Testimony

of

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Re: "The Economic Impact of America's Failure to Contain the Coronavirus"

Mr. Chairman, Mr. Vice-Chairman, members of the committee, thank you for inviting me to testify.

My name is Jeffrey A. Singer. I have been practicing general surgery in Phoenix, Arizona for more than 35 years, and I am a Senior Fellow at the Cato Institute where I work in the Department of Health Policy Studies. America's encounter with the COVID-19 pandemic has exposed many flaws in the health care regulatory infrastructure, both on the federal level and the state and local level, that impeded a quick and nimble response to the public health emergency. I have been asked to provide my perspective, as a health care practitioner and policy analyst, to assist this committee in its reassessment of existing policies, with the goal of improving readiness as well as access to health care before, during, and after the next public health emergency.

The Food and Drug Administration's test approval process resulted in an avoidable and costly delay in getting test kits out to the general public, delaying an effective response to the COVID-19 pandemic by more than a month.[1] By contrast, South Korea, having learned from it experience with the Middle Eastern Respiratory Syndrome (MERS) outbreak in 2015, enacted a reform giving almost immediate approval to testing systems developed in the private sector during an emergency.[2]

Eventually, the FDA permitted states to independently approve tests for use within their own borders even if the tests had not yet received FDA approval.[3] This temporary emergency action allowed several states that were hard-hit by the pandemic to rapidly ramp up testing. In some instances, states imported tests in use and of proven quality from other countries. When the public health crisis recedes, FDA testing policy should not return to the status quo ante. The devolution of authority to the states should remain in effect whether or not a public health emergency exists.

In 2018 Congress passed the "Right to Try" Act in support of the right of the people to try medications that may save their lives, even if they weren't approved by a federal agency. A bipartisan Congress and President understood that people must not be prevented by the government from making an informed decision to try a drug to save their lives.

As coronavirus cases began to spring up outside of China, including a small number in the U.S., the FDA should have sought to ameliorate the shortage of test kits by granting authorization for the use of tests already being used in similar countries. Just as people have the right to try medications in order to save their lives, they also have the right to try tests aimed at saving their lives.

Congress should pass legislation giving reciprocal approval to drugs and medical devices (which includes tests) in similar countries.[4] Reciprocal approval already exists among the European Union states plus Iceland, Liechtenstein, and Norway.[5] In July 2019 Senator Ted Cruz (R-TX) introduced S.2161, the Reciprocity Ensures Streamlined Use of Lifesaving Treatment (RESULT) Act, which would allow for the marketing of drugs approved in certain countries, but not yet approved by the FDA, if "there is an unmet need."[6] While this is indeed a step in the right direction, in the interest of promoting competition and consumer choice, reciprocal approval should not be contingent on an unmet need.

Along those same lines, and in keeping with the FDA emergency authorization permitting states to decide the COVID-19 tests marketed within their borders, Senators Ted Cruz (R-TX), Kelly Loeffler (R-GA), and Mike Braun (R-IN) introduced S.3769, the "Right to Test Act," which would grant such authority to states whenever the Secretary of Health and Human Services declares a public health emergency.[7] However, Congress should consider granting states the authority to approve drugs and other devices that may be marketed within their borders, independent of FDA approval, even when there is not a public health emergency.

The pandemic acutely demonstrated how state licensing laws impede the free flow of health care practitioners to where patients need them. In several of the states hardest hit by the pandemic, governors suspended state licensing laws allowing practitioners licensed in any state to come to the aid of other states' residents. These emergency actions tacitly recognize a pressing problem: state clinician licensing laws block access to care. When the crisis recedes, the state-based licensing regime should not return to the *status quo ante*.

Some states have already enacted laws recognizing the out-of-state occupational and professional licenses of those who establish permanent locations within their jurisdictions. In early 2019 Arizona became the first state to do so, and several other states have since followed suit. The remaining states and the District of Columbia should do the same.

Such reform would make it much easier for health care practitioners to provide services to patients in various parts of the country. However, the requirement that health care practitioners establish permanent locations within respective states renders the reform less effective. For greater impact, state lawmakers in all 50 states and the District of Columbia should remove this requirement. States would still retain the power, under our federal system, to license and regulate occupations and professions within their borders.

