# MSU KV KAff 1ac

### Adv One

#### Advantage One is Federalism

#### The status quo upholds “Parker immunity” – a doctrine that doesn’t account for interstate spillovers.

Rosch 12 [J. Thomas Rosch, Commissioner, Federal Trade Commission 10-3-2012 https://www.ftc.gov/sites/default/files/documents/public\_statements/returning-state-action-doctrine-its-moorings/121003stateaction.pdf]

The FTC’s State Action Report

Over a decade ago, the FTC became concerned that the lower courts had expanded the scope of the state action doctrine beyond what the Supreme Court had intended. In 2001, the FTC established a State Action Task Force, which issued a Report two years later that analyzed the current state of the law, identified areas of concern, and recommended clarifications to the law.28 The Report observed that the scope of the state action doctrine had expanded dramatically since first articulated by the Supreme Court in 1943. The doctrine had become unmoored from its original objectives, the report concluded, and was frequently invoked to protect private commercial interests with no relation to state policy.

The report identified a number of specific concerns with the way in which some lower courts had applied the state action doctrine. Chief among these was a persistent weakening of the clear articulation and active supervision requirements. In particular, some courts had found that a legislative grant of general corporate powers satisfied the clear articulation requirement. Although the exercise of these powers in the private sector had no particular antitrust significance, some courts had reached the opposite conclusion when the powers were granted through legislation.

The Report also found that there was a lack of clear standards to guide the application of the active supervision requirement. Without guidance on how to implement the various formulations of the requirement articulated by the lower courts, the active supervision requirement had had a minimal impact.

The Task Force raised several other concerns. Some courts, according to the Report, had interpreted the state action doctrine in a manner that ignored interstate spillovers, which forced the citizens of one state to absorb the costs imposed by another state’s regulations. In addition, some courts had interpreted the doctrine to shield virtually any municipal activity, despite the fact that municipalities were increasingly engaging in business on a for-profit basis, while simultaneously using their law-making power to block competitive challenges.

#### Our arg is not “State’s Rights are categorically good”. Rather, failing to account for out-of-State externalities means State reforms seem better than they truly are. Limiting Parker is key.

Sack 21 [John Sack, J.D., Duke Law School, Class of 2022, B.S. University of Michigan, 2019, 2021 – modified for language that may offend - https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1196&context=djclpp\_sidebar]

III. DOCTRINAL CRITICISM

Although the Court has continued to re-affirm Parker v. Brown’s central holding, many have criticized the Parker doctrine. Both scholars and the Federal Trade Commission (FTC) have highlighted problems with the doctrine and offered a number of solutions for how to remedy its faults.63

The first common critique of the doctrine is that it does not account for out-of-state economic effects. Unless a regulation runs afoul of another constitutional barrier, no consideration of interstate spillovers applies.64 One need not look farther than Parker itself to see how the state action doctrine can impose costs on out-of-state residents, even though those residents have diminished political capital in the state. At the time Parker was decided, between 90 and 95 percent of raisins produced in California entered interstate commerce and California provided almost all of the nation’s raisins.65 Most American raisin consumers lived outside of California and had no political means to oppose the state’s legislative program, yet they bore the costs of California’s state-sanctioned monopoly.66

Second, similar concerns about political representation animate critiques of Parker immunity. The policy at issue in Parker restricted output and artificially raised prices, two results federal antitrust law generally seeks to prohibit.67 Although the benefits of such a program were borne almost exclusively by California, the costs of the program were incurred by raisin consumers across the nation.68 The political incentives to promote such a program follow closely with economic costs and benefits.69 California raisin producers have a strong incentive to lobby their own government to install such a program, but it would be nearly impossible for non-California residents to challenge such a policy through the normal political channels.70 The government of California is not the appropriate body to properly weigh the benefits to in-state raisin producers with the costs to out-of-state consumers, yet the Parker doctrine grants California per se immunity on federalism grounds.71 Although the California program was implicitly endorsed by Congress, one is just as likely to find similar programs with no similar implicit endorsement.72

The U.S. Constitution embodies a system of federalism where the federal government is sovereign in some respects, and the several states are sovereign in others.73 This system of federalism gives states the power to regulate local matters and the federal government the power to regulate issues that states are less suited to regulate.74 When costs spill over into other states, the national government becomes the appropriate body to regulate the costs and benefits of such a program.75 The Court has recognized such spillover effects, and how political actors, even government entities, can act solely in self-interest.76 Such state self-interest can directly harm consumers outside of its territorial jurisdiction.77

Parker immunity, as it ~~stands~~ (exists), runs counter to longstanding ideals of national unity that harken back to the Founding era. The law has long prohibited states from imposing excessive costs on the nation as a whole, solely for the purpose of furthering its own intrastate policy interests. McCulloch v. Maryland illustrates the Court’s wariness of self-serving state action.78 In McCulloch, Chief Justice Marshall held that states may not tax the national bank, as they would be wielding power against the whole of the United States, even though the whole of the United States is not represented by each state.79 Similar to a state tax being problematic since it is the part acting on the whole, anticompetitive restraints by the states would unduly impose costs on the nation. The people of the United States, acting through Congress, christened competition and free markets through the Sherman Act.80 Just as one state could not tax the resources of the United States, one state should not be allowed to use state policy to burden the national economy. Because the potential costs to state-created monopolies are so high,81 federal policy should prohibit states from allocating those costs beyond their borders. Any state that wishes to impose monopoly costs outside of its borders to benefit itself and undermine competition should be carefully scrutinized when it does so. This scrutiny would not be fatal-in-fact for the legislation, but it should be enough for states to second-guess an attempt to enrich itself to the detriment of its sister states.

IV. PROPOSED SOLUTIONS

The Sherman Act, and specifically Parker immunity, should be interpreted in light of the above concerns. After all, the Sherman Act is the standard-bearer for the U.S. free market system, and so our interpretation of it should evolve with our understanding of constitutional principles and economic conditions.82 Justice Burger’s concurrence in City of Lafayette elaborates on this point:

Our conceptions of the limits imposed by federalism are bound to evolve, just as our understanding of Congress’ power under the Commerce Clause has evolved. Consequently, since we find it appropriate to allow the ambit of the Sherman Act to expand with evolving perceptions of congressional power under the Commerce Clause, a similar process should occur with respect to “state action” analysis under Parker. That is, we should not treat the result in the Parker case as cast in bronze; rather, the scope of the Sherman Act’s power should parallel the developing concepts of American federalism.83

As states impose costs on each other through state-sanctioned monopolies, the Court’s understanding of federalism and the Commerce Clause counsels scrutiny of the Parker doctrine. An entirely new doctrine is not necessary to curtail Parker immunity. Rather, the issue can be resolved by applying Parker immunity in light of the American dual system of federalism and the Commerce Clause. Modern scholarship critiques the lack of concern for interstate spillovers. By that token, the modern Parker doctrine fails to account for economic efficiency and undermines political representation values meant to be protected by federalism.84 So while scholars almost universally recognize that interstate economic spillovers are problematic, there is no consensus on what remedy is most appropriate.

#### Well-crafted models are ideal – but the iterative learning process is only *accurate* if costs are internalized

Adler 12 [Jonathan, John Verheij Memorial Professor of Law and Director of the Center for Busi‐ ness Law & Regulation, Case Western Reserve University School of Law, “INTERSTATE COMPETITION AND THE RACE TO THE TOP,” March 2, www.harvard-jlpp.com/wp-content/uploads/2013/.../35\_1\_89\_Adler.pdf]

Not only does decentralization enable policymakers to take advantage of localized information about policy problems and their potential solutions, but decentralization and interjurisdictional competition also foster policy discovery and policy entrepreneurship. Decentralization allows for states to act, in Jus‐ tice Brandeis’s famous characterization, as “laboratories of democracy.”32 Different states may adopt different approaches to various public policy concerns, whether because of regional differences, variable preferences, or different expectations about the viability or practicality of competing policy approaches. State‐level policy initiatives often are experiments from which others may learn. States learn from each others’ successes and failures, fostering an iterative process through which state‐level policy can improve over time.

Allowing state‐level experimentation also reduces the risks of policy failures. When states try different things, all of the proverbial eggs are not in a single basket. If the policy succeeds, other states retain the ability to follow suit (as does the federal government, which has often modeled federal measures on successful state initiatives).33 If the policy fails, however, only one jurisdiction must undo it, and others can learn to avoid such mistakes. This discovery process can be slow and messy, but the federal alternative—as it exists in practice—is no better.

Even though there is a strong case for presuming that decentralization is favorable, it is rebuttable. Leaving policy questions in state hands might be desirable more often than not, but in some instances there are persuasive justifications for federal intervention. Appropriate federal intervention can even reinforce the competitive dynamic across jurisdictions.

Perhaps the most compelling case for federal intervention is the existence of interstate spillovers, such as pollution generated in one state that crosses into another.34 If, for example, pollution generated in one state causes problems in another state, there is a case for federal action. Allowing such spillovers to exist undermines interjurisdictional competition because spillovers enable states to extraterritorialize the costs of their own policy decisions onto other jurisdictions.35 In a truly competitive dynamic, on the other hand, each jurisdiction would bear the costs and reap the benefits of its own decisions.

#### Pricing-in State spillovers improves the data set that informs well-crafted actions.

Adler 12 [Jonathan, John Verheij Memorial Professor of Law and Director of the Center for Busi‐ ness Law & Regulation, Case Western Reserve University School of Law, “INTERSTATE COMPETITION AND THE RACE TO THE TOP,” March 2, www.harvard-jlpp.com/wp-content/uploads/2013/.../35\_1\_89\_Adler.pdf]

Federalism is an essential part of the Constitution’s design. The division of sovereign power between the States and the federal government helps foster interjurisdictional competition, which, in turn, checks government power.1 Provided a right of exit is maintained, the excessive imposition of economic burdens in one jurisdiction will cause taxpayers and businesses to flee to other jurisdictions. For this reason, federalism often is seen as a friend of the free market.2 The existence of competing jurisdictions disciplines state intervention in the marketplace.3 But it would be a mistake to assume that interjurisdictional competition invariably favors market‐oriented policies, at least insofar as alternative policy measures would enhance the welfare of state residents. Federalism is not just for free marketeers.

Provided states cannot externalize the costs of their own policy choices, robust interjurisdictional competition facilitates the enactment of better public policy at the state level.4 Rather than inducing a “race to the bottom,” such competition can create a race toward the top.5 Although those of us who generally favor freer markets believe federalism will advance that cause, those who believe more stringent regulation is welfare‐enhancing should support interjurisdictional competition too. On both theoreticaland empirical grounds, competition among jurisdictions is a powerful means to discover and promote the policies that are most effective at providing people with what they desire.

#### With or without government, biological and synthetic tech is inevitable. Accurate data from state regulatory experiments avoids downsides and maximize benefits.

