L. 177, 177 (2016).

206 MULLIGAN, *supra* note 104, at 4.

207 International Law Commission, *Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries*, art. 31 ¶ 1, U.N. Doc. A/56/10 (2008), https://legal.un.org/ilc/texts/instruments/english/commentaries/9_6_2001.pdf [<https://perma.cc/QBV8-4C38>] [hereinafter *ILC Commentary*].

208 *Id.* at 96.

209 *Id.* (emphasis added).

210 *Id.*

211 OLLESON, *supra* note 202, at 215.

212 The ILC describes “juridical restitution” as a situation where “restitution requires or involves the modification of a legal situation either within the legal system of the responsible State or in its legal relations with the injured State.” *Id.* at 215-21; ILC Articles, *supra* note 201, at 96; OLLESON, *supra* note 202, at 215-21.

obligations under the IHR, COVID-19 *may* have been contained to the point where it did not spread to the United States. In that case, economists could predict the shape of the U.S. economy had COVID-19 been contained, and epidemiologists could predict how many fewer people would have contracted COVID-19.²¹³ Yet, the IHR requirements are not total insurance; even if China perfectly performed all of its duties under the IHR, it would be difficult to determine exactly how much COVID-19 would have been contained. Regardless, that calculation would be the exact kind of speculative damages that the ILC intended to preclude. In addition, there is nothing China took that it could give back, no contract with the United States to renegotiate, nor anything China could do (specific performance) to re-establish the situation before China breached the IHR.

There is, however, a possibility for juridical restitution. On January 27, 2020, Wuhan Mayor Zhou Xianwang gave an interview claiming that he did not report on the situation in Wuhan to the public sooner because, under China's Law on the Prevention and Control of Infectious Diseases, he was forbidden to without permission from higher authorities.²¹⁴ While there is disagreement about whether Mayor Zhou interpreted the law correctly, if an adjudicator found that the law *did* prohibit Wuhan officials from reporting, then it could be in violation of the IHR because of China's IHR declaration that "local health administrative authorities [such as the Wuhan Health Commission] are the health authorities responsible for the implementation of the IHR in their respective jurisdictions."²¹⁵ China, conversely, could argue that it did not intend to give local health authorities reporting authority but rather solely reserve that authority to China's National Focal Point, the National Health Commission. The adjudicator would have to interpret China's law and whether it is incompatible with the IHR. If the law was found to be incompatible with the IHR, China could be made to repeal or revise the law.²¹⁶

213 See *Tracking the COVID-19 Recession's Effects on Food, Housing, and Employment Hardships*, CTR. BUDGET & POL'Y PRIORITIES (June 16, 2021), <https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and> [<https://perma.cc/RX4Z-QYGK>]; *What is the Economic Cost of COVID-19?*, ECONOMIST (Jan. 9, 2021), <https://www.economist.com/finance-and-economics/2021/01/09/what-is-the-economic-cost-of-covid-19> [<https://perma.cc/4N7G-2YP5>].

214 LAWRENCE, *supra* note 124, at 11 (citing David Cowhig, *Wuhan Mayor Zhou: Reporting Delays Caused by Center, I Acted Fast Once I Got Authorization*, DAVID COWHIG'S TRANSLATION BLOG (Jan. 27, 2020), <https://gaodawei.wordpress.com/2020/01/27/wuhan-mayor-zhou-reporting-delays-caused-by-center-i-acted-fast-once-i-got-authorization> [<https://perma.cc/7QJ8-4GE8>]).

215 IHR, *supra* note 2, at 62.

216 ILC *Commentary*, *supra* note 207, at 57, 97.

3. Compensation

When restitution is not possible or does not make complete reparations for the injury caused, compensation is considered next.²¹⁷ Under ILC Article 36, compensation “shall cover any financially assessable damage including loss of profits insofar as it is established.”²¹⁸ The use of the phrase “financially assessable” damage was meant to exclude compensation for non-material injury, however, non-material damages such as mental suffering have been awarded as compensation.²¹⁹ Financially assessable damages can include incidental damage such as medical expenses and loss of earning potential.²²⁰ Compensation is not meant to be punitive.²²¹ In addition, compensation can consider both financial damage incurred by the State itself as well as financial damage suffered by its nationals, which includes both persons and companies.²²²

The biggest hurdle to establishing a right to compensation is that complaining parties often fail to establish a causal link between the wrongful act and the injury suffered.²²³ For example, in *Application of the Convention on the Prevention and Punishment of the Crime of Genocide (Genocide)*, the ICJ denied compensation to Applicants Bosnia and Herzegovina because the court was not “able to conclude from the case as a whole and with a sufficient degree of certainty that the genocide at Srebrenica would, in fact, have been averted if the Respondent had acted in compliance with its legal obligations.”²²⁴ In addition, dispute settlement bodies often will refrain from awarding compensation when they believe a declaratory judgment is sufficient to satisfy the claim for compensation.²²⁵

The consideration in the hypothetical case against China is similar to *Genocide*. The United States would have to establish with a sufficient degree of certainty that the spread of COVID-19 in the United States would have been averted if China had notified WHO earlier and shared more information sooner. This, however, is already disproven. The first case of COVID-19 in the United

²¹⁷ *Id.* at 98.

²¹⁸ *Id.*

²¹⁹ *Id.* at 99, 101-02.

²²⁰ For example, in the *Corfu Channel* case, the ICJ awarded compensation to naval personnel and their families for injuries and death suffered by the explosion of British destroyers after the ICJ found Albania responsible for the explosions. *Id.* at 100-01; *Corfu Channel (United Kingdom of Great Britain and Northern Ireland v. Albania)*, INT’L CT. J., [https://www.icj-cij.org/en/case/1\[https://perma.cc/C5Y8-APQ3\]](https://www.icj-cij.org/en/case/1[https://perma.cc/C5Y8-APQ3]).

²²¹ ILC *Commentary*, *supra* note 207, at 99.

²²² *Id.*

²²³ OLLESON, *supra* note 202, at 222-30.

²²⁴ *Id.* at 227.

²²⁵ *Guy. v. Surin.*, Award, ¶ 450-52 (Perm. Ct. Arb. 2007), <https://pcacases.com/web/sendAttach/902> [https://perma.cc/B3E7-BB38] (citing *Cameroon/Nigeria*, Judgment, 2002 I.C.J. Rep. 303, ¶ 319 (Oct. 10)).

States was confirmed on January 21, 2020, from a passenger who flew from Wuhan to Washington on January 15.²²⁶ WHO reported that China had notified them by January 4, 2020.²²⁷ Thus, earlier reporting would not have prevented the spread of COVID-19 to the United States because the first case was brought there 11 days *after* the notification was made. The consideration might be different if China had only reported to WHO after the passenger arrived in the United States. In this counterfactual, the United States might argue that measures could have been taken to prevent that passenger from traveling. Alas, that is not the case.

International adjudicators will reduce compensation owed to the complainant when the complainant either failed to mitigate or contributed to the damage caused by the respondent.²²⁸ In this case, China can allege that the United States failed to mitigate. On February 20, 2021, the Lancet Commission on Public Policy and Health in the Trump Era (Commission) published a seminal report noting that if the U.S. death rate from COVID-19 mirrored the weighted average of other G7 nations, about 40 percent of deaths would have been averted.²²⁹ The Commission, as well as other public health experts, attribute these preventable deaths directly to the policies of the Trump Administration.²³⁰ Thus, if the United States were to be awarded compensation from China, that compensation may be reduced significantly because of the United States's own actions.

4. Satisfaction

Lastly, when restitution or compensation is not possible, or in addition to restitution or compensation, a State may be ordered to give satisfaction.²³¹ According to the ILC Articles, “[s]atisfaction may consist in an acknowledgement of the breach, an expression of regret, a formal apology or another appropriate modality” as long as it is in proportion to the injury and not humiliating to the responsible state.²³² Satisfaction can also include affirmative declarations of

226 LAWRENCE, *supra* note 124, at 34; Press Release, Centers for Disease Control and Prevention, First Travel-Related Case of 2019 Novel Coronavirus Detected in the United States (Jan. 21, 2020), <https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html> [<https://perma.cc/RE4R-GC8N>].

227 LAWRENCE, *supra* note 124, at 21.

228 See ILC Commentary, ACERIS L. (June 6, 2018), <https://www.acerislaw.com/contributory-negligence-in-investment-arbitration> [<https://perma.cc/3REK-H9HE>].

229 Steffie Woolhandler et al., *Public Policy and Health in the Trump Era*, 397 LANCET 705, 711 (2021).

230 *Id.*; Drew Altman, Essay, *Understanding the US Failure on Coronavirus*, 370 BMJ 3417 (2020).

231 ILC Commentary, *supra* note 207, at 105.

232 *Id.*

wrongdoing by the court or tribunal as well as assurances or guarantees of non-repetition.²³³ Satisfaction is generally reserved for injuries that are not financially assessable or otherwise cannot be made better with restitution or compensation.²³⁴

If the adjudicators found that China was liable on the claims of failing to notify in a timely manner and withholding information about COVID-19, it would make sense from a public health perspective to order China to make a guarantee of non-repetition. This is especially so as pandemic frequency, especially for emerging diseases, is rising.²³⁵ However, ICJ precedent establishes “[a]s a general rule, there is no reason to suppose that a State whose act or conduct has been declared wrongful by the Court will repeat that act or conduct in the future, since its good faith must be presumed.”²³⁶ The court does make a caveat for “special circumstances,” however, there is not a clear standard or definition of what circumstances are considered “special.”²³⁷ Thus, whether an adjudicator would consider this hypothetical case a special circumstance is unknown, but it would most likely only award a declaration of wrongdoing.

The most likely remedies the PCA or ICJ would award are either juridical revision, which is uncertain at best, or a declaration of wrongdoing. If compensation were to be awarded, there is a viable argument that it may be reduced because of the United States’s failure to mitigate. But just because a remedy is awarded does not necessarily mean it will be conferred by the losing party. The next section will discuss enforcement and compliance with judgments.

D. Enforcement and Compliance

The problem of enforcement was predicted as early as 1951 by the Special Committee on the Draft International Sanitary Regulations, with the delegate from India noting “WHO had no means of imposing sanctions following a judgment of the [ICJ].”²³⁸ Unlike domestic courts, which can, *inter alia*, garnish wages or seize

²³³ *Id.* at 106-07.

²³⁴ *Id.*

²³⁵ Editorial, *A Pandemic Era*, LANCET (Jan. 2021), [https://www.thelancet.com/pdfs/journals/lanplh/PIIS2542-5196\(20\)30305-3.pdf](https://www.thelancet.com/pdfs/journals/lanplh/PIIS2542-5196(20)30305-3.pdf) [<https://perma.cc/HAA5-E6HR>].

²³⁶ Dispute Regarding Navigation and Related Rights (*Costa Rica v. Nicar.*), Judgment, 2009 I.C.J. 213 ¶ 150 (July 13) (citations omitted).

²³⁷ It should be clarified that when the ICJ considered nonrepetition in the *LaGrand Case*, it did not affirmatively grant Germany’s request of non-repetition but rather “considers that the commitment expressed by the United States to ensure implementations of the specific measures adopted in performance of its obligations under Article 36, paragraph 1 (*b*), must be regarded as meeting Germany’s request for a general assurance of non-repetition.” *Id.*; *LaGrand Case* (Ger. v. U.S.), Judgment, 2001 I.C.J. 466, ¶ 124 (June 27).

²³⁸ World Health Organization Regulations, *supra* note 36, at 149.

assets from a debtor, international dispute settlement bodies cannot do the same.²³⁹ Seizing China's assets in the United States without China's consent would be considered a grave violation of sovereignty. Interestingly, many if not most arbitral awards are complied with (with notable exceptions such as the *South China Sea* award); however, ICJ decisions are met with mixed results.²⁴⁰

ICJ judgments are theoretically enforced through Article 94(2) of the UN Charter, which states that ICJ judgments may be referred to the Security Council for enforcement.²⁴¹ However, it is unknown what the Security Council would (or could) actually do to enforce a judgment—States have very rarely invoked Article 94(2), and in the rare cases they have, the Security Council has declined to act.²⁴² It has been suggested that the Security Council may be able to order WHO to “withhold its programs and information from the debtor,” but that remains to be seen.²⁴³ In addition, since China is a permanent member of the Security Council, it could veto a resolution to enforce the judgment as the United States did when Nicaragua asked the Security Council to enforce a judgment against it.²⁴⁴ Regardless, since China has never been a party to the ICJ, there is no precedent to predict how it might react to a judgment against (or even for) it.

Arbitration awards are enforced by the 1958 New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York Convention).²⁴⁵ The United States and China are both parties to the New York Convention; however, both States declared that they will only apply the convention to “differences arising out of legal relationships, whether contractual or not, which are considered as *commercial* under the national law of the [United

239 Aloysius Llamzon, *Jurisdiction and Compliance in Recent Decisions of the International Court of Justice*, 18 EUR. J. INT'L L. 815, 846 (2007).

240 Colter Paulson, *Compliance with Final Judgments of the International Court of Justice Since 1987*, 98 AM. J. INT'L L. 434, 437-56 (2004); Jae Hee Suh, *Compliance with Arbitral Awards*, JUS MUNDI (Apr. 23, 2021), <https://jusmundi.com/en/document/wiki/en-compliance-with-arbitral-awards> [<https://perma.cc/8RDJ-V5J5>]; Dorothy Murray, Daisy Mallet & Charlotte Angwin, *Enforcing Arbitration Awards: The How, the Why and Latest Developments*, LEXOLOGY (Sept. 15, 2016), <https://www.lexology.com/library/detail.aspx?g=0bc6cc2c-82e5-4a98-925e-76d777fcf356> [<https://perma.cc/WR7M-DATS>].

241 Llamzon, *supra* note 239, at 847.

242 *Id.*

243 Mary Ellen O'Connell, *The Prospects for Enforcing Monetary Judgments of the International Court of Justice: A Study of Nicaragua's Judgment Against the United States*, 30 VA. J. INT'L L. 891, 911 (1990).

244 *Id.* at 908-09; Aman Mishra, *Problems in Enforcing ICJ's Decisions and the Security Council*, 15 GLOB. J. HUM.-SOC. SCI. 1, 2 (2015).

245 *The New York Convention*, N.Y. ARB. CONVENTION, <https://www.newyorkconvention.org> [<https://perma.cc/V3QK-2N5F>]; *Dispute Settlement: General Topics: 1.3 Permanent Court of Arbitration*, U.N. CONF. TRADE & DEV. (2003), https://unctad.org/system/files/official-document/edmmisc232add26_en.pdf [<https://perma.cc/5EQV-RFTP>].

States/China].”²⁴⁶ Failure to notify WHO of a PHEIC and subsequently withholding information is certainly not a commercial dispute.²⁴⁷ In addition, under Article III of the New York Convention, “[e]ach Contracting State shall recognize arbitral awards as binding and enforce them in accordance with the rules of procedure of the territory where the award is relied upon”²⁴⁸ In other words, should an award be granted to the United States, the award would need to be recognized and enforced in the domestic courts of either the United States or China, using their respective domestic laws.²⁴⁹ This is problematic, because both China and the United States recognize sovereign immunity in their domestic courts—China absolutely²⁵⁰ and the United States with limited exceptions.²⁵¹ While U.S. courts have, as recently as 2018, allowed PCA awards against sovereign nations to be enforced in the United States,²⁵² China can, and almost certainly will, just ignore the award.²⁵³

In conclusion, a case can be made that China did violate the IHR. But just because China likely committed violations does not mean it can be held accountable in a meaningful way. With every step in the adjudication process, the possibility of seeing a case through to the end becomes less probable. It is unlikely that China would voluntarily appear in front of an international dispute settlement body. The balance of factors China considers before consenting to arbitrate other types of cases, such as trade disputes, does not weigh in favor of the likelihood of this situation. In addition, the dispute settlement body may also refute jurisdiction on the grounds that the dispute does not sufficiently concern the interpretation or application of the IHR. Should a case pass through this hurdle, then it confronts the problem of appropriate remedies. Some may think victims of COVID-19 should be entitled to compensation from China. From the perspective of disease

246 *Declarations and Reservations*, N.Y. ARB. CONVENTION, <https://www.newyorkconvention.org/countries> [<https://perma.cc/2NA3-AALM>] (emphasis added).

247 See *Commercial Law*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/commercial_law [<https://perma.cc/GA8Y-RY2S>].

248 Convention on the Recognition and Enforcement of Foreign Arbitral Awards art. V, July 6, 1988, 330 U.N.T.S. 3.

249 *Id.* art. III; *Guide on the Convention on the Recognition and Enforcement of Foreign Arbitral Awards: Article III*, U.N. COMM’N INT’L TRADE L. (Sept. 2016), https://newyorkconvention1958.org/index.php?lvl=cmspage&pageid=10&menu=619&opac_view=-1 [<https://perma.cc/A8Y8-HEB7>].

250 Xianglin Chen, *Challenging and Enforcing Arbitration Awards: China*, GLOB. ARB. REV. (Feb. 28, 2021), <https://globalarbitrationreview.com/insight/know-how/challenging-and-enforcing-arbitration-awards/report/china> [<https://perma.cc/8FWA-PKDL>].

251 David P. Stewart, *The Foreign Sovereign Immunities Act: A Guide for Judges*, FED. JUD. CTR. INT’L LITIG. GUIDE (2013), <https://www.fjc.gov/sites/default/files/2014/FSIAGuide2013.pdf> [<https://perma.cc/SN75-V8JT>].

252 See, e.g., *Balkan Energy Limited v. Republic of Ghana*, 302 F. Supp. 3d 144 (D.D.C. 2018); *Tatneft v. Ukraine*, 301 F. Supp. 3d 175 (D.D.C. 2018).

253 Chen, *supra* note 250, § 49.

prevention, an assurance of nonrepetition would also seem appropriate. However, the most likely remedy a dispute settlement body would award is satisfaction through a declaration of wrongdoing. A declaration of wrongdoing would, essentially, be the end of the road. If a tangible remedy such as compensation *was* awarded, the United States would likely never see that award anyway.

The overarching lesson from the hypothetical lawsuit against China in an international dispute-settlement body is that it is not an effective tool to promote compliance with IHR duties. At any point, the violator can simply refuse to participate or otherwise recognize the outcome of the proceeding. The state of global health has not been improved by its existence, as it does not in practice, nor as we have now seen, in theory, deter noncompliance. While international legal systems have become more robust since the International Sanitary Conferences of the nineteenth and twentieth centuries, the IHR has not caught up as legitimate hard law.

Because of the recognized inefficiencies, some scholars have proposed reforms to the IHR's dispute settlement process.²⁵⁴ Ching-Fu Lin suggests compulsory arbitration.²⁵⁵ Steve Hoffman suggests a complete overhaul of the dispute settlement process and advocates for "a three-tiered model of dispute resolution . . . includ[ing] an advisory body review on appeal if a decision is unsatisfactory to one of the parties, with an adjudicative body for final resolution."²⁵⁶ However, as Lin correctly notes, these reforms still rely on a State's incentives to initiate a dispute, including time and costs.²⁵⁷ Furthermore, while these reforms include compulsory participation, it would be conceptually difficult to mandate *cooperation*. Lin instead argues for a "Compliance and Accountability Committee," a standing body composed of health law experts that answers directly to the WHA.²⁵⁸ The Committee would primarily be tasked with "monitor[ing], assess[ing], and comment[ing] upon compliance information of State Parties' measures, or lack thereof."²⁵⁹ The concept of a compliance committee is similarly echoed in amendments proposed by the United States to WHO in January 2022.²⁶⁰

254 See, e.g. Ching-Fu Lin, *COVID-19 and the Institutional Resilience of the IHR (2005): Time for a Dispute Settlement Redesign?*, 13 CONTEMP. ASIA ARB. J. 269, 281-85 (2020).

255 *Id.* at 282.

256 *Id.* (citing Steven J. Hoffman, *Making the International Health Regulations Matter: Promoting Compliance Through Effective Dispute Resolution*, in ROUTLEDGE HANDBOOK ON GLOBAL HEALTH SECURITY 239, 247 (Simon Rushton & Jeremy Youde eds., 2014).

257 *Id.*

258 *Id.*

259 *Id.*

260 World Health Org., *Proposal for Amendments to the International Health Regulations (2005)*, 8-10, C.L.2.2022 (Jan. 10, 2022), <https://healthpolicy-watch.news/wp-content/uploads/2022/02/C.L.2.2022-IHR-amendments-English.pdf> [<https://perma.cc/852E-RJZQ>].

However, while this Committee would provide a welcome addition of technical input, any resolution made by the Committee would not be legally binding and thus, if anything, serves as another layer of bureaucracy.

In late 2021, the WHO's Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, with support from many European States, approved discussions for an entirely new pandemic response treaty.²⁶¹ The Working Group noted the need for strengthened compliance with the IHR; however, "there remains divergence on how best to do that as part of strengthening the IHR (2005) or as part of a new instrument."²⁶² This thus circles back to the underlying issue with such health-related treaties: while beefing up global capacities for detection, surveillance, and response are all necessary improvements, their existence on paper is just lip service without complementary support, enforcement, and compliance mechanisms.

This clear lack of enforcement of the IHR does not mean States do nothing when faced with PHEICs. Instead, what has come to be is an informal system where global health is influenced by soft power diplomacy. This further weighs against implementing a formal dispute settlement mechanism, as there is no incentive for powerful States to undermine their already-existing geopolitical influence by agreeing to a compulsory process. The next section will discuss how China's experience with pandemics has shaped its brand of global health diplomacy, as well as how other States have responded in the context of the IHR.

IV. EFFICACY OF INFORMAL MECHANISMS

Because legal mechanisms of dispute resolution under the IHR are improbable, in practice, States defer to informal mechanisms of dispute resolution. China is one country that very much prefers diplomatic tactics over hard law. Over time, China has developed a robust brand of global health diplomacy. Examination of the changes between China's response to the 2003 SARS outbreak and COVID-19 reveals a conscious strategy in the realms of economics, geopolitics, and public relations. It is also clear that China is gaining increased confidence in its position as a global health influencer. Many States, particularly in the Global South, look to China as a leader in the global health arena—which has not gone unnoticed by the United States and other Western countries. These Western States have subsequently taken retaliatory measures against China that themselves violate the IHR, such as travel and trade restrictions. In addition, ramped-up rhetoric by U.S.

261 World Health Org., *Draft Report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the Special Session of the World Health Assembly*, A/WGPR/5/2 (2021), https://apps.who.int/gb/wgpr/pdf_files/wgpr5/A_WGPR5_2-en.pdf [https://perma.cc/8H9A-S372].

262 *Id.* at 3.

and Chinese media outlets, as well as targeted distribution of vaccines, has stirred tensions globally and domestically in both countries respectively.

A. Chinese Diplomacy and Global Health—Overview

As has been already discussed, China prefers to settle disputes with other States through diplomacy.²⁶³ It is suggested that part of the reason why China prefers diplomacy over adherence to hard law is that, historically, China has viewed the development of international law as “a tool of Western imperialism,” with many treaties implicitly favoring Western powers.²⁶⁴ For its part, China is not alone in this stance. Many countries in the Global South feel the same.²⁶⁵ Interestingly, however, not all countries considered the Global South have shied away from formal mechanisms of international law. For example, Nicaragua alone has instituted eight contentious proceedings before the ICJ.²⁶⁶ This difference in attitudes may, perhaps, reflect an amalgamation of historical, economic, and geopolitical factors that ultimately affect a State’s perceived efficacy in international systems. Regarding China, the Council on Foreign Relations notes:

In the first decade of the twenty-first century, China often proved willing to play by international rules and norms. As its economy grew, however, Beijing assumed a more active role in global governance, signaling its potential to lead and to challenge existing institutions and norms. The country boosted its power in four ways: it took on a bigger role in international intuitions, advertised its increasing influence, laid the groundwork to create some of its own organizations, and sometimes subverted global governance rules.²⁶⁷

This description accurately portrays China’s emerging brand of global health diplomacy. Through its soft power tactics, it has established itself as a leader in WHO and other global health institutions as well as increased its influence among the Global South by presenting itself as an alternative investor to the United States.²⁶⁸ Generally, China’s soft power tactics fit into two categories: information

263 Moynihan, *supra* note 176; *Declaration of Russia & China*, *supra* note 199.

264 Moynihan, *supra* note 176; *Declaration of Russia & China*, *supra* note 199.

265 See, e.g., Brian-Vincent Ikejiaku, *International Law is Western Made Global Law: The Perception of Third-World Category*, 6 AFR. J. LEGAL STUD. 337, 340-55 (2013).

266 *Contentious Cases Organized by State*, INT’L CT. J., <https://www.icj-cij.org/en/cases-by-country> [https://perma.cc/SA5E-TD8S].

267 Huang et al., *supra* note 188.

268 *Id.*

control and influence on poorer States. These tactics predate COVID-19, with the next-most recent example from China being the SARS outbreak in the early 2000s. Comparing and contrasting China's response to SARS with its response to COVID-19 will highlight how China has fine-tuned its global health diplomacy in the face of PHEICs and whether its actions help promote the purpose of the IHR.

B. Chinese Diplomacy: From SARS to COVID-19

1. Historical Background of SARS

The factual background of the SARS pandemic is incredibly similar to COVID-19. In November 2002, clusters of atypical respiratory disease (atypical pneumonia) were discovered in the Guangdong Province of China.²⁶⁹ By January 2003, the increasing incidence of this mysterious outbreak was known to China's Ministry of Health, but China did not share its report containing information regarding the atypical pneumonia outbreaks with WHO.²⁷⁰ Reports of the outbreaks were labeled "top secret" under Chinese law which made public disclosure illegal, though information about it leaked on the internet, causing panic among citizens.²⁷¹ In February 2003, a text message that read "There is a fatal flu in Guangzhou" was circulated millions of times, and similar messages were shared via email and internet chat rooms.²⁷² These messages were eventually picked up by ProMED, and on February 10, 2003, the son of a former WHO employee in China contacted WHO about these reports directly, noting that over 100 people were already dead.²⁷³ WHO reached out to China that day, and the following day China reported to WHO that there was "an outbreak of acute respiratory syndrome with 300 cases and five deaths in Guangdong Province."²⁷⁴ Chinese officials then told the public about the situation for the first time, assuring them, as well as WHO, that the outbreak was under control and cases were declining.²⁷⁵ However, by mid-February, doctors in China began raising the alarm that Chinese officials may be silencing reports of the outbreak, and China subsequently ordered a news blackout.²⁷⁶ In late February 2002, China reported to WHO that it believed the

269 David Fidler, *Brief History of the Global SARS Outbreak of 2002-03 in SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE* 71, 73 (2004), https://link.springer.com/content/pdf/10.1057%2F9780230006263_5.pdf [<https://perma.cc/AF4Z-MMET>].

270 *Id.*

271 *Id.*

272 *Id.* at 74.

273 *Id.*

274 *Id.*

275 *Id.* at 74-75.

276 *Id.* at 83; LEARNING FROM SARS: PREPARING FOR THE NEXT DISEASE OUTBREAK – WORKSHOP SUMMARY (Stacey Knobler et al. eds., 2004), <https://pubmed.ncbi.nlm.nih.gov/22553895>

outbreak was caused by *Chlamydia pneumoniae* and officially declared the outbreak over by February 27.²⁷⁷

By March 2003, cases of atypical pneumonia were reported in several Asian countries and Canada.²⁷⁸ Toward the end of March, WHO named the new disease Severe Acute Respiratory Syndrome (SARS), and contact traced it back to the original outbreak in Guangdong that was previously considered chlamydia.²⁷⁹ On March 25, WHO complained that it was getting insufficient information from China.²⁸⁰ Following WHO complaints that were published in Western news outlets, China's Minister of Health again announced on national television that the outbreak was under control, and on April 3, a pamphlet was circulated entitled "SARS is Nothing to Be Afraid Of."²⁸¹ Interestingly, China appeared to make an about-face the very next day. It pledged to cooperate more with WHO's requests for information, and the head of China's CDC even publicly apologized for "failing to inform the public about a sometime fatal respiratory illness that has infected more than 2,000 people worldwide."²⁸² However, behind the scenes in China, another story was developing, one that David Fidler characterized as "duplicitous."²⁸³ Doctors in China were accusing the government of underreporting, and WHO investigation teams were not being granted full access to hospitals.²⁸⁴ WHO responded by not just publicly shaming China's actions but stating in a worldwide press conference, "[w]e do believe that the [Chinese] government has not invested in health in the last 30 years."²⁸⁵ This appeared to be a wake-up call for China, but, as Fidler noted,

this transformation did not occur without the help of one final, embarrassing incident for the Chinese government. On 16 April, Chinese officials allowed the WHO's experts to begin visiting military and other hospitals in the Beijing area. As later reported in *Time*, 'hospital officials removed dozens of SARS patients from their isolation wards and transferred them to locations where they

[<https://perma.cc/2BUY-RP5N>] [hereinafter LEARNING FROM SARS].

277 Fidler, *supra* note 269, at 75.

278 *Id.* at 78.

279 *Id.* at 82.

280 *Id.* at 83.

281 *Id.* at 93.

282 *Id.*

283 *Id.* at 94.

284 *Id.* at 94-95.

285 *Id.* at 97.

could not be observed by the inspectors.²⁸⁶

After the hospital incident was exposed, China ordered officials to stop covering up the spread of SARS, became more transparent about the confirmed number of SARS cases, and fired top officials involved in the coverup.²⁸⁷ It also began a public health campaign to actually control the SARS virus, which proved very effective. As the *Wall Street Journal* put it, “China is as good at fighting SARS as at hiding it.”²⁸⁸

2. Information Control

China has long been criticized by Western States for its media censorship, propaganda, and revisionist history.²⁸⁹ Restrictive media policies have allowed it to regulate and control the information put out on the international stage.²⁹⁰ While the age of the internet has threatened this control, China shows no signs of stopping. Instead, its strategy has evolved. During the SARS crisis, China attempted to control what information was available to the public through blackouts and strict secrecy laws. When it did address the public, it appeared to be less concerned with its image and more about quelling public disorder. It learned, however, that suppressing information altogether was not possible with the internet.²⁹¹ Reflecting on the COVID-19 pandemic, it seems that China now focuses not on *what* information comes out but on *how* the information comes out. While government officials are no longer restricted by secrecy laws from reporting public health emergencies, it is still illegal to spread “rumors,” which, as evidenced by the case of Dr. Li, may include anything construed as a threat to China’s official narrative.²⁹² In addition, government censorship still persists in China, particularly on social media platforms.²⁹³

Furthermore, State media in China has closely echoed the narrative of State officials. Following Chinese media sources such as *Global Times*, *Beijing News*, and *Xinhua* throughout the COVID-19 pandemic, the BBC has documented how China quickly turned the narrative of COVID-19 from a disaster into a victory.²⁹⁴

²⁸⁶ *Id.*

²⁸⁷ *Id.* at 97-98.

²⁸⁸ *Id.* at 101.

²⁸⁹ Beina Xu & Eleanor Albert, *Media Censorship in China*, COUNCIL FOREIGN RELS. (Feb. 17, 2017), <https://www.cfr.org/backgroundunder/media-censorship-china> [<https://perma.cc/Y73K-G6X6>].

²⁹⁰ *Id.*

²⁹¹ LEARNING FROM SARS, *supra* note 276.

²⁹² *Id.*; Laney Zhang, *FALQs: Spreading Rumors and Police Reprimand under Chinese Law*, LIBR. CONG. (March 2, 2020), <https://blogs.loc.gov/law/2020/03/falqs-spreading-rumors-and-police-reprimand-under-chinese-law> [<https://perma.cc/NCH6-2H35>].

²⁹³ *China Covid-19*, *supra* note 189.

²⁹⁴ *Id.*; John Sudworth, *Wuhan Marks its Anniversary with Triumph and Denial*, BBC (Jan. 23,

Blame for the virus shifted from being pointed in multiple directions to being pointed at Wuhan specifically to being pointed at sources outside China while at the same time promoting a pro-China narrative.²⁹⁵ For example, in August 2020, *Global Times* tweeted “@WHO’s admission that Wuhan may not be the origin of #COVID19 may offset conspiracy theories that have put the central Chinese city and China under a bad light over virus origin: Chinese epidemiologists.”²⁹⁶ Furthermore, State media has worked to promote stories about how well the government handled the virus in order to saturate the media space with positive messaging.²⁹⁷

China has also used this positive COVID-19 messaging in a larger, ongoing narrative about China’s place in the international system. In a speech on April 4, 2021, China’s Foreign Minister Wang Yi highlighted China’s commitment and dedication to the UN and international law.²⁹⁸ Wang Yi denied accusations by the United States that China uses “coercive diplomacy,” saying instead that China itself has “[fallen] prey” to foreign coercion and aggression.²⁹⁹ At the same time, China vehemently denies accusations of unilateralism and considers itself a cooperative, global player. Recently, China has engaged in joint statements with Russia “pledg[ing] to protect global strategic security and stability, support and practice true multilateralism, oppose interference in other countries’ affairs under the guise of ‘democracy’ and ‘human rights,’ and resist unilateral coercive sanctions.”³⁰⁰ Messaging has also been blatantly ideological at times; for example, an exhibition in China remembering the one-year anniversary of COVID-19 reads “[t]he strategic success achieved in this battle [against COVID-19] fully manifested the strong leadership of the Communist Party of China and the significant advantages of the socialist system of our country.”³⁰¹ This pro-China

2021), <https://www.bbc.com/news/world-asia-china-55765875> [<https://perma.cc/C8E3-ENC7>].

²⁹⁵ *China Covid-19*, *supra* note 189.

²⁹⁶ *Id.*

²⁹⁷ Sudworth, *supra* note 294.

²⁹⁸ H.E. Wang Yi, *Focusing on Cooperation and Managing Differences: Bringing China-U.S. Relations Back to the Track of Sound and Steady Development*, MINISTRY FOREIGN AFF. CHINA (Apr. 24,

2021), https://www.fmprc.gov.cn/mfa_eng/wjdt_665385/zyjh_665391/202104/t20210424_9170543.html [<https://perma.cc/2T46-W2XT>].

²⁹⁹ *Id.*

³⁰⁰ Xi, *Putin Announce Extension of China-Russia Friendly Cooperation Treaty*, XINHUA (June 29, 2021), http://www.xinhuanet.com/english/2021-06/29/c_1310032860.htm [<https://perma.cc/3LZ4-VVDE>]; *Joint Statement by the Foreign Ministers of China and Russia on Certain Aspects of Global Governance in Modern Conditions*, LAW INFO. CHINA (March 23, 2021), <https://lawinfochina.com/display.aspx?id=8058&lib=tax&SearchKeyword=&SearchCKeyword=&EncodingName=big5> [<https://perma.cc/6FZA-J25X>].

³⁰¹ Sudworth, *supra* note 294.

messaging has at the same time been juxtaposed with messages about how “U.S. media have turned on each other, how politicians have prioritized spending on election campaigns over health care, and how a messy, endless election has led to extreme polarization.”³⁰² It is unclear whether this messaging is aimed directly at the United States, at States seen as potential allies to China, or at both.

While it was immediately clear that China’s information blackouts during SARS were considered an international embarrassment, the overall influence of China’s narrative control in the wake of COVID-19 has yet to be seen. Pew research reveals that international opinion of China has dropped, but it is important to note that this poll only included fourteen wealthy countries that already had unfavorable views of China.³⁰³ There is no research on how countries in the Global South currently view China, though research suggested that poorer countries viewed China more favorably before the pandemic.³⁰⁴ Research does indicate, however, that Chinese citizens view their own government more favorably after its handling of COVID-19, which one professor from Georgia State University believes is because China’s brand of diplomacy “doesn’t work well in the Western context, but [is] often oriented toward domestic audiences within China because it makes China seem stronger and withstanding Western pressures.”³⁰⁵ This messaging may also work with other countries that have historically felt Western pressure.