Health Care Practice Across State Lines

The social distancing measures required to address the COVID-19 pandemic led to a newfound appreciation for the use of telemedicine, a technological advance that has been available for several decades. State licensing laws for health care practitioners have impeded the widespread use of telemedicine. Most states require that health care practitioners provide telemedicine only to patients in the state in which those providers are licensed, a barrier to the free flow of health care services across state lines.

Furthermore, patients can travel to another state to receive medical treatment and even surgery from a doctor licensed in that state, but those doctors cannot travel to the patients' states to provide the same services unless they are licensed in those states.

While many states suspended the barriers to movement of health care practitioners or the delivery of telemedicine across state lines, when this emergency passes, the barriers will return. To the extent consistent with its authority to tear down barriers to interstate commerce under Article 1, Section 8 of the Constitution, Congress should define the "locus of care" as the state in which the practitioner is located as opposed to the state in which the consumer of the service resides. While states have constitutional authority to regulate the practice of medicine for residents within their borders, crossing state lines to provide telemedicine or short-term in-person care can reasonably be classified as interstate commerce.[8] This change would increase access to

care and allow patients to utilize expertise that may exist in areas of the country otherwise beyond their reach. It would also remove the protection from out-of-state competitors that health care providers otherwise enjoy. The increased competition would redound to the benefit of patients.

S.3993, introduced in the U.S. Senate on June 17 would define the locus of care as the state in which the practitioner is licensed, but would only apply during the course of the current COVID-19 pandemic and would be limited to telemedicine.[9] However, Congress should pass legislation making this definition permanent and not just limited to the duration of the pandemic. Congress should also apply this definition of the locus of care to practitioners licensed in one state who provide short-term in-person care in a state where they do not have a permanent location. Examples of providers to whom such an act would apply include those who usually work through agencies to provide care during short, temporary stints in medically underserved areas, those located very close to the border of a neighboring state, and out-of-state experts in rare and specialized medical conditions brought in to consult and help manage a fragile patient unstable for transfer. These examples are analogous to telemedicine practice.

Possessing an out-of-state license would not automatically enable a health care provider to practice at any health care facility within a new state. Health care facilities perform their own due diligence in vetting and credentialing health care staff applicants. The same vetting process could just as easily be performed on an applicant for staff privileges who is licensed in another state. That happens now when a provider relocates from another state after obtaining a license in the new state.

Defining the locus of practice as the state in which a health care practitioner is licensed would make it easier for *locum tenens* ("fill in") providers and out-of-state specialists to provide itinerant temporary health services to remote and underserved communities, free from the burden of licensing applications and fees in the several states where these communities reside. In the event that a practitioner establishes an office within a state, the practitioner would then become subject to applicable state-based practitioner licensing laws.

Adding Experienced International Medical Graduates to the Provider Pool

State licensing boards require experienced international medical graduates who are licensed in other countries to repeat their entire post-graduate training in an accredited U.S. institution before receiving a state medical license. Many experienced foreign-trained doctors take ancillary medical field positions, such as nurse, lab technician, and radiology technician, instead of starting over. Some even work as waiters or taxi drivers.

In Canada, the provinces have control over medical licensing. Several provinces grant licenses to experienced immigrant physicians who have completed postgraduate training in any of 29 approved foreign jurisdictions.[10] Instead of having to repeat that training, they are required to pass a "practice readiness assessment," a relatively short process (usually a few months) involving supervision by a licensed practitioner who must clear them as competent. In Nova Scotia, for example, family medicine practitioners from other countries may practice under the supervision of a licensed physician and, after a designated period, may then independently practice in underserved areas.[11] A similar program exists for specialists who receive their postgraduate training in countries other than the 29 approved jurisdictions. Australia, New

Zealand, and most member countries of the European Union have similar provisions for admitting experienced foreign health care practitioners into their provider pools.

States should grant reciprocity to health care practitioners licensed in certain other countries with reputations for quality medical education and develop programs to facilitate integrating practitioners from less advanced countries into the pool of health care providers. Private certification organizations could be enlisted to assist in establishing criteria.