McGinnis 11

(John, George C. Dix Professor of Law, Northwestern Law School, “LAWS FOR LEARNING IN AN AGE OF ACCELERATION,” <http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=3404&context=wmlr>)

The twenty-first century’s information age has the potential to usher in a more harmonious and productive politics. People often disagree about what policies to adopt, but the cornucopia of data that modern technology generates can allow them to better update their beliefs about policy outcomes on the basis of shared facts. In the long run, convergence on the facts can lead incrementally to more consensus on better policies. More credible factual information should over time also help make for a less divisive society, because partisans cannot as easily stoke social tensions by relying on false facts or exaggerated claims to support conflicting positions. Thus, a central task of contemporary public law is to accelerate a politics of learning whereby democracy improves a public reason focused on evaluating policy consequences. Government should be shaped into an instrument that learns from the analysis of policy consequences made available from newly available technologies of information.1 Greater computer capacity is generating more empirical analysis.2 The Internet permits the rise of prediction markets that forecast policy results even before the policies are implemented.3 The Internet also creates a dispersed media that specializes in particular topics and methodologies, gathers diverse information, and funnels salient facts about policy to legislators and citizens.4 But a public reason focused on policy consequences will improve only if our laws facilitate it. For instance, constitutional federalism must be reinvigorated to permit greater experimentation across jurisdictions, because with the rise of empiricism, decentralization has more value for social learning today than ever before.5 Congress should include mandates for experiments within its own legislation making policy initiatives contain the platforms for their own selfimprovement.6 Creating a contemporary politics of democratic updating on the basis of facts is a matter both of great historical interest and of enormous importance to our future. In the historical sweep of ideas, a government more focused on learning from new information moves toward fulfilling the Enlightenment dream of a politics of reason—but a reason based not on the abstractions of the French Revolution, but instead on the hard facts of the more empirical tradition predominating in Britain. By displacing religion from the center of politics, the Enlightenment removed issues by their nature not susceptible to factual resolution, permitting a focus on policies that could be improved by information.7 The better democratic updating afforded by modern technology can similarly increase social harmony and prosperity by facilitating policies that actually deliver the goods. For the future, a more consequentially informed politics is an urgent necessity. The same technological acceleration that potentially creates a more information-rich politics also generates a wide range of technological innovation—from nanotechnology to biotechnology to [AI] artificial intelligence. Although these technologies offer unparalleled benefits to mankind, they may also create catastrophic risks, such as rapid environmental degradation and new weapons of mass destruction.8 Only a democracy able to rapidly assimilate the facts is likely to be able to avoid disaster and reap the benefits inherent in the technology that is transforming our world at a faster pace than ever before. Every industry that touches on information—book publishing, newspapers, and college education to name just a few—is undergoing a continuous series of revolutionary changes as new technology permits delivery of more information more quickly at lower cost. The same changes that are creating innovation in such private industries can also quickly create innovation in social governance. But the difference between information-intensive private industries and political institutions is that the latter lack the strong competitive framework for these revolutions to occur spontaneously. This Essay thus attempts to set out a blueprint for reform to make better use of some available information technologies. Part I describes the reality of technology acceleration as the acceleration both creates the tools for democratic updating and prompts its necessity. Technological acceleration is the most important development of our time—more important even than globalization. Although technologists have described and discussed its significance, its implications for law and political structure have been barely noticed. Part II briefly discusses how better social knowledge can change political results. A premise of the claim is that some political disagreements revolve about facts, not simply values. As a result, better social knowledge can help democracies design policies to achieve widely shared goals. Social knowledge energizes citizens to act on those encompassing interests, like improved public education, because they come to better recognize the policy instruments to advance those interests. Better social knowledge provides better incentives for citizens to vote on these interests. Part III considers the mechanisms for creating a contemporary politics of democratic updating that begins to meet the needs of the age of accelerating technology. It focuses on two of the new resources that can have substantial synergies in improving social common knowledge and shows how an increase in common knowledge can systematically improve political results by providing better incentives for citizens to work for encompassing social goods. First, Part III considers the improvement in empirical analysis of social policy that flows from increasing computational capacity. It then discusses how specialized and innovative media does much more than disseminate opinions: it widely distributes facts and factual analysis. The combination of these technologies can better discipline experts and representatives, providing stronger incentives for them to update on the basis of new facts. Part IV discusses the information-eliciting rules that will maximize the impact of new technologies of information. These steps include a program of restoring, where possible, governmental structures that permit appropriate decentralization for experimentation, empirical testing, and learning. Congress and regulatory agencies should structure legislation and regulations to include social experiments when such experiments would help resolve disputed matters of policy. The Supreme Court should generally refrain from imposing new substantive rights for the nation so that it is easier to evaluate the consequences of different bundles of rights chosen by the states. But it should also protect the dispersed media, like blogs, from discriminatory laws, because this dispersed media plays a crucial role in modern policy evaluation. In short, the Supreme Court needs to emphasize a jurisprudence fostering social discovery and the political branches need to create frameworks for better social learning. Constitutive structures encouraging and evaluating experimentation become more valuable in an age where better evaluation of social experiments is possible. I. TECHNOLOGICAL ACCELERATION It is the premise of this Essay that technological acceleration is occurring and that our political system must adapt to the world it is creating. The case for technological acceleration rests on three mutually supporting kinds of evidence. First, from the longest-term perspective, epochal change has sped up: the transitions from hunter-gatherer society to agricultural society to the industrial age each took progressively less time to occur, and our transition to an information society is taking less time still. Second, from a technological perspective, computational power is increasing exponentially, and increasing computational power facilitates the growth of other society-changing technologies like biotechnology and nanotechnology. Third, even from our contemporary perspective, technology now changes the world on a yearly basis both in terms of hard data, like the amount of information created, and in terms of more subjective measures, like the social changes wrought by social media. From the longest-term perspective, it seems clear that technological change is accelerating and, with it, the basic shape of human society and culture is changing.9 Anthropologists suggest that for 100,000 years, members of the human species were hunter-gather- ers.10 About 10,000 years ago humans made a transition to agricultural society.11 With the advent of the Industrial Revolution, the West transformed itself into a society that thrived on manufacturing.12 Since 1950, the world has been rapidly entering the information age.13 Each of the completed epochs has been marked by a transition to substantially higher growth rates.14 The period between each epoch has become very substantially shorter.15 Thus, there is reason to extrapolate to even more and faster transitions in the future. This evolution is consistent with a more fine-grained evaluation of human development. Recently, the historian Ian Morris has rated societies in the last 15,000 years on their level of development through objective benchmarks, such as energy capture.16 The graph shows relatively steady, if modest, growth when plotted on a log linear scale, but in the last 100 years development has jumped to become sharply exponential.17 Morris concludes that these patterns suggest that there may be four times as much social development in the world in the next 100 years than there has been in the last 14,000.18 The inventor and engineer Ray Kurzweil has dubbed this phenomenon of faster transitions “the law of accelerating returns.”19 Seeking to strengthen the case for exponential change, he has looked back to the dawn of life to show that even evolution seems to make transitions to higher organisms ever faster.20 In a more granulated way, he has considered important events of the last 1000 years to show that the periods between extraordinary advances, such as great scientific discoveries and technological inventions, have decreased.21 Thus, both outside and within the great epochs of recorded human history, the story of acceleration is similar. The technology of computation provides the second perspective on accelerating change. The easiest way to grasp this perspective is to consider Moore’s Law. Moore’s Law—named after Gordon Moore, one of the founders of Intel—is the observation that the number of transistors that can be fitted onto a computer chip doubles every eighteen months to two years.22 This prediction, which has been approximately accurate for the last forty years,23 means that almost every aspect of the digital world—from computational calculation power to computer memory—is growing in density at a similarly exponential rate.24 Moore’s Law reflects the rapid rise of computers to become the fundamental engine of mankind in the late twentieth and early twenty-first centuries.25 The power of exponential growth is hard to overstate. As the economist Robert Lucas has said, once you start thinking about exponential growth, it is hard to think about anything else.26 The computational power in a cell phone today is a thousand times greater and a million times less expensive than all the computing power housed at MIT in 1965.27 Projecting forward, the computing power of computers twenty-five years from now is likely to prove a million times more powerful than computing power today. To be sure, many people have been predicting the imminent death of Moore’s Law for a substantial period now,29 but it has nevertheless continued. Intel—a company that has a substantial interest in accurately telling software makers what to expect—projects that Moore’s Law will continue at least until 2029.30 Ray Kurzweil shows that Moore’s Law is actually part of a more general exponential computation growth that has been gaining force for over a 100 years.31 Integrated circuits replaced transistors that previously replaced vacuum tubes that in their time had replaced electromechanical methods of computation.32 Through all of these changes in the mechanisms of computation, its power increased at an exponential rate.33 This perspective suggests that other methods under research—from carbon nanotechnology to optical computing to quantum computing—are likely to continue growing exponentially even when silicon-based computing reaches its physical limits.34 Focusing on the exponential increase in hardware capability may actually understate the acceleration in computational capacity in two ways. First, a study considering developments in a computer task using a benchmark for measuring computer speed over a fifteen-year period suggests that the improvements in software algorithms improved performance even more than the increase in hardware capability.35 Second, computers are interconnected more than ever before through the Internet, and these connections increase collective capacity, not only because of the increasing density among computer connections, but because of the increasing density of connections among humans made possible by computers. The salient feature of computers’ exponential growth is their tremendous range of application compared to previous improvements. Almost everything in the modern world can be improved by adding an independent source of computational power. That is why computational improvement has a far greater social effect than improvements in technologies of old. Energy, medicine, and communication are now being continually transformed by the increase in computational power.36 As I will discuss in Part II, even the formulation of new hypotheses in natural and social science will likely be aided by computers in the near future. The final perspective on accelerating technology is the experience that the contemporary world provides. Technology changes the whole tenor of life more rapidly than ever before. At the most basic level, technological products change faster.37 Repeated visits to a modern electronics store—or even a grocery store—reveal a whole new line of products within very few years. In contrast, someone visiting a store in 1910 and then again in 1920—let alone in 1810 and 1820—would not have noticed much difference. Even cultural generations move faster. Facebook, for instance, has changed the way college students relate in only a few years,38 whereas the tenor of college life would not have seemed very different to students in 1920 and 1960. Our current subjective sense of accelerating technology is also backed by more objective evidence from the contemporary world. Accelerating amounts of information are being generated.39 Information, of course, is a proxy for knowledge. Consistent with this general observation, we experience exponential growth in practical technical knowledge, as evidenced by the rise in patent applications.40 Thus, the combination of data from our present life, together with the more sweeping historical and technological perspectives, makes a compelling case that technological acceleration is occurring. It is this technological acceleration that creates both the capacity and the need for improving collective decision making. As technology accelerates, it creates new phenomena, from climate change to biotechnology to artificial intelligence of a human-like capacity. These technologies may themselves have very large positive or negative externalities and may require government decisions about their prohibition, regulation, or subsidization to forestall harms and capture their full benefits. They may also cause social dislocations, from unemployment to terrorism, that also require certain collective decisions. Society can best handle these crises not only by making better social policy to address them directly but by improving social policy more generally to create both more resources and more social harmony to endure them. Thus, society must deploy information technology in the service of democratic updating if it is to manage technological acceleration

#### Synthetic-Bio viruses already sit in labs. They cannot be wished away. Lab accidents will kill millions. Some positive regulatory scheme is needed.

Wilson ‘13

(Grant Wilson has an extremely diverse academic and professional background is former Representative for several nations at the 2010 Climate Change Conference in Cancun. Mr. Wilson \*also\* holds a JD, as well as a Certificate in Environmental and Natural Resources Law, both from the Lewis & Clark Law School. He \*also\* has worked on issues related to the environment and human rights in Kenya, South Korea, Hungary, Mexico, Belgium, the United States. He \*also\* is currently the Deputy Director at the Global Catastrophic Risk Institute (GCRI), a nonprofit think tank that engages in research, education, and professional networking in areas related to global catastrophic risks. “MINIMIZING GLOBAL CATASTROPHIC AND EXISTENTIAL RISKS FROM EMERGING TECHNOLOGIES THROUGH INTERNATIONAL LAW” – Virginia Environmental Law Journal – 31 Va. Envtl. L.J. 307 – lexis; allrev)