3. External Influence

Before SARS, China’s emergence as a global health leader was slow as China itself was considered an aid-recipient country.³⁰⁶ But after SARS revealed the severe deficiencies in China’s own public health, China recovered quickly. First, it made dramatic investments in its health system, which in turn poised it to become a leader both economically and by example.³⁰⁷ Then, it opened itself to engaging

302 *China Covid-19*, *supra* note 189.

303 Amy Mackinnon, Darcy Palder & Colum Lynch, *China’s Global Image Plummet After Coronavirus*, FOREIGN POL’Y (Oct. 6, 2020), <https://foreignpolicy.com/2020/10/06/chinas-global-image-plummet-covid-coronavirus-pandemic> [<https://perma.cc/539E-X73P>].

304 *Id.*

305 Emily Feng, *As U.S. Views of China Grow More Negative, Chinese Support for Their Government Rises*, NAT’L PUB. RADIO (Sept. 23, 2020, 11:14 AM), <https://www.npr.org/2020/09/23/913650298/as-u-s-views-of-china-grow-more-negative-chinese-support-for-their-government-ri> [<https://perma.cc/8SAK-W57U>]; Mackinnon et al., *supra* note 303.

306 Peilong Liu et al., *China’s Distinctive Engagement in Global Health*, 384 LANCET 793, 794 (2014).

307 Jennifer Bouey, *Strengthening China’s Public Health Response System: From SARS to COVID-19*, 100 AM. J. PUB. HEALTH 939 (2020); Susan Brink, *New Research: China is Winning Some Health-Care Battles—And Losing Others*, NAT’L PUB. RADIO (Oct. 5, 2019), <https://www.npr.org/sections/goatsandsoda/2019/10/05/767274984/new-research-china-is-winning-some-health-care-battles-and-losing-others> [<https://perma.cc/S7GH-9YJL>].

with global health governance bodies such as WHO, UNICEF, UNFPA, UNAIDS, and multilateral health funds, as well as regularly sending delegates to the WHA.³⁰⁸ In 2007, China backed Margaret Chan, a Hong Kong national, in her election for Director General of WHO.³⁰⁹ Despite criticism about how she handled the SARS crisis when she was the Director of Health of Hong Kong, Chan was well respected at WHO for having shared updates about SARS when WHO was pressing China for more information, and so the move to back her election “came off as a mea culpa for covering up the SARS crisis” that curried favor for China in Geneva.³¹⁰

While U.S. development assistance for health has been declining, China has increasingly made significant health-related investments in the Global South.³¹¹ Through initiatives such as the South-South Collaboration and the One Belt One Road Initiative, which aims to connect countries in the Global South together, China is leading what one scholar calls a “paradigm shift in global health assistance as we currently know it.”³¹² These initiatives not only stand to rival the traditional mechanisms of aid used by wealthy countries in terms of size of the check but also in philosophy.³¹³ In its most general sense, aid from the United States and other wealthy nations often comes with strings attached—recipients must become more like their donors politically (i.e., democratize and open their markets).³¹⁴ Aid from these countries is usually facilitated through nongovernmental organizations (such as the Red Cross) and has been criticized for being too bureaucratic, driven by the interests of the donor instead of the needs of the recipient, and generally ineffective.³¹⁵ China, on the other hand, gives aid with “no strings attached” by emphasizing independent development projects meant to help poor States

308 Liu et al., *supra* note 306, at 799; Titiporn Tuangratananon et al., *China: Leapfrogging to Become a Leader in Global Health?*, 9 J. GLOB. HEALTH 1, 3 (2019).

309 Natalie Huet, *World Looks for a Better Doctor: Margaret Chan's Controversial Legacy Shapes Search for New Head of World Health Organization*, POLITICO (Jan. 22, 2017, 10:12 PM), <https://www.politico.eu/article/world-looks-for-a-better-doctor> [https://perma.cc/576K-RF2H]; Chan Wai Yin & Ma Shu Yun, *The Making of a Chinese Head of the WHO: A Study of the Media Discourse on Margaret Chan's Contest for the WHO Director-Generalship and its Implications for the Collective Memory of SARS*, 39 INT'L J. HEALTH SERVS. 587, 592-95 (2009).

310 Huet, *supra* note 309.

311 Liu et al., *supra* note 306, at 794-97; Tuangratananon et al., *supra* note 308; Elanah Uretsky, Jennifer Bouey & Rebecca Katz, *China's Emerging Role In Global Health*, HEALTH AFFS. (Jan. 17, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180109.759800/full> [https://perma.cc/YBN9-2D9P].

312 Uretsky et al., *supra* note 311.

313 *Id.*; Liu et al., *supra* note 306, at 794-97; Tuangratananon et al., *supra* note 308.

314 Liu et al., *supra* note 306; Uretsky et al., *supra* note 311.

315 Thomas Dichter, *When Criticism Falls on Deaf Ears: The Case of U.S. Foreign Aid*, AM. FOREIGN SERV. ASS'N (Nov. 2017), <https://afsa.org/when-criticism-falls-deaf-ears-case-us-foreign-aid> [https://perma.cc/73S2-26ZQ].

transform from recipients into future economic partners.³¹⁶ In other words, because healthier populations lead to greater economic development and sustainability,³¹⁷ China believes that investing in another country's health now will yield an economic (and possibly political) return on investment later. In contrast to aid from the United States, aid from China is usually given directly from government to government and has been criticized for being non-transparent and turning a blind eye to corruption.³¹⁸ Global health aid from the United States is typically targeted toward specific diseases, with about half of its aid spent on HIV, whereas aid from China targets specific countries, with about half going to the African continent.³¹⁹

It is no surprise that since COVID-19 has hit poor countries the hardest, China has seized the pandemic as an opportunity to bolster its image as a leader in global health.³²⁰ In a government white paper from May 2020, China claims it donated much-needed medical supplies to over 150 countries as well as sent medical teams to twenty-seven.³²¹ It has offered technical assistance to many countries, including Iran, Italy, Spain, and India.³²² China has provided low-cost vaccines to nearly

316 Liu et al., *supra* note 306; Uretsky et al., *supra* note 311.

317 Jaana Remes, Matt Wilson & Aditi Ramdorai, *How Investing in Health has a Significant Economic Payoff for Developing Economies*, BROOKINGS (July 21, 2020), <https://www.brookings.edu/blog/future-development/2020/07/21/how-investing-in-health-has-a-significant-economic-payoff-for-developing-economies> [<https://perma.cc/4FCH-NQU9>].

318 Huang et al., *supra* note 188; Becky Carter, *A Literature Review on China's Aid*, K4D HELPDESK REP. (Sept. 7, 2017), https://gsdrc.org/wp-content/uploads/2017/10/177_China_aid.pdf [<https://perma.cc/6QWD-HG6Q>].

319 Uretsky et al., *supra* note 311; *Breaking Down the U.S. Global Health Budget by Program Area*, KAISER FAM. FOUND. (May 10, 2021), <https://www.kff.org/global-health-policy/fact-sheet/breaking-down-the-u-s-global-health-budget-by-program-area/#top> [<https://perma.cc/T8YR-XQSZ>]; *The U.S. Government and Global Health*, KAISER FAM. FOUND. (July 30, 2019), <https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-and-global-health> [<https://perma.cc/W2DF-U434>]; Reuters Staff, *China Says More than Half of Foreign Aid Given to Africa*, REUTERS (July 10, 2014), <https://www.reuters.com/article/us-china-aid/china-says-more-than-half-of-foreign-aid-given-to-africa-idUSKBN0FF0YN20140710> [<https://perma.cc/P7WY-7699>].

320 Akihiko Nishio, *COVID-19 is Hitting Poor Countries the Hardest. Here's How World Bank's IDA is Stepping Up to Support*, WORLD BANK BLOGS (Jan. 28, 2021), <https://blogs.worldbank.org/voices/covid-19-hitting-poor-countries-hardest-heres-how-world-banks-ida-stepping-support> [<https://perma.cc/4LJN-SBVP>]; Kathy Gilsinan, *The Problem With China's Victory Lap*, ATLANTIC (March 28, 2020), <https://www.theatlantic.com/politics/archive/2020/03/china-wuhan-xi-victory-coronavirus/608977> [<https://perma.cc/85RG-JXDT>]; Huang et al., *supra* note 188.

321 Jacob Kurtzer & Grace Gonzales, *China's Humanitarian Aid: Cooperation Amidst Competition*, CTR. STRATEGIC & INT'L STUD. (Nov. 17, 2020), <https://www.csis.org/analysis/chinas-humanitarian-aid-cooperation-amidst-competition> [<https://perma.cc/YMK2-BF42>].

322 Huang et al., *supra* note 188; Nectar Gan & Jessie Yeung, *China Offered Covid Aid to India While US Dragged its Feet, but Delhi isn't that Keen*, CNN (Apr. 28, 2021, 3:34 AM), <https://www.cnn.com/2021/04/28/china/china-india-covid-relief-mic-intl-hnk/index.html> [<https://perma.cc/3WXC-A883>].

forty African countries and has overall pledged about half a billion vaccines to over forty-five countries.³²³ It believes filling the void left by the United States and other wealthy countries that are hoarding vaccines will improve its image among poorer countries.³²⁴ It has also announced \$50 million USD in donations to WHO and the UN Global Humanitarian Response Plan to COVID-19 since March 2020,³²⁵ and in May 2021, President Xi Jinping pledged \$3 billion USD to help developing countries recover from COVID-19 over the next three years.³²⁶ In November 2021, Xi pledged another one billion COVID-19 vaccine doses to Africa and also called on Chinese companies to invest billions of dollars in the continent over the next three years.³²⁷ These doses would be provided through donations and joint production with African countries.³²⁸

While, on its face, China's response seems helpful, it has been met by skepticism in many recipient countries and has been highly scrutinized by the United States.³²⁹ In Zimbabwe, where about 90 percent of the vaccine supply comes from China, vaccine hesitancy is strongly fueled by a general distrust of the Chinese government.³³⁰ India has been reluctant to engage Chinese offers for assistance at all.³³¹ In June 2021, China threatened to block a shipment of 500,000 vaccines to Ukraine unless Ukraine withdrew its support for increased

323 *China Says Providing Vaccines to Almost 40 African Nations*, AP NEWS (May 20, 2021), <https://apnews.com/article/united-nations-africa-china-business-coronavirus-pandemic-ad395006fe0c4daf0e13c3be02f07cc7> [https://perma.cc/5E3T-F9ZK].

324 Amanda McGowan, *China's 'Vaccine Diplomacy' Fills Void in Developing World Left by US 'Vaccine Nationalism'*, THE WORLD (Jan. 12, 2021, 4:00 PM), <https://www.pri.org/stories/2021-01-12/china-s-vaccine-diplomacy-fills-void-developing-world-left-us-vaccine-nationalism> [https://perma.cc/X3B4-8M3L].

325 Kurtzer & Gonzales, *supra* note 321.

326 *China's Xi Pledges \$3 Bln Pandemic Aid for Poor Nations*, REUTERS (May 21, 2021, 7:35 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/chinas-xi-pledges-3-bln-international-aid-proposes-vaccine-cooperation-forum-2021-05-21> [https://perma.cc/2U9H-755A].

327 Edward Mcallister & Tom Daly, *China's Xi Pledges Another 1 Bln COVID-19 Vaccine Doses for Africa*, REUTERS (Nov. 30, 2021, 8:26 AM), <https://www.reuters.com/world/africa/chinas-xi-pledges-10-bln-credit-line-african-financial-institutions-2021-11-29> [https://perma.cc/WF98-4P6L].

328 *Id.*

329 See, e.g., Antony Sguazzin & Katarina Hoije, *China Suspicion, 'Foreign Plot' Fears Hamper Africa Vaccine Plan*, BLOOMBERG (Apr. 20, 2021, 12:00 AM), <https://www.bloomberg.com/news/articles/2021-04-20/china-suspicion-foreign-plot-fears-hamper-africa-vaccine-plan> [https://perma.cc/M47H-NWXQ]; Gan & Yeung, *supra* note 322; Kurtzer & Gonzales, *supra* note 321; Gilsinan, *supra* note 320.

330 Sguazzin & Hoije, *supra* note 329; Fortune Moyo, Kudzai Mazvarirwofa & Vimbai Chinenbiri, *Vaccines are a Tough Sell. Their Chinese Origin Doesn't Help.*, GLOB. PRESS J. (May 22, 2021), <https://globalpressjournal.com/africa/zimbabwe/vaccines-tough-sell-chinese-origin-doesnt-help> [https://perma.cc/62NC-ABW5].

331 Gan & Yeung, *supra* note 322.

watchfulness of human rights abuses in China.³³² It has also not gone unnoticed that many of China's public pledges to poorer countries are coupled with statements criticizing the United States. In April 2021, reporters from CNN noted how Chinese leaders and State media ramped up their criticism of the United States for its "America first" approach to COVID-19 aid, attributing values from the Trump Administration to the new Biden Administration.³³³ China has called the United States's public support of struggling countries such as India disingenuous,³³⁴ claiming that the United States has "fully exposed its selfishness in refusing to offer substantial help to India and is obstructing global efforts in vaccine distribution to developing and needy countries."³³⁵ At the same time, China continues to characterize itself "as a responsible global power" "not driven by 'selfish geopolitical interests,'" while the United States believes China is just posturing to divert attention away from its own missteps handling the pandemic.³³⁶

Before discussing China's global health diplomacy in the context of the IHR, it should be noted that during the SARS pandemic, the only diseases subject to the regulations were the plague, cholera, and yellow fever.³³⁷ Therefore, China did not violate the IHR at that time (though its actions may have violated the WHO Constitution). However, had the IHR as it exists today been in force at the time, China would have violated it. Let us not forget that the SARS epidemic was the impetus for the WHA to kick the IHR revisions they started in 1995 into gear. The question, then, is whether the evolution of China's global health diplomacy was influenced by the IHR revisions and whether its actions promote the purpose of the IHR.

After the SARS crisis, many believed China was turning a page in its engagement with the international system.³³⁸ Because China eventually cooperated with WHO and even issued a formal apology for its coverup (which is notably uncharacteristic for any country, let alone China), observers were cautiously optimistic about China's future cooperation.³³⁹ In retrospect and considering

332 Jamey Keaten, *AP: Exclusive: Diplomats Say China Puts Squeeze on Ukraine*, AP NEWS (June 25, 2021), <https://apnews.com/article/united-nations-china-europe-ukraine-health-a0a5ae8f735b92e39c623e453529cbb9> [https://perma.cc/K6XP-96ZL].

333 Gan & Yeung, *supra* note 322.

334 Liu Zongyi, *Will US 'Crocodile Tears' Prompt Indian Elites to Reflect on Who Their Allies Are*, GLOB. TIMES (Apr. 25, 2021, 10:51 PM), <https://www.globaltimes.cn/page/202104/1222059.shtml> [https://perma.cc/Y3CA-AADQ].

335 Liu Xin & Chenq Qingqing, *US Slammed for 'Selfish,' 'Indifferent' Response to India's Call for Help Amid Devastating COVID-19 Crisis*, GLOB. TIMES (Apr. 26, 2021, 12:51 AM), <https://www.globaltimes.cn/page/202104/1222068.shtml> [https://perma.cc/PMB6-D9GZ].

336 Kurtzer & Gonzales, *supra* note 321; Gilsinan, *supra* note 320.

337 World Health Organization Regulations, *supra* note 36; IHR 1982, *supra* note 162; IHR, *supra* note 2.

338 LEARNING FROM SARS, *supra* note 276.

339 *Id.*

China's COVID-19 response, these observers were spot-on with their predictions. Before SARS, China was far less engaged in the international system and was less concerned about its international image. As discussed, in between SARS and COVID-19, China made great strides economically as well as in the formal and informal international system. Its response to COVID-19 adjusted accordingly and suggests that China knows it now has a lot more to lose economically and geopolitically than it did during SARS. Thus, it was faced with a tricky situation that highlights the biggest fundamental flaw of the IHR: how can a country be expected to comply with its reporting requirements when compliance is likely to be punished with disproportionate trade restrictions? In light of this legitimate fear, China was practically left with no choice but to do what it did—cooperate minimally with WHO but maintain the narrative that it was cooperating to the full extent. It is reasonable to believe that any other country would have done the same under the same circumstances. In fact, China is not the only country that may have violated the IHR during the COVID-19 pandemic.³⁴⁰

C. The World Responds to China

1. Additional Health Measures

While this Article has focused on China's handling of COVID-19, it is important to address the elephant in the international room: many of the countries that have criticized China have done so while actively violating the IHR themselves. Throughout the pandemic, WHO consistently advised against travel and trade restrictions that would significantly interfere with international traffic.³⁴¹ Yet, many countries implemented travel and trade restrictions anyway.³⁴² In April 2020, 91 percent of the world's population lived in countries with travel restrictions, and as of March 2022, 453 notifications of trade measures had been reported by WTO member States.³⁴³ Many of these restrictions are still in place

340 Habibi et al., *supra* note 75.

341 *All Updates for Travellers*, WORLD HEALTH ORG., <https://www.who.int/travel-advice/all-updates-for-travellers> [<https://perma.cc/PWQ4-9CFD>].

342 *Public Health Considerations While Resuming International Travel*, WORLD HEALTH ORG. (July 30, 2020), <https://www.who.int/news-room/articles-detail/public-health-considerations-while-resuming-international-travel> [<https://perma.cc/PJ6T-XKE5>].

343 Phillip Connor, *More Than Nine-in-Ten People Worldwide Live in Countries with Travel Restrictions Amid COVID-19*, PEW RSCH. CTR. (Apr. 1, 2020), <https://www.pewresearch.org/fact-tank/2020/04/01/more-than-nine-in-ten-people-worldwide-live-in-countries-with-travel-restrictions-amid-covid-19> [<https://perma.cc/XF7C-ATL5>]; *WTO Members' Notifications on COVID-19*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/covid19_e/notifications_e.htm [<https://perma.cc/7U7Y-QEEH>].

today. For example, the Biden Administration has yet to lift certain Trump-era border restrictions despite bipartisan calls to do so.³⁴⁴ Between January 2020 and April 2021, States collectively made over 220 export bans or limits, citing COVID-19-related reasons.³⁴⁵ Most of the restricted products were medical goods and foodstuffs, further exacerbating the pandemic's damage.³⁴⁶

Data is still being collected on the breadth of these measures, but initial reports show that a significant amount are against WHO's advice or otherwise not based in science, thereby violating Article 43 of the IHR.³⁴⁷ It is also important to note that many of these actions may also violate WTO agreement rules that emergency trade restrictions must be "targeted, proportionate, temporary, and transparent."³⁴⁸ In addition, one report shows that "two thirds of states that had implemented additional health measures were again reported to have neglected their obligation to inform the WHO of such measures."³⁴⁹ Similarly, many WTO members violated their obligation to notify the WTO Secretariat of the restrictive trade measures.³⁵⁰

Furthermore, some scholars argue that these additional health measures also violate Article 3 of the IHR, which requires that the Regulations shall be implemented "with full respect for the dignity, human rights and fundamental freedoms of persons."³⁵¹ WTO agreements similarly have provisions that allow for flexibility when making trade restrictions to protect health so long as these restrictions "do not 'constitute a means of arbitrary or unjustifiable discrimination,' or a 'disguised restriction on international trade.'"³⁵² Some restrictions, however, are likely based in xenophobia or racism rather than science. For example, in March 2020, the Trump Administration instituted a ban on migrants crossing the border from Mexico to the United States, citing a U.S. public health law called Title 42.³⁵³ Trump cited concerns about "unscreened" and "unvetted" people who may cross the border with COVID-19, but anti-Mexican rhetoric and policies were a cornerstone of Trump's platform well before COVID-19.³⁵⁴

344 Priscilla Alvarez, *Pressure Mounts on Biden Administration to Lift Restrictions on US Borders*, CNN (July 7, 2021, 8:08 AM), <https://www.cnn.com/2021/07/07/politics/us-mexico-border-restrictions/index.html> [https://perma.cc/93QM-RXMC].

345 CHRISTOPHER CASEY & CATHLEEN CIMINO-ISAACS, CONG. RSCH. SERV., IF11551, EXPORT RESTRICTIONS IN RESPONSE TO THE COVID-19 PANDEMIC (2021).

346 *Id.*

347 Hoffman et al., *supra* note 75.

348 CASEY & CIMINO-ISAACS, *supra* note 345.

349 Hoffman et al., *supra* note 75.

350 CASEY & CIMINO-ISAACS, *supra* note 345.

351 IHR, *supra* note 2, art. 3(1).

352 CASEY & CIMINO-ISAACS, *supra* note 345.

353 Alvarez, *supra* note 344; 42 U.S.C. 2 § 1.

354 Priscilla Alvarez, Geneva Sands, Betsy Klein & Jennifer Hansler, *Trump Administration Limits Nonessential Travel Between US and Mexico*, CNN (Mar. 20, 2020, 3:05 PM), <https://www.cnn.com/2020/03/20/politics/us-mexico-border/index.html> [https://perma.cc/87GV-

While non-compliance with WHO and WTO rules on international traffic is in and of itself an immediate issue, the bigger issue is the long-term effect these unchecked restrictions will have on developing countries. In April 2020, the IMF and WTO issued a joint statement warning of the potential effect of export restrictions.³⁵⁵ They noted that

Taken collectively, export restrictions can be dangerously counterproductive. What makes sense in an isolated emergency can be severely damaging in a global crisis. Such measures disrupt supply chains, depress production, and misdirect scarce, critical products and workers away from where they are most needed. Other governments counter with their own restrictions. The result is to prolong and exacerbate the health and economic crisis — with the most serious effects likely on the poorer and more vulnerable countries.³⁵⁶

As of May 2020, forty-two WTO countries pledged to lift their emergency restrictions, but the United States, China, and European Union did not make a similar pledge.³⁵⁷ By October 2020, G-20 countries, which make up 80 percent of world GDP and 75 percent of global trade, only lifted 30 percent of their trade restrictions.³⁵⁸ One industry severely hurt by these restrictions is tourism, with a disproportionate impact felt in developing countries where tourism is often a large part of their economy.³⁵⁹ For example, “in Vanuatu, where tourism accounts for 40 percent of GDP, 70 percent of tourism jobs have been lost since mid-March 2020.”³⁶⁰ Rwanda lost an estimated \$8 million USD solely for the cancellation of twenty conferences in March and April 2020.³⁶¹ In addition, poor countries are having difficulty importing foodstuffs and have incurred significant losses from

Q2RL]; Katie Reilly, *Here Are All the Times Donald Trump Insulted Mexico*, TIME (Aug. 31, 2016, 11:35 AM), <https://time.com/4473972/donald-trump-mexico-meeting-insult> [<https://perma.cc/3XV4-GLE3>].

355 CASEY & CIMINO-ISAACS, *supra* note 345.

356 *Id.*

357 *Id.*

358 *Id.*; *About the G20*, G20, <https://www.g20.org/about-the-g20> [<https://perma.cc/4WDW-UVB2>].

359 Asif Khan et al., *Tourism and Development in Developing Economies: A Policy Implication Perspective*, 12 SUSTAINABILITY 1, 15 (2020); *Cross-Border Mobility, COVID-19 and Global Trade*, WTO (Aug. 25, 2020), https://www.wto.org/english/tratop_e/covid19_e/mobility_report_e.pdf [<https://perma.cc/Y3YS-LKCF>].

360 *Cross-Border Mobility*, *supra* note 359, at 4.

361 *Id.*

difficulties in exporting seasonal products.³⁶² Foreign direct investment in developing economies fell by 42 percent in 2020, and emerging market currencies depreciated by 15 percent.³⁶³ Overall, developing economies are expected to lose at least \$220 billion USD in income and incur between \$2.6 and \$3.4 trillion USD of total public external debt in the next two years, setting back decades of progress.³⁶⁴

If affected developing nations consider pursuing actions against Western countries in the WTO's dispute settlement body, they might find an ally in China, which has increasingly engaged in that forum. In June 2021, when asked to respond to a statement by the Australian Prime Minister that the WTO should penalize bad behavior, Chinese Foreign Ministry Spokesperson Wang Wenbin replied, "as is well known, major Western countries formulate most of the rules of world trade. It is their customary practice to maintain their hegemony and contain the growth of developing countries."³⁶⁵ He also noted, however, that trade restrictions taken by China "are in strict compliance with Chinese laws and regulations as well as WTO rules and are completely justified and lawful."³⁶⁶ Thus, any country looking to take China to the WTO over trade restrictions can expect a fight.

2. *Ramped-Up Rhetoric*

In addition to trade and travel restrictions, some Western countries are meeting China's narrative control tactics by ramping up anti-Chinese sentiment. Central to the narrative is the increasing demand to determine the origin of COVID-19.³⁶⁷ From a public health standpoint, determining the origin of COVID-19 is important for a variety of reasons, including preventive policymaking, as it is anticipated that future viruses will emerge from the same regions.³⁶⁸ But public debate on origin is clearly more political in nature than scientific. China insisted that WHO investigate potential origins outside China (including in Western

³⁶² *Id.* at 6.

³⁶³ Sung Lee, *COVID-19 Brief: Impact on the Economies of Developing Countries*, U.S. GLOB. LEADERSHIP COAL. (Apr. 8, 2021), <https://www.usglc.org/coronavirus/economies-of-developing-countries> [https://perma.cc/6SCK-BQV5].

³⁶⁴ *Id.*

³⁶⁵ *Foreign Ministry Spokesperson Wang Wenbin's Regular Press Conference on June 10, 2021*, MINISTRY FOREIGN AFFS. CHINA (June 10, 2021), <https://www.mfa.gov.cn/ce/cohk/eng/Topics/fyrbt/t1882905.htm> [https://perma.cc/F8S7-MTT5] [hereinafter *Wang's Press Conference*].

³⁶⁶ *Id.*

³⁶⁷ Guy Faulconbridge & Steve Holland, *G7 Chides China on Rights, Demands COVID Origins Investigation*, REUTERS (June 13, 2021, 10:05 AM), <https://www.reuters.com/world/china/china-cautions-g7-small-groups-dont-rule-world-2021-06-13> [https://perma.cc/J6CL-KHJH].

³⁶⁸ David M. Morens et al., *The Origin of COVID-19 and Why It Matters*, 103 AM. J. TROPICAL MED. & HYGIENE 955 (2020).

countries), while Western countries called for WHO to investigate and settle a dispute between two origin theories: namely, whether COVID-19 occurred naturally or as the result of a lab leak.³⁶⁹ But cohesion on this narrative has been a lot more difficult for the United States in particular because, unlike in China, where the government influences media, media in the United States often influences politicians.³⁷⁰

For example, the theory that COVID-19 unintentionally leaked from the Wuhan Institute of Virology (Wuhan Institute) was first suggested by Chinese researchers in February 2020.³⁷¹ U.S. Republicans quickly seized on this theory to fuel their hard-on-China platform, some even suggesting the virus was intentionally leaked.³⁷² But shortly thereafter, a prominent zoologist with financial and research ties to the Wuhan Institute, Peter Daszak, began publishing articles in well-respected scientific journals and media outlets labeling the lab leak theory a “conspiracy.”³⁷³ Daszak and his colleagues hoped that associating the theory with Donald Trump would quell interest in the lab he was invested in—and it worked.³⁷⁴ News media outlets such as CNN repeated the notion that the lab leak theory was a “conspiracy,” with Facebook labeling stories that COVID-19 was “man-made or manufactured” as misinformation.³⁷⁵ However, as investigative journalist Paul Thacker notes, when Trump left office, “the framing of the lab leak hypothesis as a partisan issue was harder to sustain.”³⁷⁶ Subsequently, media outlets, including ones that previously reported the lab leak as a conspiracy theory, have since been entertaining the theory.³⁷⁷

In addition, in March 2021, WHO released a report following its January

369 *Id.*

370 Paul Thacker, *The Covid-19 Lab Leak Hypothesis: Did the Media Fall Victim to a Misinformation Campaign?*, 374 *BMJ* 1 (2021); Alice Miranda Ollstein, *Virus Lab Leak Theory Dogs Democrats Eager to Keep Focus on Trump’s Covid Failings*, *POLITICO* (July 4, 2021, 7:00 AM), <https://www.politico.com/news/2021/07/04/wuhan-lab-leak-theory-democrats-497902> [<https://perma.cc/EN6F-BBDU>].

371 The original report, which was posted on ResearchGate, was removed shortly after publication. It is unclear who removed it or why. Thacker, *supra* note 370.

372 *Id.*; Philip Elliott, *How Distrust of Donald Trump Muddled the COVID-19 ‘Lab Leak’ Debate*, *TIME* (May 26, 2021, 3:37 AM), <https://time.com/6051414/donald-trump-wuhan-laboratory-leak/> [<https://perma.cc/4ZJW-WXYK>]; Amy Davidson Sorkin, *The Battle Over the Coronavirus Lab-Leak Theory*, *NEW YORKER* (June 13, 2021), <https://www.newyorker.com/magazine/2021/06/21/the-battle-over-the-coronavirus-lab-leak-theory> [<https://perma.cc/RB7X-WF8P>].

373 Thacker, *supra* note 370.

374 *Id.*

375 *Id.*

376 *Id.*

377 *Id.*

investigation in China that the lab leak theory was the least likely scenario, *though not impossible*.³⁷⁸ This report was met with skepticism by Western countries.³⁷⁹ The Director-General of WHO even admitted himself that the investigation was not extensive enough, warranting further research.³⁸⁰ Underlying this skepticism is the valid concern that China was not as forthcoming with its data as it should have been.³⁸¹ Fourteen nations, including the United States, Australia, Canada, Denmark, Japan, and the United Kingdom, subsequently issued a joint statement expressing concern about China's influence on WHO's January investigation.³⁸² This call was also coupled with increasing criticism by G7 allies of China's economic practices and human rights abuses, which China denies.³⁸³

Amid upcoming pressure from the 2022 mid-term elections, President Biden launched a U.S.-led intelligence investigation into the origins of COVID-19.³⁸⁴ But this investigation was no more revealing than WHO's January investigation, again likely due to China's lack of cooperation.³⁸⁵ In October 2021, WHO announced the launch of the new Scientific Advisory Group for the Origins of Novel Pathogens (SAGO), a diverse and well-qualified team of twenty-six scientists selected by WHO to further investigate the origins of COVID-19 as well as future pandemics.³⁸⁶ While the creation of SAGO is an important step toward a more

378 *Id.*; *Coronavirus: More Work Needed to Rule out China Lab Leak Theory Says WHO*, BBC NEWS (Mar. 31, 2021), <https://www.bbc.com/news/world-asia-china-56581246> [https://perma.cc/LRY2-NRKT].

379 Peter Beaumont, *UK and US Criticise WHO's Covid Report and Accuse China of Withholding Data*, GUARDIAN (Mar. 30, 2021, 2:08 PM), <https://www.theguardian.com/world/2021/mar/30/who-criticises-chinas-data-sharing-as-it-releases-covid-origins-report> [https://perma.cc/H2R6-FP6W].

380 *WHO Director-General's Remarks at the Member State Briefing on the Report of the International Team Studying the Origins of SARS-CoV-2*, WORLD HEALTH ORG. (Mar. 30, 2021), <https://www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-the-member-state-briefing-on-the-report-of-the-international-team-studying-the-origins-of-sars-cov-2> [https://perma.cc/7BUP-D339].

381 Beaumont, *supra* note 379.

382 Office of the Spokesperson, *Joint Statement on the WHO-Convened COVID-19 Origins Study*, U.S. DEP'T STATE (Mar. 30, 2021), <https://www.state.gov/joint-statement-on-the-who-convened-covid-19-origins-study> [https://perma.cc/QS7Q-AF6G].

383 Faulconbridge & Holland, *supra* note 367; Franco Ordonez & Asma Khalid, *Biden Pushes G-7 Allies to Take a Tougher Stance on China*, NAT'L PUB. RADIO (June 13, 2021, 1:58 PM), <https://www.npr.org/2021/06/13/1005969393/biden-spends-the-weekend-trying-to-persuade-g-7-leaders-to-push-back-on-china> [https://perma.cc/HV98-Q4XD].

384 Press Release, Statement by President Joe Biden on the Investigation into the Origins of COVID-19 (Aug. 27, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/27/statement-by-president-joe-biden-on-the-investigation-into-the-origins-of-covid> [https://perma.cc/BB9C-M6DT].

385 *Unclassified Summary of Assessment on COVID-19 Origins*, OFFICE OF THE DIR. OF NAT'L INTEL., <https://www.dni.gov/files/ODNI/documents/assessments/Unclassified-Summary-of-Assessment-on-COVID-19-Origins.pdf> [https://perma.cc/929Z-T2YJ].

386 Amy Maxmen, *WHO Names Researchers to Reboot Outbreak Origin Investigations*,

transparent and less objectionable investigation, concerns about China's cooperation still loom as an ultimate barrier to getting to the bottom of the issue.³⁸⁷

The ramped-up rhetoric is not as effective of a diplomacy tool for the United States as it is for China, largely because it has stirred up internal division.³⁸⁸ This is especially so for the United States, which has the highest level of division over its government's handling of COVID-19 out of thirteen other wealthy countries, according to one survey.³⁸⁹ Public opinion about media coverage of COVID-19 is correlated with political party.³⁹⁰ And public opinion, in turn, influences foreign policy.³⁹¹ In regards to global health, most European countries and the United States want to cooperate with China to prevent the spread of infectious disease.³⁹² However, while cooperation with China on epidemics is a top foreign policy priority in several EU countries, only a slim majority of Americans believe "many of the problems facing our country can be solved by working with other countries."³⁹³ Additionally, U.S.-China competition is still a cornerstone of the Biden Administration's foreign policy (albeit much less so than his predecessor's).³⁹⁴

As discussed earlier, China has called out the United States for its political

NATURE (Oct. 18, 2021), <https://www.nature.com/articles/d41586-021-02813-y> [<https://perma.cc/ED3V-4S3V>].

387 *Id.*

388 Michael Dimock & Richard Wike, *America is Exceptional in the Nature of its Political Divide*, PEW RSCH. CTR. (Nov. 13, 2020), <https://www.pewresearch.org/fact-tank/2020/11/13/america-is-exceptional-in-the-nature-of-its-political-divide> [<https://perma.cc/J6WJ-QRQS>].

389 *Id.*; Claudia Deane et al., *A Year of U.S. Public Opinion on the Coronavirus Pandemic*, PEW RSCH. CTR. (Mar. 5, 2021), <https://www.pewresearch.org/2021/03/05/a-year-of-u-s-public-opinion-on-the-coronavirus-pandemic> [<https://perma.cc/27KC-JU6D>].

390 Deane et al., *supra* note 389.

391 William A. Galston, *A Momentous Shift in US Public Attitudes Toward China*, BROOKINGS (Mar. 22, 2021), <https://www.brookings.edu/blog/order-from-chaos/2021/03/22/a-momentous-shift-in-us-public-attitudes-toward-china> [<https://perma.cc/7KGV-GFXR>].