Certificate of Need Laws

More than three decades since repeal of the 1974 federal law that incentivized states to establish "Certificate of Need" (CON) requirements before new health care facilities can develop, or existing ones can add beds or equipment, CON requirements still exist to varying degrees in 38 states. These CON commissions are heavily influenced by incumbent health care providers. Attempts to reform or repeal them are often met by fierce resistance from the incumbents who try to make the case that they only have the interests of the general public in mind. CON laws render state health care systems sclerotic and unable to rapidly adjust their infrastructure to meet the changing demands of public health emergencies. Many governors suspended CON laws during the public health emergency. The CON laws in those states and in the states where they were not suspended should be formally repealed by state legislators.[12]

The Joint Economic Committee and the relevant committees in the U.S Senate and House of Representatives should investigate whether state Certificate of Need Laws, as well as state licensing laws, constitute antitrust violations. Individual members of Congress or Congress as a whole should direct the Federal Trade Commission to use its existing authority to enhance scrutiny of these state laws.

Trade-offs

Finally, I would like to address the matter of trade-offs. All decisions in life involve trade-offs. As a medical doctor, when I advise my patients, I strive to avoid the tendency to focus exclusively on physical health considerations, while neglecting to give proper consideration to any economic, psychosocial, or other trade-offs my patients may face.

While the harmful effects of the pandemic occur in real time, the public health consequences of many pandemic policy trade-offs may not be immediately apparent but are nonetheless extremely damaging. It is important for policymakers to be sensitive to both the seen and the unseen consequences of pandemic policy.

Unseen public health consequences include the uncountable thousands people who will die from chronic illnesses and would have remained healthy had they been able to keep their routine medical appointments; the advanced cases of cancer that occurred due to bans on screening procedures and biopsies; the emergencies that arose because of moratoria on necessary elective medical procedures such as coronary bypass and organ transplants; and the many additions to the rising suicide rate in all age groups including those who suffer alone in pain because of closed pain clinics, social distancing, and shelter-in-place orders. Also unseen are those suffering from depression and other mental health disorders whose conditions become exacerbated due to mandated isolation. Down-the-road consequences include increased numbers of people with

substance use disorders and drug overdoses, as well as increased cases of spousal and child abuse; and stunted cognitive and social development in young children deprived of in-person schooling. There is also the risk that many old pandemics might make their return because of the thousands of children missing crucial immunizations against even more deadly and contagious pathogens.

Economic trade-offs factor into the social determinants of health. Never seen will be the individuals who won't have careers or jobs, the small business that will never open, and the hard-earned life savings that will never materialize due to the destruction that comes from stopping an economy. None of this will show up in any statistics.

Government officials are people, and rational people respond to incentives. A drop in new COVID-19 cases and fatalities in the wake of lockdown orders increases the likelihood of public approval and reelection. Inaction risks criticism and political punishment. The disparity between what is seen and what is not seen means that government officials have incentives to be overly cautious and impose more restrictions for longer lengths of time than what may really be necessary. That's why it is crucial to minimize the amount of decision-making authority vested in just one person.

An understanding of this dynamic should inform policy regarding public health emergencies going forward. Central governments and public health officials should use a light touch when responding to public health emergencies. On all levels of government, one-size-fits-all measures should be kept to a minimum, and civil society should be informed, guided, and entrusted to work out suitable solutions. Responses should be targeted, nuanced, flexible, and easily adjust to changes on the ground based upon local knowledge.

1 https://www.cato.org/publications/commentary/coronavirus-testing-delays-caused-red-tape-bureaucracy-scorn-private

2 https://www.theregreview.org/2020/05/14/oh-south-korea-success-against-covid-19/ ; https://elaw.klri.re.kr/kor_service/lawView.do?hseq=44278&lang=ENG ; https://elaw.klri.re.kr/kor_service/jomunPrint.do?hseq=44278&cseq=1084999

3 https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help

4 https://repository.law.miami.edu/cgi/viewcontent.cgi?article=1288&context=umblr

[5] https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines_en.pdf

[6] https://www.congress.gov/bill/116th-congress/senate-bill/2161?s=2&r=13

[7] https://www.congress.gov/bill/116th-congress/senate-bill/3769/cosponsors?s=1&r=4&overview=closed&searchResultViewType=expanded

[8] https://www.cato.org/publications/policy-analysis/liberating-telemedicine-options-eliminate-state-licensing-roadblock

[9] https://www.congress.gov/bill/116th-congress/senate-bill/3993?s=1&r=1

[10] http://www.royalcollege.ca/rcsite/credentials-exams/assessment-international-medical-graduates-e

[11] https://cpsns.ns.ca/registration-licensing/future-practice/practice-ready-assessment/

[12] https://www.cato.org/blog/certificate-need-laws-will-impede-preparedness-expected-surge-covid-19-cases