States should consider creating an international treaty to regulate emerging technologies if they perceive these technologies to pose a GCR/ER. This section considers the current and future risks and benefits posed by three emerging technologies--bioengineering, [\*313] nanotechnology, and AI. This section concludes that bioengineering is the only emerging technology that poses an immediate GCR/ER, while nanotechnology and AI pose future GCR/ERs. 1. Bioengineering Simply defined, bioengineering is the "engineering of living organisms." n23 Bioengineering is commonly associated with genetically modified ("GM") foods made from crops that scientists develop to have qualities like pest resistance or increased nutrition. However, bioengineering is rapidly expanding beyond agriculture into fields like medicine, disease control, and life-extension. The technology behind bioengineering has also developed quickly, with scientists now able to understand and manipulate life at the molecular level such that biology is viewed as a "machine" that can be tweaked, like in genetic engineering, or even built from the ground up, like in synthetic biology. n24 While breakthroughs in bioengineering research could significantly benefit mankind and the environment, bioengineering research can also be misused to the detriment of humans, animals, and environmental health. n25 Such "dual use" research currently poses significant risks to humankind and even greater risks in the future. Furthermore, both current and future bioengineering technologies pose the risk of an accident that has significant detrimental effects. In exploring these issues, this section demonstrates that bioengineering poses an immediate GCR/ER. a. Current technology Bioengineering is already widely used to modify existing organisms, and scientists are on the cusp of creating entirely synthetic organisms. For example, scientists controversially use bioengineering to "improve" natural biological products and activities, resulting in increased nutrient value, bigger yields, and insect and disease resistance n26 in various types of crops. n27 In 2011, ninety-four percent by acre of soybeans in the [\*314] United States were genetically engineered, while seventy-three percent of all U.S. corn was genetically engineered to be insect resistant and sixty-five percent to be herbicide tolerant. n28 Another controversial current bioengineering technology is genetically engineered viruses, highlighted by the 2011 genetic engineering of the H5N1 virus to become highly contagious amongst ferrets. Many scientists argue that creating this genetically engineered virus was necessary to develop a remedy in case the H5N1 virus mutates naturally, but skeptics argue that the modified H5N1 virus is dangerous because of risks that the virus will escape or that malicious actors will engineer a similar virus. n29 Another example of recent advancements in bioengineering is a project spearheaded by biologist Craig Venter that transplanted a completely synthetic DNA sequence, or "genome," into an E. coli bacteria. Scientists then also added DNA "watermarks" such as the names of researchers and famous quotes. Craig Venter termed this "the first self-replicating species we've had on the planet whose parent is a computer." n30 Bioengineering has also become vastly cheaper and more accessible to the general public. For example, massive databases of DNA sequences are available online from the Department of Energy Joint Genome Institute ("JGI") and the National Center for Biological Information's GenBank(R) database. n31 To materialize these DNA sequences, individuals can order custom genomes online for a few thousand dollars, which are "printed" from a DNA synthesis machine and shipped to them, opening the door for amateur biologists to engage in genetic engineering. n32 DNA synthesis machines can print DNA strands long enough for certain types of viruses, which untrained [\*315] individuals can obtain within six weeks of purchase. n33 Even the synthesizing machines themselves can be purchased on the Internet on sites like eBay. n34 Much like bioengineering costs, the necessary expertise to engage in bioengineering is also plummeting. For example, since 2003, teams of entrepreneurs, college students, and even high school students submitted synthetic biology creations to the International Genetically Engineered Machine ("IGEM") competition, such as UC Berkeley's "BactoBlood" creation--a "cost-effective red blood cell substitute" developed by genetically engineering E. coli bacteria. n35 b. Forthcoming technology Perhaps the greatest forthcoming development in bioengineering is synthetic biology, which includes techniques to "construct new biological components, design those components and redesign existing biological systems." n36 This is in contrast to the traditional form of bioengineering that utilizes "recombinant DNA" techniques in which the DNA from one organism is stitched together with DNA from other organisms or synthetic DNA. n37 One method of synthetic biology involves "cataloguing" DNA sequences like "Lego bricks" and assembling them in unique ways (assembling natural molecules into an unnatural system, like combining the molecules from several types of bacteria to create new bacteria with novel properties). Another method of synthetic biology involves using DNA synthesizers to create life "entirely from scratch" n38 in what has been called the "the biological equivalent of word processors" n39 (using unnatural molecules to emulate a natural system, like creating the synthetic equivalent of a natural strand of influenza). n40 One way to generate synthetic DNA is to insert [\*316] the DNA into a "biological shell"--an organism, often a bacteria, that had its own genes removed--that can run the synthetic DNA like a computer runs software. n41 And while the technology to create eukaryotic cells (i.e., "a cell with a nucleus, such as those found in animals, including human beings") is a long ways away, synthetic viruses and bacteria are just around the comer. n42 c. Benefits of bioengineering Bioengineering is already demonstrating its potential to remedy major human health and environmental problems. For example, bioengineering is responsible for some important pharmaceuticals and vaccines, such as modern insulin and a vaccine for Hepatitis B, while "gene therapy" employs genetically engineered viruses to help treat cancer. n43 Environmental benefits resulting from the 15.4 million farmers who grew genetically modified crops in 2010 include increased yield of six to thirty percent per acre of land, pest-resistant crops that require fewer pesticides (resulting in 17.1 percent less pesticide use globally in 2010), lower water use for drought-resistant crops, decreased CO[2] emissions, and crops that do not require harmful tilling practices. n44 Forthcoming benefits to human health could be a new wave of ultra-effective drugs (e.g. antimalarial and antibiotic drugs), bioengineered agents that kill cancer cells, and the ability to rapidly create vaccines in response to epidemics. n45 Bioengineering could also serve as a beacon of human diagnostics by analyzing "thousands of molecules simultaneously from a single sample." n46 Meanwhile, forthcoming benefits to the environment could be organisms that remedy harmful pollution and superior forms of biofuel, for example. n47 Bioengineering could also spur an environmental revolution in which industries reuse modified waste from biomass feedstock and farmers grow [\*317] bioengineered crops on "marginally productive lands" (e.g. switchgrass). n48 d. Risks from bioengineering While bioengineering offers current and future benefits to humans and the environment, there are also significant yet uncertain risks that could devastate human life, societal stability, and the environment. n49 This paper focuses on three predominant GCR/ER risks arising from bioengineering: (1) the accidental release of harmful organisms (a "biosafety" issue), (2) the malicious release of harmful organisms ("bioterrorism"), and (3) the bioengineering of humans. The first two are current GCRs/ERs, while the third is a future GCR/ER. i. Risk of an accident The accidental release of a bioengineered microorganism during legitimate research poses a GCR/ER when such a microorganism has the potential to be highly deadly and has never been tested in an uncontrolled environment. n50 The threat of an accidental release of a harmful organism recently sparked an unprecedented scientific debate amongst policymakers, scientists, and the general public in reaction to the creation of an airborne strain of H5N1. n51 In September 2011, Ron Fouchier, a scientist from the Netherlands, announced that he had genetically engineered the H5N1 virus--his lab "mutated the hell out of H5N1," he professed--to become airborne, which was tested on ferrets; a laboratory at the University of Wisconsin-Madison similarly mutated the virus into a highly transmittable form. n52 The "natural" H5N1 killed approximately sixty percent of those with reported infections (although the large amount of unreported cases means that this is higher than the actual death rate), but the total number of fatalities--346 people--was relatively small because the virus is difficult to transmit from human to human. The larger risk comes from the possibility that a mutated virus would spread more easily amongst [\*318] humans, n53 which could result in a devastating flu pandemic amongst the worst in history, if not the very worst. n54 To put this in context, about one in every fifteen Americans--twenty million people--would die every year from a seasonal flu as virulent as a highly transmittable form of H5N1. n55 Lax regulations and a rapidly growing number of laboratories exacerbate the dangers posed by bioengineered organisms. While lab biosafety n56 guidelines in the United States and Europe recommended that projects like reengineering the H5N1 virus be conducted in a BSL-4 facility (the highest security level), neither laboratory that reengineered the H5N1 virus met this non-binding standard. n57 Meanwhile, a 2007 Government Accountability Office ("GAO") report indicated that BSL-3 and BSL-4 labs are rapidly expanding in the United States. While there is significant public information about laboratories that receive federal funding or are registered with the Centers for Disease Control and Prevention ("CDC") and the U.S. Department of Agriculture's ("USD") Select Agent Program, much less is known about the "location, activities, and ownership" of labs that are not federally funded and not registered with the CDC or the USD Select Agent Program. n58 The same report also concluded that no single U.S. agency is responsible for tracking and assessing the risks of labs engaging in bioengineering. n59 While some claim that critics are overreacting to the risk from this genetically engineered H5N1 virus, there have been a series of accidental releases of microbes from laboratories that demonstrate the risks of largely unregulated laboratory safety. In 1978, an employee died from an accidental smallpox release from a laboratory on the floor below her. n60 Many scientists believe that the global H1N1 ("swine flu") [\*319] outbreak in the late 2000s originated from an accidental release from a Chinese laboratory. n61 Reports concluded that the accidental releases of Severe Acute Respiratory Syndrome ("SARS") in Singapore, Taiwan, and China from BSL-3 and BSL-4 laboratories all resulted from a low standard of laboratory safety. n62 In the United States, a review by the Associated Press of more than one hundred laboratory accidents and lost shipments between 2003 and 2007 shows a pattern of poor oversight, reporting failures, and faulty procedures, specifically describing incidents at "44 labs in 24 states," including at high-security labs. n63 In 2007, an outbreak of Foot and Mouth Disease likely came from a laboratory that was the "only known location where the strain [was] held in the country" n64 because of a leaky pipe that had known problems. n65 This long history of faulty laboratory safety is why some experts, such as Rutgers University chemistry professor and bioweapons expert Richard H. Ebright, believe that the H5N1 virus will "inevitably escape, and within a decade," citing the hundreds of germs with potential use in bioweapons that have accidentally escaped from laboratories in the United States. n66 While the effects of such lapses in laboratory safety have not yet been felt aside from relatively small events such as the swine flu outbreak mentioned above, the increasing ability of less-sophisticated scientists to engineer more deadly organisms vastly increase the possibility that a lapse in biosafety will have detrimental effects. An accidental or purposeful release of a bioengineered organism has potentially grave consequences. For example, researchers in Australia recently accidentally developed a mousepox virus with a 100 percent [\*320] fatality rate when they had merely intended to sterilize the mice. n67 Scientists in the United States also created a "superbug" version of mousepox created to "evade vaccines," which they argue is important research to thwart terrorists, sparking a debate amongst scientists and policymakers about whether the benefits of such research is worth the associated risks. n68 If such a bioengineered organism escaped from a laboratory, the results would be unpredictable but potentially extremely deadly to humans and/or animals.

#### Ironically, SynBio’s upsides are important since the way to counter accidental releases is re-utilizing SynBio against itself.

Philp ‘14

et al; Jim C. Philp – formerly a Reader in Environmental and Industrial Biotechnology at Edinburgh Napier University. The report was drafted primarily by Jim Philp with significant contributions from Mineko Mohri. Mohri earned her law degree at Keio University in Tokyo. She has also served as a lecturer at Keio University. From: “Emerging Policy Issues in Synthetic Biology”, which was published June 4th, 2014. Available in full text via Google Books. p. 40

Synthetic biology principles are providing new opportunities for the design of attenuated pathogens for use as vaccines. Wimmer and Paul (2011) described the first synthesis of a virus (poliovirus) in 2002 accomplished outside living cells. They commented on the reaction of lay people and scientists to the work, which shaped the response to de novo syntheses of other viruses. In pioneering a safe live vaccine Coleman et al (2008) synthesised de novo large DNA molecules for the rational design of live attenuated poliovirus vaccine candidates. They postulated that this strategy could be used to attenuate many kinds of viruses. Similarly, the synthetic attenuated virus engineering approach was applied to influenza virus strain A/PR/8/34 for the rational design of live attenuated influenza virus vaccine candidates. Mueller et al. (2010) state that the approach can be applied rapidly to any emerging influenza virus in its entirety, an advantage that is especially relevant for seasonal epidemics and pandemic threats, such as H5N1 or the 2009 H1N1 influenza. During the latter pandemic, vaccines for the virus became available in large quantities only after human infections peaked. To accelerate vaccine availability for future pandemics, a synthetic approach that rapidly generates vaccine viruses from sequence data has been developed (Dormitzer et al.. 2013).

(Note: A/PR/8/34 - internally referenced – is a strain of influenza)

## Plan

#### The United States Federal Government should limit the state action immunity doctrine

### Adv Two

#### Adv Two is Practitioner Shortages:

#### Antitrust authority would check such shortages. The FTC does challenge State-Level “*Scope Of Practice*” restrictions on Nurse Practitioners. But they lose due to Parker immunity. An untouched market can’t solve - local elites use leverage to cement a physician-only squo.

McMichael ‘20

Internally quoting the Udalova and MEPS data sets. Benjamin McMichael – Faculty, University of Alabama School of Law. McMichael earned a BS in Mathematical Economics from Wake Forest University and a JD and PhD in law and economics from Vanderbilt University. Before joining the faculty at Alabama, Benjamin served as a law clerk to Judge Carolyn Dineen King on the United States Court of Appeals for the Fifth Circuit. Benjamin’s research is interdisciplinary, relying on empirical methods developed in the social sciences—particularly economics—to generate new insight into the ways in which the law influences the provision of healthcare - “Occupational Licensing and the Opioid Crisis” 54 U.C. Davis L. Rev. 887 - December, 2020 – some footnotes included for context and elaboration – but no text omitted other than the OG Table of Contents after the opening abstract - #E&F - https://lawreview.law.ucdavis.edu/issues/54/2/articles/files/54-2\_McMichael\_color.pdf

The United States’ affordable care crisis and chronic physician shortage have required nurse practitioners to assume increasingly important roles in the healthcare system. Nurse practitioners can address critical access-to-care problems, provide safe and effective care, and lower the cost of care. However, restrictive occupational licensing laws — specifically, scope-of-practice laws — have limited their ability to care for patients. Spurred by interest groups opposed to allowing nurse practitioners to practice independently, states require physician supervision of nurse practitioners. Research has discredited many of the traditional reasons for these restrictive laws, but emerging arguments assert that independent practice will deepen the ongoing opioid crisis by allowing unsupervised nurse practitioners to overprescribe opioids. The opioid crisis has become one of the defining public health emergency of this generation, so these arguments warrant serious investigation. If granting nurse practitioners independence will exacerbate the opioid epidemic, restricting their practices may be justified despite the clear benefits that independence could create for patients and the healthcare system.