392 Carroll Doherty et al., *Majority of Americans Confident in Biden's Handling of Foreign Policy as Term Begins*, PEW RSCH. CTR. (Feb. 24, 2021), <https://www.pewresearch.org/politics/2021/02/24/majority-of-americans-confident-in-bidens-handling-of-foreign-policy-as-term-begins/#americans-narrowly-see-solutions-to-u-s-problems-through-international-cooperation> [<https://perma.cc/APE4-LHR7>]; Richard Turcsányi et al., *European Public Opinion on China in the Age of COVID-19*, CENTRAL EUR. INST. ASIAN STUD. (2020), https://ceias.eu/wp-content/uploads/2020/11/COMP-poll-report_3.pdf [<https://perma.cc/HSA4-V7VV>].

393 Doherty et al., *supra* note 392.

394 *Id.*; Turcsányi et al., *supra* note 392; Cheng Li, *Biden's China Strategy: Coalition-Driven Competition or Cold War-Style Confrontation?*, BROOKINGS (May 2021), <https://www.brookings.edu/research/bidens-china-strategy-coalition-driven-competition-or-cold-war-style-confrontation> [<https://perma.cc/P63X-36NX>].

divides as well as its poor handling of the pandemic. Interestingly, many of the United States's allies agree with China in this regard.³⁹⁵ Out of seventeen nations surveyed, only Italy had a higher than 50 percent approval rating of how the United States handled the pandemic and every country surveyed except Japan believes that China handled the pandemic better than the United States.³⁹⁶ In addition, Americans and Europeans are not united on a COVID-19 origin theory.³⁹⁷ As of fall 2020, the prevailing origin theory in the United Kingdom, Sweden, and other European countries is that COVID-19 was spread through a Chinese person eating an infected bat.³⁹⁸ The prevailing theory in Germany and Russia in this same time period is that COVID-19 jumped naturally from animals to humans.³⁹⁹ As of summer 2021, polls show the prevailing theory in the United States and Poland is the lab leak theory (intentional and unintentional).⁴⁰⁰ Similar to the lack of data on how the Global South views China post-COVID-19, there is no robust data on how the Global South views the United States and its allies. In the same vein, however, it is likely that the anti-China rhetoric is more effective with domestic audiences than worldwide, though it may contribute to the vaccine hesitancy in some States receiving Chinese vaccines.⁴⁰¹

3. "Vaccine Diplomacy"—The United States Counters

China's efforts to vaccinate the world have not gone unnoticed by the United States.⁴⁰² But until recently, the United States's vaccination efforts prioritized vaccinating Americans first.⁴⁰³ In February 2021, President Biden announced a \$2 billion USD commitment to COVAX, a program co-led by WHO to accelerate country readiness and vaccine delivery with a focus on the most vulnerable

395 Kat Devlin, Moira Fagan & Aidan Connaughton, *Global Views of How U.S. has Handled Pandemic have Improved, but Few Say it's Done a Good Job*, PEW RSCH. CTR. (June 10, 2021), <https://www.pewresearch.org/fact-tank/2021/06/10/global-views-of-how-u-s-has-handled-pandemic-have-improved-but-few-say-its-done-a-good-job> [https://perma.cc/X5JQ-DN6T].

396 *Id.*

397 Turcsányi, *supra* note 392.

398 *Id.*

399 *Id.*

400 *Id.*; Alice Miranda Ollstein, *POLITICO-Harvard Poll: Most Americans Believe Covid Leaked from Lab*, POLITICO (July 9, 2021, 6:00 AM), <https://www.politico.com/news/2021/07/09/poll-covid-wuhan-lab-leak-498847> [https://perma.cc/ML8Z-GLAR].

401 Huizhong Wu & Kristen Gelineau, *Chinese Vaccines Sweep Much of the World, Despite Concerns*, AP (Mar. 1, 2021), <https://apnews.com/article/china-vaccines-worldwide-0382aefa52c75b834fbaf6d869808f51> [https://perma.cc/E3ZJ-AHXC].

402 Ciara Nugent & Charlie Campbell, *The U.S. and China are Battling for Influence in Latin America, and the Pandemic has Raised the Stakes*, TIME (Feb. 4, 2021, 6:07 AM), <https://time.com/5936037/us-china-latin-america-influence> [https://perma.cc/SN2R-PJHK].

403 *Id.*

countries.⁴⁰⁴ In June 2021, the Biden Administration announced a framework to ship at least eighty million vaccines globally by the end of June, 75 percent through COVAX and 25 percent government-to-government.⁴⁰⁵ Of those, the first twenty-five million doses will be distributed to specifically targeted countries, and the rest will prioritize countries in Latin America and the Caribbean.⁴⁰⁶

As of July 1, 2021, the United States fell about fifty-six million doses short of its eighty million dose goal, citing regulatory hurdles, though shipments have picked up since then.⁴⁰⁷ This may be considered by some as a blow to the United States as it attempts to play catch-up with China, which had delivered over 350 million doses globally as of this date (China has now allegedly delivered 1.56 billion doses worldwide).⁴⁰⁸ Interestingly, the two competing countries have sung very different tunes when it comes to this so-called “vaccine diplomacy.” On the

404 Press Release, White House, Fact Sheet: President Biden to Take Action on Global Health through Support of COVAX and Calling for Health Security Financing (Feb. 18, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/18/fact-sheet-president-biden-to-take-action-on-global-health-through-support-of-covax-and-calling-for-health-security-financing> [<https://perma.cc/7QFD-PUUR>].

405 Press Release, White House, Fact Sheet: Biden-Harris Administration Unveils Strategy for Global Vaccine Sharing, Announcing Allocation Plan for the First 25 Million Doses to be Shared Globally (June 3, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/03/fact-sheet-biden-harris-administration-unveils-strategy-for-global-vaccine-sharing-announcing-allocation-plan-for-the-first-25-million-doses-to-be-shared-globally> [<https://perma.cc/3CBC-TDHM>].

406 *Id.*

407 Zeke Miller, *Biden Misses Vaccine-Sharing Goal, Cites Local Hurdles*, AP (July 1, 2021), <https://apnews.com/article/joe-biden-coronavirus-pandemic-coronavirus-vaccine-health-government-and-politics-37174e3cc360d56550b3d5f90477ad01> [<https://perma.cc/Y3G5-VD6G>]; Susan Heavey, *Moldova Gets 500,000 Doses of J&J's COVID-19 Vaccine from U.S.-State Dept.*, REUTERS (July 13, 2021, 8:53 AM), <https://www.reuters.com/world/europe/moldova-gets-500000-doses-jjs-covid-19-vaccine-us-state-dept-2021-07-13> [<https://perma.cc/Q9PP-SY2J>]; Andrea Shalal, *U.S. Shipping COVID-19 Vaccines to Indonesia, Bhutan, Nepal*, REUTERS (July 9, 2021, 11:41 AM), <https://www.reuters.com/world/asia-pacific/us-shipping-covid-19-vaccines-bhutan-nepal-friday-2021-07-09> [<https://perma.cc/929H-3K3E>].

408 Jonah Shepp, *The U.S. is Playing Catch-Up at Vaccine Diplomacy*, N.Y. MAG. (May 9, 2021), <https://nymag.com/intelligencer/2021/05/the-u-s-is-playing-catch-up-at-vaccine-diplomacy.html> [<https://perma.cc/NX75-UUAK>]; Wang's Press Conference, *supra* note 365; *China COVID-19 Vaccine Tracker*, BRIDGE BEIJING (Apr. 11, 2022), <https://bridgebeijing.com/our-publications/our-publications-1/china-covid-19-vaccines-tracker> [<https://perma.cc/T35H-GERQ>]. It should be noted that there is a discrepancy on reporting of whether the United States or China has shipped more doses of vaccines as of July 1, 2021. Zeke Miller of the AP News reported that the 24 million doses the United States has shipped is more than China, though the Chinese Foreign Ministry claims it has shipped over 350 million doses, which was also reported by CNN. Compare Miller, *supra* note 407, with Julia Hollingsworth, Saruul Enkhbold & Amy Sood, *Why Covid-19 Outbreaks in Countries Using Chinese Vaccines Don't Necessarily Mean the Shots have Failed*, CNN (July 3, 2021, 12:56 AM), <https://www.cnn.com/2021/07/02/china/vaccines-sinovac-sinopharm-intl-hnk-dst/index.html> [<https://perma.cc/95J3-7WUL>].

one hand, when asked in June to comment on President Biden's pledge to donate millions of vaccine doses to COVAX, Spokesperson Wang replied, "[a]s we all know, until recently, the US has been stressing that its top priority with vaccines is domestic rollout. Now that it has announced donation to COVAX, we hope it will honor its commitment as soon as possible."⁴⁰⁹ He stressed the cooperation and solidarity of the international community in fighting the virus.⁴¹⁰ Wang has otherwise denied China's use of vaccines for geopolitical purposes.⁴¹¹ On the other hand, U.S. officials have taken digs at China while simultaneously denying "vaccine diplomacy." For example, in March 2021, U.S. Navy Admiral Craig Fuller testified before the Senate that China is "taking advantage of the pandemic, deploying medical diplomacy and disinformation campaigns."⁴¹² On June 3, 2021, Biden stated, "[w]e are sharing these doses not to secure favors or extract concessions. We are sharing these vaccines to save lives and to lead the world in bringing an end to the pandemic, with the power of our example and with our values."⁴¹³

In reality, the United States's targeted vaccine delivery is certainly its own brand of vaccine diplomacy, though it is less about being seen as a leader in global health than a global leader in general. In a particularly telling piece, TIME Magazine reported that

The U.S. State Department is engaged in its own counter-operation, sources tell TIME. By cross-referencing pure numbers of PPE dispatched by Beijing and private Chinese entities like the Jack Ma Foundation with medical need and existing cordial ties, Washington is learning where China is placing strategic bets and deciding where to send its own coronavirus aid to compete most effectively.⁴¹⁴

It noted that Latin America, as the United States's neighbor, has always been an important locus of U.S. foreign policy since the 1823 Monroe Doctrine and the

⁴⁰⁹ Wang's Press Conference, *supra* note 365.

⁴¹⁰ *Id.*

⁴¹¹ *Xinhua Commentary: Accusing China of "Vaccine Diplomacy" Simply Groundless*, XINHUA (Dec. 31, 2020), http://www.xinhuanet.com/english/2020-12/31/c_139631853.htm [<https://perma.cc/299G-2G2Z>].

⁴¹² *Southcom's Posture Statement to Congress Before the S. Armed Serv. Comm.*, 117th Cong. (2021) (statement of Admiral Craig S. Fuller), https://www.armed-services.senate.gov/imo/media/doc/Faller_03-16-21.pdf [<https://perma.cc/ED9Y-TRAV>].

⁴¹³ Press Release, White House, Statement by President Joe Biden on Global Vaccine Distribution (June 3, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/03/statement-by-president-joe-biden-on-global-vaccine-distribution> [<https://perma.cc/25XS-NSNF>].

⁴¹⁴ Nugent & Campbell, *supra* note 402.

Cold War.⁴¹⁵ In particular, the Panama Canal and the free trade zone the United States helped establish around it have historically been a boon to U.S.-based businesses.⁴¹⁶ Yet, in the past few years, China has made giant in-roads with Latin American countries. Most significantly, nineteen countries in Latin America and the Caribbean have joined China's Belt and Road Initiative, and in the past four years, four countries have switched their official recognition of the Chinese government from Taiwan to Beijing.⁴¹⁷ One expert warns that these in-roads, in conjunction with the negative actions of the Trump Administration, may lead some Latin American countries to "stick with China" if forced to choose between it and the United States.⁴¹⁸ However, it may simply be the case that developing nations see through the veil. Commentators from Latin America to Africa have called out both the United States and China for their "[C]old-[W]ar adjacent behavior"—they simply want to end the pandemic.⁴¹⁹

V. CONCLUSION

Since COVID-19, global health law experts are once again calling for revisions of the IHR.⁴²⁰ As noted above, the global health community has even gone so far as to seriously discuss an entirely new treaty on pandemic preparedness. But needing to revise the IHR after every major disease outbreak is a sign that the concept itself is not working. Even if a revised treaty contained more stringent obligations or a compulsory dispute settlement mechanism, there is no guarantee that perpetual violators such as the United States and China would recognize those obligations or processes, and they may even withdraw altogether.

415 *Id.*

416 *Id.*

417 *Id.*

418 *Id.*

419 Winnie Makau, *The Impact of COVID-19 on the Growing North-South Divide*, E-INT'L. RELS. (Mar. 15, 2021), <https://www.e-ir.info/2021/03/15/the-impact-of-covid-19-on-the-growing-north-south-divide> [<https://perma.cc/4TTT-PAHM>]; *see also* Nugent & Campbell, *supra* note 402 ("In January, Sixto Pereira, an opposition Senator in Paraguay who earlier coordinated the Chinese donation of PPE, accused the country's government in local media of bowing to U.S. pressure in rejecting offers of vaccine support from China. 'We must overcome political and ideological barriers if we're going to fight the evil of the pandemic,' he says. It may be a simple reading of geopolitics, but it's a frustration that many in Latin America are feeling as the region navigates not only its path out of COVID-19, but also its road to future trade and development in the emerging world order. 'The Berlin Wall fell, the Cold War finished,' Pereira says. 'In this globalized world, we don't want to be any country's backyard.'"); Liu et al., *supra* note 306.

420 *See, e.g.*, Lawrence O. Gostin, Roojin Habibi & Benjamin Mason Meier, *Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats*, 48 J. L. MED. & ETHICS 376 (2020), <https://scholarship.law.georgetown.edu/facpub/2264/> [<https://perma.cc/CMM7-Z3X9>].

The biggest failure with the current IHR is the unchecked ability of countries to implement harmful trade and travel restrictions after an outbreak. These travel and trade restrictions incentivize delayed reporting and have a disproportionate impact on poorer countries. Decades of State practice have shown that the motivating factor for State actions is not reputational but economic concern. Thus, WHO should consider compliance mechanisms with economic, and not reputational, stakes.

One potential solution suggested by Lawrence Gostin, a global health law expert, is a global funding mechanism that would allow for “the development of new or global governance institutions to pool international funding and bolster technical support for the development of sustainable national public health systems to prevent, detect, and respond to outbreaks.”⁴²¹ Going further, assistance from these development programs could be tied to compliance, thus creating more tangible incentives than reputational concerns. For example, member States with good track records for compliance with any of the IHR requirements may qualify for additional financial, technical, or logistical support from WHO for WHO programs. This would promote compliance for several reasons. For one, it rewards good State behavior but does not punish bad behavior. Punishing noncompliance by, say, withholding WHO assistance would be contrary to the overall goal of improving global health and may further incentivize States to cover up concerning health situations. Rewarding positive behavior, however, would promote cooperation and may also create domestic pressure from residents who stand to benefit from WHO programs.

Another potential solution is for WHO to do more to encourage bilateral or multilateral agreements among member States to encourage feelings of reciprocal obligations, which are more likely to be observed. Article 57 of the IHR provides that “nothing in these Regulations shall prevent States Parties having certain interests in common owing to their health, geographical, social or economic conditions from concluding special treaties or arrangements in order to facilitate the application of these Regulations”⁴²² This would be particularly helpful in the management of trade relations. Whereas the expansion to a non-exhaustive list of health hazards made it impossible for the IHR to include an exhaustive list of appropriate additional health measures, the parameters of bilateral or multilateral agreements would be significantly pared down to country or region-specific considerations. States could mutually agree on a forum to settle disputes, which would increase the likelihood of submitting to jurisdiction (i.e., China may select the WTO dispute settlement body). In addition, the WHA may consult in the agreement-making process as a safeguard against agreements by powerful States

⁴²¹ *Id.*

⁴²² IHR, *supra* note 2.

that may have the potential to negatively affect poor States. This could be achieved through an amendment to Article 57 of the IHR that specifically allows for and confers on WHA the ability to consult with States on public-health-related treaties. It is likely not possible, however, to mandate WHA approval of such treaties, though there is nothing to stop the WHA from commenting on other treaties' compatibility with IHR requirements. In addition, while future revision to the IHR is highly plausible, there are too many factors weighing against the consensus necessary to pass a compulsory dispute settlement mechanism. Similarly, the other proposed reforms to promote compliance are not legally binding, and even if implemented, their likely impact, at best, would be more influence on soft power behaviors.

The current version of the IHR has led to some health improvements, such as core capacity-building. But its ineffectiveness as a legal tool to combat the international spread of infectious disease has proven how just one violation can contribute to the decimation of a health system. In addition, the IHR has not been effective at preventing unnecessarily restrictive trade and travel measures in the face of crises. Without legitimate repercussions, States have the unfettered ability to implement restrictions that benefit themselves at the expense of other countries that often have much more to lose. Furthermore, efforts at global health diplomacy have helped to pick up the slack when most needed but have also contributed to rising geopolitical tensions. Ideally, the IHR should function in a way that mitigates the opportunities for powerful countries such as the United States and China to take advantage of global health needs for political and economic gain. Whether that change comes from within the existing framework of the IHR or a more innovative solution is up to WHO and its Member States, but the current status quo leaves the world woefully unprepared for the next major pandemic.

Data Privacy in the Time of Plague

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Abstract:

Data privacy is a life-or-death matter for public health. Beginning in late fall 2019, two series of events unfolded, one everyone talked about and one hardly anyone noticed: The greatest world-health crisis in at least 100 years, the COVID-19 pandemic; and the development of the Personal Data Protection Act Committee by the Uniform Law Commissioners (ULC) in the United States. By July 2021, each of these stories had reached a turning point. In the developed, Western world, most people who wanted to receive the vaccine against COVID-19 could do so. Meanwhile, the ULC adopted the Uniform Personal Data Protection Act (UPDPA) at its annual meeting, paving the way for state legislatures to adopt it beginning in 2022. It has so far been introduced in three jurisdictions.

These stories intersect in public health. Public health researchers struggled with COVID-19 in the United States because they lacked information about individuals who were exposed, among other matters. Understanding other public health threats (e.g., obesity, opioid abuse, racism) also requires linking diverse data on contributing social, environmental, and economic factors. The UPDPA removes some barriers to public health practice and research resulting from the lack of comprehensive federal privacy laws. Its full potential, however, can be achieved only with involvement of public health researchers and professionals. This article analyzes the UPDPA and other comprehensive state privacy statutes, noting the ways that they could promote—and hinder—public health. It concludes with recommendations for public health researchers and professionals to get involved in upcoming legislative debates on data privacy. Lives will depend on the outcomes.

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INTRODUCTION	155
I.THE CONTEMPORARY PUBLIC HEALTH AND LEGAL LANDSCAPES	159
A. PUBLIC HEALTH RESEARCH AND PRACTICES	159
1. PUBLIC HEALTH RESEARCH	160
2. SURVEILLANCE	161
3. PUBLIC HEALTH PROGRAMS AND POPULATION INTERVENTIONS	162
4. INDIVIDUAL-BASED INTERVENTIONS.....	164
B. AMERICAN DATA PROTECTION AND PRIVACY LAW.....	168
1. THE CURRENT PATCHWORK OF LAW	168
2. CHANGES ON THE HORIZON.....	171
C. NORMATIVE CONCERNS AT THE BOUNDARIES	174
1. IS “NOTICE AND CHOICE” POSSIBLE?	175
2. IS “NOTICE AND CHOICE” DESIRABLE?	177
3. DEFAULTS SHOULD PLAY AN IMPORTANT ROLE	182
II. ANALYSIS OF THE UPDPA AND CAVACO STATUTES	186
A. SUBSTANTIVE INFORMATION CONTENT	189
B. DATA IDENTIFIABILITY	192
C. DATA SENSITIVITY	197
D. REGULATED ENTITY	199
E. DATA PRACTICES	202
1. FAVORED DATA PRACTICES	202
2. RESTRICTED DATA PRACTICES.....	205
3. PROHIBITED DATA PRACTICES	208
F. OTHER REQUIREMENTS OF CONTROLLERS AND PROCESSORS.....	209
G. THE UPDPA VOLUNTARY CONSENSUS STANDARDS.....	211
H. ENFORCEMENT AND PENALTIES	213
I. INTERACTION WITH OTHER STATUTES.....	214
III. EVALUATION AND INTERVENTIONS	216
A. THE UPDPA AND THE CAVACO STATUTES VS. NORMATIVE PRIVACY	

YALE JOURNAL OF HEALTH POLICY, LAW, AND ETHICS 21:1 (2022)

FRAMES 216

B. HELPING AND HINDERING PUBLIC HEALTH ACTIVITIES 219

1. REAL AND PERCEIVED BARRIERS TO DATA USE FOR PUBLIC
HEALTH PRACTICE AND RESEARCH 220

2. DATA USES FOR RESEARCH..... 221

3. DATA USES FOR PUBLIC HEALTH PRACTICE 224

CONCLUSION 226



INTRODUCTION

It is a commonplace and a cliché in legal scholarship and the broader culture that American data privacy laws are a “patchwork” of solutions to discrete privacy issues that leave significant gaps and open questions about which personal data are subject to protection and to what extent.¹ There is no blanket of privacy law that covers all subjects, types, and users of data. Patches cover some, overlapping in some cases with each other, but in other cases leaving large parts of the body of data uncovered.² One impetus for this Article grows from a series of events in 2021 that respond to this patchwork: Adoption by Virginia and Colorado of comprehensive data privacy legislation and approval by the Uniform Law Commissioners (ULC)³ of the Uniform Personal Data Protection Act (UPDPA).⁴ These developments occurred against the backdrop of significant changes to California’s 2018 comprehensive privacy act resulting from a 2020 referendum. This Article is the first to our knowledge to critically assess the

1 *E.g.*, Thorin Klosowski, *The State of Consumer Data Privacy Laws in the US (And Why It Matters)*, N.Y. TIMES (Sep. 6, 2021), <https://www.nytimes.com/wirecutter/blog/state-of-privacy-laws-in-us/> [<https://perma.cc/RG26-2CPC>] (“The United States doesn’t have a singular law that covers the privacy of all types of data. Instead, it has a mix of laws that go by acronyms and initialisms like HIPAA, FCRA, FERPA, GLBA, ECPA, COPPA, and VPPA”); Brouse McDowell, Craig S. Horbus & Jarman J. Smith, *Corporate TIPS: U.S. Data Privacy Law Patchwork Grows as States Enact New Legislation*, LEXOLOGY (Aug. 18, 2021), <https://www.lexology.com/library/detail.aspx?g=e24fedac-cea7-412a-a5eb-5d736276e8d6> [<https://perma.cc/RLQ2-J4GE>]; Natasha Singer, *An American Quilt of Privacy Laws, Incomplete*, N.Y. TIMES (Mar. 30, 2013), <https://www.nytimes.com/2013/03/31/technology/in-privacy-laws-an-incomplete-american-quilt.html> [<https://perma.cc/G4UU-DLMZ>]; Anthony Jones, *Autonomous Cars: Navigating the Patchwork of Data Privacy Laws That Could Impact the Industry*, 25 CATH. U.J.L. & TECH. 180 (2017); Kiran K. Jeevanjee, *Nice Thought, Poor Execution: Why the Dormant Commerce Clause Precludes California’s CCPA from Setting National Privacy Law*, 70 AM. U. L. REV. F. 75 (2020); Stephanie Comstock Ondrof, “Senator, We Run Ads”: *Advocating for a US Self-Regulatory Response to the EU General Data Protection Regulation*, 28 GEO. MASON L. REV. 815, 819 (2021). The reporters for the American Law Institute describe it instead as an “interrelated amalgam of different types of law,” PRINCIPLES OF THE LAW OF DATA PRIVACY § 1 (AM. L. INST. 2019) [hereinafter PRINCIPLES OF DATA PRIVACY], as “a complex aggregation of overlapping and inconsistent laws that represent an increasingly significant compliance burden,” and as “sectoral,” contrasting with “omnibus” regulatory regimes. *Id.* § 1, cmt. e. (We use “comprehensive” below to refer to “omnibus” regimes.) The reporters for ALI’s initiative were leading data-privacy scholars Professors Paul M. Schwartz and Daniel J. Solove. *Id.* at vii.

2 See *infra* text accompanying note 85.

3 The group is also known the National Conference of Commissioners on Uniform State Laws. *About Us*, UNIF. L. COMM’N, <https://www.uniformlaws.org/aboutulc/overview> [<https://perma.cc/HD2M-PCDW>] (last visited Sept. 14, 2021).

4 Consumer Data Protection Act, VA. CODE ANN. §§ 59.1-575 to 59.1-585 (2021) (effective Jan. 1, 2023) [hereinafter VCDPA]; Colorado Privacy Act, COLO. REV. STAT. §§ 6-1-104 to 110, 6-1-1301 to 1313 (2021) (effective July 1, 2023) [hereinafter CPA] UNIF. PERS. DATA PROT. ACT (Unif. L. Comm’n 2021) [hereinafter UPDPA]; see also California Consumer Privacy Act, CAL. CIV. CODE §§ 1798.100–1798.199.100 (2021) (effective Jan. 1, 2023) [hereinafter CCPA].

UPDPA and the adopted comprehensive acts in California, Virginia, and Colorado—which we refer to as the “CAVACO statutes”—side by side. This analysis is timely, as the UPDPA has already been introduced in three U.S. jurisdictions as of February 2022 and may prove an influential model for state privacy law.

Personal data also play a critical role in public health interventions and research, and a second impetus for this Article grows from public health crises that have rocked the United States in 2020–21 and the need for researchers to have access to so-called “big data” to address these crises. Talk of COVID-19 has been ubiquitous in the media, of course, but a second set of newsworthy events highlights other equally pernicious public health crises: racism and health risks associated with the poverty that disproportionately afflicts persons of color in the United States. Furthermore, media coverage of these crises has overshadowed other persistent and growing public health threats, like obesity, opioid abuse, homelessness, climate change, and mental health. These crises plague America, and data privacy legislation holds the potential to make ameliorating them less—or more—difficult.

As a preliminary matter, data protection laws raise particular concerns for promoting public health. Readers might wonder why these statutes are of concern to public health researchers and professionals. After all, many public health agencies are arms of local and state governments, and the UPDPA and the CAVACO statutes exclude government agencies from their coverage. The point is well taken, but it does nothing to allay concerns of public health researchers who may be affiliated with private institutions. Furthermore, the key challenge here relates to “secondary uses.” Primary uses are those that permit us to live in the digital world, the very uses for which the data are collected. Secondary uses are those where data are collected for one purpose and reused for a different purpose, particularly where private entities gather data for business purposes and public health researchers and practitioners seek access to those data for public health purposes.

There are various ways that personal data—not just health data—can be used to improve public health.⁵ Of course, there is research for scientific purposes. University and non-profit researchers want data to understand if two things are related; for example, whether a public-health initiative—perhaps a “nudge” for consumers to choose to donate their organs⁶—is effective at achieving its goals. They also want to learn about how the world works; how poverty and racism relate to disease, for example. Research based on secondary use of existing data is much cheaper than research that requires collecting new data from individuals,

5 For more details, *see* Part I(A).

6 RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE* 254 (Final ed. 2021).

and it permits using sizable longitudinal datasets accumulated over time. In addition, some research is not possible without re-using existing data. Researchers and public health professionals can also make secondary use of aggregated data to promote population health and well-being. For example, personal data about health diagnoses and outcomes can be linked to other data to understand the cause of injuries, diseases, or poor health and to help officials develop prevention strategies.

Personal data can also be used for interventions that seem less benign. For example, an employer could use data about employees to change their health insurance premiums based on whether the employees have been vaccinated against a disease.⁷ The government could use contact-tracing information regarding a pandemic illness to identify carriers and potential carriers and impose isolation or quarantine orders.⁸ As we explain below, these examples highlight differences between using data for what is often called “human subjects research” and for public health interventions. The Common Rule, the regulations for research using human subjects, which is supported by twenty federal agencies, governs research on human subjects in many settings.⁹ An Institutional Review Board (IRB) that “has been formally designated to review and monitor” research generally supervises such research projects.¹⁰

The UPDPA and the other state acts apply to most such secondary data practices, so understanding *how* they do so is critical. They may have an especially significant potential to affect the use of personal data for public health interventions and research. For that reason, an evaluation of the UPDPA and the

7 Niraj Chokshi, Margot Sanger-Katz & Tara Siegel Bernard, *Delta's Extra \$200 Insurance Fee Shows Vaccine Dilemma for Employers*, N.Y. TIMES (Aug. 26, 2021), <https://www.nytimes.com/2021/08/26/business/delta-insurance-fee-unvaccinated.html> [https://perma.cc/ZY8B-7ECT].

8 See *Frequently Asked Questions: Contact Tracing*, CTRS. DISEASE CONTROL, <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#:~:text=Discussions%20with%20health%20department%20staff,or%20local%20health%20department> [https://perma.cc/8JZN-MAZX] (last visited Sept. 18, 2021).

9 Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017) (to be codified at 6 C.F.R. Part 46 and several other points) [hereinafter Common Rule]. The Federal Food and Drug Administration regulations that govern human subjects research are also highly similar to the Common Rule regulations. 21 C.F.R. § 50.1 (2020).

10 U.S. FOOD & DRUG ADMIN., *Institutional Review Boards (IRBs) and Protection of Human Subjects in Clinical Trials* (Sept. 11, 2019), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-review-boards-irbs-and-protection-human-subjects-clinical-trials> [https://perma.cc/GFU5-AJPZ]. Universities and similar research institutions typically have their own IRBs and subject most of their research to their supervision. See, e.g., Committee on the Use of Human Subjects, HARVARD UNIVERSITY, <https://cuhs.harvard.edu/> [https://perma.cc/67AR-2M69] (last visited Feb. 12, 2022); Institutional Review Boards (IRBMED), U. OF MICH. MED. SCH., <https://research.medicine.umich.edu/our-units/institutional-review-boards-irbmed> [https://perma.cc/XQJ2-B8CH] (last visited Feb. 12, 2022).

other state comprehensive acts from the perspective of public health is particularly important now. To our knowledge, this Article is the first to closely examine the effect on public health of any state comprehensive privacy statute, including California's now-four-year-old law.

Part I introduces the present landscape in public health and U.S. data protection law, considering both the existing laws and some proposals for reorganizing and reimagining the privacy paradigm within American law. We explain why we focus the balance of this Article on the "notice and choice" paradigm that is evident in the existing legislation. Our position is that an ethics of data privacy should focus on the autonomy of data subjects, their ability to know of and consent to data practices to which their personal data are subjected. At the same time, given that certain "defaults" are at play in modern consent processes—click-through privacy policies and the like—regulators should establish consent defaults that favor some secondary uses of personal data in line with public interests and preferences, uses that minimize social harms and maximize community benefits, including uses for public health and research.

Part II provides a conceptual framework for data protection law in the "notice and choice" paradigm. It defines terms and identifies important characteristics of any data-protection regime, providing an extension of existing conceptual frameworks, such as the American Law Institute's *Principles of the Law of Data Privacy*.¹¹ Part II analyzes the UPDPA and CAVACO statutes using this conceptual framework. The detailed analysis is essential for privacy-law theorists, legislators, and groups interested in proposed privacy legislation that is being deliberated today.¹²

Part III assesses the UPDPA and CAVACO statutes against the normative frameworks previously discussed and recommends ways in which public health researchers and professionals may wish to intervene in coming months and years in the deliberations on data protection statutes. As Table 1 shows, the Colorado Privacy Act is the most supportive of public health practices and research, exempting a wide swath of them from its coverage and permitting most others without the necessity of disclosing them to data subjects. Some ethicists might go as far as to say it is *too* friendly to public health because of this lack of disclosure, and we'd agree. The California Consumer Privacy Act broadly supports research, but generally requires that those collecting data from consumers for public health activities, like public health surveillance and interventions, must disclose the practices and give data subjects the chance to opt out. This most closely fits the normative frameworks we outline below. The

¹¹ PRINCIPLES OF DATA PRIVACY, *supra* note 1.

¹² Part II cannot claim, however, to provide a comprehensive analysis of all aspects of these acts.

UPDPA raises a concern regarding the need for data subjects to opt in for uses of sensitive personal data—the kind of data often at issue in public health practices and research. Finally, the Virginia Consumer Data Protection Act requires consumers to opt in for almost all public health data practices, which could gravely impair public health activities subject to that act. We propose that public health researchers and professionals should seek to amend the Colorado and Virginia acts and should seek to revise the UPDPA as it is adopted in states to conform them to the normative frameworks we provide. We offer other suggestions as well.

In theory, a comprehensive privacy law is a smooth blanket, covering all circumstances while permitting appropriate socially desirable and beneficial uses, like those for research and public health. Our review of the UPDPA and CAVACO statutes shows that they do privilege some public health activities, particularly generalizable research, but that public health professionals must involve themselves actively in legislative and regulatory activity surrounding future adoption of such acts to improve them and to ensure that legislators and regulators do not forget public health in their rush to protect private data. A comprehensive data protection framework should provide a protective blanket unmarred by patchwork holes—not merely a sheet to cover the bodies of the dead.

I. THE CONTEMPORARY PUBLIC HEALTH AND LEGAL LANDSCAPES

Analyzing and evaluating the UPDPA and the CAVACO statutes requires some background in the public health and legal landscapes in the United States. This includes a basic understanding of public health practices, an overview of U.S. data privacy and protection law, and a discussion of normative concerns at the boundaries of these two disciplines.

A. Public Health Research and Practices

Public health, as both a science and a practice, is data driven. Data inform epidemiologists about the nature of disease and conditions that affect health. These data can help public health practitioners understand whether a disease spreads through air, touch, bodily fluids, animal contact, or consumption of tainted food.¹³ Data can also help build an understanding of how social and environmental factors—such as walkable communities, food deserts,

13 See J.A. Magnuson et al., *Informatics in Disease Prevention and Epidemiology*, in PUBLIC DISEASE HEALTH INFORMATICS AND INFORMATION SYSTEMS 239, 239–57 (J.A. Magnuson & Brian E. Dixon, eds., 3d ed. 2020), https://link.springer.com/chapter/10.1007/978-3-030-41215-9_14 [<https://perma.cc/BKU5-BPX4>] (describing public health informatics and disease investigation generally).

environmental contamination, economic inequities, and structural racism—affect health.¹⁴ We can divide the activities that use these data into public health research, which seeks generalized knowledge; surveillance, which monitors health data to enable and assess interventions; community interventions or health programs designed to improve population health; and individual interventions, intended to serve at-risk individuals or protect the rest of the population from them.

The COVID-19 pandemic exposed the limitations of the traditional public health system, as it was unable to acquire, ingest, and share the unprecedented volumes of data needed to understand and control a rapidly spreading virus.¹⁵

1. Public Health Research

The field of public health is grounded in scientific evidence. This body of evidence includes, but is not limited to, microbiology, physiology, sociology, and policy research.¹⁶ Public health research aims to generalize the results from a

14 Sandro Galea et al., *Estimated Deaths Attributable to Social Factors in the United States*, 101 AM. J. PUB. HEALTH 1456, 1462–63 (2011) (estimating hundreds of thousands of deaths associated with non-biological factors, including education, racism, and economic inequity); see also Paula Braveman & Laura Gottlieb, *The Social Determinants of Health: It's Time to Consider the Causes of the Causes*, 129 PUB. HEALTH REPS. 19, 27 (2014) (describing the difficulty obtaining the cross-sectoral data needed to study social determinants of health).