This Article provides new empirical evidence on the role of nurse practitioner independence in opioid prescriptions by analyzing a dataset of approximately 1.5 billion individual opioid prescriptions. Containing information on approximately 90% of all prescriptions filled at outpatient pharmacies between 2011 and 2018, this dataset provides unprecedented insight into the ongoing opioid epidemic. An analysis of these data reveals that allowing nurse practitioners to practice independently reduces the quantity of opioids prescribed across all physicians and nurse practitioners. Thus, this Article demonstrates that, contrary to exacerbating the opioid crisis, granting nurse practitioners independence is a valid policy option for addressing this crisis. These results can inform the ongoing state and national debates over nurse practitioner scope-of-practice laws and the opioid epidemic more generally. And based on these results, the Article proposes several policy options at the state and federal levels that could both address restrictive scope-of-practice laws and ameliorate the ongoing opioid crisis.

INTRODUCTION

For many people, access to healthcare means the difference between life and death, the difference between constant pain and the ability to get out of bed in the morning, or the difference between an all-consuming mental illness and the ability to remain an active member of society. Even nearly a decade after the passage of the Affordable Care Act (“ACA”), however, access to healthcare continues to dominate local and national health policy debates, and the issue remains unresolved. The ACA certainly reinvigorated the country’s interest in access to care in unprecedented ways, and it drastically altered healthcare and healthcare provision in the United States. Unfortunately, it effected both of these changes with a near laser-like focus on increasing access to health insurance.1 For all of its virtues, this treatment of access to healthcare as effectively coextensive with access to health insurance has obscured a more fundamental problem with access to care as the following example from the New York Times illustrates.

A lifelong resident of rural Nebraska and registered nurse, Murlene Osburn saw a desperate need for mental health care in her community.2 To meet this need in an area where psychiatrists refused to practice, Osburn completed a master’s degree and a national certification process to become a psychiatric nurse practitioner (“NP”).3 Unfortunately, when she was ready to begin caring for patients, Osburn found herself stymied by the problem that spurred her to action in the first place: the lack of psychiatrists. Nebraska law prohibited NPs from practicing without physician supervision, and the nearest physician who could supervise her “was seven hours away by car and wanted to charge her $500 a month” for that supervision.4

This example illustrates the importance of access to healthcare providers in addition to access to health insurance. 5 And access to providers is far from given, with many areas of the country experiencing shortages of healthcare providers that experts expect to worsen over the next decade. 6 The New York Times example also highlights both a viable policy option to address these shortages - the increased use of NPs to provide care - and an important obstacle to implementing this policy - restrictive laws.

NPs are registered nurses who have undergone additional training to provide healthcare services historically provided by physicians. 7 They represent the principal source of care in many geographic areas 8 and are more likely than physicians to practice in rural and underserved communities. 9 This makes the 200,600 practicing NPs a natural option to address chronic, critical, and worsening physician shortages across the country. 10 While NPs provide healthcare services across the country, their ability to do so is not equal in all areas. State scope-of-practice ("SOP") laws - a subset of the occupational licensing laws that govern NPs and many other professionals - determine what services [\*891] NPs may provide and the conditions under which they may provide those services.

States often justify SOP laws as necessary to ensure patient safety by preventing unqualified individuals from providing care. 11 Though these laws can further this goal, excessively restrictive SOP laws undermine the ability of NPs to care for patients. Prior work has shown that eliminating restrictive SOP laws and allowing NPs to practice independently of physicians can facilitate access to care, 12 improve the quality of care, 13 reduce the use of intensive medical procedures, 14 and reduce the price of some healthcare services. 15 Based on this evidence, the Obama and Trump administrations along with the National Academy of Medicine and other organizations have urged states to relax their SOP laws. 16 A minority of states have responded by granting NPs the authority to practice independently, but the ongoing debate and [\*892] political battle over SOP laws has only intensified over the last decade. 17 Physician organizations, in particular, vigorously oppose the relaxation of these laws and have been successful in discouraging states from granting NPs independence. 18

9 See Peter I. Buerhaus, Catherine M. DesRoches, Robert Dittus & Karen Donelan, Practice Characteristics of Primary Care Nurse Practitioners and Physicians, 63 NURSING OUTLOOK 144, 144-50 (2015) [hereinafter Practice Characteristics] (finding that NPs are more likely to care for Medicaid patients, vulnerable populations, and rural populations); Grant R. Martsolf, Hilary Barnes, Michael R. Richards, Kristin N. Ray, Heather M. Brom & Matthew D. McHugh, Employment of Advanced Practice Clinicians in Physician Practices, 178 JAMA INTERNAL MED. 988, 988-89 (2018) (finding that NPs are likely to be employed in primary care).

10 Occupational Employment and Wages, May 2019, 29-1171 Nurse Practitioners, U.S. BUREAU LAB STAT., https://www.bls.gov/oes/current/oes291171.htm (last visited Nov. 11, 2020) [https://perma.cc/5A4C-9H7S].

11 See Morris M. Kleiner, Enhancing Quality or Restricting Competition: The Case of Licensing Public School Teachers, 5 U. ST. THOMAS J.L. & PUB. POL’Y 1, 3, 8 (2011) (“The general rationale for licensing is the health and safety of consumers. Beyond that, the quality of service delivery . . . [is] sometimes invoked.”).

12 Benjamin J. McMichael, Beyond Physicians: The Effect of Licensing and Liability Laws on the Supply of Nurse Practitioners and Physician Assistants, 15 J. EMPIRICAL L. STUD. 732, 764-65 (2018) [hereinafter Beyond Physicians]; Jeffrey Traczynski & Victoria Udalova, Nurse Practitioner Independence, Health Care Utilization, and Health Outcomes, 58 J. HEALTH ECON. 90, 103-04 (2018); see also John A. Graves, Pranita Mishra, Robert S. Dittus, Ravi Parikh, Jennifer Perloff & Peter I. Buerhaus, Role of Geography and Nurse Practitioner Scope-of-Practice in Efforts to Expand Primary Care System Capacity, 54 MED. CARE 81, 83-88 (2016).

13 Traczynski & Udalova, supra note 12, at 97

14 See, e.g., Sara Markowitz, E. Kathleen Adams, Mary Jane Lewitt & Anne L. Dunlop, Competitive Effects of Scope of Practice Restrictions: Public Health or Public Harm?, 55 J. HEALTH ECON. 201, 209-16 (2017) (showing a reduced probability of intensive procedures related to pregnancies in states that allow nurse practitioners to practice with no barriers).

When opposing NP independence, physician groups often argue that requiring physician supervision promotes patient safety and the delivery of high-quality care. 19 Although existing clinical evidence undermines these claims, 20 physician groups have recently emphasized the troubling possibility that allowing NPs to practice independently will increase opioid prescriptions. 21 The reasoning offered is straightforward: If NPs can prescribe opioids without physician supervision, then they will inappropriately overprescribe opioids and deepen the ongoing opioid crisis. 22 This Article engages with the debate [\*893] over NP SOP laws by empirically analyzing the impact these laws have on opioid prescriptions. Given the severity of the ongoing opioid crisis, the claim that allowing NP independence will deepen that crisis by increasing opioid prescriptions warrants careful consideration. On one hand, allowing NPs to practice independently can address critical access-to-care issues and improve the healthcare system in other important ways. On the other hand, restricting the practices of NPs may be justified despite these benefits if doing so avoids exacerbating the opioid crisis. This Article provides critical new evidence on the effect that NP SOP laws have on opioid prescriptions. Specifically, I analyze a dataset of approximately 1.5 billion individual opioid prescriptions, which represent approximately 90% of all opioid prescriptions filled at outpatient pharmacies between 2011 and 2018. This dataset provides unprecedented insight into the ongoing opioid epidemic and the role of healthcare providers in that epidemic. Because this dataset covers nearly the universe of opioid prescriptions in the United States over eight years and is organized at the individual-prescription level, I am able to develop more complete and more granular evidence on the role of NP SOP laws in opioid prescriptions than has previously been possible. The analysis reveals that allowing NPs to practice independently reduces the quantity of opioids prescribed across all physicians and NPs by approximately 4.4%. 23 In contrast to physician groups' claims, the evidence developed here suggests that relaxing NP SOP laws reduces opioid prescriptions. Thus, this Article demonstrates that, rather than exacerbating the opioid crisis, granting NPs independence is a valid policy option for addressing that crisis. These results can inform the ongoing debates over both NP SOP laws and the opioid epidemic more generally, and this Article uses this evidence to recontextualize the debate over SOP laws and offer specific policy recommendations. In addition to joining various scholars and [\*894] organizations in urging states to reform their SOP laws, this Article engages with potential federal policy options that can both address the dire healthcare provider shortages across the country while ameliorating the opioid crisis. Federal options, such as the ones discussed below, will become increasingly relevant as state legislation has proven difficult to obtain in certain states. 24 This Article proceeds in four parts. Part I details the contributions that NPs make to the healthcare system and the ways SOP laws impact their ability to do so. 25 Part II provides context for the empirical analysis that is the focus of the Article by detailing the progression of the opioid crisis. 26 Part III discusses the empirical methodology and reports the results of the empirical analysis. 27 Part IV engages with the policy implications stemming from the results of that analysis, 28 and a brief conclusion follows.

I. REGULATING HEALTHCARE PROVIDERS

Historically, physicians have delivered most of the healthcare in the United States. While other providers, such as registered nurses, have always played important roles in healthcare, physicians have been responsible for directing most care delivery. Physician dominance, however, has begun to recede as NPs and other types of healthcare providers are providing "[a] growing share of health care services." 29 And this trend will likely continue because the growth rate of NPs outstrips that of physicians, 30 which only adds urgency to resolving the debate over NP SOP laws. To provide context to that debate, this Part [\*895] begins by discussing the role of NPs in the healthcare system before outlining the contours of the debate over the SOP laws that regulate NPs.

A. Nurse Practitioners and the Laws that Govern Them

To qualify as an NP, an individual must first become a registered nurse, which often involves completing a bachelor's degree in nursing. 31 Most registered nurses practice for several years before returning to complete a master's or doctoral degree to become an NP. 32 Their training involves clinical and didactic courses that prepare future NPs to diagnose and treat patients, order and interpret tests, and prescribe medication. 33 Following their training, NPs practice in a wide variety of medical settings, but over 60% choose to provide some form of primary care. 34 With this training, NPs provide care alongside physicians across the country, 35 but where they choose to practice and which patients they choose to care for often differs substantially from the choices made by physicians. Relative to physicians, NPs more often choose to practice in primary care and to care for underserved populations, including Medicaid patients. 36 They also provide care in rural or underserved areas to a [\*896] greater extent than physicians. 37 The predilection of NPs to practice in isolated areas and care for patients who have difficulty accessing care is particularly important in an era of worsening physician shortages. For example, the Association of American Medical Colleges estimates that, by 2032, the United States will face a physician shortage of between 46,900 and 121,900. 38 Such a shortage has implications for the country generally, but it will impact rural areas to a greater degree. Recent estimates suggest that the number of physicians practicing in these areas could decline by 23% by 2030. 39 With approximately 200,600 NPs delivering care in 2019 40 NPs can alleviate physician shortages in rural and other areas. Indeed, NPs outnumber primary care physicians, 41 practice in convenient locations like retail and urgent care clinics, 42 and represent the principal source of healthcare in many parts of the country. 43 However, the ability of NPs to function as the principal source of healthcare depends heavily on the SOP laws in place. Prior work has [\*897] classified NP SOP laws in slightly different ways. 44 Each classification system has advantages and disadvantages, but I adopt a classification scheme based on two recent studies that that focus on specific statutory and regulatory language. 45 Where necessary, I updated the classifications based on more recent statutory and regulatory information. This approach to classification eliminates the risk of mis-classification that can occur by relying on inconsistent secondary sources. It also isolates the specific statutes and regulations that policymakers may change to achieve specific results in their healthcare systems. 46 Using these statutes and regulations, I classify each state in each year as either allowing NPs to practice independently or restricting the practices of NPs. To be classified as allowing "independent practice," a state must (1) have no requirement that physicians supervise NPs and (2) grant NPs full prescriptive authority, i.e., allow NPs to prescribe the same range of medications as physicians. 47 States that either require physician supervision of NPs or restrict their prescriptive authority fall into the "restricted practice" category. [\*898] Figure 1 provides an overview of NP SOP laws during the time period analyzed here. In 2011, fourteen states allowed NPs to practice independently, and thirty-seven states restricted the practices of NPs. 48 Of the thirty-seven states restricting NP practice, fourteen changed their laws prior to the end of 2018 to allow NPs to practice independently. 49 Figure 1 separately highlights each of the states that always allowed NPs to practice independently, always restricted NP practice, and changed from restricted to independent practice. As Figure 1 illustrates, the trend among states decidedly favors NP independence, with half of all states that currently allow independent practice adopting a law to that effect in the last decade. This trend has not emerged without opposition, however, and the debate between opponents of relaxing NP SOP laws and advocates of greater NP autonomy has become quite heated. The next subpart engages with this [\*899] ongoing debating, tracing the contours of each side's arguments and the evidence that supports their arguments.

B. The Scope-of-Practice Debate

As NPs have assumed greater roles in the delivery of care, some groups have objected to liberalizing the SOP laws that govern NPs to allow them to provide more services and practice with greater autonomy. Principal among the opponents of relaxing NP SOP laws are physician groups, with the American Medical Association ("AMA") offering some of the strongest resistance to granting NPs greater independence. 50 Advocates of greater NP autonomy include nursing groups, policy think tanks of various political orientations, the National Academy of Medicine, and the Obama and Trump administrations. 51 Opponents of greater NP autonomy often emphasize the greater education completed by physicians and argue that NPs cannot provide safe or high-quality care without physician supervision. 52 Proponents often respond that NPs deliver care of similar quality as physicians and that allowing greater NP autonomy lowers the cost of care and improves access to care. 53 This Part engages with each of these sets of arguments in turn.

1. Independent Nurse Practitioners and the Quality of Care

Perhaps the most contentious point in the debate over NP SOP laws concerns the ability of NPs to deliver high-quality care without physician oversight. Opponents of NP independence generally argue that, without physician supervision, NPs cannot safely care for patients. For example, the California Medical Association has stated that it "opposes any attempts to remove physician oversight over [NPs] and believes that doing so would put the health and safety of patients at risk." 54 Some groups frame their arguments about quality of care in [\*900] terms of the different levels of education completed by NPs and physicians. 55 These arguments require the additional inferential step that more education is required to provide the type of care delivered by NPs, but they are effectively equivalent to statements that unsupervised NPs cannot safely care for patients. 56 Advocates of greater NP autonomy respond to these arguments by pointing to the available evidence that demonstrates NPs generally deliver care of comparable quality to that delivered by physicians. 57 Multiple studies have investigated the ability of NPs to deliver high-quality care, often comparing NP-supplied care to physician-supplied care. 58 A recent comprehensive analysis compared the quality of care delivered to Medicare beneficiaries by NPs and physicians and found that physicians perform better on certain quality measures and NPs perform better on other measures. 59 Related work has found no meaningful differences between NPs and physicians in caring for HIV [\*901] patients, 60 managing diabetes, 61 providing primary care, 62 prescribing medications, 63 or providing critical care. 64 Reviewing the evidence, the National Academy of Medicine concluded "that access to quality care can be greatly expanded by increasing the use of ... [NPs] in primary, chronic, and transitional care." 65 Opponents of broader NP SOP laws have criticized this evidence as irrelevant because these studies are often "performed in a setting of physician oversight and collaboration." 66 They argue that "using data from studies of nurse practitioners working under physician supervision to demand independent practice is a flawed practice, as there is no proof that nurse practitioner care without physician oversight is either safe or effective." 67 However, studies that have explicitly examined the role of relaxing NP SOP laws - as opposed to the role of NPs generally - in promoting the delivery of high-quality care have concluded that NP independence either improves or has little effect on the quality of care delivered. A 2017 study found that NP "independence had no statistically significant effect on any of the three [clinically verified indicators of [\*902] healthcare quality] studied." 68 In contrast to claims that NP SOP laws are necessary for the protection of patients, 69 this study "did not substantiate the use of [SOP] restrictions for the sole purpose of consumer protection." 70 A separate study "cast[] further doubt on the theory that state regulations limiting NPs practice are associated with quality of care." 71 Examining patient-reported quality across many years of a nationally representative dataset, a recent study found that NP independence increases the probability that patients report being in excellent health. 72 Another study found that NP independence had no effect on infant mortality rates, an important indicator of healthcare quality. 73 Overall, existing evidence does not support the contention that unsupervised NPs provide unsafe or low-quality care. To be sure, physician groups are correct in their assertion that NPs are not trained to provide the same range of services as physicians - NPs do not perform surgery, for example. Within the scope of their training, however, the evidence demonstrates that NPs perform similarly to physicians.

72 Traczynski & Udalova, supra note 12, at 98, 99 tbl.7.

2. Scope-of-Practice Laws and the Cost of Healthcare

Though healthcare quality tends to receive the most attention from experts within the SOP law debate, concerns over the cost of care predominate among the patients who are most affected. Indeed, the health policy conversation over the last two decades has focused heavily [\*903] on the ability of patients to obtain affordable care. 74 Advocates of greater NP autonomy have argued that removing restrictive SOP laws will facilitate the use of lower cost providers and ultimately reduce costs within that system. For example, Kathleen Adams and Sara Markowitz have explained that "achieving productivity gains is one way to reduce cost pressures throughout the health-care system" and that such gains can be realized "by using lower-cost sources of labor to achieve the same or better outcomes." 75 The "high payment rates for physicians in the United States" makes the increased use of NPs a particularly appealing strategy for cost-reduction. 76 Recent research has demonstrated that abrogating restrictive SOP laws can reduce costs within the healthcare system to the benefit of patients and the public. A study by Morris Kleiner and others found that granting NPs independence reduces the price of a common medical examination by between 3% and 16%. 77 A separate economic evaluation estimated that liberalizing SOP laws would save approximately $ 543 million annually in emergency department visits alone. 78 Though specific to certified nurse midwives instead of NPs, a recent study found that eliminating restrictive SOP laws for nurse midwives would save $ 101 million by reducing reliance on more intensive forms of care during birth. 79 Other studies have found that payments in connection with Medicare beneficiaries cared for by NPs were between 11% and 29% lower than those cared for by physicians, 80 the savings achieved by using retail health clinics in lieu of emergency departments are higher when NPs have more independence, 81 and Medicaid costs either decrease or remain flat when NPs are granted more autonomy. 82 On the other side of the debate, opponents of NP independence can point to some evidence that NPs and SOP laws allowing them to practice independently may increase healthcare costs. In a recent report, the [\*904] Medicare Payment Advisory Commission ("MedPAC") highlighted several studies finding that NPs tend to increase costs. 83 One study found that NPs utilized more healthcare resources in caring for patients than physicians, suggesting that more extensive use of NPs may increase costs. 84 A separate study found that NPs order more medical imaging services than physicians in primary care settings. 85 Medical imaging, such as magnetic resonance imaging ("MRI") and computed tomography ("CT") scans can be expensive, so this study suggests that NP independence may increase costs over time. More recent work that examines a larger population contradicts these results, however. Examining data on Medicare and commercial insurance claims, a 2017 study found that NP independence does not result in more medical imaging and does not increase healthcare costs. 86 Similarly, research conducted by economists at the Federal Trade Commission ("FTC") revealed no evidence that relaxing NP SOP laws increases healthcare costs or prices. 87 Overall, a growing body of research suggests that allowing NPs to practice independently can reduce costs and the prices patients must pay for care, while only a few studies have found evidence to the contrary. 88

3. Nurse Practitioners and Access to Healthcare

Turning to the debate over the role of SOP laws in access to healthcare, the evidence more heavily favors advocates of greater NP autonomy than it does in either the cost or quality debates. Advocates of greater NP autonomy have argued that "by unnecessarily limiting the tasks that qualified [NPs] can perform, SOP restrictions exacerbate [healthcare provider] shortages and limit access to care." 89 An Obama administration report noted that "easing scope of practice laws for APRNs represents a viable means of increasing access to certain primary care services," 90 and the evidence generally supports this conclusion. For example, one study concluded that states with less restrictive SOP laws "overall had more geographically accessible" NPs. 91 Similarly, a 2018 study found that relaxing SOP laws increases access to healthcare generally but has the largest positive effect in counties that have the least access to healthcare. 92 This evidence suggests that "restrictive licensing laws limit the growth in the supply of [NPs] who could deliver care in communities with relatively few practicing physicians." 93 Extending this evidence to more specific measures of healthcare access, a third study concluded that granting NPs more autonomy increases the likelihood that individuals receive a routine check-up, have access to a usual source of care, and can obtain an appointment with a provider. 94 NP independence also reduces the use of emergency departments for conditions that can be addressed in less intensive (and less expensive) settings, as patients can more easily access a healthcare provider when NPs can practice independently. 95 [\*906] The response to the argument that allowing NPs greater autonomy increases access to healthcare by opponents of NP independence often does not focus explicitly on healthcare access. While not every study has found that relaxing SOP laws increases access to healthcare providers, 96 the existing evidence generally supports this conclusion. 97 Opponents, therefore, typically offer only indirect arguments on the access issue. In opposing a bill that would relaxing California's SOP laws, the president of the California Medical Association offered an example of a common argument: "We must ensure that every American, regardless of age or economic status, has access to a trained physician who can provide the highest level of care. Expanding access to care should not come at the expense of patient safety and we will not support unequal standards of care... ." 98 In other words, expanding access to NP-supplied care does not amount to expanding access to care generally because NPs provide inferior care. Though framed as an access-to-care argument, this contention is more accurately characterized as an argument about the quality of care provided by NPs, which as addressed above, appears to be equal in basic practice areas.

4. The State of the Scope-of-Practice Debate

The debate over NP SOP laws is not new, and multiple national organizations - both governmental and non-governmental - have weighed in on this debate after conducting extensive reviews of the available evidence. Perhaps the most relevant organization to opine on SOP laws to date has been the National Academy of Medicine (formerly, the Institute of Medicine). The Academy criticized restrictive SOP laws, noting that "what nurse practitioners are able to do once they graduate varies widely for reasons that are related not to their ability, education or training, or safety concerns, but to the political decisions of the state in which they work." 99 Calling for an end to restrictive SOP laws, the Academy clearly stated that NPs "should practice to the full extent of their education and training." 100

[\*907] Researchers at the FTC reached a similar conclusion, albeit for somewhat different reasons. The FTC has no authority to enforce federal antitrust laws against states that restrict the practices of NPs with SOP laws because these laws fit squarely within the state-action immunity articulated in Parker v. Brown. 101 However, FTC researchers applied the economic principles that underlie those antitrust laws and concluded that restrictive SOP laws "deny[] health care consumers the benefits of greater competition." 102 They further concluded that the harms to healthcare services markets - higher prices and decreased access to care - associated with restrictive SOP laws were not offset by any attendant benefits. 103 Consistent with these conclusions, the FTC has regularly opposed state laws that restrict the practices of NPs and supported the passage of bills that relax the SOP laws. 104

#### Scope of Practice – or “S.O.P.” – restrictions *block access* and *hamper options for patient health*.

LDI ‘20

Internally quoting Dr. Margo Brooks Carthon - LDI Senior Fellow, a Nurse Practitioner, PhD, RN, FAAN, and is also an Associate Professor at Penn’s School of Nursing. The LDI is the Leonard Davis Institute of Health Economics at the University of Pennsylvania (Penn). Six expert panelists are quoted and we are quoting the section from Margo Brooks Carthon – “Scope of Practice Restrictions and Vulnerable Populations: LDI Virtual Conference Explores The Issue's Changing Dynamics” - November 21, 2020 - #E&F - https://ldi.upenn.edu/our-work/research-updates/scope-of-practice-restrictions-and-vulnerable-populations/

The most heavily publicized debates around the SOP issue over the last 60 years have been about nurse practitioners whose work is often focused on underserved communities that lack the most basic kinds of medical care. Panelist and LDI Senior Fellow Margo Brooks Carthon, PhD, RN, FAAN, is an NP and health services researcher in that field. She is also an Associate Professor at Penn’s School of Nursing, and a core faculty member at the Penn Center for Health Outcomes Policy Research.