15 See generally Willem G van Panhuis et al., *A Systematic Review of Barriers to Data Sharing in Public Health*, 14 BMC PUB. HEALTH 1144 (2014); Drew Armstrong, *Data Failures Keep the CDC From Seeing the Whole Picture on COVID*, BLOOMBERG (Dec. 21, 2021), <https://www.bloomberg.com/news/articles/2021-12-21/cdc-public-health-data-failures-mean-u-s-lacks-whole-picture-on-covid> [<https://perma.cc/5LQS-ASVH>]; Xenia Shih Bion, *Crumbling Data Infrastructure Undermines Nation's Pandemic Reponse*, CAL. HEALTH CARE FOUND. BLOG, <https://www.chcf.org/blog/crumbling-data-infrastructure-undermines-nations-pandemic-response/> [<https://perma.cc/42G3-NPXT>] (last visited Apr. 11, 2022). Many of these deficiencies are due to the three challenges in the U.S. public health system. First, public health in the United States is chronically underfunded, particularly after state and local budget cuts following the 2008 Great Recession. Second, the decentralized U.S. public health system—a product of the Tenth Amendment of the Constitution—imposes legal, political, and relationship barriers between local, state, and federal public health partners seeking to share public health information. See generally Panhuis et al., *supra*. Third, many available data that are relevant to public health are subject to restrictive data protection laws. See generally Rachel Hulkower, Matthew Penn & Cason Schmit, *Privacy and Confidentiality of Public Health Information*, in PUBLIC HEALTH INFORMATICS AND INFORMATION SYSTEMS 147 (J.A. Magnuson & Brian E. Dixon eds., 3d ed. 2020). However, a comprehensive overview of the challenges facing public health informatics and public health data systems is beyond the scope of this work.

16 See generally PUBLIC HEALTH INFORMATICS AND INFORMATION SYSTEMS (J.A. Magnuson & B.E. Dixon eds., 3d ed. 2020); Evan Anderson et al., *Measuring Statutory Law and Regulations for Empirical Research*, PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS 237 (A. C. Wagenaar & S. Burris eds., 1st ed. 2013); see PUBLIC HEALTH INFORMATICS, *supra*, at 71–73; Braveman & Gottlieb, *supra* note 14, at 27.

discrete study sample in a specified period in time to a broader population.¹⁷ This is in contrast to the *practice* of public health, which involves ongoing efforts to monitor an entire community or population.¹⁸ Public health research includes studies that require data collection (e.g., surveys, environmental sample collection) as well as studies that rely on pre-existing data (e.g., electronic health records).¹⁹ Whenever public health research uses data from identifiable human data subjects, the Common Rule regulations protecting human subjects research will likely apply.²⁰

2. Surveillance

There are several different types of public health surveillance that help public health professionals understand the threats to population health. Unlike health research, public health surveillance is “the *ongoing*, systematic collection, analysis, and interpretation of health-related data essential to *planning, implementation, and evaluation of public health practice*.”²¹ Critically, the ongoing surveillance data-collection activities ensure that public health professionals have current data to inform public health activities. For example, healthcare providers are required by law to report if a patient has one or more conditions of public health concern.²² These case reports assist public health professionals to understand where a disease is spreading within a community.

Importantly, these ongoing surveillance activities are not research under the Common Rule, so public health agencies can swiftly collect data and respond to public health threats within their statutory capacity without additional regulatory burdens.²³ Consequently, this surveillance information provides critical situational awareness required for deploying scarce public health resources

17 James G. Hodge & Lawrence O. Gostin, *Public Health Practice vs. Research*, COUNCIL OF STATE & TERRITORIAL EPIDEMIOLOGISTS, May 24, 2004, at 14–20.

18 *Id.* at 14–21.

19 H. M. Xu et al., *Lead Concentrations in Fine Particulate Matter After the Phasing Out of Leaded Gasoline in Xi'an, China*, 47 *ATMOSPHERIC ENV'T* 217, 219–22 (2012) (describing an observed decrease in environmental lead concentrations associated with a decrease in the use of leaded gasoline); Tara I. Chang & Wolfgang C. Winkelmayer, *Comparative Effectiveness Research: What Is It and Why Do We Need It in Nephrology*, 27 *NEPHROLOGY, DIALYSIS, TRANSPLANT* 2156, 2156–60 (2012) (providing an overview of comparative effectiveness research, which often relies on electronic health records to evaluate the comparative health outcomes associated with different treatment options).

20 See *supra* Introduction; Common Rule, *supra* note 9.

21 *Introduction to Public Health Surveillance*, CTRS. DISEASE CONTROL, <https://www.cdc.gov/training/publichealth101/surveillance.html> [https://perma.cc/65PT-CXVL] (last visited Oct. 5, 2021) (emphasis added).

22 Public health reporting is typically required by state law and requirements can vary substantively by jurisdiction. See, e.g., N.M. CODE R. § 7.4.3 (LexisNexis 2021).

23 Hodge & Gostin, *supra* note 17.

efficiently and effectively.²⁴

In addition to acute public health threats, social, economic, and environmental factors may have a far greater impact on an individual's health than biological factors.²⁵ Public health professionals often have access to aggregate data on these factors (e.g., census data), but data records or person-level data—the type needed to link datasets and understand complex problems—are far more difficult to obtain.²⁶ Data on these social, economic, and environmental factors are nevertheless often abundant in commercial datasets, including data useful to market products and services or to determine things like loan eligibility.²⁷ Businesses sharing data about social, economic, and environmental factors with public health agencies is a promising but largely unexplored opportunity to better understand threats to public health, and by extension, develop viable interventions to address those threats.²⁸

3. *Public Health Programs and Population Interventions*

Public health practice involves collective actions that assure the conditions for people to be healthy.²⁹ These actions, whether an ongoing program or new intervention, rely on data to ensure that scarce resources are used efficiently. Consequently, public health programs and interventions require data in the planning phase to determine the most effective deployment of limited resources; they require data throughout implementation to ensure activities are proceeding as intended; and they require data to evaluate whether, and to what extent, the

24 For example, syndromic surveillance systems can detect symptom-based anomalies in local emergency rooms that can provide public health departments with rapid information of emerging infectious disease (e.g., influenza, anthrax). See Deborah W. Gould et al., *The Evolution of BioSense: Lessons Learned and Future Directions*, 132 PUB. HEALTH REPS. 7S, 7S–10S (2017); see also Matthias Linden et al., *Case Numbers Beyond Contact Tracing Capacity Are Endangering the Containment of COVID-19*, 117 DEUTSCHES ARZTEBLATT INT'L 790, 790–91 (2020) (describing the capacity limitations that hindered the public health response to COVID-19).

25 See generally Galea et al., *supra* note 14, at 1462–63.

26 Braveman & Gottlieb, *supra* note 14, at 27.

27 See generally CATHY O'NEIL, *WEAPONS OF MATH DESTRUCTION* (2016); *Id.* at 68–83, 141–60 (describing the often discriminatory and destructive ways that data are used that nonetheless may be profitable to companies).

28 Mattia Prosperi et al., *Big Data Hurdles in Precision Medicine and Precision Public Health*, BMC MED. INFORMATICS & DECISION MAKING 1, 5–10 (Dec. 29, 2018); Sonja A. Rasmussen et al., *Precision Public Health as a Key Tool in the COVID-19 Response*, 324 JAMA 933, 934 (2020); Cason Schmit et al., *Cross Sector Data Sharing: Necessity, Challenge, and Hope*, 47 J. L., MED. & ETHICS 83, 83 (2019); Braveman & Gottlieb, *supra* note 14, at 27.

29 This reflects the Institute of Medicine's definition of public health: "Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy." INST. MED., *THE FUTURE OF PUBLIC HEALTH* (1988). The definition implies a distinction between public health and healthcare. The former focuses on prevention and maintenance of health, the latter treats and mitigates existing ill health.

program or intervention is achieving population health benefits.³⁰

For example, during the early deployment of the COVID-19 vaccinations, public health agencies relied on data to determine the most vulnerable sub-populations and used that data (in some cases) to deploy vaccines and set up vaccination sites.³¹ Throughout vaccination deployment, public health agencies collected data to determine whether the clinics were indeed serving those vulnerable populations,³² adjusting strategies as necessary.³³ Finally, public health agencies closely monitored case reports and hospital and mortality data to determine whether the vaccinations were affecting the spread of COVID-19 and its health outcomes.³⁴

Increasingly, public health agencies are exploring and leveraging non-traditional public health data to inform population-based interventions. Traditional public health data include mandated case reports of infectious disease (e.g., drug-resistant tuberculosis, HIV), vital statistics, reports of foodborne illness, and other surveillance data.³⁵ The New York City Department of Health and Mental Hygiene, however, developed a program that scanned publicly available restaurant reviews—like those on Yelp!—for evidence of foodborne illness (e.g., “food made me sick”).³⁶ Using big-data analytics, public health

30 James Aspevig, *Project Management and Public Health Informatics*, PUBLIC HEALTH INFORMATICS AND INFORMATION SYSTEMS 211, 221–35 (J.A. Magnuson & Paul C. Fu, Jr. eds., 2014); see also CASON SCHMIT, PUBLIC HEALTH LAW AND POLICY INNOVATIONS: SOCIAL IMPACT BONDS 2–3, and generally (2014).

31 *Ensuring Equity in COVID-19 Vaccine Distribution*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/coronavirus/health-center-program> [<https://perma.cc/P6ZL-L77K>] (last visited Oct. 10, 2021).

32 As opposed to merely reaching “vaccine tourists.” See Claire Gillespie, *What is Vaccine Tourism, and Is It Legal? Here’s What You Need to Know*, HEALTH (Jan. 28, 2021), <https://www.health.com/condition/infectious-diseases/coronavirus/what-is-vaccine-tourism> [<https://perma.cc/VWW3-KQBM>] (“Vaccine tourism means visiting another country or state to get a vaccine not available to you at home.”).

33 *Strategies to Engage Communities Most Vulnerable to Covid-19*, NAT’L ACADS. SCIS. ENG’G MED., <https://www.nap.edu/resource/26068/interactive/vulnerable-communities.html> [<https://perma.cc/8UHH-DLZT>] (last visited Oct. 7, 2021); see also Megan Cerullo, *State Vaccine Incentives Do Little to Boost Vaccination Rates, Research Shows*, CBS NEWS (Sep. 8, 2021), <https://www.cbsnews.com/news/statewide-vaccine-incentives-lotteries-do-not-boost-vaccination-rates/> [<https://perma.cc/UV9D-WU5X>] (describing evaluations of vaccine incentives).

34 Dvir Aran, *Estimating real-world COVID-19 Vaccine Effectiveness in Israel Using Aggregated Counts* 1–6 (medRxiv, Working Paper, 2021), <https://www.medrxiv.org/content/10.1101/2021.02.05.21251139v3.full.pdf> [<https://perma.cc/D8C7-FGB4>].

35 John R. Lumpkin & J.A. Magnuson, *History of Public Health Information Systems and Informatics*, in PUBLIC HEALTH INFORMATICS AND INFORMATION SYSTEMS 17–29 (J.A. Magnuson & Paul C. Fu, Jr. eds., 2014).

36 See generally Cassandra Harrison et al., *Using Online Reviews by Restaurant Patrons to Identify Unreported Cases of Foodborne Illness—New York City, 2012–2013*, 441 MORBIDITY & MORTALITY WKLY. REP. 63 (2014); Elaine O. Nsoesie, *Online Reports of Foodborne Illness*

professionals were able to identify previously unreported outbreaks.³⁷ With this information, they were able to focus their limited enforcement budget only on highly probable events.

4. *Individual-based Interventions*

Prevention is a central focus for public health practitioners. Preventing adverse health outcomes—as opposed to treating those that develop—is often less expensive and leads to better population health.³⁸ While prevention efforts can target entire communities, such as building sidewalks to promote active living, many preventative interventions require identifying at-risk individuals who stand to benefit the most.³⁹

For example, maternal and child health is a critical ongoing public health issue. Prenatal contact with expectant mothers can have a tremendously beneficial effect on birth outcomes and maternal health.⁴⁰ Moreover, the benefits can extend far into a family's future.⁴¹ In commercial settings, advanced data analytics can predict whether a customer is pregnant based on changes to purchasing behavior.⁴² These predictions are immensely valuable to companies seeking to gain loyal customers at a point when purchasing behavior will change substantially.⁴³ For public health, this predictive ability can help direct scarce

Capture Foods Implicated in Official Foodborne Outbreak Reports, 67 PREVENTATIVE MED. 264–69 (Aug. 11, 2014).

37 Harrison et al., *supra* note 36.

38 See generally Thomas R. Frieden, *A Framework for Public Health Action: The Health Impact Pyramid*, 100(4) AM. J. PUB. HEALTH 590 (2010).

39 See Karen A. Monsen et al., *Public Health Nurses Tailor Interventions for Families at Risk*, 28 PUB. HEALTH NURSING 119, 119–21 (Mar.–Apr. 2011); see generally R. J. Donovan et al., *TARPARE: A Method for Selecting Target Audiences for Public Health Interventions*, 23-3 AUSTL. & N.Z. J. PUB. HEALTH 280 (June 23, 1999).

40 In some cases, the benefits of prevention can be leveraged to support profitable investments. See ASS'N STATE AND TERRITORIAL HEALTH OFFICIALS, FINANCING PUBLIC HEALTH INTERVENTIONS THROUGH PAY FOR SUCCESS (2017) <https://opioidspreparedness.org/Health-Systems-Transformation/Pay-for-Success-South-Carolina-Issue-Brief/> [https://perma.cc/UKZ4-629Y].

41 *Id.*; Monsen et al., *supra* note 39.

42 Kashmir Hill, *How Target Figured Out a Teen Girl Was Pregnant Before Her Father Did*, FORBES (Feb. 16, 2012, 11:02 AM), <https://www.forbes.com/sites/kashmirhill/2012/02/16/how-target-figured-out-a-teen-girl-was-pregnant-before-her-father-did/?sh=a82d6c66686d> [https://perma.cc/7GP4-NS3T].

43 Charles Duhigg, *How Companies Learn Your Secrets*, N.Y. TIMES (Feb. 16, 2012) <https://www.nytimes.com/2012/02/19/magazine/shopping-habits.html> [https://perma.cc/Z5HU-VFC8]. Importantly, the scarcity of resources for public health interventions is a substantial limitation to the public health use of these data. While the ability to identify at-risk individuals can help public health agencies be more efficient with existing resources, these data are less useful when public health practitioners lack the capacity to act. For example, public health surveillance techniques can monitor trends of suicide ideation in near-real time, but if public health agencies

resources to at-risk individuals for programs and benefits.⁴⁴ Recent advances in machine learning and artificial intelligence have the capacity to further amplify these benefits but also raise concerns about unacceptable uses.⁴⁵ For example, commercial data brokers have increasingly detailed information about individuals that they sell to businesses, individuals, and governments, using artificial intelligence and machine learning tools to identify groups of people with certain health conditions, such as diabetes, HIV, depression, and pregnancy, based on their aggregated consumer data,⁴⁶ and enabling businesses to target these individuals with goods or services they might want or need. Certainly, these practices are problematic when they enable exploitation of the vulnerable, but these data can also facilitate interventions that promote social, economic, and health equity.

In public health contexts, it is important to identify and address population health threats, which can span varied domains, including hazardous products, environmental contamination, occupational hazards, infectious disease, law, and policies. The value of non-traditional public health data in advancing these aims is becoming increasingly clear. It might be important to identify individuals with an infectious disease who might pose a risk to others. In the case of sexually transmitted infections, contact-tracing efforts can be essential to identify and notify individuals of this risk.⁴⁷ This contact-tracing can enable timely treatment and inform people of the need for precautions.⁴⁸ In the COVID-19 pandemic, contact-tracing apps were developed to notify individuals if they were near someone who tested positive for the virus.⁴⁹ This information can prompt individuals to get a test to confirm infection and notify them of the need for

lack the financial, human, or political capital to enact preventative interventions, the surveillance data is not useful beyond informing the community of the public health issue. *See generally* Marissa L. Zwald et al., *Monitoring Suicide-Related Events Using National Syndromic Surveillance Program Data*, 11 ONLINE J. PUB. HEALTH INFORMATICS (2019); Deb Stone et al., *Preventing Suicide: A Technical Package of Policy, Programs, and Practices*, CTRS. DISEASE CONTROL (2017) <https://www.cdc.gov/violenceprevention/pdf/suicidetechnicalpackage.pdf> [<https://perma.cc/HMX8-LFMK>].

⁴⁴ Monsen et al., *supra* note 39, at 119–21.

⁴⁵ Alicia Solow-Niederman, *Information Privacy and the Inference Economy*, 117 NW. UNIV. L. REV., (forthcoming 2022) (manuscript at 45), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3921003 [<https://perma.cc/YK5P-W3F7>].

⁴⁶ DATA BROKERS: LAST WEEK TONIGHT WITH JOHN OLIVER, at 5:50 – 8:30, <https://www.youtube.com/watch?v=wqn3gR1WTcA> [<https://perma.cc/7MZT-LBFL>].

⁴⁷ Megan S. C. Lim et al., *SMS STI: A Review of the Uses of Mobile Phone Text Messaging in Sexual Health*, 19 INT’L J. STD AIDS 287, 288 (May 2008).

⁴⁸ *Id.*

⁴⁹ Nadeem Ahmed et al., *A Survey of COVID-19 Contact Tracing Apps*, 8 IEEE ACCESS 134577, 134578 (July 31, 2020); *see generally* Vittoria Colizza et al., *Time to Evaluate COVID-19 Contact-Tracing Apps*, 27 NATURE MED. 361 (Feb. 15, 2021).

precautions around others.⁵⁰ These contact-tracing apps had the potential to fill a critical gap in the early pandemic as professional public health contact tracers—chronically underfunded—were quickly overwhelmed by the highly contagious disease.⁵¹ However, low adoption severely limited their utility.⁵² Specifically, the apps often required users to opt in (e.g., downloading or turning the feature on). Since the contract tracing apps required a critical mass of users to be effective, the opt-in default settings—compounded by trust issues in the tech companies developing the apps—were substantial barriers to the effective use of these contract tracing apps in the U.S. response to COVID-19.⁵³

Public health activities can have both positive and negative effects on individual interests. For example, identifying an expectant mother to enroll in a nurse-family partnership program will provide that person with services that will directly improve their health and welfare. However, identifying an individual with a dangerous infectious disease could lead to required isolation from vulnerable individuals, interfering with the individual's liberty interests. Regardless, public health interventions should always be intended to promote community health. Consequently, even public health actions that infringe on some individual interests should confer at least some indirect personal or community benefits.

Generally, public health agencies have been slow to adopt big data approaches and tools. Limited funding and capacity, heavily siloed data sources, complex data protection laws, and a decentralized public health system are substantial barriers to U.S. public health agencies modernizing public health informatics infrastructure.⁵⁴ Consequently, public health agencies rely heavily on traditional data sources, like disease reporting, surveys, public health registries,

50 *Contact Tracer's Interview Tool: Notifying People About an Exposure to COVID-19*, CTRS. DISEASE CONTROL (Updated Sept. 22, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/php/notification-of-exposure.html> [https://perma.cc/52RA-H6PK] (Updated Sept. 22, 2021).

51 Linden et al., *supra* note 24, at 790.

52 Ahmed, *supra* note 49, at 134598; Eugene Y. Chan & Najam U. Saqib, *Privacy Concerns Can Explain Unwillingness to Download and Use Contact Tracing Apps when COVID-19 Concerns are High*, COMPUT. HUM. BEHAV. (Jan. 28, 2021).

53 De la Garza, A., *Why Aren't COVID-19 Contact Tracing Apps Working?* TIME (Nov. 10, 2020), <https://time.com/5905772/covid-19-contact-tracing-apps/> [https://perma.cc/B2TB-2KVN]; J. Rich, *How Our Outdated Privacy Laws Doomed Contact-Tracing Apps*, BROOKINGS (2021), <https://www.brookings.edu/blog/techtank/2021/01/28/how-our-outdated-privacy-laws-doomed-contact-tracing-apps/> [https://perma.cc/B2TB-2KVN].

54 See generally Panhuis et al., *supra* note 15; CDC Public Health Data Failures Mean U.S. Lacks Whole Picture on COVID, BLOOMBERG, <https://www.bloomberg.com/news/articles/2021-12-21/cdc-public-health-data-failures-mean-u-s-lacks-whole-picture-on-covid> [https://perma.cc/5T4H-QXYE] (last visited Apr. 11, 2022); *Crumbling Data Infrastructure Undermines Nation's Pandemic Response*, CAL. HEALTH CARE FOUND. BLOG, <https://www.chcf.org/blog/crumbling-data-infrastructure-undermines-nations-pandemic-response/> [https://perma.cc/N4YP-WQJ6] (last visited Apr. 11, 2022).

and syndromic surveillance. Nevertheless, there is intense study on the potential of non-traditional data sources to promote population health.⁵⁵ These efforts include calls to promote investigation of new digital health applications—such as using data from health information technology, wearable devices, mobile applications, and other big data—to identifying challenges and opportunities to incorporate new data sources to supplement public health responses.⁵⁶ For example, Katsis et al. applied big data methods to identify the top determinants of life expectancy in San Diego, including data on the physical and built environment and consumer buying patterns, and successfully identified important factors (e.g., violent crime, parks, fast food density). However, their analysis had to contend with differentially aggregated datasets that could not be combined, in contrast to many private sector big data applications that utilize non-aggregated data that are highly linkable.⁵⁷ Widespread efforts to incorporate new data into public health applications, including occupational and environmental health, policymaking, and disaster response, are nascent and promising. However, their success will hinge on the existence of data protection laws that permit data to be used for these purposes.⁵⁸

⁵⁵ See generally Yannis Katsis et al., *Big Data Techniques for Public Health: A Case Study*, 2017 IEEE/ACM INT'L CONF. ON CONNECTED HEALTH: APPLICATIONS, SYS. AND ENG'G TECH. (CHASE) 222, <https://ieeexplore.ieee.org/document/8010636> [<https://perma.cc/SV8B-2LQZ>]; Sudip Bhattacharya et al., *Applications of m-Health and e-Health in Public Health Sector: The Challenges and Opportunities*, 8 INT'L J. MED. & PUB. HEALTH 56–57 (2018); Jennifer L. Chan & Hemant Purohit, *Challenges to Transforming Unconventional Social Media Data into Actionable Knowledge for Public Health Systems During Disasters*, 14 DISASTER MED. & PUB. HEALTH PREPAREDNESS 352–359 (2020), <https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/article/abs/challenges-to-transforming-unconventional-social-media-data-into-actionable-knowledge-for-public-health-systems-during-disasters/8E422A5362F4D81F9C7BFE51531DEF6A> [<https://perma.cc/J3QH-55US>]; David M. Stieb et al., *Promise and Pitfalls in the Application of Big Data to Occupational and Environmental Health*, 17 BMC PUB. HEALTH 1–4 (2017), <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4286-8> [<https://perma.cc/6VP7-62VP>]; Michelina Mancuso et al., *Proof of Concept Paper: Non-Traditional Data Sources for Public Health Surveillance*, PROC. OF THE 6TH INT'L CONF. ON DIGIT. HEALTH CONF. 91 (2016) <https://dl.acm.org/doi/10.1145/2896338.2896369> [<https://perma.cc/J9AK-4Y2B>]; Zachary H. Seeskin et al., *Uses of Alternative Data Sources for Public Health Statistics and Policymaking: Challenges and Opportunities*, 2018 JOINT STATISTICAL MEETINGS (2018) https://www.norc.org/PDFs/Publications/SeeskinZ_Uses%20of%20Alternative%20Data%20Sources_2018.pdf [<https://perma.cc/R624-5FDL>].

⁵⁶ Eric R. Buhi, *Digital Health and AJPH: The Time Has Come!*, 105 AM J. PUB. HEALTH 420 (2015), <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2015.302585> [<https://perma.cc/US2E-XWLT>]. See generally Chan & Purohit, *supra* note 55; Shawn Dolley, *Big Data's Role in Precision Public Health*, 6 FRONTIERS IN PUB. HEALTH 68 (2018).

⁵⁷ Katsis et al., *supra* note 55, at 226.

⁵⁸ See Panhuis et al., *supra* note 15, at 1–9 (noting the legal barriers to public health data use); Schmit et al., *supra* note 28, at 83–86.

B. American Data Protection and Privacy Law

In the United States, statutes typically govern personal data, if they do so at all, based on their substantive content. Many different federal laws do so, as do some state laws. Until 2021, only one state—California—had a comprehensive data privacy law. In that year, two more states—Virginia and Colorado—adopted statutes similar in many ways to each other and quite different from California's. Also in 2021, the Uniform Law Commissioners adopted the Uniform Personal Data Protection Act. This Section explains these developments.

1. The Current Patchwork of Law

Sectoral laws that define protected data by their substantive content are typical in the U.S. federal data protection framework. Most of them are *sui generis* approaches to specific types of information or specific regulated entities. Laws regulate health information,⁵⁹ education records,⁶⁰ substance use disorder records,⁶¹ financial aid information,⁶² financial transaction records,⁶³ video rental history,⁶⁴ children's internet activity,⁶⁵ government records,⁶⁶ laboratory data,⁶⁷ customer records,⁶⁸ scientific research data,⁶⁹ and social service data.⁷⁰ Many of these were enacted to address specific problems. For instance, the Genetic Information Nondiscrimination Act of 2008 (GINA)⁷¹ was enacted to address fears that advancements in genomic science—specifically the discovery of genetic markers predictive of future health conditions—would enable discrimination by employers and insurers. Similarly, the Protection of Pupil

59 Health Insurance Portability and Accountability Act of 1996 (HIPAA), H.R. 3103, 104th Cong. (1996); 45 C.F.R. §§ 164.102–164.534 (2021).

60 Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g; 34 C.F.R. §§ 99.1–99.67 (2021).

61 Confidentiality of Substance Use Disorder Patient Records, 42 C.F.R. §§ 2.1–2.67 (2021).

62 Higher Education Act, 20 U.S.C. § 1092b; 34 C.F.R. Part 5b (2021).

63 Gramm-Leach-Bliley Act (GLBA), S. Res. 900, 106th Cong. (1999) (enacted); 16 C.F.R. § 313 (2021).

64 Video Privacy Protection Act (VPPA), S. Res. 2361, 100th Cong. (1988) (enacted) (amended by H.R. Res. 6671, 112th Cong. (2013) (enacted)); 18 U.S.C. § 2710.

65 Children's Online Privacy Protection Act (COPPA), S.R. 2326, 105th Cong. (2000) (enacted); 15 U.S.C. §§ 6501–6506.

66 Privacy Act of 1974, S. Res. 3418, 93rd Cong. (1974) (enacted), 5 U.S.C. § 552.

67 Clinical Laboratory Improvement Amendments of 1988, H.R. Res. 5471, 100th Cong. (1988) (enacted); 42 C.F.R. § 493 (2021).

68 FTC Act, 15 U.S.C. §§ 41–58, as amended; Fair Credit Reporting Act (FCRA), H.R. Res. 15073, 91st Cong. (1970); 15 U.S.C. § 1681.

69 Common Rule, *supra* note 9.

70 See the confidentiality provisions of 7 U.S.C. Ch. 51; 7 C.F.R. § 246.26.

71 H.R. Res. 493, 110th Cong. (2008) (enacted).

Rights Amendment (PPRA)⁷² was enacted to address parents' concerns that school-based surveys would collect information from children that parents deemed inappropriate (e.g., politics, religion, sex, mental and behavioral health, income).

State data privacy laws also usually limit their scope to data records with certain kinds of information or regulated entities in certain industries.⁷³ And many states have long had comprehensive regulations regarding data records that *governments themselves* collect.⁷⁴ Here, too, many states have deliberated on comprehensive bills, but until California in 2018 and now Virginia and Colorado in 2021, none have been adopted.⁷⁵

In public health, defining protected data records by the substantive content of the information makes sense where the risks of inappropriate information use or disclosure are sufficiently different than other data with different substantive content. For example, during the early years of the AIDS epidemic, there was enormous concern that AIDS and HIV records would be used to facilitate discrimination and social stigma.⁷⁶ In response, many states enacted special data laws regulating HIV data differently than other health data.⁷⁷ However, studies cast doubt on whether these additional privacy protections were efficacious for public health outcomes.⁷⁸ Nevertheless, HIV and AIDS information carry substantively different risks than other types of health information. Consequently, such sensitive information may appropriately be subjected to greater protections or restrictions than less sensitive information (e.g., phone book information).

Critically, differential data protection on data types has consequences. For example, health records can contain data that are regulated by different laws. The Health Insurance Portability and Accountability Act (HIPAA) governs health

⁷² 20 U.S.C. § 1232(h).

⁷³ See, e.g., DEL. CODE ANN. tit. 18, §§ 8601, 8602 (2021) (The Delaware Insurance Data Security Act, covering security breaches of data records with financial and health information retained by insurance licensees in the state).

⁷⁴ See, e.g., MINN. STAT. § 13.02(7) (2020) (Minnesota Government Data Practices Act governing “all data collected, created, received, maintained or disseminated by any government entity”).

⁷⁵ Anupam Chander, Margot E. Kaminski, & William McGeveran, *Catalyzing Privacy Law*, 105 MINN. L. REV. 1733, 1772–76 (2021); see also VCDPA, *supra* note 4; CPA, *supra* note 4.

⁷⁶ Matthew L. Levine, *Contact Tracing for HIV Infection: A Plea for Privacy*, 20 COLUM. HUM. RTS. L. REV. 157, 183 (1988); James M. Tesoriero et al., *The Effect of Name-Based Reporting and Partner Notification on HIV Testing in New York State*, 98 AM. J. PUB. HEALTH 728, 728 (2008).

⁷⁷ Laura Lin & Bryan A. Liang, *HIV and Health Law: Striking the Balance Between Legal Mandates and Medical Ethics*, 7 VIRTUAL MENTOR. 687, 687–89 (2005).

⁷⁸ See Tesoriero et al., *supra* note 76, at 732–34 (finding evidence that the benefits of name-based reporting outweigh any potential deterrent effect).

information collected or held by covered entities generally, but a health record could contain information about HIV status, which may be subject to state laws, or substance use disorder information, which is governed by the restrictive 42 CFR Part 2 regulations.⁷⁹ In 2015, researchers railed against a decision by the U.S. Centers for Medicare and Medicaid Services (CMS) to strip research datasets of all records containing substance use disorder codes to protect against Part 2 violations.⁸⁰ Researchers argued that the CMS application of Part 2 not only left researchers and public health practitioners flying blind during the opioid epidemic but also that the decision caused substantial harm by creating bias within the remaining data and specifically tainting HIV and Hepatitis C research.⁸¹ Additionally, distinct legal protections on different data types limit opportunities to link datasets to discover important associations between various factors.⁸² For instance, low education is one of the most significant causes of death in the United States, killing approximately the same number of people annually as heart attacks.⁸³ However, the research exception in the Family Educational Rights and Privacy Act of 1974 (FERPA) does not permit use of identifiable education records for health research, effectively hobbling data scientists' ability to understand this substantial cause of mortality.

Moreover, when datasets contain substantive information covered by different data protection laws, multiple laws might apply simultaneously. For example, up to six different data protection laws can apply to health records held by the U.S. Department of Veterans Affairs (VA).⁸⁴ Consequently, a legal analysis of a proposed VA health data use or disclosure requires an analysis of six different laws to determine which provisions of the laws are most stringent and should apply.⁸⁵ Public health data projects using data on different social,

79 45 C.F.R. Parts 160 and 164. (n.d.); 42 C.F.R. Part 2. (n.d.); See Pennsylvania's Confidentiality of HIV-Related Information Act, 35 Pa. Stat. Ann. § 7601, et al. (West).

80 See generally Austin B. Frakt & Nicholas Bagley, *Protection or Harm? Suppressing Substance-Use Data*, 372 NEW ENG. J. MED. 1879–1881 (2015).

81 *Id.* at 1881.

82 Braveman & Gottlieb, *supra* note 14, at 27; SCHMIT ET AL., *supra* note 30, at 2–3.

83 Galea et al., *supra* note 14, at 1462.

84 The Freedom of Information Act, 5 U.S.C. § 552, implemented by 38 C.F.R. §§ 1.550–1.562; the Privacy Act, 5 U.S.C. § 552a, implemented by VA at 38 CFR 1.575–1.582; the VA Claims Confidentiality Statute; 38 U.S.C. § 5701, implemented by 38 CFR Section 1.500–1.527; Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Human Immunodeficiency Virus (HIV) Infection, and Sickle Cell Anemia Health Records, 38 U.S.C. § 7332, implemented by 38 CFR 1.460–1.496; HIPAA, 45 CFR Parts 160 and 164; Confidentiality of Medical Quality Assurance Review Records, 38 U.S.C. § 5705, implemented by 38 CFR 17.500–17.511.

85 DEP'T OF VETERANS AFFS., VHA DIRECTIVE 1605.01: PRIVACY AND RELEASE OF INFORMATION 1, 3 (2016), https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3233 [<https://perma.cc/73Z2-N9ZB>] (providing that “all six statutes will be applied simultaneously” and “the result will be the application of the more stringent provision for all uses or disclosures of VHA health care data”).

economic, and environmental factors frequently face similar issues because these data are often covered by different laws within the U.S. patchwork.

2. *Changes on the Horizon*

Most of the laws we have discussed here are federal laws. There have been efforts to adopt a federal comprehensive data protection act, so far with no success. At least eleven bills that would have provided a comprehensive federal data protection regime were introduced in Congress between 2018 and 2020.⁸⁶ Hearings continue on new initiatives.⁸⁷ “The prospect for a comprehensive federal privacy law coming to the fore in 2022 is slim,” however, thanks in part to it being an election year in a closely divided Congress.⁸⁸

States are beginning to move into the gap. In 2018, California adopted the California Consumer Privacy Act (CCPA), which became operative on January 1, 2020.⁸⁹ Nevertheless, the voters considerably amended its provisions with a referendum adopted in the 2020 general election, titled the “California Privacy Rights Act of 2020,” with provisions taking effect January 1, 2023.⁹⁰ While the older provisions of the CCPA remain in effect through December 31, 2022, we focus our attention in this Article on versions of the provisions that will be effective in 2023.

Other states have not remained entirely idle during this time. There were several failed attempts in various states to enact comprehensive privacy legislation,⁹¹ but in 2021, two states succeeded where others failed: Virginia

⁸⁶ Chander et al., *supra* note 75, at 1734 n.6 (2021); *see also* Solow-Niederman, *supra* note 45, at 38–39 (noting the “116th Congress, which convened from January 2019 to January 2021 and featured a score of comprehensive (also sometimes called ‘omnibus’) information privacy statutes alongside a bevy of bills that emphasize a particular aspect of information privacy”); Julie E. Cohen, *How (Not) to Write a Privacy Law*, KNIGHT FIRST AMENDMENT INSTITUTE (Mar. 23, 2021), <https://knightcolumbia.org/content/how-not-to-write-a-privacy-law> [<https://perma.cc/MPX6-22A8>].

⁸⁷ *See, e.g.*, Cameron F. Kerry, *Senate Hearing Opens the Door to Individual Lawsuits in Privacy Legislation*, BROOKINGS TECHTANK (Oct. 8, 2021), <https://www.brookings.edu/blog/techtank/2021/10/08/senate-hearing-opens-the-door-to-individual-lawsuits-in-privacy-legislation/> [<https://perma.cc/A334-Q6EE>].

⁸⁸ Jake Holland, *2022 Privacy Legislation Success Viable as Three States Lead Way*, BLOOMBERG LAW (Jan. 3, 2022, 4:00 AM), <https://news.bloomberglaw.com/privacy-and-data-security/2022-privacy-legislation-success-viable-as-three-states-lead-way> [<https://perma.cc/TTG5-NRQ2>].

⁸⁹ 2018 Cal. Legis. Serv. Ch. 55 (A.B. 375) (West). The legislature amended it two times within its first year of existence. 2018 Cal. Legis. Serv. Ch. 735 (S.B. 1121) (West); 2019 Cal. Legis. Serv. Ch. 757 (A.B. 1355) (West).

⁹⁰ 2020 Cal. Legis. Serv. Prop. 24 (West).

⁹¹ *See* David Stauss, *Status of Proposed CCPA-Like State Privacy Legislation as of June 14, 2021*, BYTE BACK (June 13, 2021), <https://www.bytebacklaw.com/2021/06/status-of-proposed-ccpa-like-state-privacy-legislation-as-of-june-14-2021/> [<https://perma.cc/NGR8-Q4H8>].

adopted its Consumer Data Protection Act,⁹² with its terms slated to become effective January 1, 2023,⁹³ and Colorado followed suit when Governor Polis signed the Colorado Privacy Act,⁹⁴ with its terms taking effect July 1, 2023.⁹⁵ Most recently, Utah and Connecticut became the fourth and fifth states to enact a comprehensive privacy law, borrowing elements from the California, Virginia, and Colorado statutes.⁹⁶

Meanwhile, the Uniform Law Commissioners had decided to consider a uniform statute, authorizing a drafting committee for the UPDPA in summer 2019 and adopting a final version of it in July 2021.⁹⁷ ULC was formed to promote consistency among state laws,⁹⁸ and its uniform statutes have often been met with great success. For example, the 2015 Revised Uniform Fiduciary Access to Digital Assets Act (RUFADAA) has been adopted in forty-five states (along with the District of Columbia and the Virgin Islands).⁹⁹ It provides means for fiduciaries like executors of estates, trustees, and attorneys-in-fact to gain access to a principal's intangible digital assets—including websites and domains

92 2021 Va. Legis. Serv. 1st Sp. Sess., Ch. 36 (S.B. 1392).

93 *Id.* § 4.

94 2021 Colo. Legis. Serv. Ch. 21-190 (West).

95 *Id.* § 7.

96 Utah Consumer Privacy Act, SB 227 (2022); Connecticut Data Privacy Act, S.B. 6, (2022). Unfortunately, we were unable to incorporate these most recent developments into our analysis due to its proximity to publication.

97 Katie Robinson, *New Drafting and Study Committees to be Appointed*, UNIF. L. COMM'N (July 24, 2019, 4:37 PM), [https://www.uniformlaws.org/committees/community-home/digestviewer/viewthread?MessageKey=bc3e157b-399e-4490-9c5c-608ec5caabcc&CommunityKey=d4b8f588-4c2f-4db1-90e9-48b1184ca39a&tab=digestviewer;UPDPA, supra note 4 \(see title page\) \[https://perma.cc/EQ74-4HS6\].](https://www.uniformlaws.org/committees/community-home/digestviewer/viewthread?MessageKey=bc3e157b-399e-4490-9c5c-608ec5caabcc&CommunityKey=d4b8f588-4c2f-4db1-90e9-48b1184ca39a&tab=digestviewer;UPDPA, supra note 4 (see title page) [https://perma.cc/EQ74-4HS6].)

98 UNIF. L. COMM'N, *supra* note 3. State governments appoint ULC commissioners, all of whom are members of the bar—some practicing lawyers and some legal scholars. ULC is not the only national organization promoting uniform or model privacy legislation, though. In 2017, the National Association of Insurance Commissioners, which represents state insurance regulators, promulgated a state “Insurance Data Security Model Law.” INSURANCE DATA SECURITY MODEL LAW (NAT'L ASS'N OF INS. COMM'RS (2017), <https://content.naic.org/sites/default/files/inline-files/MDL-668.pdf>. [https://perma.cc/5BJ5-RL8L]. As of June 2020, NAIC claimed eleven states had adopted the act. NAT'L ASS'N OF INS. COMM'RS & THE CTR. FOR INS. POL'Y & RSCH., STATE LEGISLATIVE BRIEF (2020), https://www.naic.org/documents/cmte_legislative_liaison_brief_data_security_model_law.pdf [https://perma.cc/8BHX-W9KQ]; *See, e.g.*, DEL. CODE ANN. tit. 18, § 8601 (2021).

99 *Fiduciary Access to Digital Assets Act, Revised*, UNIF. L. COMM'N, <https://www.uniformlaws.org/committees/community-home?CommunityKey=f7237fc4-74c2-4728-81c6-b39a91ecd4f22> [https://perma.cc/L5RN-JSL3]; *see also Summary*, UNIF. L. COMM'N, <https://www.uniformlaws.org/acts/ucc> [https://perma.cc/256S-F3DV] (noting that all fifty U.S. states have adopted the Uniform Commercial Code, which governs common commercial transactions, such as sales of goods, negotiable instruments, and secured transactions); UNIF. ANATOMICAL GIFT ACT (UNIF. L. COMM'N 2007) (governing organ donations and adopted in every state—along with the District of Columbia, Puerto Rico, and the Virgin Islands—except Delaware, Florida, New York, and Pennsylvania).

and computer files in the cloud—just as such fiduciaries have been able to access tangible assets (like cars, real estate, etc.) to carry out the wishes of the principal.¹⁰⁰ Not all of ULC’s uniform statutes have been so widely adopted.¹⁰¹ Nor should the reader be misled by the “uniform” in each of these statutes’ names, because each jurisdiction may adopt the act with variations.¹⁰² As a consequence of these limitations, it’s difficult to know whether, when, and how provisions of the UPDPA will become the law in states.

Nevertheless, the interest that some populous states have shown in privacy legislation and the speed with which the RUFADAA (and its revised version) have been widely adopted suggest that the UPDPA may be on many legislatures’ agendas in spring 2022.¹⁰³ Indeed, within six months of ULC’s adoption of the UPDPA, three jurisdictions had introduced it for deliberation.¹⁰⁴ In addition to the UPDPA, the California, Virginia, and Colorado laws are serving as alternative templates to states exploring comprehensive privacy legislation.¹⁰⁵

The existing complexity in U.S. privacy law supports an argument for comprehensive federal data privacy legislation that would preempt state acts: Additional inconsistent privacy laws adopted state by state could further complicate efforts to monitor public health issues across jurisdictions. We do not

100 FIDUCIARY ACCESS TO DIGITAL ASSETS ACT, REVISED (UNIF. L. COMM’N 2015).

101 For example, only eight jurisdictions (seven states and D.C.) have adopted 2007’s Limited Cooperative Association Act. *See Limited Cooperative Association Act*, UNIF. L. COMM’N, <https://www.uniformlaws.org/committees/community-home?CommunityKey=22f0235d-9d23-4fe0-ba9e-10f02ae0bfd0> [<https://perma.cc/SXA7-FZ5C>]. And so far, only four states (as of April 28, 2022) have enacted 2019’s Registration of Canadian Money Judgments Act. Two more have introduced legislation to adopt it. *Registration of Canadian Money Judgments Act*, UNIF. L. COMM’N, <https://www.uniformlaws.org/committees/community-home?CommunityKey=49ecb2a9-a8b7-4041-8eba-e9d6f7293ea5> [<https://perma.cc/5N42-J2BE>].

102 I. Richard Ploss, *Estate Planning for Digital Assets: Understanding the Revised Uniform Fiduciary Access to Digital Assets Act and Its Implications for Planners and Clients*, J. FIN. PLANNING Apr. 2018 (noting that “state legislatures are free to pick and choose which sections [of a uniform act] they wish to enact . . .” so though “the RUFADAA defines a ‘fiduciary’ to include a court-appointed conservator, New Jersey’s version of the RUFADAA specifically excludes a conservator from the definition of a fiduciary”).

103 Stauss, *supra* note 91 (summarizing 2021 legislative initiatives from June 2021 and identifying more than twenty states where bills had been introduced, of which only Virginia’s and Colorado’s were adopted); *see also* CS/CS/HB 969 (2021) - Consumer Data Privacy, FLA. H. REP., <https://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=72062> [<https://perma.cc/ZC3A-E3XP>] (showing that this Florida bill failed to be adopted).

104 Personal Data Protection Act, UNIFORM LAW COMMISSION, <https://www.uniformlaws.org/committees/community-home?CommunityKey=28443329-e343-4cbc-8c72-60b12fd18477> [<https://perma.cc/H4B6-YVUQ>].

105 As of April 7, 2022, fifteen U.S. states had at least one legislative proposal introduced in both legislative houses, and Utah had adopted a statute. Taylor Kay Lively, *US State Privacy Legislation Tracker*, IAAP.COM (Apr. 7, 2022), <https://iapp.org/resources/article/us-state-privacy-legislation-tracker/> [<https://perma.cc/MS5Q-2RPY>].

have the space here to analyze all the potential preemption issues relating to the UPDPA and the CAVACO statutes. We can note, however, as Professors Chander, Kaminski, and McGeveran have done, that the new comprehensive state laws are not likely preempted by any existing federal law under the Dormant Commerce Clause.¹⁰⁶ And a new comprehensive federal privacy law, when enacted, might provide only a floor that state law could build on—much as the previous sectoral federal laws have done—rather than a preemptive ceiling.¹⁰⁷ Public health advocates on the whole view preemption with skepticism, however, because such legislation has sometimes been proposed as a tool to suppress innovative public health measures by local governments (e.g., taxes on sugar-sweetened beverages, menu labeling).¹⁰⁸ Nevertheless, within public health informatics, variation in data protection laws stands as a barrier to public health practice in and of itself.¹⁰⁹ For similar reasons, data privacy advocates—and even some members of the ULC—suggest that a comprehensive and preempting federal privacy law is a preferred approach to the current U.S. patchwork.¹¹⁰

Legal scholars have not been silent regarding these developments, both from the perspective of privacy law and of public health. Many of their commentaries focus on normative concerns generally and particularly at the boundaries of these two disciplines.

C. Normative Concerns at the Boundaries

Professors Daniel Solove and Paul Schwartz conceive of privacy as “a constitutive element of civil society.”¹¹¹ Professor Solove further identifies nearly a dozen bases upon which privacy is therefore valuable.¹¹² Deliberations on bills covering data protection and data privacy occur against a backdrop of legal

106 Chander et al., *supra* note 75, at 1794–96.

107 *Id.* at 1797–99.

108 Policy Statement, AM. PUB. HEALTH ASS’N, *Impact of Preemptive Laws on Public Health, Policy Number: 201511* (Nov. 03 2015), <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2016/01/11/11/08/impact-of-preemptive-laws-on-public-health> [<https://perma.cc/59J8-65GL>].

109 Schmit et al., *supra* note 28, at 84.

110 Joseph Duball, *Uniform Law Commission Takes Up Privacy Law Endeavor*, IAPP (Feb. 25, 2020), <https://iapp.org/news/a/uniform-law-commission-takes-up-privacy-law-endeavor> [<https://perma.cc/CKN8-MMV3>].

111 Daniel J. Solove, *The Myth of the Privacy Paradox*, 89 GEO. WASH. L. REV. 1, 28 (2020) (quoting Paul M. Schwartz, *Privacy and Democracy in Cyberspace*, 52 VAND. L. REV. 1609, 1613 (1999)).

112 *Id.* at 31–33 (identifying them as limiting government and company power, respecting individuals, allowing reputation management, maintenance of appropriate social boundaries, trust, “control over one’s life,” “freedom of thought and speech,” “freedom of social and political activities,” the opportunity to “change and have second chances,” “protection of intimacy, body, and sexuality,” and “not having to explain or justify oneself”).

scholarship that theorizes the paradigm exhibited most in existing U.S. statutes as the “notice and choice” or “consumer protection” paradigm.¹¹³ Its central tenet is that those who gather and process data should be able to use it as they please, so long as data subjects are able to decide whether to share data for primary and secondary uses after being given notice of the intended uses. Much recent scholarship has criticized this paradigm, including work that has noted weaknesses in “notice and choice” on its own terms and work that has proposed instead paradigms focused on other interests. We discuss them briefly here, identifying normative concerns, especially as they relate to public health. We will assess those concerns in relation to the UPDPA and CAVACO statutes in Part III.

1. *Is “Notice and Choice” Possible?*

Consumers’ attitudes reflect a preference for limiting the collection of their personal information and a skepticism of sharing of their information with third parties.¹¹⁴ Of course, consumer privacy attitudes vary considerably within populations. For example, research has measured differences in privacy concerns and behaviors between different age groups on social-network websites.¹¹⁵ Additionally, consumer experience can affect privacy concerns. For example, individuals with more positive healthcare experiences were less concerned with the privacy of their health records.¹¹⁶ Consumer privacy concerns are also frequently a topic in national news coverage of data breaches, or novel data uses, increasing public awareness and concerns.¹¹⁷

113 Solow-Niederman, *supra* note 45, at 17 (asserting that the California Act “remains focused on individual rights and attempts to empower individuals by providing opportunities to opt-out of data collection”); Cohen, *supra* note 86 (arguing that almost all current congressional approaches “adopt a basic structure that is indebted to property thinking”).

114 CISCO CYBERSECURITY, CONSUMER PRIV. SERIES 3, 3–7, 11–12 (Nov. 2019) https://www.cisco.com/c/dam/global/en_uk/products/collateral/security/cybersecurity-series-2019-cps.pdf [<https://perma.cc/LL99-M5S2>]; H. Jeff Smith, Sandra J. Milberg & Sandra J. Burke, *Information Privacy: Measuring Individuals’ Concerns about Organizational Practices*, 20 MIS Q. 167, 189, 195 (1996). See generally Timothy R. Graeff & Susan Harmon, *Collecting and Using Personal Data: Consumers’ Awareness and Concerns*, 19 J. CONSUMER MKTG. 302 (2002); Mary J. Culnan, “How Did They Get My Name?”: *An Exploratory Investigation of Consumer Attitudes Toward Secondary Information Use*, 17 MIS Q. 341, 345 (1993).

115 See generally Murat Kezer, et al., *Age Differences in Privacy Attitudes, Literacy and Privacy Management on Facebook*, 10 J. PSYCH. RSCH. CYBERSPACE CYBERPSYCHOLOGY (2016).

116 Vaishali Patel, et al., *The Role of Health Care Experience and Consumer Information Efficacy in Shaping Privacy and Security Perceptions of Medical Records: National Consumer Survey Results*, 3 JMIR MED. INFORMATICS 12–13 (2015).

117 Rob Copeland, *Google’s ‘Project Nightingale’ Gathers Personal Health Data on Millions of Americans*, WALL ST. J. (Nov. 11, 2019), <https://www.wsj.com/articles/google-s-secret-project-nightingale-gathers-personal-health-data-on-millions-of-americans-11573496790> [<https://perma.cc/VCW5-QDMK>]; Kevin Granville, *Facebook and Cambridge Analytica: What*

While consumers often demand notice and choice rights, a growing body of literature suggests that the sense of control they provide may be illusory. As Alicia Solow-Niederman has noted, “individual rights to opt into or out of data collection or subsequent uses won’t help if there are flaws in the individual control model to begin with.”¹¹⁸

For example, there is a well-documented disconnect between consumers’ stated privacy attitudes and consumers’ privacy behaviors. The literature on this “privacy paradox” describes a phenomenon where individuals who express strong privacy concerns often will casually give personal information to businesses or organizations that request it, receiving in return only a *de minimis* benefit.¹¹⁹ Professor Daniel Solove has proposed to dissolve the privacy paradox by noting that consumers’ abstract privacy preferences and their personal practices in particular contexts are conceptually distinct.¹²⁰ In his view, it is quite consistent on the one hand for consumers to have privacy-enhancing preferences in the abstract and on the other hand, for them to fail to protect their own privacy when faced with a plethora of privacy policies and terms of use. The problem lies in the structural implementation and context where notice and choice rights are provided to consumers.

Unquestionably, the cost in time to assess each individual privacy option a consumer has, what Solove calls “privacy self-management,” is great.¹²¹ Even carefully designed interfaces intended to help consumers understand their choices better¹²² are of little help if the consumer confronts hundreds of them during a

You Need to Know as Fallout Widens, N.Y. TIMES (Mar. 19, 2018), <https://www.nytimes.com/2018/03/19/technology/facebook-cambridge-analytica-explained.html> [<https://perma.cc/HLT5-W3KS>].

118 Solow-Niederman, *supra* note 45, at 7.

119 Patricia A. Norberg, Daniel R. Horne & David A. Horne, *The Privacy Paradox: Personal Information Disclosure Intentions Versus Behaviors*, 41 J. CONSUMER AFFS. 100, 118 (2007); Patricia A. Norberg & Daniel R. Horne, *Privacy Attitudes and Privacy-Related Behavior*, 24 PSYCH. & MKTG. 829, 830 (2007); Susanne Barth & Menno D.T. de Jong, *The Privacy Paradox: Investigating Discrepancies Between Expressed Privacy Concerns and Actual Online Behavior*, 34 TELEMATICS & INFORMATICS 1038, 1039 (2017); Spyros Kokolakis, *Privacy Attitudes and Privacy Behaviour: A Review of Current Research on the Privacy Paradox Phenomenon*, 64 COMPUTS. & SEC. 122, 131 (2017).

120 Solove, *supra* note 111, at 4 (stating that “behavior involves risk decisions within specific contexts,” while “[a]ttitudes are more general views about value and can exist beyond specific contexts”).

121 *Id.* at 5 (“Managing one’s privacy is a vast, complex, and never-ending project that does not scale; it becomes virtually impossible to do comprehensively.”).

122 See, e.g., Patrick Gage Kelley et al., *Standardizing Privacy Notices: An Online Study of the Nutrition Label Approach*, CHI ‘10: PROC. SIGCHI CONF. ON HUMAN FACTORS IN COMPUTING SYS. 1573 (Apr. 2010) (describing development and testing of a graphical interface to facilitate consumer privacy choices).

year.¹²³ Other legal scholars have also questioned whether consumers have the capacity to understand the implications of their consent when increasingly sophisticated algorithms are being developed to make predictions or inferences about them or persons like them.¹²⁴ These and other concerns raise legitimate questions on whether notice and choice rights provide consumers meaningful protections.

2. *Is “Notice and Choice” Desirable?*

Many scholars have challenged the “notice and choice” paradigm on the grounds that it starts with the wrong assumptions. These include scholars who propose that there are interests at stake in data privacy and protection other than those of the data subjects and those who collect and process the data; others advocate for a model of “information fiduciaries.” There exists debate, too, as to the extent that the European Union’s General Data Protection Regulation (GDPR) should be a model for American regulation. Professor Julie Cohen has noted that “[c]urrent approaches to crafting privacy legislation are heavily influenced by the antiquated private law ideal of bottom-up governance via assertion of individual rights, and that approach, in turn, systematically undermines prospects for effective governance of networked processes that operate at scale.”¹²⁵ The individual rights approach may fail in terms of being both over- and underprotective of individual interests.

The individual-rights paradigm is underprotective when it fails to account for the ways that data may be used about consenting and non-consenting data subjects. As Solow-Niederman has noted, “[i]t’s difficult to imagine that a social media user who consented to a platform’s terms of service imagined that disclosure in that context would permit . . . emergent profiling. When any bit of data might be relevant in any range of future contexts, it becomes impossible for an individual to conceptualize the risks of releasing data.”¹²⁶ This is especially true when data are processed by “downstream” recipients who have no direct

123 See generally Jacob Leon Kröger, Otto Hans-Martin Lutz & Stefan Ullrich, *The Myth of Individual Control: Mapping the Limitations of Privacy Self-Management* (July 15, 2021) (unpublished manuscript), <https://dx.doi.org/10.2139/ssrn.3881776> [<https://perma.cc/FS7G-9TKS>]. See also Cohen, *supra* note 86, at 4 (“The continuing optimism about consent-based approaches to privacy governance is mystifying, because the deficiencies of such approaches are well known and relatively intractable.”); *id.* at 5 (“The issues that users must navigate to understand the significance of consent are too complex and the conditions surrounding consent too easy to manipulate.”).

124 Solow-Niederman, *supra* note 45, at 24 (“Machine learning analytics make it practically impossible for an individual to determine how data might or might not be significant or sensitive in a future setting.”); Cohen, *supra* note 86, at 5, n.8–9.

125 Cohen, *supra* note 86, at 3.

126 Solow-Niederman, *supra* note 45, at 26.

relationship with data subjects.¹²⁷ The individual-rights paradigm also fails to account for the ways that publicly available information about data subjects may be combined using complex and opaque machine learning to profile persons who have not consented to being profiled, a long-standing concern in the privacy literature.¹²⁸

The individual-rights paradigm is overprotective when it prevents data uses that would produce significant public benefits. As Professors Jane Bambauer and Brian Ray have noted, efforts to use technology to track the spread of COVID-19 were hampered by “state and federal governments (as well as influential private firms) . . . prioritizing a fetishized notion of individual privacy over collective public health.”¹²⁹ The focus on individual privacy above all else led to poor designs, destined to fail.¹³⁰ They contrasted the efforts of the South Korean government, which used “multiple independent sources of information—geolocation, credit card data, closed-circuit television, facial recognition, and old-fashioned interviews—to better trace contacts and predict the risk of transmission for each person.”¹³¹ Bambauer and others have noted that “it doesn’t make sense, given the particular characteristics of [COVID-19], to treat each individual’s privacy choices as a matter for individual control. As with lockdowns, the decision must be made at a collective level. A user choice conception of privacy must give way to other societal interests.”¹³² Likewise, Professor Alan Rozenshtein offered a full-throated defense of the principle that mandatory “digital disease surveillance” is valuable but nevertheless refused to endorse the idea, saying it is “conceivable . . . that digital disease surveillance is never the right option; even well-designed digital disease surveillance presents many dangers to privacy, liberty, and equality, and there is no guarantee that such surveillance will be well designed.”¹³³

Importantly, “notice and choice” is used to promote the ethical principle of “respect for persons,” but it is not the only mechanism to do so. The foundational

127 Solow-Niederman, *supra* note 45, at 47.

128 See Brian N. Larson & Genelle I. Belmas, *Second Class for the Second Time: How the Commercial Speech Doctrine Stigmatizes Commercial Use of Aggregated Public Records*, 58 S.C. L. REV. 1, 23–29 (and sources cited therein).

129 Jane Bambauer & Brian Ray, *COVID-19 Apps are Terrible—They Didn’t Have to Be 2* THE DIGITAL SOCIAL CONTRACT: A LAWFARE PAPER SERIES (Nov. 2020), <https://www.lawfareblog.com/covid-19-apps-are-terrible-they-didnt-have-be> [<https://perma.cc/2EA4-8XDT>].

130 *Id.*

131 *Id.* at 7.

132 Jane Bambauer et al., *It’s Time to Get Real About COVID Apps*, MEDIUM (May 14, 2020), <https://medium.com/@DataVersusCovid/its-time-to-get-real-about-covid-apps-dd82e08895f2> [<https://perma.cc/H9UD-Z7CP>].

133 Alan Z. Rozenshtein, *Digital Disease Surveillance*, 70 AM. UNIV. L. REV. 1511, 1517 (2021).

declarations of bioethics—including the Declaration of Helsinki and the Belmont Report¹³⁴—established the central tenets of bioethics and placed a special importance on the principle of respect for persons. In clinical research contexts, this often required taking steps to enable the autonomy of research subjects who were seen as particularly vulnerable to abuse given the significant knowledge gaps and power dynamics between researchers and their subjects. Informed consent (i.e. “notice and choice”) became the primary tool to promote autonomy and, by extension, respect for persons. In the context of established researcher-subject relationships, where a duty of care exists (i.e., nonmaleficence), “notice and choice” requirements can be powerful protections.

However, this bioethical approach to respect for persons is not well-suited for all contexts. For example, in 1991 the Council for International Organizations of Medical Sciences noted that traditional bioethical guidance did not adequately cover the special features of epidemiological research, which concerns itself with groups of people rather than individual research subjects.¹³⁵ In the context of public health surveillance, “notice and choice” protections can be problematic because nonparticipation of a relative few can bias results and impede community benefits.¹³⁶ Consequently, public health ethicists recommend different approaches to the “respect for persons” principle. Instead of relying on “notice and consent,” public health ethicists recommend involving communities in the decision-making process for population-level interventions.¹³⁷ Like public health, big data applications also must reckon with the unique ethical challenges associated with population-scale activities as opposed to just the ethical

134 WORLD MED. ASS’N, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (1964); NAT’L COMM’N FOR THE PROT. OF HUM. SUBJECTS OF BIOMED. & BEHAV. RSCH., *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979) [hereinafter BELMONT REPORT].

135 *Preamble*, COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, INTERNATIONAL GUIDELINES FOR ETHICAL REVIEW OF EPIDEMIOLOGICAL STUDIES (1991).

136 One can argue that a right of “consent” has a countervailing “right to be counted.” For example, the residents of Love Canal, N.Y., fought for a community-wide assessment of the health effects of a nearby toxic waste dump. The empirical evidence showing a connection between the waste and the community’s health empowered the community to force a governmental response. Jordan Kleiman, *Love Canal: A Brief History*, SUNY GENESEO, https://www.geneseo.edu/history/love_canal_history [<https://perma.cc/LZ5M-9ZFN>]. The “right to be counted” asserts that what isn’t counted, doesn’t count, implying that assessing public health and social problems is an essential step to correcting them. See Amy L. Fairchild, Ronald Bayer, & James Colgrove, *Searching Eyes: Privacy, the State, and Disease Surveillance in America*, 14 EMERGING INFECTIOUS DISEASES 1826 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630762/> [<https://perma.cc/LK6J-DLVA>].

137 WORLD HEALTH ORG., *Who Guidelines on Ethical Issues in Public Health Surveillance* (2017), <http://apps.who.int/iris/bitstream/10665/255721/1/9789241512657-eng.pdf> [<https://perma.cc/G7YE-H3ZF>]. We choose “notice and choice” as our default term for this paradigm, but when quoting the work of others, we use “notice and consent” if they do so.

challenges typical of researcher-participant relationships.¹³⁸

Another emerging alternative to the “notice and choice” paradigm uses the concept of “information fiduciaries.” Professor Jack Balkin casts the information fiduciary model as a “movement to viewing privacy in relational terms of trust and trustworthiness.”¹³⁹ For Balkin, fiduciary obligations are borne “out of social relationships, and the power and vulnerability inherent in these relationships,” whether those relationships are with a doctor, lawyer, or Facebook. Balkin argues that the model is needed to respond to the vulnerability and dependence created by information capitalism.¹⁴⁰ Under this model, Balkin argues that digital companies that collect and use end-user data should have three duties: care, confidentiality, and loyalty. He argues that the duties of “confidentiality and care require digital companies to keep their customers’ data confidential and secure” and that these must “run with the data” (imposing a duty to “vet” partners and downstream data processors).¹⁴¹ For Balkin, the duty of loyalty “means that digital companies may not manipulate end users or betray their trust.”¹⁴²

Interestingly, for Balkin, the duty of loyalty and to act in the interest of the data subject extends beyond the individual to the public more broadly. He argues that “large platforms like Facebook, Google, and Amazon have so many end users that a requirement that they must act in the interests of their end users *effectively requires them to act in the interests of the public as a whole*.”¹⁴³ This last point suggests the fiduciary model—which appears consumer-focused when described as a relationship between a data subject and a data controller—could function as a public-benefit model when applied to big data across many data subjects or the whole population. From a public health perspective, a “best interests” analysis could take into account community benefits from uses for public health that result perhaps only in small marginal benefits to the individuals to whom the data refer or only indirect benefits in the form of positive externalities. Balkin’s fiduciary approach could be more consistent with a bioethical (or even public ethics) approach to data protection given that fiduciary obligations implicate other ethical principles beyond “respect for persons” and because traditional “notice and consent” practices fall short of these

¹³⁹ Lisa M. Lee, *Public Health Ethics Theory: Review and Path to Convergence*, 40 J. LAW MED. & ETHICS 85–98 (2012).

¹⁴⁰ Jack M. Balkin, *The Fiduciary Model of Privacy*, 134 HARV. L. REV. F. 11 (2020).

¹⁴¹ For example, he argues that to “live without interacting with any of these services means greatly constricting one’s life and opportunities,” making the explicit point that “dependencies will increase over time” and the implicit point that notice and choice models are quasi-illusory because withholding consent has adverse consequences for an individual. *Id.* at 13.

¹⁴² *Id.* at 14.

¹⁴³ *Id.*

¹⁴⁴ *Id.* at 18 (emphasis added).

considerations.¹⁴⁴ The information fiduciary model is subject to continued debate,¹⁴⁵ and we do not have the space here to explore it fully.

Finally, there is debate about whether U.S. jurisdictions should shift away from the consumer-focused data privacy model traditionally used in U.S. laws and toward a more European data protection framework. Professors Chander, Kaminski, and McGeeveran argue that the traditional consumer-focused U.S. approach to data privacy relies on the tenuous ability of “notice and choice” to adequately protect consumers, assuming consumers get the benefit of their bargain with data-collecting businesses. In contrast, they argue that a data protection regime like the GDPR has protections that “follow the data” and establishes the “default in Europe . . . that personal information cannot be collected or processed unless there is a specific legal justification for doing so.”¹⁴⁶ Professors Chander, Kaminski, and McGeeveran argue that the California act “shares the presumption of most other American privacy law that personal data may be collected, used, or disclosed unless a specific legal rule forbids these activities.”¹⁴⁷ Moreover, based on their analysis of an early draft of the UPDPA and several state and federal privacy bills, they posit the idea that California is driving comprehensive privacy regulation in American jurisdictions as opposed to Europe.¹⁴⁸ They conclude that California is poised to catalyze comprehensive privacy regulation in American jurisdictions.¹⁴⁹ We conclude below that the

144 The Belmont Report describes the “respect for persons” as having two primary considerations: First, actions that promote an individual’s autonomy (i.e., informed consent); second, protection of vulnerable persons. BELMONT REPORT, *supra* note 134. Balkin’s information fiduciary model, in many respects, promotes the latter respect for persons principle in that it creates a duty to act in the best interests of data subjects who might not fully understand the risks and benefits associated with certain big data applications. *See also* Solow-Niederman, *supra* note 45.

145 *See generally id.*; Lina M. Khan & David E. Pozen, *A Skeptical View of Information Fiduciaries*, 133 HARV. L. REV. 497 (2019); Neil M. Richards & Woodrow Hartzog, *A Duty of Loyalty for Privacy Law*, 99 WASH. U. L. REV. (forthcoming) <https://doi.org/10.2139/SSRN.3642217> [<https://perma.cc/74PL-QE8F>].

146 Chander et al., *supra* note 75, at 1747–48.

147 *Id.* at 1756.

148 *Id.* at 1771, 1772–76.

149 *Id.* at 1771, 1772–76. We note that Chander, Kaminski, and McGeeveran discussed only state legislative proposals that were not enacted and not the bills eventually enacted in Colorado and Virginia. Chander et al., *supra* note 75, at 1772–76. This is no surprise as their article came out about the time of these enactments. The timing also makes it likely that the version of the UPDPA they analyzed was a draft from summer 2020, which looked radically different than the draft eventually adopted in 2021. *Compare* Collection and Use of Personally Identifiable Data Act [draft for discussion only] (Apr. 24, 2020), <https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.aspx?DocumentFileKey=f897ee80-6e47-13cd-1370-2f8c395bdde6&forceDialog=0> [<https://perma.cc/65L4-R22J>], *with* UPDPA, *supra* note 4. One report of an empirical study of privacy policies since the GDPR and CCPA sought evidence of the effect of these statutes on companies behavior. Jens Frankenreiter, *The Missing ‘California Effect’ in Data Privacy Law*, 39 YALE J. REGUL., manuscript at 8-9

UPDPA and CAVACO statutes chart a different route.¹⁵⁰

Though, as we explain in the next subsection, we adopt the “notice and choice” framework as our own normative paradigm, we do so with some modifications reflecting this literature, and we will attempt to touch in Part III on points where these other frameworks may be valuable.

3. *Defaults Should Play an Important Role*

Given that “notice and choice” is the predominant paradigm in existing law in the United States, both at federal and (as we shall see) state levels, the normative framework we adopt here is grounded in that paradigm. A common theme of many justifications for privacy is autonomy or agency of citizens; in this case, data subjects.¹⁵¹ This aligns well with a foundational document on research ethics well known among public health researchers and practitioners, the Belmont Report.¹⁵² The Belmont Report values “respect for persons,” the principle “that individuals should be treated as autonomous agents.”¹⁵³ “An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.”¹⁵⁴ Thus, “[t]o show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment”¹⁵⁵

Our view is that for this autonomy to be possible, the data subject must know how a controller will use their personal data—what we will call transparency—and have a meaningful opportunity to deliberate on whether to enter the relationship that involves the controller’s data practices. As we noted in the previous subsection, such deliberation may be impossible or unlikely, and in that event, regulators should set “defaults” in line with collective expectations about data privacy. Within our framework, this means that most public health data uses, whether primary or secondary, should be disclosed to data subjects but either not subject to their consent or subject only to an opt-out, what we call

(forthcoming 2022) <https://dx.doi.org/10.2139/ssrn.3883728> [<https://perma.cc/M3ZU-6DK4>] (finding “the impact of EU data privacy law on the relationship between U.S. businesses and their U.S. customers might be more limited than is commonly assumed”); *id.* at 9–10 (“cast[ing] doubt” on the “expectation that the [sic] California’s new data privacy law (the CCPA) will have nationwide effects”).

150 *See infra* Part III(A).

151 *See, e.g.,* Solove, *supra* note 111, at 39–41.

152 BELMONT REPORT., *supra* note 134, pt. B(1).

153 *Id.*

154 *Id.*

155 *Id.*

“passive consent.”¹⁵⁶

Normatively, regulators should prefer that data practices that do not require the consent of data subjects be disclosed wherever possible, even if they involve data practices in which a data custodian or “controller”¹⁵⁷ would be forced to engage. For example, a privacy policy should inform data subjects that the controller may disclose their personal data in response to a court order. Even if all controllers acknowledge this data practice, leaving consumers with little choice among them, it permits the (admittedly rare) consumer who is a privacy hawk to choose to withhold their personal data from all such controllers.

Defaults play a different role, because they have an outsized impact on what consumers will select.¹⁵⁸ Requiring only passive consent (allowing for an opt-out)¹⁵⁹ may be appropriate for data practices that data subjects would accept in principle or that serve public policy goals; by default, the data subject consents to them. Active consent (requiring an opt-in)¹⁶⁰ may be appropriate for those practices that data subjects typically reject or doubt in principle or that undermine public policy goals; by default, the data subject does not consent. This does not address all the concerns, as controllers may use a variety of other techniques to pressure data subjects into actively consenting.¹⁶¹ Nevertheless, as we see below, such a default approach has a critical role to play for public health matters.¹⁶² Absent regulatory defaults, data controllers will likely adopt the most self-serving approach, often at the expense of or risk to data subjects.

Of course, accepting that defaults are a good idea and knowing what they should be are two very different things. Despite some notable differences in privacy attitudes within the broader population, there is a growing body of literature showing broad support for the use of data for research purposes.¹⁶³ The public is generally comfortable sharing their personal information if they believe

156 See *infra* Part II(E)(2).

157 See *infra* Part II (defining terms).

158 See *infra* Part II(E)(2).

159 *Infra* Part II(E)(2).