“There are over two hundred thousand NPs in the United States working under varying degrees of scope of practice restrictions, depending on the states where they’re employed,” Carthon said. “These barriers have implications for population health as well as health equity.”

“Twenty-two states and the District of Columbia fully license NPs to practice independently. Others require career-long collaborative agreements with a supervising physician. Some require a physician to review a percentage of NP charts — ten percent every year in Alabama and Georgia; twenty percent every 30 days in Tennessee. NPs are often limited in the distance they can be from a physician and are required to jump through other hoops just to provide basic care.”

#### Solvency is *empirical* and the *impact is significant*. Some States have relaxed SOP restrictions to differing degrees. Studies confirm this has saved many lives *per day* *per State*.

Chung ‘20

Bobby W. Chung is a labor economist. He receives his Ph.D.in Economics at Clemson University. He is now a postdoctoral research associate at the School of Labor and Employment Relations in the University of Illinois (Urbana-Champaign). He is also a network member of the Human Capital and Economic Opportunity Global Working Group. His recent work includes social network, occupational licensing, and kidney-exchange network. “The Impact of Relaxing Nurse Practitioner Licensing to Reduce COVID Mortality: Evidence from the Midwest” - #E&F - http://publish.illinois.edu/projectformiddleclassrenewal/files/2020/06/The-Impact-of-Relaxing-Nurse-Practioner-Licensing8413.pdf

Nurse practitioners (NP) are well-trained health care personnel for primary, acute, and specialty care in the US. However, 32 states have restrictions on their scope of practice and Illinois is one of them.

In response to the shortage of health care workers during the coronavirus pandemic, twenty-one states granted NP full practice authority to cope with the increasing demand for health care services. In the Midwest, Kansas, Indiana, Michigan, Missouri, and Wisconsin, adopted a more expansive scope of service for NP.

This report evaluates the effect of this policy change on the rate of COVID-related deaths in the Midwest states, which expanded NP authority and sheds light on healthcare policy in Illinois.

Findings:

NP in Illinois have full practice authority only if they have had 4,000 hours of clinical experience and completed 250 training hours.

Illinois and Ohio are the only two Midwest states, which did not expand the scope of practice for NP during the pandemic.

In the states that did expand the scope of practice for NP, COVID related deaths were potentially reduced by 10 cases per day

If Illinois had expanded the scope of practice, 8% fewer COVID-19 deaths would have occurred in Cook County, which is the most affected area in the state.

The findings reveal that granting NP full practice authority is effective in easing the shortage of health care workers and improves health care quality. Our result echoes the findings by other healthcare researchers that granting NP independent practice authority improves patient outcomes. This report recommends that health care regulators in Illinois grant all NP independent practice authority in order to meet the states’ growing health care demand.

Introduction

The shortage of healthcare professional in the US has been a notable concern among health policy makers. According to the Bureau of Health Workforce, in 2017 only 55 percent of the need for primary care professional was met.1 For Illinois, the Bureau estimated that 468 extra primary care health providers were needed to address the shortage problem, which is roughly 188% of the existing number of primary care providers in the state. The shortage problem is the biggest in the Midwest.

The nationwide healthcare labor force shortage manifests itself even more during the COVID-19 pandemic. To address the health workforce shortage, a number of states temporarily expanded the scope of practice for nurse practitioners (NP). NP are well-trained health care personnel, typically requiring post-graduate training. According to the American Association of Nurse Practitioners (AANP), NP with full autonomy are authorized to \evaluate patients; diagnose, order and interpret diagnostic tests; and initiate and manage treatments".2 Although they are well-prepared to provide primary, acute, and specialty care, their scope of practice varies by state. According to the classification by AANP, in a state with "restricted/reduced practice," NP need to have a collaborative agreement with, or work under direct supervision of a licensed health professional (e.g. physician, dentist). The limited authority of NP has not only reduced health access in rural areas, but also significantly increased the administrative burden of the supervising personnel. It has also reduced the amount of time dedicated for patient care (Traczynski and Udalova, 2018). Healthcare researchers have claimed that granting NP independent practice authority would have a positive impact on patient outcomes.

This report estimates the impact of expanding the scope of practice for NPs on COVID mortality in the Midwest. In the region, seven states were classified prior to the pandemic as "restricted/reduced NP practice" by the AANP. Among those, Kansas, together with Indiana, Michigan, Missouri, and Wisconsin granted NPs independence, whereas Illinois and Ohio did not implement changes.3 In the empirical exercise, we leverage on this quasi-experimental setting to compare daily COVID mortality in the treated states with that in Illinois and Ohio before and after the emergency response. Although the discussion evaluates the recent emergency response under the pandemic, the finding here contributes to the ongoing debate of whether NP should be granted independent authority.

According to our estimates, expanding the scope of practice for NPs potentially reduced COVID-related deaths by ten per day. To put this figure into context, the number amounts to a reduction of 8% of in those states that implemented the changes the average death toll in Cook County during the sample period. These results add support to granting NP full independent authority to ease the healthcare workforce shortage.

Restriction on NP and State Emergency Response

The scope of practice for nurse practitioners varies by state. According to the American Association of Nurse Practitioners (AANP), five of the Midwest states allow full practice (light blue in Figure 1a), meaning that NP can work independently and are authorized for patient diagnosis and prescription.

Illinois with four other Midwest states (Figure 1a) classify NP under "reduced practice" restrictions. Illinois regulations amended in 2017 do allow a subset of NP full practice authority, but the change only applies to NP who have had at least 4,000 hours of clinical experience and completed 250 training hours.4 In contrast, North Dakota, South Dakota, Nebraska, Minnesota and Iowa permit a full scope of practice for all NP without a minimum threshold of accrued work hours.

In Illinois, NP are required to have a collaborative agreement with a health professional (e.g. licensed physician), listing the types of care, treatment and procedures the NP is allowed to perform. NP in Illinois and five other Midwest states can work quasi-independently because physicians are not required to be physically present with the NP. Prior to the pandemic outbreak, Missouri and Michigan had the most restrictive rules, requiring that NP work under direct supervision of a physician (Figure 1a).

As the pandemic unfolded, states with reduced or restricted practice authority began to expand the scope of practice for NP. The aim of the change was to enlarge the healthcare workforce capable of providing COVID-19 care.

Among the Midwest states shown in Figure 1b, Missouri and Indiana were the first to waive part of the supervision requirements. At the date of this report, Illinois and Ohio were the only two states, which have not taken action to expand the scope of practice for NP.

Policy Effect on COVID-related Mortality

To evaluate the effectiveness of expanded scope of practice, this report looks into the impact on COVID-related mortality. Data on county level daily mortality are retrieved from the New York Times.5

To estimate a cause-and-effect relationship between expanded scope of practice and COVID-19 mortality, this report employs the synthetic control method (Abadie and Gardeazabal, 2003; Abadie, Diamond, and Hainmueller, 2010). The essence of this statistical technique is to construct a counterfactual which mirrors the post-policy mortality that would have been observed had the policy not happened. We then obtain the daily policy effect by directly comparing the counterfactual mortality with the observed mortality. To ensure the counter-factual offers a valid comparison, we make use of several important indicators that would predict COVID-related deaths. These include the pre-policy number of COVID death, pre-policy number of confirmed cases (also retrieved from the New York Times database), and county characteristics (number of NPs, population size, percent of 65+ population, percent of black, number of hospital, and number of beds) obtained from the Area Health Resource Files (AHRF, 2020).

An important property of the synthetic control technique is that the pre-policy number of COVID death has to be informative enough to produce reliable post-policy predictions. In other words, we rely on the pre-policy trend to predict the post-policy movement. This limits the start of the sample period to late March because many counties did not record any COVID deaths until then. For this reason, we are not able to produce a dependable counterfactual for the counties in Missouri and Indiana because they granted authority to NP prior to reporting any COVID-19 deaths.

Figure 2, shows the estimation result for Kansas, Wisconsin, and Michigan. The solid line of each graph represents the actual daily mortality of a state (average of all counties), whereas the dotted line shows the predicted counterfactual using the synthetic control technique. The red vertical line in the middle of each graph represents the day before the policy takes place. For example, in the top-left corner, the solid line shows that Kansas counties recorded an increasing number of COVID-related death with a modest decline in magnitude since April 22, which is the date Kansas started to authorize temporary independent practice for NPs. The trend afterward clearly diverges from the predicted no-policy counterfactual, which implies that the policy slowed down the death toll. Until the end of the sample period, the maximum impact by the policy reduces the daily death toll by 10 cases. We also observe a similar pattern in Wisconsin and Michigan, though the magnitude of death reduction in Michigan is smaller.

There is however the possibility that the reduction in deaths was caused by some other concurrent policies and any reduction in fatalities would then be falsely attributed to the expanded scope of practice. This concern is particularly valid because there were many policies adopted in response to the nationwide health risk.

Therefore, to check the robustness of our prediction of reduced deaths associated with NP scope of authority, we tested to see if the social distancing policy, a major attempt by states in response to the pandemic, had the same associated improvement on the cases of COVID-19 deaths.

For Kansas, Wisconsin, and Michigan, social distancing measures were implemented in late March. We therefore implemented the same estimation procedures using the synthetic control method but moving the treatment date in each state to correspond to the start of the state's shelter-in-place order. As shown in Figure 3, in each of the three states, the actual cases of death continues to grow at a higher rate than the predicted counterfactual. This finding suggests that the lock down policies did not produce the same reduction in the number of COVID-related fatalities as the expanded scope of practice

Conclusion and Policy Implication

Amid the unprecedented health crisis, it is important that state regulators consider the cost of occupational regulations.

The argument for occupational licensing is that it protects the consumer. In the case of NPs scope of practice, regulators often worry about the quality of service if the scope is widened. This report however suggests there is empirical evidence that granting NPs independent authority has contributed to a reduction in COVID-19 deaths.

#### The Aff can solve.

#### Malleability holds in contingent instances - Health access is distinct from other modes of violent power. Claiming it as “liberalism” creates false equivalencies. Such State-Alarmism is wrong and generates support for ACA rollback.

Schotten ’15

Dr. C. Heike Schotten is an Associate Professor of Political Science and an affiliated faculty in Women’s and Gender Studies at The University of Massachusetts-Boston. What following is from Schotten’s own faculty bio: Her research lies at the unlikely intersection of Nietzsche studies, queer theory, and revolution. “Against Totalitarianism: Agamben, Foucault, and the Politics of Critique,” Foucault Studies, No. 20, pp. 155-179, December 2015, Modified for language that may be objectionable - #E&F – the letter “u” is moved from Capitalized to a lower-case in one instance – this is for readability. <http://rauli.cbs.dk/index.php/foucault-studies/article/view/4935/5361>

III. Moralism and Totalitarianism

Foucault’s methodological and political commitments are all the more significant in light of Agamben’s demanded corrective of Foucaultian biopolitics and understanding of sovereignty. For even as Foucault expands his methodological rejection of the state as ahistorical political principle or sociological object, Agamben effects not simply a return to sovereignty, as already argued, but a return to sovereignty in what, following Foucault, we must recognize as totalitarian forms. This is the case not only methodologically, as will become clear, but also morally, an aspect of political critique that does not even enter into the Foucaultian schema. Methodologically, Agamben’s persistent focus on Auschwitz as the West’s political paradigm and Nazism as the teleological culmination of sovereignty’s political trajectory results in his offering an “anti-totalitarian” theory of sovereignty that renders any other historical or political outcome besides totalitarianism impossible. Hence Agamben’s dispute with Foucault is actually a “corrective” of Foucault, a disappointingly moralizing rebuke rather than a constructive scholarly engagement.