160 *Id.*

161 *Id.*

162 See *infra* Part I(C)(3).

163 See, e.g., Mhairi Aitken et al., *Public Responses to the Sharing and Linkage of Health Data for Research Purposes: A Systematic Review and Thematic Synthesis of Qualitative Studies*, 17 BMC MED. ETHICS 12, 4–5 (Nov. 10, 2016); Laura J. Damschroder, et al., *Patients, Privacy and Trust: Patients’ Willingness to Allow Researchers to Access Their Medical Records*, 64 SOC. SCI. & MED. 223, 224 (2007); S.B. Haga & J. O’Daniel, *Public Perspectives Regarding Data-Sharing Practices in Genomics Research*, PUB. HEALTH GENOMICS 319, 321–22 (Apr. 27, 2010); Emily C. O’Brien, et al., *Patient Perspectives on the Linkage of Health Data for Research: Insights from an Online Patient Community Questionnaire*, 136 INT’L J. MED. INFORMATICS 9, 12–15 (2019); Donald J. Willison, et al., *Patients’ Consent Preferences for Research Uses of Information in Electronic Medical Records: Interview and Survey Data*, 326 B. MED. J. 1, 3 (Feb. 15 2003).

that their information will contribute to the furtherance of scientific knowledge. This is particularly true for health research where participants may believe that sharing their personal health information may confer some indirect benefit in the form of new discoveries or improved treatments for their health conditions.¹⁶⁴

Further evidence of the public's attitudes is provided by a series of studies that two of the authors (Schmit and Kum) have been performing with others.¹⁶⁵ In February 2020, they conducted a survey of 504 adults in the United States who were fluent in English and recruited by a consumer research company hired to identify a representative national sample.¹⁶⁶ The respondents were balanced for gender, race/ethnicity, age, education, income, and census region. Their health insurance coverage was also similar to the national distribution in data published by the U.S. Census Bureau. Researchers sought consumers' relative preferences among scenarios that varied based on the source of identifiable data, who would be using it, and the proposed data use (taking into account both legal restrictions and exceptions for data use or disclosure). The fractional factorial design the researchers used in the study allowed them to test seventy-two different data-use scenarios to determine consumers' relative preferences among them and to assess the weight that each variable had in the consumers' decisions. Through this design, the researchers were able to test whether consumer preferences aligned with the patchwork approach to U.S. privacy laws by using scenarios that varied according to the purpose for which their data would be used, the persons or entities using the data, and the type of data used. Use of these methods by the researchers allowed them to assess comparative weighting for various features in a manner not typically pursued in the research literature.

For these consumers' preferences, information about the purpose for which the data would be used was the highest priority, the identity of the user of second-greatest importance, and the nature of the data used of least importance. First, consumers supported uses for promoting population health and for research leading to scientific knowledge; they disfavored uses for identifying criminal activity, marketing and recruitment, and, most significantly, undifferentiated profit-driven activities. Second, consumers preferred data uses by university researchers, followed by non-profit organizations; they disfavored government and business users. Finally, consumers were most tolerant of uses of educational and health records and less tolerant of data from government sources and data relating to consumers' economic activity or customer behavior. The four sources

¹⁶⁴ Aitken et al., *supra* note 163, at 12.

¹⁶⁵ See generally Cason D. Schmit et al., *US Privacy Laws Go Against Public Preferences: Impeding Public Health and Research: Survey Study*, 23 J. MED. INTERNET RES. 1 (July 5, 2021). Another study, looking at changes to responses nine months into the COVID-19 pandemic, is in preparation.

¹⁶⁶ *Id.*

of data, however, were fairly close to being neutral in consumers' assessments.

When Schmit, Kum, and their colleagues combined the factors in the scenarios, they found that the top ten most acceptable scenarios all involved use by a university researcher or non-profit for scientific research or public health. Represented among the top ten were all four data sources: education, health, government-program related, and economic or customer activity. The five most *disfavored* scenarios involved for-profit businesses using data for profit-driven or marketing activities—regardless of the nature of the consumer data used. Rounding out the bottom ten least-favored uses were those involving for-profit or government uses to market programs or products and to identify criminal activity.

The researchers noted the inconsistency between consumer preferences and existing privacy laws: “Ironically, our data indicate that the U.S. public’s most preferred data re-use scenario is currently prohibited under FERPA while the U.S. public’s least preferred data re-use is completely legal and ubiquitous under the permissive FTC Act.”¹⁶⁷

The true picture of the public’s preferences is of course far more complex. Public support for some data uses and for privacy frequently does not square with the fact that data privacy and data utility are competing interests. Data controllers can substantially increase data privacy, but these efforts will often make the data more difficult (or impossible) to use for certain purposes. Alternatively, fewer privacy restrictions make data more useful, but they increase the privacy risks for data subjects. For example, data can be deidentified to protect the identity of data subjects, but without identifiers, these data can no longer be linked to other databases to answer otherwise unsolvable problems. Similarly, individual privacy preferences can be incongruent. For example, some patients want their information used for research to be deidentified, and they also want to be asked before their information is reused for new research projects.¹⁶⁸ These wishes are incompatible: Researchers have no way to notify a deidentified data subject, much less ask for their consent to subsequent data uses. Consequently, policy and good data governance practices, grounded in data subjects’ preferences and interests, are critical tools to balance the competing interests of privacy and data utility.

Trust, transparency, and individual control are critical factors for sharing data for research purposes.¹⁶⁹ The absence of any one of these can swiftly undermine public support in research data uses. For example, Google and the Ascension health system partnered to develop and test new big-data tools for

¹⁶⁷ *Id.*

¹⁶⁸ Aitken et al., *supra* note 163, at 12.

¹⁶⁹ *Id.* at 12–14.

healthcare applications.¹⁷⁰ This partnership was not publicly transparent, and patients were not notified or asked to opt in to the research partnership.¹⁷¹ The absence of a consent undermined Ascension's patients' sense of control. The lack of transparency of the partnership with the commercial entity Google raised suspicions and undermined trust in the endeavor. As a result, the partnership faced substantial backlash.

In summary, privacy is popular with consumers in principle, but their conduct seems often to run counter to their expressed preferences. A resolution of this *privacy paradox* requires transparency from controllers and action from regulators to set the *defaults* of consumer consent, defaults that reduce social harms and promote social benefits. Informing those defaults should be our developing knowledge of consumers' preferences and an awareness of the tension between data privacy and data utility, recognizing that public health practices receive considerably more support from consumers than profit-driven activities.

Effective public health responses sometimes require balancing the rights of individuals and their autonomy with the needs of the community. It may be necessary for the community's well-being to use personal data without data subjects' opportunity to deliberate and to choose to participate.¹⁷² Decisions to do so should not be taken lightly, however.¹⁷³

In Part II, we will examine the three state comprehensive statutes adopted so far and the new uniform data privacy act to assess their substantive provisions, particularly those related to public health. In Part III, we will assess them against these normative frameworks and propose next steps for public health researchers and professionals.

II. ANALYSIS OF THE UPDPA AND CAVACO STATUTES

The descriptive task of this Article is somewhat daunting, and it may seem that we are getting quite far down "into the weeds," but for the reader interested in making a comparative assessment of the UPDPA and California, Virginia, and Colorado acts—what we have called the "CAVACO statutes"—a thorough doctrinal description is necessary before a normative evaluation. Those readers who are legislators or planning to take part in legislative deliberation, lobbying, etc., over similar acts will likely benefit from the detailed analysis in this Part.

170 Copeland, *supra* note 117.

171 Nevertheless, this project was likely compliant with HIPAA's requirements. The Google and Ascension had a signed business associate agreement, and the development of software tools likely falls within the HIPAA allowance for use and disclosure for healthcare operations or under HIPAA's generous research exception. 45 CFR § 164.501, 502. 512(i); Copeland, *supra* note 117.

172 Bambauer et al., *supra* note 132; Rozenshtein, *supra* note 133, at 1517.

173 Rozenshtein, *supra* note 133, at 1517.

Other readers may prefer to skip to Part III, our normative assessment of these statutes, referring back to this Part only for details of interest.

Here, we lay out a conceptual framework, which allows us to define terms to use as representational devices in a discussion of the subject matter. We intend it as a vocabulary where the definitions are stipulated but expected to be consistent with a layperson's intuitions about what they mean and how they are used. This framework could prove useful for other efforts to compare privacy paradigms and statutes.¹⁷⁴ The CAVACO statutes and the UPDPA have some common requirements and some that differ. This Part examines the UPDPA in more detail, setting out its basic requirements; scope; favored, restricted, and prohibited data practices; and enforcement and penalties, noting its differences from the CAVACO statutes and their differences from each other. Along the way, we will point out interesting features and address terms that will be of interest to public health professionals and researchers.

For our conceptual framework, we have drawn from the European Union's GDPR,¹⁷⁵ the American Law Institute's 2019 statement of the principles of data privacy law,¹⁷⁶ and the legislative enactments we analyze below when we have found them conceptually sound.

As a preliminary matter, a distinction between "information" and "data" is tenable on grounds that the data that are recorded may or may not accurately represent the information about the individual or the world. We can think of "information" as the truth about the world and "data" as what's collected.¹⁷⁷ We'll refer to a "data record" to denote data that are stored in some readable form.¹⁷⁸ "Personal data" is any data "relating to an identified or identifiable natural person . . ."¹⁷⁹ "[A]n identifiable natural person is one who can be identified, directly or indirectly."¹⁸⁰ A "personal data record" is thus a data record containing personal data. The individual about whom a personal data record purports to record information is a "data subject."¹⁸¹ We will refer to a "data-record practice," or just "data practice" for short, as "collection, recording,

174 See, e.g., Chander et al., *supra* note 75, at 1749–62 (comparing CCPA, GDPR, and proposed state legislation).

175 See generally 2016 O.J. (L 119).

176 See generally PRINCIPLES OF DATA PRIVACY, *supra* note 1.

177 Cf. PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(a) (2019). Of course, one can make a statement about data, i.e., offer information about data. But here we are generally concerned with information about and data relating to human beings.

178 See, e.g., Privacy Act of 1974, 5 U.S.C. § 552a(a)(4) ("[T]he term 'record' means any item, collection, or grouping of information about an individual that is maintained by an agency.").

179 2016 O.J. (L 119), art. 4(1). See also PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(b) (2019).

180 2016 O.J. (L 119), art. 4(1).

181 2016 O.J. (L 119), art. 4(1). This is also the language the UPDPA uses. UPDPA, *supra* note 4, § 4. See also PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(c) (2019).

organi[z]ation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction” of personal data records.¹⁸²

Some individual or entity must engage in a data practice for there to be a legal question. We define a “data controller” as a natural person or entity that “determines the purposes and means” of a data practice,¹⁸³ and a “processor” as the natural person or entity that actually performs a data practice.¹⁸⁴ If the same entity both decides what data practices to undertake and also performs them, it is both a controller and a processor regarding that data practice.¹⁸⁵ Because of their power to decide, “data controllers have greater responsibilities than data processors.”¹⁸⁶ Not all controllers are created equal, however. Acting together or with others, one controller “collects personal data directly from a data subject”¹⁸⁷—it is the “collecting controller.” As a controller, the collecting controller “determines the purpose and means of processing” of the data records,¹⁸⁸ but it may also make the data records available to another controller, a “third-party controller.”¹⁸⁹

Many uses of personal data are “secondary uses” or “secondary data practices,” where data collected for one purpose is re-used for a different purpose. These secondary uses often require dissemination by the collecting controller to some other controller. For example, consumers might consent to having their local dry cleaner share records about their dry-cleaning purchases with a university researcher, who might then process the records for purposes of

182 2016 O.J. (L 119), Art. 4(2). This is the definition that the GDPR provides for “processing,” and is quite similar to the activities that the Privacy Act of 1974 defines as “maintaining” a record. 5 U.S.C. § 552a(a)(3) (“[T]he term ‘maintain’ includes maintain, collect, use, or disseminate.”). The UPDPA defines “maintain” more narrowly. UPDPA, *supra* note 4, § 2(8) (“‘Maintains,’ with respect to personal data, means to retain, hold, store, or preserve personal data as a system of records used to retrieve records about individual data subjects for the purpose of individualized communication or decisional treatment.”). *See also* PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(d) (listing “collection,” “access,” “retention,” “use,” “sharing,” and “destruction” as “personal data activities”).

183 *Compare* 2016 O.J. (L 119), Art. 4(7) with PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(e).

184 *Compare* 2016 O.J. (L 119), Art. 4(8) with PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(f). *But see* Solow-Niderman, *supra* note 45, at 48 (taking “controller” to mean collecting controller and “processor” to include third-party controllers).

185 The UPDPA takes a different tack, seeming to make “controller” and “processor” mutually exclusive. UPDPA, *supra* note 4, § 2(12) (defining “processor” as one “that processes personal data on behalf of a controller” (emphasis added)).

186 PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2 cmt. g.

187 UPDPA, *supra* note 4, § 2(1).

188 *Id.* § 2(3).

189 *Id.* § 2(21).

research. In this example, the dry cleaner is a collecting controller, the university researcher is a third-party controller, and their research practices are secondary data practices.

Along this pipeline, any controller may use one or more processors. Controllers need not use external processors, in which case they would engage in the processing in-house. Thus, a collecting controller may be the only stop in a pipeline that it builds and maintains. The dry cleaner in the example above, for example, might use its own customer data records to market related services to its customers. It is then the sole collecting controller of the data records, and there are no other processors. Much more elaborate pipelines are, however, possible.

Given this basic vocabulary, we can consider several components that a conceptual framework for data protection must have. A critical one—and thus the first we address—is the definition of which data records are subject to the regulation. Second, we take up some considerations relating to controllers and processors. Third, we discuss common data practices that are subject to regulation. Fourth, we consider matters of the scope and jurisdiction of data privacy law. Finally, we will briefly mention enforcement mechanisms and penalties for violating the data privacy laws.¹⁹⁰

A. Substantive Information Content

The UPDPA and CAVACO statutes are comprehensive personal data protection laws. Like the European Union’s General Data Protection Regulation, the CAVACO statutes and the UPDPA include within their scope all personal data; importantly, though, they carve out a variety of exceptions and exemptions. Other U.S. federal and state data protection laws define protected data records using some form of description of the substantive content of the information they purport to represent or the nature of the controllers or processors.¹⁹¹ We discuss the normative consequences of those choices in Part III.¹⁹²

Subject to the UPDPA are “personal data” that relate to a “data subject” that a “collecting controller” collects and of which the controller maintains a “record.”¹⁹³ Personal data under the UPDPA is “a record that identifies or describes a data subject by a direct identifier or is pseudonymized data,” tracking the CAVACO statutes fairly closely.¹⁹⁴ UPDPA and the CAVACO statutes

190 Because our principal focus is on public health activities, we assume that the actors involved will avoid violating the laws’ requirements and may therefore be less concerned about enforcement. Readers attempting to assess risks for private actors under UPDPA and the CAVACO statutes should review those provisions of the acts and advise clients accordingly.

191 *Supra* Section I(B).

192 *Infra* Section III(B).

193 UPDPA, *supra* note 4, §§ 2(1), 2(4), 2(10).

194 *Id.* § 2(10); CCPA, *supra* note 4, § 140(o)(1) (“‘Personal information’ means information

exclude some data from “personal data” based on their identifiability or sensitivity, discussed further below. There are also some substantive categories of data excluded: For example, these acts do not cover personal data “processed or maintained in the course of a data subject’s employment or application for employment.”¹⁹⁵

The UPDPA and CAVACO statutes take slightly different approaches to an exemption for personal data “processed or disclosed as required or permitted by a warrant, subpoena, or court order or rule, or otherwise as specifically required by law.”¹⁹⁶ The UPDPA exempts these practices from its own application, but we argue it would protect data subjects better if it covered these data while permitting their disclosure only to the extent required by law, categorizing such disclosures as favored or “compatible” data practices, leaving them subject to the act.¹⁹⁷ The CAVACO statutes take the latter approach, not exempting these types of data from coverage but expressly not limiting a controller or processor’s ability to respond to the situations described in this paragraph.¹⁹⁸

that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household.”); VCDPA, *supra* note 4, § 59.1-575 (“any information that is linked or reasonably linkable to an identified or identifiable natural person”); CPA, *supra* note 4, § 6-1-1303(17)(a) (identical to VCDPA).

195 UPDPA, *supra* note 4, § 3(c)(5). Though the official comment does not explain this exclusion, it would be reasonable to conclude that it has been excepted here because of the significantly different nature of the employment relationship and because state laws presently offer varied protections for data relating to employees. *See also* CCPA, *supra* note 4, § 145(m)(1) (excluding a variety of employment-related activities); VCDPA, *supra* note 4, § 59.1-575 (excluding from definition of “consumer,” VCDPA’s counterpart to data subject, “a natural person acting in a commercial or employment context”); *id.* § 59.1-575(c)(14) (excluding employment-related data from application under the act); CPA, *supra* note 4, § 6-1-1304(k) (excluding “data maintained for employment records purposes”). Such a limitation in UPDPA is not without its likely critics. Elizabeth A. Brown, *The Fitbit Fault Line: Two Proposals to Protect Health and Fitness Data at Work*, 16 YALE J. HEALTH POL. L. & ETHICS 1, 14 (2016) (detailing employer uses of surveillance data); *id.* at 24 (asserting that HIPAA does not cover them); *id.* at 46–47 (proposing that HIPAA’s definition of covered entities include employers, fitness-app developers, and wearable-device manufacturers).

196 UPDPA, *supra* note 4, § 3(c)(3). This is peculiar, and possibly a drafting error, in part because personal data relating to a data subject, even sensitive data, would be taken out of protection of UPDPA in the event the controller or processor had to disclose it in litigation with a third party. Thanks to this exemption, it appears the third party would be under no restriction where further processing and disclosure of the data are involved. The controller or processor might reasonably seek a protective order when disclosing the data. Perhaps the act should require this.

197 In fact, UPDPA elsewhere implies that type of disclosure is a compatible data practice. *See* UPDPA, *supra* note 4, § 7(b)(2), (7), (9) (defining compatible data practices to include processing “reasonably necessary to comply with a legal obligation or regulatory oversight of the controller,” processing in a manner that “is reasonably necessary to prevent, detect, investigate, report on, prosecute, or remediate an actual or potential” crime, and processing that “is reasonably necessary to comply with or defend a legal claim”).

198 CCPA, *supra* note 4, § 145(a); VCDPA, *supra* note 4, § 59.1-582(A); CPA, *supra* note 4, § 6-1-1304(3)(a).

A second exemption from the UPDPA of interest here relates to research: the UPDPA does not apply to personal data “processed or maintained *solely* as part of human-subjects research conducted in compliance with legal requirements for the protection of human subjects.”¹⁹⁹ This appears broadly to support the use of personal data for research purposes subject to the Common Rule and potentially other regimes for research ethics. Personal data collected, analyzed, and used in accord with such a research protocol would thus entirely escape the application of the UPDPA. The “solely” in the UPDPA is important, however. Data “processing” under the UPDPA includes collecting data.²⁰⁰ This exemption, applying only to personal data *collected solely* for research, probably does not cover disclosures by controllers and processors to secondary data researchers. For example, if Amazon were to provide personal data about its customers’ transactions (identifying customers) to a researcher solely so that the researcher could do IRB-approved research, this does not appear to be processing “*solely* as part of human-subject research” because the data was initially collected for a non-research purpose (i.e., commercial transaction). This data would be useful to public health researchers because consumer behavior data can be used to infer and predict health status. Similarly, these data would enable researchers to determine whether there is a connection between using certain products and certain health outcomes.

Getting such data from companies like Amazon is a boon for researchers because it removes the cost of recruiting survey participants from the public and provides a complete picture of the population (at least of Amazon users). But the researchers do their processing, limited by the IRB protocol, solely as part of human-subjects research, while Amazon, the collecting controller of the personal data, collects and processes the data for other reasons. As the UPDPA covers these data, researchers would instead have to determine whether the data practice is permitted under it.²⁰¹

Slightly less strict is the Virginia Act, which broadly exempts data records in research conducted according to applicable ethical standards.²⁰² But it goes further and exempts information used “only for public health activities and purposes as authorized by HIPAA,”²⁰³ which includes disclosures to a “public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health

199 UPDPA, *supra* note 4, § 3(c)(2) (emphasis added).

200 *Id.* § 2(11).

201 *See infra* Part II(E).

202 VCDPA, *supra* note 4, § 59.1-576(C)(4).

203 *Id.* § 59.1-576(C)(9).

investigations, and public health interventions.”²⁰⁴ This exemption, however, affects disclosures only by “covered entities,” which are a “health plan,” “health care clearinghouse,” or “health care provider who transmits any health information in electronic form in connection with a transaction covered by” the act.²⁰⁵ And the “only” in the operative Virginia provision again prevents the secondary uses contemplated in the Amazon example.

More relaxed still are the California and Colorado Acts. The California statute starts with a somewhat similar approach to the UPDPA, exempting from its application personal data that are either (a) deidentified as provided in the Code of Federal Regulations and “derived from patient information that was originally collected, created, transmitted, or maintained by an entity regulated by [HIPAA], the Confidentiality Of Medical Information Act, or . . . the Common Rule;”²⁰⁶ or (b) “collected, used, or disclosed in research, as defined in [45 C.F.R. § 164.501] . . . and that is conducted in accordance . . . the Common Rule” or similar regulations.”²⁰⁷ But the California statute exempts use *and disclosure* in research. Colorado’s statute also exempts data records *collected* in IRB-approved research, but like California’s, it goes further in exempting “personal data *used or shared* in research.”²⁰⁸ Either statute would allow our hypothetical researcher to get access to the hypothetical Amazon data discussed in the previous paragraph, arguing it is not covered by the applicable statute.

B. Data Identifiability

U.S. data protection laws predominantly protect only identified or identifiable data records.²⁰⁹ Consequently, how identifiability is defined in a law is essential to determine whether the law protects a data record. Such definitions often include one or more of three factors: The presence of direct identifiers, the presence of indirect identifiers, and the likelihood of identification through inference. In some cases, identifiability definitions are difficult to apply, so some laws include legal standards for taking identified data and rendering it pseudonymous or deidentified by law. A law may then provide different levels of protection for these levels of identifiability, or it may exclude one or more of

204 45 C.F.R. § 164.512.

205 45 C.F.R. § 160.103.

206 CCPA, *supra* note 4, § 146(a)(4)(A).

207 *Id.* § 146(a)(5).

208 CPA, *supra* note 4, § 6-1-1304(2)(d) (emphasis added).

209 There are some notable exceptions of laws that protect information based on its content. For example, trade secret laws protect information that can be identifiable (e.g., customer lists) or non-identifiable (e.g., marketing strategies). See TEX. CIV. PRAC. & REM. CODE ANN. § 134A.002(6) (West, 2021). Similarly, the Freedom of Information Act excludes certain sensitive government records from its disclosure requirements. 5 U.S.C. § 552.

them from its application. This Section describes these different degrees of identifiability—direct identifiers, indirect identifiers, and inferences—and explains deidentification and pseudonymized data.

Direct identifiers are data that can in theory be used by themselves to identify a specific individual. Common examples of direct identifiers include names, social security numbers, home addresses, email addresses, and phone numbers. Most direct identifiers are insufficient by themselves, however, to identify a specific individual with certainty. For example, the name “John Smith” is common and does not differentiate one John Smith from another, and even social security numbers are not always unique to an individual.²¹⁰ Still, these data can practically identify many individuals. Consequently, direct identifiers are often a core part of legal definitions of identifiability.²¹¹

Indirect identifiers can identify an individual, but only in combination with other data. For example, a million or more Americans may share a birthday, excluding the year—an indirect identifier—so date of birth cannot, by itself, identify an individual. However, knowing the date of birth of John Smith might enable someone to distinguish one “John Smith” from another. Similarly, postal (ZIP) codes, race, and gender information are indirect identifiers that, together with other data, can help identify a data subject.²¹²

Laws that define identifiable personal data as including indirect identifiers can impede socially beneficial secondary data practices. For example, health, economic, and social outcomes can vary considerably depending on an individual’s race or where they live, and data about them are often essential to research on public health. If a data processor strips data of all indirect identifiers to free it from a law’s restrictions, the secondary use of the data records for research can be severely limited.

Some laws define identifiability by the possibility that an individual might determine the identity of a particular data subject by inference rather than by the presence of specific direct or indirect identifiers, for example, where “there is a reasonable basis to believe the information can be used to identify the individual,”²¹³ or where there is information “alone or in combination” that “would allow a reasonable person in the . . . community, who does not have

210 Frank Hayes, *Not So Unique*, COMPUTERWORLD (Aug. 6, 2007, 12:00 AM), <https://www.computerworld.com/article/2552992/not-so-unique.html> [<https://perma.cc/2T6S-26CC>].

211 GDPR, for example, gives the following examples of direct identifiers: “a name, an identification number, location data, [or] an online identifier . . . of [a] natural person.” 2016 O.J. (L 119), art. 4(1).

212 GDPR gives the following examples of indirect identifiers: “one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.” 2016 O.J. (L 119), art. 4(1).

213 45 C.F.R. § 160.103.

personal knowledge of the relevant circumstances, to identify the [data subject] with reasonable certainty.”²¹⁴ All of these approaches to defining legally identifiable data ask data processors to consider the possibility that someone else could identify a data subject of a data record.²¹⁵

Therein lies a critical problem: when data pertain to individual data subjects, often it is mathematically possible to identify at least some data subjects within a dataset.²¹⁶ Quantitatively minded data processors are of course keenly aware that without substantial redaction or data manipulation, there will always be a lingering possibility that a data subject may be reidentified if a disclosed dataset is combined with external information.²¹⁷ Consequently, absent clear safe-harbor provisions, laws that define identifiability using the possibility, foreseeability, or reasonable belief that a data subject may be reidentified using inference will always create uncertainties due to persistent possibilities of reidentification.

Perhaps because of ambiguities in legal definitions of identifiability, some laws include standards for deidentifying data. Deidentified data are data once protected by a data protection law that have been modified or redacted in such a way that they have much-diminished or even no protection under the law. Deidentification standards are particularly important for laws with broad or ambiguous definitions for identifiable data because persistent uncertainties about a law’s applicability may prevent a data processor from disclosing data for socially desirable purposes. For example, HIPAA defines protected data as that which “identifies an individual” or where there is a reasonable belief that it can identify an individual. Absent a specific deidentification standard, it is difficult to know what data elements need to be redacted or modified so the data no longer meets this definition. Fortunately, HIPAA regulations contain standards that permit data processors to render data legally deidentified.²¹⁸

Some data protection laws define a middle ground between identifiable data and deidentified data. Data in this middle ground are sometimes called

214 34 C.F.R. § 99.3 (2021).

215 Contrast the Common Rule, which draws the boundary here: “identity of the subject is or may readily be ascertained by the investigator.” 45 C.F.R. § 46.102. This is narrower and more easily determined than the other tests. *See also* PRINCIPLES OF DATA PRIVACY, *supra* note 1, § 2(b) (including in definitions whether “there is a moderate probability” or “low probability” that data “could be linked to a specific natural person”).

216 Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, UCLA L. REV. 1701, 1713 (2010). *But see*, Victor Janmey & Peter L. Elkin, *Re-Identification Risk in HIPAA De-Identified Datasets: The MVA Attack*, AMIA ANN. SYMP. PROC. 1329, 1329 (2018); Kathleen Benitez & Bradley Malin, *Evaluating Re-identification Risks with Respect to the HIPAA Privacy Rule*, 17 J. AM. MED. INFORMATICS ASS’N 169, 169 (2010).

217 Hye-Chung Kum et al., *Social Genome: Putting Big Data to Work for Population Informatics*, 47 COMPUT. 56, 61–63 (2014); Benitez & Malin, *supra* note 216; *see also* Ohm, *supra* note 216.

218 45 C.F.R. § 164.514(b).

“pseudonymized,” “coded,” or “limited” data. We will use the first of these terms. For example, GDPR defines pseudonymous data as personal data that “can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organi[z]ational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.”²¹⁹ Other laws define it as data that is partially deidentified (or less identifiable) but does not have a key or code that connects a pseudonym with data subject identifiers.²²⁰

Pseudonymized data is an important category for public health research and public health population interventions. Often, research proceeds with protocols in place to replace direct identifiers in the data, such as participants’ names and email addresses, with codes that allow data about a single participant to be examined in the aggregate without identifying the participant. Often researchers will keep a “key” that would allow reidentification.

By incorporating reduced restrictions for less identifiable data, laws implicitly recognize the tradeoff between privacy and data utility. Provisions that give additional flexibility for less-identifiable data enable greater data use than would typically be permitted under an all-or-nothing approach where data are either identifiable and fully protected or not identifiable and not protected. Data in these categories often receive a lower level of protection under the data protection laws. Laws that have special provisions for pseudonymized data often require some information redaction or modification (usually the removal of enumerated direct or indirect identifiers), but not so much as to render the data fully deidentified. For example, HIPAA allows for the disclosure of limited datasets. In contrast to fully deidentified datasets, limited datasets can include much more geographic information, including city, county, and ZIP code. These data permit analyses that would not be possible under fully deidentified data; however, limited datasets are often still viewed as “identifiable” data and HIPAA rules still apply.²²¹ Similarly, the Common Rule permits an exemption from some requirements where researchers record otherwise identifiable data in such a manner that data subjects cannot be identified.²²² Other laws, like GDPR, do not expressly provide less restrictive provisions for less identifiable data, but instead cite pseudonymization as a method to meet legal requirements for use, disclosure, or secure maintenance of data.²²³

Turning to the UPDPA and CAVACO statutes, the UPDPA’s three

219 2016 O.J. (L 119), art. 4(5).

220 *See, e.g.*, 45 C.F.R. § 164.514(e).

221 45 C.F.R. § 164.514(e).

222 45 C.F.R. § 46.104(d)(4).

223 *See, e.g.*, 2016 O.J. (L 119), art. 89 (citing pseudonymization as an example for a data safeguard that can be used when disclosing information for research or public interest purposes).

categories of data identifiability are personal data, deidentified data, and non-identified data. Personal data are the central focus of the Act. A data record is “personal data” if it “direct[ly] identif[ies]”²²⁴ the data subject or if it has been “pseudonymized,” meaning that it does not directly identify the subject but “can be reasonably linked to a data subject’s identity or is maintained to allow individualized communication with, or treatment of, the data subject.”²²⁵ The three CAVACO statutes define “personal data” in ways similar, but not quite identical, to the UPDPA.²²⁶ All include pseudonymized data in personal data.

In practice, the UPDPA employs the term “pseudonymized” in only three places: eliminating the controller’s responsibility to provide the data subject a copy of data if the data are “pseudonymized and not maintained with sensitive data”;²²⁷ defining the creation of pseudonymized data as a compatible data practice;²²⁸ and prohibiting reidentification of pseudonymized data unless certain conditions are met.²²⁹

The CAVACO statutes introduce an additional requirement to the definition of pseudonymized data: “that the additional information is kept separately and is subject to technical and organizational measures to ensure that the personal information is not attributed to an identified or identifiable consumer.”²³⁰ Given that IRBs typically expect researchers to explain how they will achieve these very tasks, the UPDPA and CAVACO statute definitions of pseudonymized data do not appear more stringent than current research practices, though the UPDPA might be less so.

“Deidentified data”—“personal data that is modified to remove all direct identifiers and to reasonably ensure that the record cannot be linked to an identified data subject by a person that does not have personal knowledge or special access to the data subject’s information”²³¹—is subject to some

224 “‘Direct identifier’ means information that is commonly used to identify a data subject, including name, physical address, email address, recognizable photograph, and telephone number.” UPDPA, *supra* note 4, § 2(6).

225 “The term [pseudonymized] includes a record without a direct identifier if the record contains an internet protocol address, a browser, software, or hardware identification code, a persistent unique code, or other data related to a particular device. The term does not include deidentified data.” UPDPA, *supra* note 4, § 2(14).

226 CCPA, *supra* note 4, § 140(v)(1)(K); VCDPA, *supra* note 4, § 59.1-575; CPA, *supra* note 4, § 6-1-1303(17) (identical to VCDPA).

227 UPDPA, *supra* note 4, § 5(a). To do otherwise would be exceptionally difficult because the pseudonymization makes it difficult to know whose record belongs to who or whose needs correction; and may actually compromise privacy more through the reidentification process.

228 UPDPA, *supra* note 4, § 7(b)(5).

229 *Id.* § 9(b).

230 CCPA, *supra* note 4, § 140(aa). Accord VCDPA, *supra* note 4, § 59.1-575; CPA, *supra* note 4, § 6-1-1303(22). This language mirrors the GDPR. See *supra* note 219.

231 UPDPA, *supra* note 4, § 2(5).

restrictions under the UPDPA but is not its focus.²³² Because deidentified data are personal data that are modified, we can also think of them as “personal data, but for the fact that they’ve been deidentified.” The California statute defines “deidentified data” similarly to the UPDPA.²³³ Virginia and Colorado’s statutes narrow the definition slightly, considering data to be deidentified only if it cannot be linked to the data subject or “a device linked to” the data subject.²³⁴ These acts probably thus consider indirect identifiers, such as IP and MAC addresses on computers, sufficient to identify a data subject through a device linked to them. The Colorado and California acts also require—in very similar language—controllers and processors of deidentified data to take certain steps to keep it from being reidentified.²³⁵

As noted above, deidentified data are practically difficult to keep that way. In theory, statutes could specify standards for deidentification to resolve just this issue, but neither the UPDPA nor the CAVACO statutes do so.²³⁶

The third data category of identifiability, one not actually named or described in the UPDPA or CAVACO statutes, can be defined by elimination and consists of data about entities other than human data subjects. These acts do not regulate use of such “non-personal data.”

C. Data Sensitivity

Assuming that data records are identifiable, there is still a question of how sensitive they are. The extant privacy acts appear to recognize at least three levels of data record sensitivity: “sensitive” personal data, publicly available personal data, and everything else, what we’ll call “general personal data.” Publicly available data includes public government records and information “available to the general public in widely distributed media,” including most widely available websites, directories, media programs, and news media.²³⁷ “Sensitive data” is

232 *Id.* § 9(b) provides it is a “prohibited data practice to collect or create personal data by reidentifying or causing the reidentification of pseudonymized or deidentified data.” The same section provides some technical exceptions to that rule. *Id.*

233 CCPA, *supra* note 4, § 140(m).

234 VCDPA, *supra* note 4, § 59.1-575; CPA, *supra* note 4, § 6-1-1303(11).

235 CCPA, *supra* note 4, § 140(m); CPA, *supra* note 4, § 6-1-1301(11). The UPDPA practically includes similar provisions, but it does not tie them to the definition of “deidentified data.” See UPDPA, *supra* note 4, § 9(b) (making it a prohibited practice for any regulated entity to “collect or create personal data by reidentifying . . . deidentified data”); § 6(a) (requiring disclosure in the controller’s privacy policy of uses); and § 4 (requiring controllers and processors to comply with instructions of, and obligations laid on, collecting controllers).

236 Oddly, the Colorado statute, which already limits the duties of controllers and processors where deidentified data are concerned, places data deidentified under the standards in 45 C.F.R. 164 entirely outside its application. § 6-1-1304(2)(g).

237 UPDPA, *supra* note 4, § 2(15).

information in categories defined by the statute that are usually subject to greater protections or more processing restrictions.²³⁸ General personal data is a catch-all category that consists of personal data that is neither publicly available nor sensitive.

The UPDPA recognizes these three levels of personal-data sensitivity. It defines “publicly available information” to include public government records; information “available to the general public in widely distributed media,” including most widely available websites, directories, media programs, and news media; information made available to the public lawfully; and observations of the data subject made “from a publicly accessible location.”²³⁹ The UPDPA excludes such data entirely from its protection, not considering them part of “personal data.”²⁴⁰ Though the CAVACO statutes vary in their terms from the UPDPA, they appear practically to have similar meanings, and they also exclude publicly available information from their coverage.²⁴¹

The UPDPA defines “sensitive data” as “personal data that reveals” any information in a broad range of categories: “racial or ethnic origin, religious belief, gender, sexual orientation, citizenship, or immigration status”; “a credit or debit card number or financial account number”; most government-issued identification numbers, including SSN, taxpayer ID, etc.; present geolocation coordinates; “diagnosis or treatment for a disease or health condition” or “genetic sequencing information”; criminal records; and any “information about a data subject the controller knows or has reason to know is under 13 years of age.”²⁴² It also includes a subject’s ID and password for services to be accessed remotely.²⁴³ Of these, criminal record and income are unique to the UPDPA. There are other variations between the UPDPA and the CAVACO statutes and among them that are interesting, but mostly minor.²⁴⁴

238 ALI’s principles do not define sensitive data categories, but the drafters nevertheless claim that the principles are adaptable to concerns about sensitive data. *PRINCIPLES OF DATA PRIVACY*, *supra* note 1, § 2 cmt. e. For a list of data categories considered sensitive under the UPDPA and CAVACO statutes, see *infra* Section II(C).

239 UPDPA, *supra* note 4, § 2(15).

240 UPDPA, *supra* note 4, § 3(c).

241 CCPA, *supra* note 4, § 140(v)(2); VCPDA § 59.1-575; CPA, *supra* note 4, § 6-1-1303(17)(b). Note that Solow-Niederman expresses concern about the negative externalities of processing of publicly-available data. Solow-Niederman, *supra* note 45, at 5, 31-38.

242 UPDPA, *supra* note 4, § 2(17).

243 *Id.* (“credentials sufficient to access an account remotely”).

244 The Virginia and Colorado statutes use almost identical language and are the least expansive in covering sensitive data, not including account credentials; financial accounts and credit and debit card numbers; Social security, taxpayer ID, driver’s license, or military identification number; or geolocation. VCPDA § 59.1-575; CPA, *supra* note 4, § 6-1-1303(24). California and Colorado cover “sex life,” while Virginia does not. CCPA, *supra* note 4, § 140(ae)(2)(c); VCPDA § 59.1-575; CPA, *supra* note 4, § 6-1-1303(24). California alone covers philosophical beliefs, union membership and “contents of a consumer’s mail, email, and text

The “sensitive data” category varies in its importance in the statutes, as well. Its key role in the UPDPA is to differentiate between cases where the data subject must opt in to restricted data practices (called “incompatible data practices” in the Act) involving sensitive data via “express consent in a signed record for each practice.”²⁴⁵ The controller need only provide notice and the opportunity to opt-out of incompatible data practices using non-sensitive data.²⁴⁶ The significant effect of the “sensitive” category under the California statute is that data subjects have certain rights to restrict their use, though the statute expresses this in a confused jumble of limitations and exceptions.²⁴⁷ The California act also provides for specific means for the data subject to opt out of disclosure and distribution of their sensitive data.²⁴⁸ Virginia and Colorado require consent for any data practice involving sensitive data.²⁴⁹ Each also requires that controllers and processors perform a “data protection assessment” for processing where sensitive data are concerned.²⁵⁰

The third, catch-all category of data sensitivity, what we call “general personal data,” is not named or defined in the UPDPA or CAVACO statutes, but consists of personal data that is neither publicly available nor sensitive data.

D. Regulated Entity

Central to many data protection laws is a delineation of particular types of data controllers or processors subject to the law, in other words, the regulated entities. In comprehensive data protection laws, the definition of the regulated entity is often broad. GDPR applies to processing of personal data by controllers and processors established within the European Union—the location of the regulated entity—and “personal data of data subjects who are in the Union by a

messages unless the business is the intended recipient of the communication.” CCPA, *supra* note 4, § 140(ae)(1)(D)-(E). It also allows the listed to be extended by regulation. CCPA, *supra* note 4, § 185(a)(1). There are some variations in the identification of geolocation, biometric, and genetic data among the statutes. UPDPA, *supra* note 4, § 2(17); CCPA, *supra* note 4, § 140(ae)(1)(c), (1)(f), (2)(a); VCPDA § 59.1-575; CPA, *supra* note 4, § 6-1-1303(24).

²⁴⁵ UPDPA, *supra* note 4, § 8(c).

²⁴⁶ The notice must be sufficient for the “data subject to understand the nature of the incompatible data processing.” UPDPA, *supra* note 4, § 8(b). The UPDPA also affects the data subject’s right to request a copy of data from a controller. *Id.* § 5(a).

²⁴⁷ See CCPA § 121. California also subjects a controller to greater disclosure obligations to the data subject regarding the collection of sensitive data. CCPA, *supra* note 4, § 100(a)(2)-(3).

²⁴⁸ CCPA, *supra* note 4, § 135.

²⁴⁹ VCDPA, *supra* note 4, § 59.1-578(A)(5); CPA, *supra* note 4, § 6-1-1308(7).

²⁵⁰ CPA, *supra* note 4, § 6-1-1309(2) (categorizing the processing of any sensitive data as “processing that presents a heightened risk of harm to a consumer”); *id.* § 6-1-1309(1) (requiring data protection assessments for practices that present a heightened risk); VCDPA, *supra* note 4, § 59.1-580(A)(4) (requiring data protection assessments for practices that involve the “processing of sensitive data”).

controller or processor not established in the Union”—the location of the data subject at the time of the processing.²⁵¹ GDPR also defines some entities that are not regulated (e.g., natural persons engaged with personal or household activities).²⁵² In existing U.S. federal laws, the limited scope of separate statutes results in the sectorial “patchwork” of regulation, which is not particularly analytically useful with the comprehensive state statutes discussed here. The newer statutes do a more thorough job of conceptually identifying various controllers and processors in the “pipeline” of data processing.²⁵³

Importantly, U.S. data protection laws are not mutually exclusive when it comes to the defined regulated entities. For example, most entities regulated as substance-abuse treatment programs are also HIPAA-covered entities. Consequently, they have to comply with HIPAA and the 42 CFR Part 2 regulations. This also creates complexities between federal and state regulatory approaches. For example, health information exchange organizations are regulated under HIPAA as business associates of covered entities,²⁵⁴ but in 2016, thirty-one states had privacy laws specifically regulating health information exchanges.²⁵⁵ When different data protection laws overlap on a single regulated entity, it can be especially difficult to determine which legal provisions apply and which policies to implement to ensure compliant data practices.

Turning to the UPDPA, at its broadest level, it applies to any person—whether individual or legal entity²⁵⁶—that is a controller or processor of personal data, provided the controller or processor “conducts business in [the adopting] state or produces products or provides services purposefully directed to residents of” the adopting state.²⁵⁷ Like the CAVACO statutes, the UPDPA excludes from its effect the adopting state and any “agency or instrumentality . . . or a political subdivision” of it.²⁵⁸ Not-for-profit enterprises may or may not be covered,

251 2016 O.J. (L 119), art. 3.

252 *Id.* art. 1–2, 18.

253 See text accompanying notes 183–190.

254 45 C.F.R. § 160.103 (2021).

255 Cason D. Schmit, Sarah A. Wetter & Bitu A. Kash, *Falling Short: How State Laws Can Address Health Information Exchange Barriers and Enablers*, 25 J. AM. MED. INFORMATICS ASS’N 635, 635–644 (2018).

256 The definition of “person” includes both individuals and entities but excludes any “public corporation or government or governmental subdivision, agency, or instrumentality.” UPDPA, *supra* note 4, § 2(9).

257 UPDPA, *supra* note 4, § 3(a).

258 *Id.* § 3(b); see CCPA, *supra* note 4, § 140(d)(1) (defining “business”—the entities regulated under the act—as any “sole proprietorship, partnership, limited liability company, corporation, association, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners,” thus implicitly excluding government entities); VCDPA, *supra* note 4, § 59.1-576(B) (withholding application from “body, authority, board, bureau, commission, district, or agency of the Commonwealth or of any political subdivision of the Commonwealth”); COLO. REV. STAT. ANN. § 6-1-102 (West 2021) (defining, for purposes of CPA,

depending on state-law determinations about what counts as “conducting business.” The Colorado act is silent on that matter. California, meanwhile, defines the businesses to which CCPA applies as those “organized or operated for the profit or financial benefit of its shareholders or other owners,” seemingly excluding non-profits.²⁵⁹ Virginia’s act expressly excludes from its application any non-profit organization²⁶⁰ or “institution of higher education.”²⁶¹

Like the CAVACO statutes, the UPDPA has certain size thresholds for regulated entities. A controller or processor that “maintains personal data about more than [50,000] data subjects who are residents of this state”²⁶² or that “earns more than [50] percent of its gross annual revenue during a calendar year from maintaining personal data as a controller or processor” is fully subject to the UPDPA.²⁶³ It’s up to each enacting state to fill in the bracketed thresholds.²⁶⁴ Similarly, the California Consumer Privacy Act applies to a smaller entity if it “[d]erives 50 percent or more of its annual revenues from selling or sharing consumers’ personal information.”²⁶⁵ The Virginia Consumer Data Protection Act and Colorado Privacy Act never apply to smaller controllers or processors.²⁶⁶

“person” as “an individual, corporation, business trust, estate, trust, partnership, unincorporated association . . . , or any other legal or commercial entity,” again implicitly excluding government entities).

259 CCPA, *supra* note 4, § 140(d)(1).

260 Defined as “any corporation organized under the Virginia Nonstock Corporation Act . . . or any organization exempt from taxation under § 501(c)(3), 501(c)(6), or 501 (c)(12) of the Internal Revenue Code.” VA. CODE ANN. § 59.1-575 (West 2021).

261 VA. CODE ANN. § 59.1-576(B)(iv)-(v) (West 2021).

262 UPDPA, *supra* note 4, § 3(a)(1) (“excluding data subjects whose data is collected or maintained solely to complete a payment transaction”). Note that the square brackets in the quoted language in the original. Whether a data subject is protected by a state’s adoption of the UPDPA appears to be unrelated to whether the data subject is a resident of the adopting state. This is because the definition of regulated entities noted above relates to whether the controller or processor does business in the adopting state or purposefully directs its services to the state’s residents and not whether any breach involves data records of a resident of the adopting state. *See* the discussion, *infra* Section H, for implications in enforcement.

263 UPDPA, *supra* note 4, § 3(a)(2). A processor working for a controller or processor that meets either of these size requirements is also held to be in this category. UPDPA, *supra* note 4, § 3(a)(3).

264 “The threshold numbers are in brackets [so] each State can determine the proper level of applicability.” UPDPA, *supra* note 4, § 3 cmt.

265 CCPA, *supra* note 4, § 140(d)(1)(C). Otherwise, CCPA governs only larger controllers and processors, those that have “annual gross revenues in excess of twenty-five million dollars (\$25,000,000) in the preceding calendar year” or that “annually buy[], sell[], or share[] the personal information of 100,000 or more consumers or households.” *Id.* § 140(d)(1)(A)–(B).

266 CPA, *supra* note 4, § 6-1-1304(1) (applying only to a controller or processor that “controls or processes the personal data of one hundred thousand consumers or more . . . [or] derives revenue . . . from the sale of personal data and processes or controls the personal data of twenty-five thousand consumers or more”); VCDPA, *supra* note 4, § 59.1-576(A) (processors and controllers that “control or process personal data of at least 100,000 consumers or . . . control or

Normatively, these acts are practically equivalent on the issue of covered entities, but one concern under the UPDPA is its coverage of smaller players. A controller or processor of *any size* is subject to the UPDPA if it engages in any of the “restricted” or “incompatible” data practices described below.²⁶⁷ On the one hand, it’s unclear how much expense smaller players will have to incur to educate themselves about the Act so that they understand what they may do without becoming subject to *all* of the UPDPA’s requirements. The result might be widespread confusion, and a catastrophic implementation of the Act in a state that affects small-business owners could sour legislators on the act in general. On the other hand, exempting small controllers and processors—who likely make up a large proportion of the players in this space—could leave much data entirely unprotected, much as they are by the CAVACO statutes.

E. Data Practices

Our framework recognizes three types of data practices in which controllers and processors may engage: *avored*, *restricted*, and *prohibited* data practices. Favored and restricted data practices each have two subcategories. Those that are favored may be disclosed or undisclosed and do not require data subject’s consent; those that are restricted require the data subject’s consent, passively through an opt-out or actively through an opt-in mechanism. Thus, permitted data practices represent a continuum from those that least constrain the controller, undisclosed favored; to those that most constrain it, active-consent restricted. All other data practices are prohibited.

1. Favored Data Practices

Generally, data protection laws will permit the use of collected data for enumerated purposes without any consent from the data subjects other than their choice to enter a relationship with the controller. These favored practices will almost always include the primary data use, or the use for which the data was collected. This “purpose limitation” often intends that “personal information should be collected only for a specified purpose and not further processed in a manner incompatible” with it.²⁶⁸ For example, HIPAA permits covered entities to use protected information for treatment, payment, and healthcare operations. Similarly, FERPA permits educational entities to use protected education records for legitimate educational interests. These purposes align with reasonable data-subject expectations for the use of collected data.

process personal data of at least 25,000 consumers and derive over 50 percent of gross revenue from the sale of personal data”).

²⁶⁷ UPDPA, *supra* note 4, § 3(a)(4).

²⁶⁸ PRINCIPLES OF DATA PRIVACY, *supra* note 1, at 3.

Data protection laws may also permit some secondary data uses—data collected for one purpose but reused for another purpose—without a data subject’s consent. Secondary data uses may be favored data practices if they advance government interests, data subjects’ interests, or social interests. A secondary data use could advance a government interest if it facilitates government oversight or enforcement (e.g., fraud detection). Similarly, a secondary data use could promote the data subject’s interest, as, for example, when federal public assistance programs permit program data to be used to assess a beneficiary’s eligibility for additional benefits. Finally, some laws permit some secondary uses without consent to advance social interests, as when they permit data to be used for research or public health purposes.²⁶⁹ All these favored uses can be either *disclosed*, meaning that the collecting controller discloses—usually in a privacy policy—that it will engage in the data practice, or *undisclosed*, meaning that the controller does not disclose them.

The basic regime of the UPDPA is to permit what it calls “compatible data practices” without consumer consent, though the collecting controller must disclose those favored data practices in which it routinely engages in its privacy policy. These are thus disclosed favored practices in our framework. There are three bases upon which a data practice can be a compatible data practice under the UPDPA. The most straightforward basis is for the practice to fall within an enumerated list of compatible practices: section 7(b)–(c) of the Act. This includes managing transactions between controller and data subject and managing controller’s business—both part of the primary purposes for which the data are collected—and permitting oversight of controller’s data practices, preventing or investigating crime, complying with legal requirements, and defending against legal claims—data practices that the drafters regarded as sufficiently integral to the primary purposes of the data collection to warrant this status.²⁷⁰

The second basis upon which a data practice may be classified as compatible under the UPDPA is if it entails “processing [that (1)] is consistent with the ordinary expectations of data subjects or [(2)] is likely to benefit data subjects substantially.”²⁷¹ Note that elements (1) and (2) here are disjunctive, so either will do. The Act offers six factors for assessing whether a particular data practice would satisfy this requirement.²⁷²

269 Hulkower, *supra* note 15, 150–60; *see generally* Tara Ramanathan, Cason Schmit, Akshara Menon & Chanelle Fox, *The Role of Law in Supporting Secondary Uses of Electronic Health Information*, 43 J. L. MED. & ETHICS 48 (2021).

270 UPDPA, *supra* note 4, § 7(b).

271 *Id.* § 7(a).

272 *Id.* ((1) the data subject’s relationship with the controller; (2) the type of transaction in which the personal data was collected; (3) the type and nature of the personal data that would be processed; (4) the risk of a negative consequence on the data subject by the use or disclosure of the personal data; (5) the effectiveness of a safeguard against unauthorized use or disclosure of the

The third basis under the UPDPA for classifying a data practice as compatible is in accordance with a voluntary consensus standard (VCS). This is a formal standard that a controller or processor can adopt, developed (probably) by an industry group in consultation with consumers and others, and approved by the attorney general (or other privacy official designated by the enacting state). As the VCS is a significant innovation of the UPDPA that provides value to public health researchers and professionals, we treat it in more detail below.²⁷³

Under the UPDPA, the collecting controller must disclose in its privacy policy any compatible data practices it or its authorized processors “appl[y] routinely to personal data.”²⁷⁴ The UPDPA’s use of the word “routinely” seems unnecessarily vague here. For example, a controller may disclose personal data that provides evidence of criminal activity to a law enforcement agency without listing this practice” if “this type of disclosure is unusual.”²⁷⁵ There is no definition of “routinely” in the UPDPA, and it does not appear in other uniform acts of the ULC. Even *Black’s* struggles to define “routine practice” without appeal to the synonym “regular”: “A customary action or procedure that is regularly followed; a habitual method adhered to as a matter of regularity.”²⁷⁶

The California act does not require specific consent for data practices “reasonably necessary and proportionate to achieve the purposes for which the personal information was collected or processed, or for another disclosed purpose that is compatible with the context in which the personal information was collected.”²⁷⁷ It does require that the collecting controller disclose the categories of personal information (including sensitive data), its expected uses, and the duration of its retention.²⁷⁸ Virginia and Colorado also require these disclosures²⁷⁹ and do not require consent for “collection of personal data to what is adequate, relevant, and reasonably necessary in relation to the purposes for which such data is processed, as disclosed to the consumer”²⁸⁰ or processing for those purposes or for purposes “compatible” with them,²⁸¹ provided the data are

personal data; and (6) the extent to which the practice advances the economic, health, or other interests of the data subject.)

273 See *infra* Section II.G.

274 UPDPA, *supra* note 4, § 6(a)(3).

275 *Id.* § 6 cmt.

276 *Routine Practice*, BLACK’S LAW DICTIONARY (11th ed. 2019).

277 CCPA, *supra* note 4, § 100(c).

278 *Id.* § 100(a).

279 VCDPA, *supra* note 4, § 59.1-578(C); CPA, *supra* note 4, § 6-1-1308(1) (using language very similar to Virginia’s).

280 VCDPA, *supra* note 4, § 59.1-578(A)(1); see also CPA, *supra* note 4, § 6-1-1308(3) (using very similar language).

281 VCDPA, *supra* note 4, § 59.1-578(A)(2); see also CPA, *supra* note 4, § 6-1-1308(4) (using very similar language).

not sensitive.²⁸²

The UPDPA and the CAVACO statutes differ from each other somewhat in their overt treatment of public health. The UPDPA classifies as a compatible data practice—a disclosed favored practice—one that “permits analysis . . . to discover insights related to public health, public policy, or other matters of general public interest and does not include use of personal data to make a prediction or determination about a particular data subject.”²⁸³ This provision also appears to permit public health surveillance and development of population interventions to protect public health, but it specifically excludes individualized interventions.²⁸⁴ California establishes a narrow undisclosed favored practice for public health: Reidentification of deidentified records for public health purposes and for research subject to the Common Rule.²⁸⁵ Colorado, on the other hand, offers a broad permission for public health practices, providing that the act does not “restrict a controller’s or processor’s ability . . . to process personal data for reasons of public interest in the area of public health, but solely to the extent that the processing . . . (a) is subject to suitable and specific measures to safeguard the rights of the consumer whose personal data are processed; and (b) is under the responsibility of a professional subject to confidentiality obligations under federal, state, or local law.”²⁸⁶ This is also an undisclosed favored practice in our framework. The California and Virginia acts treat public health practices as restricted data practices, thus requiring consent, though the consent need only be passive (opt out) in California’s case but must be active (opt in) in Virginia’s. See the next subsection for further discussion.

2. *Restricted Data Practices*

Restricted data practices are those that require the data subject’s consent. There are two subsets of restricted data practices: *passive consent* and *active consent*. They represent default states for data practices. In passive consent, the data subject is presumed to consent unless they opt out; in active consent, the data subject is presumed not to consent unless they opt in. There may also be heightened requirements for notice and more formal requirements for consent for

282 See VCDPA, *supra* note 4, § 59.1-578(A)(5).

283 UPDPA, *supra* note 4, § 7(b)(6)(A). In fact, the controller has to disclose the data use only if it is “routine.”

284 UPDPA, *supra* note 4, § 7 cmt. (A compatible practice “would include the use of personal data to initially train an AI or machine learning algorithm. However, subsequent use of such an AI or machine learning algorithm in order to make a prediction or decision about a data subject . . . must comply with this act through another provision.”).

285 CCPA, *supra* note 4, § 148(a)(2), (3).

286 *Id.* § 6-1-1304(3)(a)(xi).

some restricted data practices.²⁸⁷

The UPDPA refers to restricted data practices as “incompatible data practices.”²⁸⁸ Despite their name, the UPDPA does not prohibit them, instead merely requiring the data subject’s consent. There is considerable variation in the acts’ determinations of which restricted data practices are passive-consent, permitting data subjects to opt out, and active-consent, requiring data subjects to opt in. The UPDPA and California require active consent in the smallest class of cases, while Virginia and Colorado appear to require active consent in a broad class of cases.

Considering passive consent first, when the data controller collects data for an incompatible data practice under the UPDPA, the subject must be informed and have a chance to opt out.²⁸⁹ The California act provides a data subject an opt-out right to “to direct a business that sells or shares personal information about the consumer to third parties” without regard to the reason for which the controller is selling or sharing data.²⁹⁰ Similarly, uses of sensitive data outside those that are favored give rise to a data subject’s right to opt out in California.²⁹¹ Virginia and Colorado provide that data subjects may opt out of “(i) targeted advertising, (ii) the sale of personal data, or (iii) profiling in furtherance of decisions that produce legal or similarly significant effects concerning the consumer.”²⁹² Based on these provisions, a controller will have to provide at the

287 And there may be a variety of kinds of consent. As background, 2017 revisions to the Common Rule introduced a new type of consent, called “broad consent.” *Revised Common Rule FAQs*, HHS.GOV OFFICE FOR HUMAN RESEARCH PROTECTIONS, <https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html> [<https://perma.cc/ZXE9-LCHC>] (last visited Feb. 12, 2022). This new provision allows researchers to solicit consent that covers a broad range of potential research applications. *Id.* Rather than seeking specific consent for each new research project. Anecdotally, we believe that IRBs are struggling to practically implement a “broad consenting” process and that it is consequently an underutilized legal tool. It may be that “consent” in most commercial settings—click-through privacy policies—is a lot like a broad consent but without the rigor of IRB review.

288 UPDPA, *supra* note 4, § 8(a) (defining the term by process of elimination, labeling data practices that are not compatible or prohibited “incompatible,” and also including violations of a privacy policy).

289 *Id.* § 8(b); *see also* UPDPA, *supra* note 4, § 6 (requiring a collecting controller to have a privacy policy that identifies categories and purpose of data it maintains and distributes to others and identifies all incompatible data practices it will apply unless the consumer opts out).

290 CCPA, *supra* note 4, §§ 120(a), 115(d). The act’s authorization of regulations, however, suggests that the reasons might be spelled out. § 185(a)(19)(A)(vi). *See also* CCPA, *supra* note 4, § 120(b) (requiring a controller to disclose any selling or sharing of data in which it engages).

291 CCPA, *supra* note 4, § 121(a). *See also id.* § 135 (detailing methods for providing this opt out).

292 VCDPA, *supra* note 4, § 59.1-577(A)(5); CPA, *supra* note 4, § 6-1-1306(1)(a)(i) (using identical language). “‘Targeted advertising’ means displaying advertisements to a consumer where the advertisement is selected based on personal data obtained from that consumer’s activities over time and across nonaffiliated websites or online applications to predict such consumer’s

least notice and an opportunity to opt out before providing data for public health practices or research if they cannot be considered favored practices but are instead restricted practices. Practically speaking, this is not much more of an impediment than that imposed for disclosed favored practices: With passive consent, the default is participation, and harried data subjects are unlikely even to notice that they may opt out. However, in contrast to disclosed favored practices, data controllers seeking to share passive-consent data for public health have implementation costs to develop systems and workflows to collect, manage, and enforce opt-out preferences.

But the UPDPA and the California and Virginia acts include some data practices that require active consent. The Virginia statute provides that all data practices beyond the favored ones described above, and any processing involving sensitive data, are subject to the data subject's consent.²⁹³ As it defines consent as "a clear affirmative act signifying a consumer's . . . agreement to process personal data relating to the consumer,"²⁹⁴ this appears to be an opt-in form of consent. The Colorado statute's requirements are similar, but it classifies public health activities as favored practices that do not require consent. In California, a very small class of cases—where the controller wants to enroll the data subject in "into a financial incentive program"²⁹⁵—are subject to active consent. Under the UPDPA, only where sensitive data²⁹⁶ are concerned must the data subject consent specifically to each incompatible data practice.²⁹⁷

preferences or interests." VCDPA, *supra* note 4, § 59.1-575; *see also* CPA, *supra* note 4, § 6-1-1301(25) (adopting very similar language. "'Profiling' means any form of automated processing performed on personal data to evaluate, analyze, or predict personal aspects related to an identified or identifiable natural person's economic situation, health, personal preferences, interests, reliability, behavior, location, or movements." VCDPA, *supra* note 4, § 59.1-575; *see also* CPA, *supra* note 4, § 6-1-1301(20) (adopting nearly identical language).

293 VCDPA, *supra* note 4, § 59.1-578(A)(2), (5); *see also* CPA, *supra* note 4, § 6-1-1308(4), (7) (using very similar language).

294 VCDPA, *supra* note 4, § 59.1-575; *see also* CPA, *supra* note 4, § 6-1-1303(5) (using very similar language). California appears at first to define consent more broadly as "any freely given, specific, informed, and unambiguous indication of the consumer's wishes by which the consumer . . . , including by a statement or by a clear affirmative action, signifies agreement to the processing of personal information relating to the consumer for a narrowly defined particular purpose." CCPA, *supra* note 4, § 140(h). The "including" before "by a statement or by a clear affirmative action" suggests there are other possibility. The section proceeds to provide that "[a]cceptance of a general or broad terms of use, or similar document, that contains descriptions of personal information processing along with other, unrelated information, does not constitute consent. Hovering over, muting, pausing, or closing a given piece of content does not constitute consent. Likewise, agreement obtained through use of dark patterns does not constitute consent." *Id.* *See generally* Jamie Luguri & Lior Jacob Strahilevitz, *Shining a Light on Dark Patterns*, 13 J. LEGAL ANALYSIS 43 (2021) (providing an explanation and analysis of dark patterns).

295 CCPA, *supra* note 4, § 1798.125(b)(3).

296 *See supra* Section II(C).

297 UPDPA, *supra* note 4, § 8(c).

3. *Prohibited Data Practices*

Prohibited data practices are those practices that are never permitted. The CAVACO statutes do not define prohibited data practices, except to the extent that prohibition arises from going beyond what is permitted in favored and restricted practices.²⁹⁸ In contrast, the UPDPA expressly describes several prohibited data practices.²⁹⁹ As a preliminary matter, the UPDPA makes it a prohibited practice to reidentify deidentified data, subject to certain exceptions.³⁰⁰ This Section thus brings deidentified data within the UPDPA's scope, but only to the extent that a processor attempts to reidentify it. The UPDPA inventories other categories of prohibited data practices into three groups: breaking rules elsewhere, personal harms, and security harms. The Act prohibits data processing if the processor engages in processing that would otherwise be a restricted ("incompatible") data practice and fails to get the data subject's consent.³⁰¹

The UPDPA also makes it a prohibited data practice to process personal data in a manner that would "constitute a violation of other law, including federal or state law against discrimination."³⁰² The Virginia and Colorado acts contain similar prohibitions.³⁰³

The personal harms against which the UPDPA protects data subjects arise from data practices likely to "subject a data subject to specific and significant: (A) financial, physical, or reputational harm; (B) embarrassment, ridicule, intimidation, or harassment; or (C) physical or other intrusion on solitude or seclusion."³⁰⁴ These UPDPA strictures could have effect on some public health practices.³⁰⁵ For example, individualized public health interventions might under certain circumstances have the negative effects described in the UPDPA. The CAVACO statutes do not call out these particular harms as relating to prohibited data practices, again, because they do not specifically define prohibited practices.

The security harms against which the UPDPA protects data subjects arise from data practices likely to "result in misappropriation of personal data to assume another's identity," or "fail to provide reasonable data-security measures."³⁰⁶ The CAVACO statutes imply similar requirements in their overall use limitations and in their requirements for risk assessments.³⁰⁷

298 See, e.g., CCPA, *supra* note 4, §§ 100(a), 100(c), 120(d), 121(b).

299 UPDPA, *supra* note 4, § 9(a).

300 *Id.* § 9(b).

301 *Id.* § 9(a)(5).

302 *Id.* § 9(a)(3).

303 VCDPA, *supra* note 4, § 59.1-578(A)(4); CPA, *supra* note 4, § 6-1-1308(6).

304 UPDPA, *supra* note 4, § 9(a)(1).

305 See *infra* Part III.

306 UPDPA, *supra* note 4, § 9(a)(2), (4).

307 CCPA, *supra* note 4, § 1798.185(a)(15); VCDPA, *supra* note 4, § 59.1-580; CPA, *supra*

F. Other Requirements of Controllers and Processors

Recall that a smaller data controller or processor that engages only in compatible data practices is not bound to meet any other requirements under the UPDPA.³⁰⁸ As for the larger controller or processor, or the smaller one that wishes to engage in incompatible data practices, the UPDPA's key requirements are to engage in incompatible data practices only with the data subject's consent (opt-in or opt-out, depending on data-content sensitivity) and not to engage in prohibited data practices. The UPDPA imposes other obligations on these data controllers and processors. They fall into three categories: offering a public privacy policy, responding to data subject's requests, and performing data risk assessments.

The UPDPA requires that a controller make its privacy policy available in two ways: First, it must be "reasonably available to a data subject at the time personal data is collected about the subject," and second, the controller must post its privacy policy on its website, if it has one.³⁰⁹ The CAVACO statutes do not impose the latter requirement. As for the contents of privacy policies, they fall into two categories, one relating to the controller's data practices and the other to the procedures and laws under which it operates. The UPDPA and the CAVACO statutes have similar requirements for privacy policies regarding data practices, discussed above.³¹⁰ Where procedures and laws are concerned, the UPDPA and the CAVACO statutes require that the privacy policy provide "the procedure for a data subject to exercise a right" requiring the controller's response.³¹¹ Under the UPDPA, the controller must also identify "federal, state, or international privacy laws or frameworks with which the controller complies," and explain whether the controller has adopted "any voluntary consensus standard."³¹²

The second major category of responsibilities for data controllers under the UPDPA and CAVACO statutes involves responding to requests from data subjects, including requests for copies of data, for correcting data, and for deleting data. The collecting controller is principally responsible here because it has (or had) a relationship with the data subject at the time of collection. The collecting controller is responsible for providing to a data subject a copy of their personal data and correcting errors in the data.³¹³ The data controller is responsible for coordinating activities of processors and downstream controllers

note 4, § 6-1-1309.

308 UPDPA, *supra* note 4, § 3(a)(1)–(4).

309 UPDPA, *supra* note 4, § 6(b)–(c).

310 *Supra* Section II.F.

311 UPDPA, *supra* note 4, § 6(a)(5); accord VCDPA, *supra* note 4, § 59.1-578(C); CPA, *supra* note 4, § 6-1-1308(1)(a)(iii).

312 UPDPA, *supra* note 4, § 6(a)(5)–(7).

313 *Id.* §§ 4(a)(1)–(2), 5(a).

to comply with these requirements, and those processors and controllers are bound to cooperate.³¹⁴ The controller may not retaliate against a data subject for making any of these requests.³¹⁵ California, Virginia, and Colorado all provide that the controller must comply with a data subject request to delete personal data.³¹⁶ The UPDPA does *not* provide a right for the data subject to request the deletion of personal data.³¹⁷ Nevertheless, all four statutes provide some individual rights that persist throughout the data processing lifecycle, which some legal scholars argue is characteristic of the European GDPR.

The CAVACO statutes provide for a duty of care “to implement and maintain reasonable security procedures and practices appropriate to the nature of the information.”³¹⁸ The UPDPA makes it a prohibited data practice to “fail to provide reasonable data-security measures, including appropriate administrative, technical, and physical safeguards to prevent unauthorized access.”³¹⁹

The final major category of responsibility for data controllers and processors under the UPDPA is that they must “conduct and maintain . . . a data privacy and security risk assessment” that addresses risks, their characteristics, and efforts taken to mitigate them.³²⁰ The California statute provides for regulations addressing risk assessments, but regulations promulgated under the previous version of the California Consumer Privacy Act do not address them, despite the statutory requirement that they do so.³²¹ Colorado and Virginia require assessments for processing of sensitive data and some other data practices.³²² Neither the UPDPA nor the CAVACO statutes directly require periodic updates of risk assessments. Under the UPDPA, the controller or processor must update

314 *Id.* § 5(b).

315 *Id.* § 5(c). There are some special cases where the controller can change its relationship with the data subject after changing data at the subject’s request or if the subject withholds consent from an incompatible data practice. *Id.* §§ 5(c), 7(c), 8(c).

316 CCPA, *supra* note 4, § 105(a); VCDPA, *supra* note 4, § 59.1-577; CPA, *supra* note 4, § 6-1-1306(1)(d). *But see* CCPA, *supra* note 4, § 105(d)(6) (providing that a controller need not delete data records at the data subject’s request if the data are being processed for research to which the subject consented and “deletion of the information is likely to render impossible or seriously impair the ability to complete” the research).

317 UPDPA, *supra* note 4, § 4, official comment.

318 CCPA, *supra* note 4, § 150(a)(1). *Accord* VCDPA, *supra* note 4, § 59.1-578(A)(3); CPA, *supra* note 4, § 6-1-1308(5).

319 UPDPA, *supra* note 4, § 9(a)(4).

320 *Id.* § 10(a).

321 CCPA, *supra* note 4, § 185(a)(15)(B) (requiring the California Attorney General to adopt regulations by July 1, 2020, “requiring businesses whose processing of consumers’ personal information presents significant risk to consumers’ privacy or security, to . . . [s]ubmit to the California Privacy Protection Agency on a regular basis a risk assessment with respect to their processing of personal information”). As of this writing, no such regulations appear to have been promulgated.

322 CPA, *supra* note 4, § 6-1-1309(2); VCDPA, *supra* note 4, § 59.1-580(A).

the assessment if “there is a change in the risk environment or in a data practice that may materially affect the privacy or security of the personal data.”³²³ Language of the CAVACO statutes might be construed to require a new assessment when similar changes occur.³²⁴

Among these provisions, only the right to deletion raises concerns for public health, and then only if a significant proportion of data subjects request it.