In BB, Foucault says his choice to talk about governmentality rather than the state is purposeful, a methodological choice that is “obviously and explicitly a way of not taking as a primary, original, and already given object, notions such as the sovereign, sovereignty, the people, subjects, the *state, and civil society*, that is to say, all those universals employed by sociological analysis, historical analysis, and political philosophy.”92 Rather, Foucault says, he would like to do “exactly the opposite” and, instead of using “state and society, sovereign and subjects, etcetera” as points of departure, he wants to show how they “were actually able to be formed” so that their status can be called into question.93 At one level, this is simply Foucault’s methodological preference. At another level, as we have seen, it is a political commitment, insofar as refusing to begin with these sociological givens facilitates resistance to the power-effects of what he calls “totalitarian theories.” While, in “SMBD,” these totalitarian theories were Marxism and psychoanalysis, in BB the target is now what Foucault calls “historicism,” which he describes as a practice of taking universals and running them through the mill of history in order to deduce their “meaning.” Significantly, historicism, like Marxism and psychoanalysis, unfolds a similarly reductive and deductive logic that “starts from the universal and, as it were, puts it through the grinder of history.”94 Instead, Foucault suggests the supposition “that universals do not exist. And then I put the question to history and historians: How can you write a history if you do not accept a priori the existence of things like the state, society, the sovereign, and subjects?”95 Insofar as historicism in BB functions the way Marxism and psychoanalysis do in “SMBD,” then historicism can also be considered a totalitarian theory that Foucault seeks to critique. In seeking to undertake an analysis that is “exactly the opposite of historicism,”96 Foucault is in some sense continuing his practice of thwarting or undermining totalitarian theories, a methodology that is animated by a specifically political commitment to insurrection.97

Foucault is also cautious about indulging the fearful discourse of the all-powerful state. He names this anxiety “state ~~phobia~~” 98 (“state alarmism”) and says it has two related versions: first,

the idea that the state possesses in itself and through its own dynamism a sort of power of expansion, an endogenous imperialism constantly pushing it to spread its surface and increase in extent, depth, and subtlety to the point that it will come to take over entirely that which is at the same time its other, its outside, its target, and its object, namely: civil society.99

If this leaves the impression of a kind of suffocating beast whose tentacled grasp is ever extending over and sliding in between any cracks of resistance to its domination, this is no accident: Foucault refers to this as the “cold monster” version of the state, the “threatening organism above civil society.”100 Foucault does not spend much time unpacking the problems with this theory, presumably because they are self-evident on the basis of his earlier work: not only is the state here presupposed as a causal entity that exists “above” its subjects, but it is also possessed of a kind of vitalism or life principle that Foucault dismisses out of hand as an inadequate or irresponsible account of power. The state as “cold monster” is, quite literally, yet another version of the Leviathan, the great sea monster from the book of Job, for whose beheading Foucault has already vigorously advocated.

The second bit of “critical commonplace”101 regarding the state that Foucault seeks to avoid is the notion that there are no significant differences between or among different forms of it. This is the notion that, as Foucault puts it,

there is a kinship, a sort of genetic continuity or evolutionary implication between different forms of the state, with the administrative state, the welfare state, the bureaucratic state, the fascist state, and the totalitarian state all being, in no matter which of the various analyses, the successive branches of one and the same great tree of state control in its continuous and unified expansion.102

Here Foucault explicitly puts totalitarianism and the state together in order to distinguish “the totalitarian state” as a *distinct*ive state form, rather than the paradigm case of the state itself.

Indeed, here we might understand Foucault as attempting to disentangle a kind of doubling of totalitarianism in state phobia, wherein the cold monster view anoints the state with the kind of omniscience and omnipotence often ascribed to totalitarian versions of it. This specifically totalitarian version ultimately becomes synonymous with the state itself.

What links the “cold monster” view and the “genetic continuity” view is their consideration of the state as a malevolent principle in itself, such that distinctions among types become irrelevant and *any state action* can be interpreted as a sign of its increasing repressiveness and violence. Foucault uses the example of an unduly harsh criminal sentence, which he says can be interpreted as evidence of the increasing fascism of the state, regardless of whatever may actually be true—this is once again a correct answer produced by the particular truth mill that is “state phobia.” Foucault warns that this kind of thinking can verge on ~~paranoid~~ (alarmist) fantasy, which ~~sees~~ (perceives) evidence of the ever-growing, increasingly-fascistic state everywhere it looks. In this case, one’s “grasp of reality”103 is not what matters, but rather the endless confirmation and reproduction of the theory itself. It can also issue in absurd (illogical) conclusions, such as the following:

As soon as we accept the existence of this continuity or genetic kinship between different forms of the state, and as soon as we attribute a constant evolutionary dynamism to the state, it then becomes possible not only to use different analyses to support each other, but also to refer them back to each other and so deprive them of their specificity. For example, an analysis of social security and the administrative apparatus on which it rests ends up, via some slippages and thanks to some plays on words, referring us to the analysis of concentration camps. And, in the move from social security to concentration camps the *requisite* specificity of analysis is diluted.104

While Foucault is referencing right-wing fantasies about governmental power (one is reminded of Sarah Palin’s warnings about “death panels” should Obama’s Affordable Health Care Act pass the U.S. Congress), his caution is also apposite to left anarchist discourses that similarly ~~see~~ (perceive) the state as a malevolent principle in itself. In suggesting that the state has no essence or is “nothing else but the mobile effect of a regime of multiple governmentalities,”105 Foucault is not claiming that we should be uncritical of the state or exercises of state power. Quite the opposite. In destabilizing the operative presumptions about the state in history, sociology, philosophy, and politics, Foucault is instead working to make the state something that is possible to critique and resist. We lose sight of this possibility when the state is presumed to be a prime mover of history or politics, an omnipotent principle or an essentially annihilatory institution that culminates, inevitably, in the genocidal logic of concentration camps. Part of the task of proceeding in the exact opposite manner as that of historicism is admitting that mechanisms of power *are* transferable and that they do not exhaustively characterize any particular society.106 Foucault’s resistance to historicism and state phobia, then, are yet further resistances to totalitarianism—of theory (or science) but also of specific state forms and beliefs about the state and its forms that function in totalitarian ways.

As is perhaps already evident, Agamben’s approach to the state in Homo Sacer epitomizes both the historicism and state ~~phobia~~ (“state alarmism”) that Foucault explicitly rejects. Rather than seeking, from below, to untangle and document the subjugated knowledges that have produced existing dominations, Agamben instead seeks to read these latter for what they reveal about the essential workings of Western politics. Indeed, Agamben presumes that power inheres in the sovereign demarcation of the zoē/bios divide, the status of which exhaustively defines life and politics in “the West” (itself an underspecified geographical and historical entity). The method of Homo Sacer is thus clearly expressed in Foucault’s description of “historicism”: Agamben starts from a universalist claim regarding the sovereign exception and then proceeds to examine how history has inflected it in the West. This is what allows him to conflate all versions of the state with the totalitarian one and also to suggest that all versions of sovereignty culminate inevitably in the Nazis’ creation of concentration camps. As he says, the camp is “the hidden paradigm of the political space of modernity, whose metamorphoses and disguises we will have to learn to recognize.”107

Like all declension narratives, this one too echoes the chronology of the fall from grace, except that, in Agamben’s version, the pre-lapsarian moment dates from Aristotle rather than the Creation. The result, however, is a valorized hypostatization of an at-best questionable moment of origin, from which the logic of the events of Western history can be understood to have unfolded and to be still in the process of unfolding to this day.108 At one end, then (at “the beginning,” or archē), stands the Aristotelian distinction between zoē and bios; at the other end (“now,” or in modernity), lie the Nazi death camps. These two moments are tied inevitably, irretrievably together by the exceptional logic of sovereignty:

The totalitarianism of our century has its ground in this dynamic identity of life and politics, without which it remains incomprehensible. If Nazism still appears to us as an enigma, and if its affinity with Stalinism (on which Hannah Arendt so much insisted) is still unexplained, this is because we have failed to situate the totalitarian phenomenon in its entirety in the horizon of biopolitics. When life and politics—originally divided, and linked together by means of the no-man’s-land of the state of exception that is inhabited by bare life—begin to become one, all life becomes sacred and all politics becomes the exception (148, original emphasis).

Nazism will remain “an enigma,” on this telling, insofar as we fail to “situate” it within the essential principle of Western biopolitics—the sovereign exception, the zoē/bios divide. Once we do that, however, the meaning of Nazism becomes clear and we understand how there could ever have been death camps, perhaps the real question Agamben is trying to answer in this text. Already latent in the zoē/bios divide, then, is the concentration camp, which is why its historical development inevitably culminates there.

Agamben’s political theory thus not only re-iterates the assumptions of the sovereign model as Foucault explains it, but itself becomes a kind of totalitarian theory of sovereignty in the West that can only ever issue in the same answer over and over again: the camp. Agamben’s methodological historicism is what allows him to come to the political conclusions Foucault explicitly repudiates above; namely, that there is no meaningful difference between democratic states and totalitarian ones, and this because the sovereign exception is a formation of power that fundamentally defines the entity “Western politics” from its earliest days through to its catastrophic contemporaneity. Thus it is perhaps also unsurprising that Agamben concludes there is no difference between democratic and totalitarian regimes insofar as their “fundamental referent” is bare life; the “only real question to be decided,” he says, is “which form of organization would be best suited to the task of assuring the care, control, and use of bare life.”109 As well, Agamben’s state ~~phobia~~ (“state alarmism”) , in which we can recognize both the “cold monster” and “genetic” versions, predictably culminates, as do the absurdist theories Foucault documents, with nothing other than concentration camps. U(u)nless the enigma of the sovereign exception is solved, Agamben insists, we will remain mired in totalitarianism and death camps: “Today politics knows no value (and, consequently, no nonvalue) other than life, and until the contradictions that this fact implies are dissolved, Nazism and fascism—which transformed the decision on bare life into the supreme political principle— will remain stubbornly with us.”110 The consequence of Agamben’s methodology here is not simply a return to sovereignty, then, but in fact a resurrection of the sovereign and the restoration of his omnipotence in what, following Foucault, can be called totalitarian forms. Agamben’s reading of the text of Western politics from the guiding principle of the sovereign exception leaves us no other option, no other conclusion, than that with which Foucault claims his work is constantly being misinterpreted as saying: “This is the way things are; you are trapped.”111 This outcome is all the more ironic, of course, given that the entire exercise of Homo Sacer was ostensibly spurred by Agamben’s desire to “correct” Foucault’s oversight regarding 20th century totalitarian regimes and, presumably, overcome the disastrous legacy of Nazism and totalitarianism.

\*Note to students: the word “endogenous” means having an internal cause or origin)

#### Elements of the squo echo this call for an untouched market. That pro-rollback perspective would place *millions of lives at risk*.

Gee ‘20

et al; Emily R. Gee is a senior fellow and the senior economist for Health Policy at American Progress. In her role, she guides policy development and advocates for reforms to expand coverage and improve care. Her areas of expertise include health coverage and affordability, health care financing, and the Affordable Care Act. She has been quoted and her work has been cited in The New York Times, The Washington Post, Politico, Forbes, Vox, and other publications. Prior to joining American Progress, she was an economist in the Office of the Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services and worked on implementation of the Affordable Care Act. Gee also served as an economist on the staff of the Council of Economic Advisers in the Obama White House, tracking health care coverage and reviewing regulation related to provider payments, prescription drugs, and insurance. Gee earned her doctorate in economics from Boston University, where she researched health insurance markets and taught health economics. She holds a bachelor’s degree in government from Harvard College. “10 Ways the ACA Has Improved Health Care in the Past Decade” - March 23, 2020 - #E&F – modified for language that may offend - https://www.americanprogress.org/issues/healthcare/news/2020/03/23/482012/10-ways-aca-improved-health-care-past-decade/

Ten years ago this month, the Affordable Care Act (ACA) was signed into law. Since then, the law has transformed the American health care system by expanding health coverage to 20 million Americans and saving thousands of lives. The ACA codified protections for people with preexisting conditions and eliminated patient cost sharing for high-value preventive services. And the law goes beyond coverage, requiring employers to provide breastfeeding mothers with breaks at work, making calorie counts more widely available in restaurants, and creating the Prevention and Public Health Fund, which helps the Centers for Disease Control and Prevention (CDC) and state agencies detect and respond to health threats such as COVID-19.

Despite the undeniably positive impact that the ACA has had on the American people and health system, President Donald Trump and his allies have (~~been on a mission~~ (strived) to dismantle the law and reverse the gains made over the past decade—first through Congress and now through a lawsuit criticized by legal experts across the political spectrum. Even if the U.S. Supreme Court rules the ACA constitutional after it hears the California v. Texas health care repeal lawsuit this fall, President Trump’s administration cannot be trusted to put the health of the American people ahead of its political agenda. Trump’s administration hasn’t delivered on Trump’s commitment to “always protect patients with pre-existing conditions.”

The consequences of ACA repeal would be dire:

Nearly 20 million people in the United States would lose coverage, raising the nonelderly uninsured rate by more than 7 percent.

135 million Americans with preexisting conditions could face discrimination if they ever needed to turn to the individual market for health coverage.

States would lose $135 billion in federal funding for the marketplaces, Medicaid, and the Children’s Health Insurance Program (CHIP).

Insurance companies would no longer be required to issue rebates when they overcharge Americans. In 2019, insurance companies returned $1.37 billion in medical loss ratio rebates to policyholders.

The tax revenue that funds the expanded health coverage under the ACA would become tax cuts for millionaires, who would receive an average of $46,000 each.

As the nation awaits a final ruling on the lawsuit, the Center for American Progress is celebrating how the ACA has helped the American people access affordable health care in the past decade. In honor of the law’s 10th anniversary, here are 10 ways in which it has changed Americans’ lives for the better. Each of these gains remains at risk as long as the Trump administration-backed lawsuit remains unresolved.

1. 20 million fewer Americans are uninsured

The ACA generated one of the largest expansions of health coverage in U.S. history. In 2010, 16 percent of all Americans were uninsured; by 2016, the uninsured rate hit an all-time low of 9 percent. About 20 million Americans have gained health insurance coverage since the ACA was enacted. The ACA’s coverage gains occurred across all income levels and among both children and adults, and disparities in coverage between races and ethnicities have narrowed.

Two of the biggest coverage expansion provisions of the ACA went into full effect in 2014: the expansion of Medicaid and the launch of the health insurance marketplaces for private coverage. Together, these programs now cover tens of millions of Americans. Nationwide, 11.4 million people enrolled in plans for 2019 coverage through the ACA health insurance marketplaces. Medicaid expansion currently covers 12.7 million people made newly eligible by the ACA, and the ACA’s enrollment outreach initiatives generated a “welcome-mat” effect that spurred enrollment among people who were previously eligible for Medicaid and CHIP.

2. The ACA protects people with preexisting conditions from discrimination

Prior to the ACA, insurers in the individual market routinely set pricing and benefit exclusions and denied coverage to people based on their health status, a practice known as medical underwriting. Nearly 1 in 2 nonelderly adults have a preexisting condition, and prior to the ACA, they could have faced discrimination based on their medical history if they sought to buy insurance on their own.

The ACA added a number of significant new protections for people with preexisting conditions. One group of reforms involved changes to the rating rules, prohibiting insurers from making premiums dependent on gender or health status and limiting their ability to vary premiums by age. The ACA also established guaranteed issue, meaning that insurers must issue policies to anyone and can no longer turn away people based on health status.

Another crucial protection for people with preexisting conditions is the ACA’s requirement that plans include categories of essential health benefits, including prescription drugs, maternity care, and behavioral health. This prevents insurance companies from effectively screening out higher-cost patients by excluding basic benefits from coverage. The law also banned insurers from setting annual and lifetime limits on benefits, which had previously prevented some of the sickest people from accessing necessary care and left Americans without adequate financial protection from catastrophic medical episodes.

3. Medicaid expansion helped millions of lower-income individuals access health care and more

To date, 36 states and Washington, D.C., have expanded Medicaid under the ACA, with 12.7 million people covered through the expansion. While the Medicaid program has historically covered low-income parents, children, elderly people, and disabled people, the ACA called for states to expand Medicaid to adults up to 138 percent of the federal poverty level and provided federal funding for at least 90 percent of the cost.

Medicaid expansion has led to better access to care and health outcomes for low-income individuals and their families across the country. A large body of evidence shows that Medicaid expansion increases utilization of health services and diagnosis and treatment of health ailments, including cancer, mental illness, and substance use disorder. Medicaid expansion is associated with improvements in health outcomes such as cardiac surgery outcomes, hospital admission rates for patients with acute appendicitis, and improved mortality rates for cardiovascular and end-stage renal disease. Beyond health outcomes, evidence points to improved financial well-being in Medicaid expansion states, including reductions in medical debt and improved satisfaction with one’s current financial situation. A study that assessed eviction rates in California found that Medicaid expansion is “associated with improved housing stability.”

Evidence shows that Medicaid expansion saves lives. According to a 2019 study, Medicaid expansion was associated with 19,200 fewer deaths among older low-income adults from 2013 to 2017; 15,600 preventable deaths occurred in states that did not expand Medicaid. As the Center on Budget and Policy Priorities points out, the number of adults ages 55 to 64 whose lives would have been saved in 2017 had all states expanded Medicaid equals about the number of lives of all ages that seatbelts saved in the same year.

#### We do not defend the law in all instances – but in the contingent realm of health provision, government policy is much better than the de facto Alt of an untouched market.

Parento ‘12

Professor Emily Whelan Parento is as Associate Professor and the Gordon D. Schaber Health Law Scholar at McGeorge School of Law at the University of the Pacific. Her primary scholarly focus is the intersection of domestic health law and policy with the human rights framework for the right to health and health equity. The author holds a JD and LLM, from The Georgetown University Law Center and a BBA, from the University of Notre Dame. Earlier in her career she served as a federal judicial clerk and practiced litigation at Davis Polk & Wardwell in New York and California. From the article: “Health Equity, Healthy People 2020, and Coercive Legal Mechanisms as Necessary for the Achievement of Both” - 58 Loyola Law Review 655 - Fall, 2012 - #CutWithRJ – Modified for potentially offensive language – This Loyola Law Review article was re-published at Racism.org – http://www.racism.org/index.php?option=com\_content&view=article&id=1424:racisthealthcare&catid=88&Itemid=274&showall=1&limitstart=

Although health equity was not a part of seventeenth-century political discourse, Montesquieu accurately captured the conflict that surrounds the concept today. In theory, people are born with equal potential for healthy lives, yet the minute their lives begin, a confluence of factors render some people immensely more likely than others to have the capability to lead healthy lives. These disparities in individuals' capabilities to achieve good health raise important social justice questions--What obligation does society have to take measures to reduce health disparities based on race or ethnicity, socioeconomic status (SES), gender, sexual orientation, education, disability, and other factors, particularly where behavioral risk factors are a contributing factor to disease? Stated differently, how much “choice” do individuals *truly* possess regarding their health, and what can and should government do to address the societal influences that negatively impact health status?

Routinely, society looks at an individual health outcome and ascribes the result to modifiable lifestyle choices, good or bad, with the implicit assumption that people who are healthy deserve praise for their responsible choices and those who are not deserve at least partial blame for failing to act in ways that would improve their health. However, this personal responsibility framework fails at a population level. It is well-documented that there is a socioeconomic gradient to health, in which individuals are likely to be healthier as their socioeconomic status increases. But no serious scholar ascribes population level socioeconomic health disparities to the superior willpower of the wealthy in making healthy lifestyle choices. Similarly, there is a persistent racial and ethnic component to health that is not explained by other factors, pursuant to which certain racial and ethnic groups are more likely to have worse health outcomes than others. But no one argues that African-Americans have worse health outcomes on average than whites because African-Americans are not as motivated as whites to protect their health. There is no basis for making such population-wide generalities about motivation regarding health behavior. Yet in the face of these widespread and presumptively inequitable disparities, the law has done little. This paper argues that coercive legal mechanisms are an essential element of eliminating health disparities and achieving health equity. Moreover, the paper argues that Healthy People 2020 (HP 2020), which is the nation's “master blueprint for health” and explicitly seeks to achieve health equity, has not fully incorporated the principles of health equity in the formulation of its objectives and indicators because HP 2020 fails to recognize the varying distributive effects of policies that could achieve population health targets. To truly incorporate the principles of health equity, HP 2020 should advocate for those demonstrably effective coercive legal mechanisms that would both achieve its population health objectives and reduce health disparities.

The federal government has monitored health disparities in one form or another since at least 1985 and has advocated for the elimination of health disparities since at least 2000, with the release of the Healthy People 2010 goals. However, decisive action on the reduction of disparities has been lacking, and, on average, disparities have not improved over at least the past fifteen years. Although health equity is a mainstay of health law and policy discourse, the concept has not had a significant role in mainstream political discussions. As it is commonly understood, health equity exists when “all people have an equal opportunity to develop and maintain their health, through fair and just access to resources for health.” There are strong philosophical and social justice reasons that support government action to reduce disparities--among them are human rights principles of equality underlying the right to health; Nussbaum's theory of health as an essential human capability necessary to fully function in life; Amartya Sen's theory of the capability for health as an instrumental human freedom; and principles of equality and nondiscrimination among people based on characteristics such as SES, race or ethnicity, gender, sexual orientation, religion, disability, rural/urban geography, and other characteristics historically linked to discriminatory treatment.

The question, then, is, What means are both necessary and effective for reducing health disparities and achieving health equity? It is here that distributive consequences of policies become important, leading to the conclusion that coercive legal mechanisms such as direct regulation and taxation are essential to a serious strategy to reduce disparities. While coercive legal mechanisms are not suited to solve every problem and must always be balanced against concern for personal liberties and principles of autonomy, there are many instances in which coercive legal mechanisms are demonstrably *the most effective way of reducing health dispariti*es and improving population health. Unfortunately, when discussing these mechanisms, advocates are often cowed by advocates of “personal choice” into watering down interventions to the point that the likely result is--even with an improvement in population health--no change or a worsening in health disparities. This approach is problematic from a health equity standpoint, given that health equity by its nature requires the elimination of health disparities associated with social disadvantage.

The U.S. government has made the achievement of health equity and the elimination of health disparities a national priority in HP 2020, recognizing the importance of working toward the realization of health equity. Every ten years since 1979, the Department of Health and Human Services (HHS) issues new “Healthy People” nationwide health goals for the forthcoming decade, the most recent of which are HP 2020. The essential aim of the Healthy People project (the Project) is to establish national health priorities by setting targets for improvement of health across a broad spectrum of topics, ranging from access to health services to environmental health to more discrete diseases such as cancer and heart disease and, for the first time in HP 2020, including the social determinants of health. In some instances, HP 2020 advocates the adoption of specific coercive legal mechanisms that would both further a population health goal and reduce disparities--for example, passage of smoke-free legislation would both reduce overall population exposure to secondhand smoke and more strongly affect disadvantaged groups (who have higher rates of smoking and are more likely to work in places where smoking is permitted), thereby resulting in a reduction in the disparity in rates of exposure to secondhand smoke. This advocacy is laudable. However, in most instances, HP 2020 chooses to set broad, population-based targets for health measures without expressing a preference between means of achieving those targets, as in the case of access to health insurance coverage, where HP 2020 sets a target of 100% coverage without acknowledging the obvious--that there is no evidence that anything other than a coercive legal mechanism is a realistic way to achieve that goal.

The determination of which coercive legal mechanisms HP 2020 supports appears to be made not on the ground of epidemiological evidence of a policy's effectiveness; rather, HP 2020 seems to be willing to advocate for direct regulation only in areas that are relatively politically uncontroversial, such as helmet laws and certain tobacco control measures. This paper argues that a true internalization of the principles of health equity requires that HP 2020 acknowledge the predictably different distributive consequences of various policy interventions and urge the adoption of those coercive legal mechanisms that are demonstrably effective in reducing health disparities. Without such a framework under which to operate, the likely result is that, even if overall population health improves, health disparities will widen between the most vulnerable population groups and the already advantaged, or remain essentially stagnant, as they did under HP 2010.

More broadly, this paper argues that health equity demands the use of coercive legal mechanisms in certain circumstances given the existence of current disparities and the evidence of effectiveness of direct regulation as compared to its alternatives. This is true for a number of reasons, including that purely voluntary policy initiatives often result in little impact on the most vulnerable populations (e.g., in the case of trans fat initiatives, discussed infra Part III.B.3), and because market-based initiatives have failed to adequately account for the health needs of certain population groups (as in the case of access to health services, discussed infra Part III.B.1). Only with a candid assessment and acceptance of the critical role that coercive legal mechanisms play in furthering population health can progress be made toward the achievement of the HP 2020 goals and ultimately, health equity. Part II of this paper discusses health equity in the U.S. and how HP 2020 incorporates health equity into its goals. Part III discusses the importance of law in public health and health equity and uses specific HP 2020 goals and objectives as examples of the essential role of coercive legal mechanisms in achieving those goals while also furthering health equity. Part IV proposes certain additional legal mechanisms that could inform selection of strategies for achieving the HP 2020 goals and health equity, including the use of a “health in all policies” approach to government, the use of health impact assessments in policymaking, and the use of various indices to measure the effects of various policies and assess progress toward disparities reduction.