G. The UPDPA Voluntary Consensus Standards

A marked innovation in the UPDPA is its use of VCSs. As one official comment on the Act notes: “[H]ow these obligations are implemented may depend on the particular business sector [a]nd consumers have vastly different expectations about the use of their personal information depending on the underlying transaction for which their data is sought.”³²⁵ According to the UPDPA reporter, “[p]roviding an opportunity for industry sectors, in collaboration with stakeholders including data subjects, to agree on methods of implementing privacy obligations provides the flexibility any privacy legislation will require.”³²⁶ The comment notes the apparent success of such standards under the Children’s Online Privacy Protection Act (COPPA).³²⁷

In the UPDPA, the result is a process for groups of stakeholders to gather and set baselines for particular industries or types of project. Such stakeholders could include industry groups and public health researchers and professionals. In brief, a group of “stakeholders”³²⁸ gathers to adopt a set of baselines relating to various requirements of the Act, those not spelled out in the Act itself. For example, what counts as a compatible data practice in a particular industry?³²⁹ The Act categorizes data practices by a controller or processor subject to a VCS as “compatible data practices” if the VCS defines them so.³³⁰ How must a controller obtain consent from data subjects when it is required?³³¹ What are industry-standard practices for responding to a consumer request for access to

323 UPDPA, *supra* note 4, § 10(a)-(b).

324 See VCDPA, *supra* note 4, § 59.1-580; CPA, *supra* note 4, § 6-1-1309.

325 UPDPA, *supra* note 4, § 12, official comment.

326 *Id.*

327 *Id.* See also BBB NAT’L PROGRAMS, INC., TWENTY YEARS OF SUCCESSFUL CO-REGULATION UNDER COPPA:

A MODEL FOR FOSTERING CONSUMER PRIVACY (Oct. 2019), <https://bbbnpp-bbbp-stf-use1-01.s3.amazonaws.com/docs/default-source/whitepapers/bbb-np-report---20-years-of-coppa-self-regulation---10-15-2019.pdf> [<https://perma.cc/4CBW-ULEM>].

328 UPDPA, *supra* note 4, § 2(19).

329 *Id.* § 13(1).

330 *Id.* § 7(d).

331 *Id.* § 13(2).

and correction of data?³³² A controller must announce in its privacy policy that it is complying with a VCS.³³³ A controller that adopts and complies with a VCS setting out those standards is compliant with the UPDPA.³³⁴ This approach offers a frank acknowledgment that data privacy is not a matter of *one size fits all*.³³⁵

Four sections of the UPDPA's twenty sections, and a considerable proportion of its word count, are dedicated to explaining the effect of VCSs, what they contain, how they are developed, and how they are recognized by the attorney general (or other privacy officer).³³⁶ Key for developing a VCS is that the process must be open and deliberative in a way similar to ULC's own deliberative process, with "stakeholders representing a diverse range of industry, consumer, and public interests," and must give effort to hearing, responding to, and resolving stakeholder concerns.³³⁷ The result does not have to be unanimous, and stakeholders can file "statement[s] of dissent."³³⁸ The attorney general must be satisfied that the group adopted and followed a set of procedures to "provide adequate notice of meetings and standards development."³³⁹ The attorney general evaluates requests to recognize a VCS according to rules the attorney general adopts for the requests.³⁴⁰ If the attorney general recognizes the VCS, it becomes a public record and thus usable by any regulated entity.³⁴¹ The attorney general can later withdraw recognition, if they determine the VCS "or its implementation is not consistent with" the act.³⁴²

Practically speaking, there is nothing like VCSs in the CAVACO statutes. There are provisions that enable some change and development, however. For example, California's act provides authority for the state's privacy authority to issue and maintain regulations that address changes in technology and providing for many details of the relationship between controller and data subject.³⁴³ It neither expressly permits nor forbids the industry-specific approach that the VCSs contemplate. The Colorado act provides its attorney general a one-time grant of authority to "adopt rules that govern the process of issuing opinion letters and interpretive guidance to develop an operational framework for

332 *Id.* § 13(3).

333 *Id.* § 6(a)(7).

334 *Id.* § 12.

335 PRINCIPLES OF DATA PRIVACY, *supra* note 1, at 3 (noting that "uniformity and specificity is not always desirable in light of the necessity for contextual shaping of [fair information practices] in different areas of data use").

336 UPDPA, *supra* note 4, §§ 12–15.

337 *Id.* § 14(1).

338 *Id.* § 14(1), (5).

339 *Id.* § 14(4).

340 *Id.* § 15(b).

341 *Id.* § 15(I).

342 *Id.* § 15(d).

343 CCPA, *supra* note 4, § 1798.185.

business that includes a good faith reliance defense of an action that may otherwise constitute a violation” of the act.³⁴⁴ Virginia provides no such mechanisms.

For public health researchers and professionals, a VCS might prove a very valuable way to identify as many of their data practices as possible as being either exempt from the UPDPA or as being disclosed favored practices, what the UPDPA calls “compatible data practices.”

H. Enforcement and Penalties

Typically, the remedies and penalties under a statute and who can enforce it are determined by the statute. Professor Cohen describes—and criticizes—conventional enforcement strategies broadly as “private remedial litigation initiated by affected individuals and public enforcement action initiated by agencies.” In practice, these penalties can consist of civil damages, civil penalties, injunctions, and criminal penalties. Professor Cohen proposes three alternatives to these conventional approaches that she argues could lead to more impactful enforcement of privacy violations: 1) deputizing online intermediaries to discipline actors within their information ecosystems, 2) disgorgement of profits that accrue from privacy violations, and 3) permitting senior executives to be held personally liable for privacy violations. However, none of Professor Cohen’s alternatives—or criminal penalties for that matter—play a significant role in the statutes we discuss in in this Article.

The UPDPA assumes that the adopting state’s attorney general (or the state data privacy officer that the adopting state substitutes for the attorney general in the Uniform Act) will have a significant role in enforcement of the Act and adoption of VCSs.³⁴⁵ As for enforcement authority, though, that depends on the adopting state’s consumer protection act, which the UPDPA cross-references for “enforcement authority, remedies, and penalties” under the Act.³⁴⁶ In some states, this may mean that only the state attorney general may enforce the act, that only the attorney general and local district attorneys may enforce the Act, or that affected data subjects might have their own private rights of action against controllers and processors. Similar variability exists regarding remedies and penalties.

The CAVACO statutes do not take a single approach, either. California provides for a private civil right of action, with actual damages or statutory damages between \$100 and \$750 per consumer per incident,³⁴⁷ and power for its

344 CPA, *supra* note 4, § 6-1-1313(3).

345 UPDPA, *supra* note 4, § 16.

346 *Id.* § 16(a).

347 CCPA, *supra* note 4, § 150(a).

privacy authority to enforce the act administratively, with penalties of \$2,500 per incident.³⁴⁸ Both the privacy authority and private litigants can seek injunctions.³⁴⁹ Virginia allows only its attorney general to enforce its act, seeking injunction, civil penalties up to \$7,500 per violation, or both.³⁵⁰ Colorado provides that its attorney general and district attorneys can bring actions, with remedies the same as Colorado's statute governing deceptive trade practices.³⁵¹

I. Interaction with Other Statutes

The UPDPA and CAVACO statutes have certain exclusions from their coverage grounded in federal laws, while the UPDPA takes an unusual approach to other states' laws. The UPDPA takes a different approach to federal privacy laws than the CAVACO statutes. The UPDPA provides that a "controller or processor complies with [the Act] with regard to processing" if they are compliant with any of six federal statutes: HIPAA, Fair Credit Reporting Act (FCRA), Gramm-Leach-Bliley Act (GLBA), Driver's Privacy Protection Act (DPPA), FERPA, and COPPA, all of which we discussed above.³⁵² In the patchwork metaphor, The UPDPA is the blanket laid behind the patches that these federal laws represent. In this "two-ply" protection, if a controller or processor complies with the applicable federal law, it is also complying with the UPDPA. If it violates the federal law, it may also violate the UPDPA.³⁵³

The CAVACO statutes take different—dare we say "patchwork"?—approaches to the federal laws. California carves out several exceptions, some of them relating to controllers and processors, some relating to types of personal data, and some relating to particular data practices. It excludes controllers and processors that are "provider[s] of health care" and medical information subject to HIPAA;³⁵⁴ it excludes personal data that are "collected, processed, sold, or disclosed" pursuant or subject to GLBA and DPPA;³⁵⁵ and it excludes data practices governed by the FCRA.³⁵⁶ Similarly, Virginia carves out entities and data subject to GLBA and HIPAA;³⁵⁷ data subject to the DPPA, FERPA, and the Farm Credit Act;³⁵⁸ and data practices subject to FCRA.³⁵⁹ And Colorado

348 *Id.* § 155(b).

349 *Id.* §§ 155(b), 199.90(a).

350 VCDPA, *supra* note 4, § 59.1-584(A), (C).

351 CPA, *supra* note 4, § 6-1-1311(1).

352 See UPDPA, *supra* note 4, § 11(a), (b). Virginia takes the same approach with COPPA.

353 Subject to a pre-emption analysis.

354 CCPA, *supra* note 4, § 145(a)(1-2).

355 *Id.* § 145(e), (f).

356 CCPA, *supra* note 4, § 145(d).

357 VCDPA, *supra* note 4, § 59.1-576(B)(ii), (B)(iii), (C)(1).

358 *Id.* § 59.1-576(C)(11)–(13).

359 *Id.* § 59.1-576(C)(10).

excludes some healthcare information and data subject to HIPAA³⁶⁰ and data subject to GLB, DPPA, COPPA, and FERPA;³⁶¹ data practices subject to FCRA;³⁶² and controllers subject to GLBA.³⁶³ In the CAVACO states, these personal data, processors, and practices are simply not covered by their statutes: They rely entirely on the cited federal acts to govern these types of data practices, in contrast to the UPDPA in enacting states, which provides the two-ply protection mentioned above. Neither the UPDPA nor the CAVACO statutes give a pass to controllers and processors complying with privacy provisions of other federal laws not named here.

The UPDPA is different from the CAVACO statutes in another way: It is attentive to the laws of other states. The UPDPA expressly directs courts “applying and construing” the Act that they should “consider the promotion of uniformity of the law among jurisdictions that enact it.”³⁶⁴ The UPDPA also includes a bootstrap provision that allows a controller or processor to seek from the adopting state’s attorney general (or designated privacy officer) a determination that complying with another jurisdiction’s privacy law provides equal or greater protections than the adopting state’s UPDPA.³⁶⁵ Thus, a controller working in California and the adopting state might ask the attorney general in the adopting state to conclude that its compliance with the California Consumer Privacy Act of 2018 and California Privacy Rights Act of 2020 is sufficient to meet the requirements of the adopting state’s implementation of the UPDPA.³⁶⁶ The CAVACO statutes are silent on the laws of other states.

360 CPA, *supra* note 4, § 6-1-1304(2)(I)(e).

361 *Id.* § 6-1-1304(2)(j).

362 *Id.* § 6-1-1304(2)(i).

363 *Id.* § 6-1-1304(2)(q).

364 UPDPA, *supra* note 4, § 18. It also requires the attorney general (or other privacy officer) to “consider the need to promote predictability and uniformity among the states and give appropriate deference to a voluntary consensus standard developed . . . and recognized by a privacy-enforcement agency in another state,” *id.* § 15(c), and to “consider the need to promote predictability for data subjects, controllers, and processors, and uniformity among the states” when considering adopting rules under the act, *id.* § 16(c).

365 UPDPA, *supra* note 4, § 11(a).

366 This is an arguable contention on the data controller or processor’s part because, as this Article has shown, there are respects in which the CCPA does not cover personal data, regulated entities, or data practices quite the same way as UPDPA. The attorney general may set a fee for providing that this determination “reflect[s] the cost reasonably expected to be incurred . . . to determine” whether the other jurisdiction’s law is good enough.” *Id.* The UPDPA’s drafters conclude that the attorney general would then be able to enforce the other jurisdiction’s law against any controller or processor that had asserted another jurisdiction’s privacy regime as a “substitute” for the adopting state’s UPDPA. UPDPA, *supra* note 4, § 11, official comment (“Adoption of this act confers on the state attorney general, or other privacy data enforcement agency, authority not only to enforce the provisions of this act but also to enforce the provisions of any other privacy regime that a company asserts . . . as a substitute for compliance with this act.”).

For public health researchers and professionals, the UPDPA's goal of uniformity is critically valuable. Though there are certainly public health projects based in single states, many research projects and interventions seek to operate across the country. If a state-by-state patchwork of non-uniform privacy laws supplements the substantive patchwork of federal privacy laws, public health researchers and professionals face the very real challenge of complying with an ever-larger number of regulatory regimes.³⁶⁷

III. EVALUATION AND INTERVENTIONS

We have so far provided a conceptual framework for data protection and analyzed how the enacted CAVACO statutes and the proposed UPDPA fit into that framework. This Part first briefly considers how these statutes relate to some of the normative assertions in the privacy-law literature.³⁶⁸ It then evaluates how these statutes' provisions advance and impede public health work within our normative framework³⁶⁹ and suggests ways that public health researchers and professionals should intervene to improve the situation in the coming months and years.

A. *The UPDPA and the CAVACO Statutes vs. Normative Privacy Frames*

As we noted above, the copious literature relating to data protection and privacy law in the United States casts a critical eye on the existing patchwork of laws. As a preliminary matter, we do not see evidence in the UPDPA and the Colorado and Virginia statutes that they have adopted the GDPR as their model, but neither do we see them adopting the California statute as a model, as Professors Chander, Kaminski, and McGeeveran suggested they would. Among other things, Professors Chander, Kaminski, and McGeeveran made much of the facts that the GDPR and California statutes differ greatly in length, with a “paperback of the GDPR run[ning] some 130 pages” and the CCPA being “around 25 pages”,³⁷⁰ that the CCPA “affords individuals little control” compared to the GDPR’s “data protection” model,³⁷¹ that the CCPA does not provide private rights of action for individuals, while the GDPR did,³⁷² that the GDPR spelled out broad principles, while the CCPA provided much more specific enforcement mechanisms;³⁷³ and that “the backdrop against which these

367 See *supra* Section I.B.

368 See *supra* Section I.C.

369 See *Id.*

370 Chander et al., *supra* note 75, at 1746.

371 *Id.* at 1757.

372 *Id.* at 1759.

373 *Id.* at 1760.

two privacy laws were enacted, or . . . their legal setting, differs significantly,” particularly as a result of First and Fourth Amendment jurisprudence.³⁷⁴

Taking at face value the differences that Professors Chander, Kaminski, and McGeeveran identified between the GDPR and CCPA, the Colorado and Virginia statutes and the UPDPA appear to exhibit as much difference from the CCPA as CCPA does from the GDPR. Of course, all the American acts arose in a similar “legal setting.” As for length, however, the California act (after the 2020 referendum amendments) weighs in at more than 24,000 words, while Virginia’s is around 6,000 words, Colorado’s is under 8,300, and the UPDPA comes in under 4,800.³⁷⁵ We have noted³⁷⁶ a considerable number of differences between California on the one hand and Virginia and Colorado on the other, including several places where Colorado’s statutes followed Virginia’s verbatim. Nevertheless, we have also noted that the UPDPA departs from approaches that the CAVACO states use, both some on which the CAVACO states agree and some on which they differ. As we also noted above,³⁷⁷ California does provide a private right of action, though only for breaches of data security,³⁷⁸ but Virginia and Colorado do not provide any private right of action at all.³⁷⁹ The UPDPA, on the other hand, defers to the adopting state’s consumer protection act, which the UPDPA cross-references for “enforcement authority, remedies, and penalties” under the act,³⁸⁰ and which may or may not provide a private right of action.

Chander et al. concluded that “GDPR’s vagueness is arguably deliberate,” and that “EU authorities wanted to allow companies and sectors to fill in details of how to comply with the law over time, whether formally by establishing codes of conduct or certification mechanism . . . or informally through self-regulation”³⁸¹ Our description above³⁸² of the voluntary consensus standard that is integral to the UPDPA sounds more like the GDPR than the CCPA here, as VCSs allow for industry groups to build customized substantive and procedural regimes under the UPDPA that differ from each other.

In summary, we don’t have space here fully to explore the question, but we expect that there is a new set of practical norms coalescing around discussions associated with the Virginia, Colorado, and Uniform Law Commission statutes,

³⁷⁴ *Id.* at 1761.

³⁷⁵ Indeed, even the difference between the CCPA and GDPR may not be as great as Chander et al. suggested, as the GDPR’s operative provisions are under 31,000 words, with a considerable portion of its length consisting of more than 24,000 words of recitals.

³⁷⁶ *Supra* Section II.E.

³⁷⁷ *Supra* Section II.E.

³⁷⁸ CCPA, *supra* note 4, § 1798.150(a).

³⁷⁹ VCDPA, *supra* note 4, § 59.1-584(A), (C); CPA, *supra* note 4, § 6-1-1311(1).

³⁸⁰ UPDPA, *supra* note 4, § 16(a).

³⁸¹ Chander et al., *supra* note 75, at 1760.

³⁸² *Supra* Section II.G.

as they were being developed at the same time in 2020 and 2021. In any event, the new practical normative model of the UPDPA, if it is new, clearly still embraces the “notice and choice” model already at the heart of the U.S. patchwork of sectoral privacy laws, as opposed to an information fiduciary model, for example. The CAVACO statutes and the UPDPA in some ways do exhibit the “follow the data” data-protection characteristic of GDPR that Chander et al. use when distinguishing it from the California model: The UPDPA regulates “data practices” and includes some as “prohibited,” which cannot be consented to. In any event, these acts are thus unlikely to satisfy the expectations of scholars who are asking for more. Though, as we shall see, these acts set some defaults in a way that favors public goods—namely public health—some other defaults they set generally favor commercial uses of the kind that we found consumers comparatively disfavor.

Colorado and Virginia come closest to requiring opt-in, active consent for the data practices that consumers appear to disfavor.³⁸³ As we noted above,³⁸⁴ these statutes do not require consent for “collection of personal data to what is adequate, relevant, and reasonably necessary in relation to the purposes for which such data is processed, as disclosed to the consumer”³⁸⁵ or processing for those purposes or for purposes “compatible” with them,³⁸⁶ provided the data are not sensitive.³⁸⁷ They require passive consent for certain uses, including “(i) targeted advertising, (ii) the sale of personal data, or (iii) profiling in furtherance of decisions that produce legal or similarly significant effects concerning the consumer.”³⁸⁸ But they require active consent, an opt-in, for almost all other data practices. The California and the UPDPA laws require active consent in the smallest number of cases: In California, only where the controller wants to enroll the data subject in “into a financial incentive program”,³⁸⁹ and under the UPDPA, only where sensitive data are concerned.³⁹⁰ Given the default choices for consumers under these acts, they do little to address the concerns we identified above.³⁹¹

These acts also do nothing to address the use of publicly available

383 *Supra* Section I.C.3.

384 *Supra* Section II.E.

385 VCDPA, *supra* note 4, § 59.1-578(A)(1); *see also* CPA, *supra* note 4, § 6-1-1308(3) (using very similar language).

386 VCDPA, *supra* note 4, § 59.1-578(A)(2); *see also* CPA, *supra* note 4, § 6-1-1308(4) (using very similar language).

387 *See* VCDPA, *supra* note 4, § 59.1-578(A)(5).

388 *Id.* § 59.1-577(A)(5); CPA, *supra* note 4, § 6-1-1306(1)(a)(i). *See also supra* Section II.E (discussing favored, restricted, and prohibited data practices).

389 CCPA, *supra* note 4, § 1798.125(b)(3).

390 UPDPA, *supra* note 4, § 8(c).

391 *Supra* Section I.C.

information, which critics have noted can function to profile data subjects in ways they could not expect and to which they would likely not consent.³⁹² As for personal data that are covered, the UPDPA and California acts do provide some implied and express limitations on inferential data practices, which some have argued are not adequately addressed in current laws.³⁹³ Neither the UPDPA nor the CAVACO statutes heed Professor Cohen's call for updated enforcement mechanisms. Finally, none of these acts overtly establishes an "information fiduciary" model, though they do take some steps to manage the information pipeline that begins with the collecting controller. For example, as we noted above,³⁹⁴ each act requires the collecting controller to provide copies of data to subjects, to correct errors in the data, and to employ reasonable security measures; and the collecting controller is responsible for imposing those requirements on processors and third-party controllers downstream. The CAVACO acts, but not the UPDPA, also give the data subject a right to have data deleted.

Given our goal of addressing public health concerns under these statutes, we turn now to an evaluation of them from that perspective, providing recommendations for public health researchers and practitioners to intervene.

B. Helping and Hindering Public Health Activities

This Section considers whether the UPDPA and CAVACO statutes help or hinder public health activities. After giving a brief overview, it examines the real and perceived barriers that data privacy laws can create and then examines the effects of these statutes on data practices for research and on public health practices. As a preliminary matter, public health researchers and professionals must claim a seat at the table during deliberations on comprehensive data privacy or protection statutes, whether at the state or federal level. Legislators in general are not experts in public health and are not well situated to evaluate the effects of legislative proposals on public health. Other private and public interest groups are generally very skilled at advancing their objectives with legislatures, but those objectives may not fully support public health activities. Interventions by

³⁹² See *supra* Section I.C.2.

³⁹³ See *Id.* CCPA covers includes in covered personal data any "[i]nferences drawn from . . . [personal information] to create a profile about a consumer reflecting the consumer's preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes." CCPA, *supra* note 4, § 1798.140(o)(1)(K). The UPDPA may attempt to address this by limiting the use of personal data "to make a prediction or determination about a particular data subject," making it one of the factors used to determine whether a data practice is a favored (i.e., compatible) data practice. Nevertheless, this UPDPA provision likely does not go as far as Professor Solow-Niederman might like, as the UPDPA applies to only to identifiable and pseudonymized data.

³⁹⁴ *Supra* Section II.F.

public health researchers and professionals matter. For example, in June 2021, the authors wrote a letter to the ULC committee developing the UPDPA—effectively in the eleventh hour of the committee’s work, as it planned to introduce the final UPDPA to the full Commission in July—urging changes to support public health.³⁹⁵ The committee made some of those changes, and the committee’s reporter credited the letter for prompting them.³⁹⁶

From a normative perspective, transparency and autonomy for data subjects are probably well-protected under all four statutes for IRB-approved research where the data are collected for the primary purpose of research, as such research protocols typically require voluntary participation and consent or similar protections. The UPDPA and Virginia acts cover data in research that makes secondary use of data and in some public health practices.³⁹⁷ From the data subject’s perspective, this may be desirable, but it may create impediments to public health practice and research by bringing them within the purview of the acts. The California and Colorado acts exempt the greatest swaths of data, diminishing to some extent the data subjects’ autonomy but removing barriers to public health research that makes secondary use of data and to public health practice. Exempting public health practice and research from the coverage of the UPDPA and the CAVACO statutes is only one way the acts might encourage public health, as we discuss below.

A legislator or lobby proposing legislation for data protection or privacy will most likely model it on one of the existing acts, the UPDPA or one of the CAVACO statutes. In that event, we have specific recommendations for changes, based on our normative model. Table 1 summarizes key characteristics of the UPDPA and CAVACO statutes as they affect public health practices and research; the entries in it that are highlighted in ***bold italic text*** are those that raise concerns according to our normative frameworks.

1. Real and Perceived Barriers to Data Use for Public Health Practice and Research

Evaluating the impact of a data protection law on secondary data use requires acknowledging that both real and perceived data-use barriers exist. Data protection laws impose real barriers when the text of the laws prohibits or impedes (i.e., through complicated requirements or procedures) the use of data.

395 Letter from Cason Schmit et al., Faculty, Texas A&M University, to Harvey Perlman, Chair, Drafting Committee, Collection and Use of Personally Identifiable Data Act, Uniform Law Commission (June 6, 2021) (on file with authors).

396 Letter from Jane Bambauer, Professor of Law, University of Arizona, to Cason Schmit et al., Faculty, Texas A&M University (July 6, 2021) (on file with authors).

397 Schmit et al., *supra* note 28, 83–86.

For example, the UPDPA creates real data-sharing barriers for prohibited data practices because the law expressly prohibits those activities.³⁹⁸ Similarly, although FERPA technically does permit some public health uses of education data by permitting the use of aggregate data or the use of personal data with the express consent of all individuals,³⁹⁹ the utility deficiencies of aggregate data and the practical difficulties associated with consent in big-data applications effectively mean that FERPA poses real data sharing barriers to public health data practices.⁴⁰⁰

Perceived data-sharing barriers are different because the language of the law does not actually create a real barrier to secondary data practices. Instead, barriers exist when controllers or processors believe a barrier does, or could, exist. These perceived barriers are most likely to exist when data protection laws are complex, lack specific language, or carry substantial penalties that encourage hyper-conservative organizational practices. For example, HIPAA is often cited as a data-sharing barrier when, in fact, it contains generous provisions permitting research and public health activities.⁴⁰¹

The vague definitions of protected data in these acts could also introduce perceived barriers. The CAVACO statutes and the UPDPA all use reasonableness to define protected data, which creates uncertainty for data controllers that wish to share data for public health practice or research. With this uncertainty, controllers will likely consider legal deidentification exceptionally difficult to practically accomplish without a clear safe-harbor exception (i.e., like the HIPAA regulations).

2. *Data Uses for Research*

Provisions in data protection laws that permit data gathering where the primary use is human subjects research regarding public health are beneficial to

398 UPDPA, *supra* note 4, § 9.

399 34 C.F.R. § 99.30 (2021).

400 ASS'N OF STATE & TERRITORIAL HEALTH OFFS., PUBLIC HEALTH AND SCHOOLS TOOLKIT, FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT, <https://www.astho.org/advocacy/state-health-policy/legal-preparedness-series/public-health-and-schools-toolkit/> [https://perma.cc/R5PM-WDPH].

401 45 CFR 164.512 (b), (i) (2021); Steve Alder, *Do HIPAA Rules Create Barriers That Prevent Information Sharing?*, HIPAA JOURNAL (Nov. 19, 2018), **Error! Hyperlink reference not valid.**<https://www.hipaajournal.com/hipaa-rules-barriers-to-information-sharing/> [https://perma.cc/F4ZK-BYVG]; see also 21st Century Cures Act, Pub. L. No. 114–255, 130 Stat. 1033 (2016), where Congress made “information blocking” illegal for certain health data applications to address restrictive organizational and technological practices that interfere with legitimate data sharing. Had there been real legal barriers, Congress likely would have needed to create or expand HIPAA data use provisions.

the public.⁴⁰² Data gathered particularly for public health research, including health records, environmental conditions, and consumer behavior data, can help public health professionals understand the causes of poor health and investigate interventions that promote well-being.

All four statutes provide some protections for transparency and autonomy in research contexts. But there are also some impediments research makes secondary uses of data.⁴⁰³ As Table 1 shows, the UPDPA and CAVACO statutes exempt from their application data gathered for public health research according to contemporary ethical principles. These provisions are beneficial from a public health perspective because they do not add additional requirements on top of the existing regulatory framework established by the already expansive federal Common Rule.⁴⁰⁴

Where human subject research relies on secondary data, however, there are some variations among these acts. As the second row of Table 1 shows, the UPDPA and the California and Colorado statutes generally permit such uses. The Virginia act, however, requires active consent before a data controller discloses data for the secondary purpose of research. At a minimum, public health researchers and professionals should seek to have research that is subject to the Common Rule classified as disclosed favored data practices or as passive-consent restricted data practices. The default on consent here is critical to ensuring that data a controller provides to researchers is representative. Of course, researchers will also have to satisfy IRBs that they are taking appropriate steps to protect data subjects from harms associated with research. For states considering the UPDPA, they should propose that Common Rule research be a “compatible data practice” under the Act. If a state data privacy act entirely exempts research from its application, controllers could in theory provide data to researchers without disclosing the fact to data subjects at all; and that would prevent data subjects having the right to opt out, either of the data practice or of a relationship with the controller altogether. Given that active consent is a poor default where obtaining consent for research is required, we urge public health researchers and professionals to oppose such requirements in acts in other states, and we suggest those in Virginia may want to seek an amendment to the Virginia act to correct this default.

402 See generally Ramanathan et al., *supra* note 269.

403 Public health practices and data disclosures entirely within and among government agencies are not covered. See *supra* Section II.D.

404 Common Rule, *supra* note 9.

Table 1: Status of data practices relevant for public health under each act
 (matters of concern for public health in *highlighted text*). “Favored” means that data may be used for the purpose without consent; “restricted” that data may be used only with active consent (opt-in) or with passive consent (chance to opt-out).

Human subjects research (HSR) ⁴⁰⁵				
	UPDPA	California	Virginia	Colorado
—HSR is primary use	Act does not cover activity if data are <i>collected solely</i> for HSR	Act does not cover activity if data are <i>collected</i> for HSR	Act does not cover activity if data are <i>collected</i> for HSR	Act does not cover activity if data are <i>collected</i> for HSR
—HSR is secondary use	Act favors activity: no consent required but must be disclosed if “routine”	Act does not cover activity if data are <i>disclosed</i> for HSR	<i>Act restricts activity: permitted only with active consent (opt-in required)</i>	Act does not cover activity if data are <i>used or shared</i> for HSR
Other public health activities				
	UPDPA	California	Virginia	Colorado
Public health surveillance	Act favors activity: no consent required but must be disclosed if “routine”	Act restricts activity: permitted with passive consent (opt-out offered).	<i>Generally, act restricts activity: permitted only with active consent (opt-in required)</i> (Exception: If HIPAA permits the activity by covered entities for public health and public health is the data’s primary use, Virginia act does not cover it.)	Act favors activity: no consent required; <i>no disclosure required</i> (subject to certain conditions)
Public health population interventions				
Public health individual interventions	Act restricts activity: permitted with <i>active consent (opt-in required)</i> for sensitive data; passive consent for all others			

⁴⁰⁵ Subject to IRB/Common Rule, *supra* note 9.

3. *Data Uses for Public Health Practice*

Provisions in data protection laws that permit secondary use of data for public health practices are also beneficial to the public. Many factors beyond biology, including social, environmental, and economic factors, determine an individual's health status.⁴⁰⁶ Traditional public health data sources consist mainly of health records and surveillance data, such as reports of infectious diseases, but the myriad of data protection laws have created both real and perceived barriers to access data on many social, environmental, and economic factors.⁴⁰⁷ These data are essential to fully leverage data to promote population well-being.⁴⁰⁸ Moreover, research data-use exemptions are often not sufficient for public health activities that require swift action, such as surveillance for outbreak investigations.

As Table 1 shows, the California and Colorado acts broadly support data practices, primary and secondary, for all three categories of public health activity: surveillance, population interventions, and individual interventions. California restricts these activities, requiring notice and choice, but the choice is via passive consent and thus opt-out. The Colorado statute provides broad permission for data practices for "reasons of public interest in the area of public health."⁴⁰⁹ In Colorado, these activities are favored, requiring no consent or disclosure to the data subject, provided those performing the activities meet the statute's requirements. Though supportive of public health, these provisions raise concerns on normative grounds that they deny data subjects transparency and autonomy. As a normative matter, we would prefer to see disclosure, which would allow data subjects either to opt out of the data practice or choose not to disclose data to the collecting controller in the first place. Public health professionals in Colorado might seek a revision to that act to address this concern.

The Virginia statute may have grave effects on the use of personal data for public health practices, and the UPDPA may have such effects on the use of sensitive personal data for public health practices. The Virginia act provides significant impediments to all public health activities, as it permits them generally only with active consent, requiring notice and opt in. (There is an exception for HIPAA-covered entities using data for the primary purpose of public health, but this is a narrow category.) The UPDPA favors data practices,

406 See Frieden, *supra* note 38; Galea et al., *supra* note 14.

407 Schmit et al., *supra* note 28, at 83–86; Braveman & Gottlieb, *supra* note 14, at 19–31.

408 Kum et al., *supra* note 217.

409 CPA, *supra* note 4, § 6-1-1304(3)(a)(xi) (2021).

primary and secondary, for public health surveillance and population interventions, requiring no consent but disclosure to the data subject. The UPDPA requires active consent, however, for individualized interventions involving sensitive data. When the default is to require active consent from the data subject—an opt in—subjects are much less likely to agree to participate, likely leaving public health efforts with spotty data that may be severely skewed based on which data subjects do decide to opt-in. As sensitive data under the UPDPA include sex, gender, etc., this problem may be particularly acute in adopting states. Though these provisions value personal autonomy, they do so at considerable danger to public health. Public health professionals in Virginia should seek to modify its act to align it more closely with the other CAVACO statutes and the UPDPA. They should also seek to modify the requirement for active consent for public health uses of sensitive data so that they require only passive consent.

Public health professionals may also seek a voluntary consensus standard⁴¹⁰ to clarify that such interventions *for public health* are indeed compatible data practices that do not require complicated consent. For example, one of the factors that can be weighed when determining whether an activity is a compatible data practice is whether the activity advances “the economic, health, or other interests of the data subject.”⁴¹¹ Given that this is the goal of many public health interventions, it is possible that many public health activities—even individual interventions—could be permitted under the UPDPA’s factor-based definition for compatible data practices. On the other hand, the UPDPA’s flexible, factor-based approach to compatible data practices creates substantial uncertainty about public health interventions that target specific individuals because of the absence of express permissive language. There are thus opportunities to improve or clarify the UPDPA rules to maximize data practices to promote population health. Some public health data practices, particularly if they result in individualized interventions and involve sensitive data, could be seen as restricted practices that require active consent.

Public health professionals would thus be wise to seek provisions in a VCS for practices that they want to be classified as favored. Such a VCS would greatly facilitate the work of public health professionals and researchers. But development of a VCS requires a critical mass of experts from the field, representatives of consumer groups, and others. It will take time and money. On the bright side, because the UPDPA calls for states to respect each other’s judgments when approving VCSs, public health professionals need not create a VCS for only one state. Rather, they can collaborate to develop a national

⁴¹⁰ See *supra* Section II.G.

⁴¹¹ UPDPA, *supra* note 4, § 7(a)(6).

standard with a hope that most or all the UPDPA states will adopt it and that the CAVACO states and others modeling their legislation on CAVACO statutes would amend their acts to come into conformity with the VCS.

Of course, the next step after developing a VCS is getting it accepted in the UPDPA states. We suggest that public health professionals focus their efforts on states with larger populations whose adoption will function to influence attorneys general more strongly in other states to accept it. A strategic effort to seek early adoption of the VCS in states with diverse political climates (e.g., some strongly Democratic and some strongly Republican) may also make it easier to obtain wider adoption by avoiding any apparent taint of partisanship.

The work of public health professionals is not over when the statutes and VCSs are adopted. Key for public health professionals in California and the UPDPA states is making sure that collecting controllers disclose proposed public health uses of data. They need to persuade private-sector controllers who may be their partners to provide notice in their privacy policies indicating they are engaging in these activities. This is probably not a burdensome requirement where private controllers are concerned, as the public health researchers and professionals must generally form relationships with them to obtain data anyway. In California and Virginia, collecting controllers that partner with public health researchers and practitioners may need to add the means for consumers to opt out or in for various proposed data practices. Similarly, if the UPDPA is adopted without modification from ULC's model, uses of sensitive data in individual public health interventions will also require an opt-in mechanism. Public health researchers and professionals in those jurisdictions would have to work with private-sector partners to provide disclosure and probably some kind of incentive to for data subjects to opt in.

In the UPDPA states where a VCS is adopted, controllers and processors will still need to indicate that they are complying with the VCS in their privacy policies so that public health uses can be considered "compatible" data practices under the UPDPA. In states that model their statutes on the CAVACO acts, further work may be necessary to ensure that private-sector controllers and processors can comply with requests from public health researchers and professionals to work with them.

CONCLUSION

Ideally, data privacy laws create restrictions to protect against risky or harmful data practices while permitting socially desirable data practices. Governmental and public interest in new privacy regulations is a reaction against the existing U.S. privacy approach to this balance. To a great extent, the advent of the UPDPA and CAVACO statutes may help to create the blanket of data

privacy protection many have called for in recent years. For the most part, they appear to cover those areas left uncovered by the long-standing patchwork of data privacy protections. However, allowances for socially beneficial data uses in new privacy regulations are just as critical. There are great opportunities in these laws to extend and support public health practices and research under these blankets. Public health professionals should be alert to legislative and regulatory efforts, however, and engage with them to prevent restrictions that prevent public health work for the public good.

