10-22-2020

Federal COVID-19 Response Unlawfully Blocks State Public Health Efforts

Ellen Wright Clayton
Vanderbilt University Law School

Barbara J. Evans
Univ. of Florida, College of Engineering

Federal COVID-19 Response Unlawfully Blocks State Public Health Efforts

October 22, 2020 (https://blog.petrieflom.law.harvard.edu/2020/10/22/federal-covid19-response-nevada-preemption/) The Petrie-Flom Center Staff (https://blog.petrieflom.law.harvard.edu/author/petrieflom/) FDA (https://blog.petrieflom.law.harvard.edu/category/fda/), Featured (https://blog.petrieflom.law.harvard.edu/category/featured/), Health Law Policy (https://blog.petrieflom.law.harvard.edu/category/health-law-policy/), Liability (https://blog.petrieflom.law.harvard.edu/category/liability/), Public Health (https://blog.petrieflom.law.harvard.edu/category/public-health/), Supreme Court (https://blog.petrieflom.law.harvard.edu/category/supreme-court/)

By Barbara J. Evans (https://www.law.ufl.edu/faculty/barbara-evans) and Ellen Wright Clayton (https://law.vanderbilt.edu/bio/ellen-clayton)

The federal government recently used preemption unlawfully to prevent state public health efforts to protect vulnerable people from COVID-19.

As 1,000 current and former CDC epidemiologists noted in an open letter, the federal government has failed (https://medium.com/@eis1984/open-letter-by-epidemic-intelligence-service-officers-past-and-present-in-support-of-cdc-759cdc0666c3) to use legal powers it *does* have to manage the crisis,

leaving states to "invent their own differing systems" to manage COVID-19. We add that the federal government is now asserting emergency powers it *does not* have to disable state public health responses.

Early this month, Nevada officials halted the use of two rapid coronavirus tests (https://www.nytimes.com/2020/10/07/health/nevada-covid-testing-nursing-homes.html) that produced high false-positive rates when used for screening vulnerable people in Nevada's nursing homes, assisted-living, long-term care, and other congregate facilities. More than half the positive test results were false.

On October 8, the U.S. Department of Health and Human Services (HHS) sent a letter (https://skillednursingnews.com/wp-content/uploads/sites/4/2020/10/Final-Letter-and-Attachment-Responding-to-Nevada-Bulletin-SIGNED-10.8.20.pdf) threatening that the Nevada officials' action was "inconsistent with and preempted by federal law and, as such, must cease immediately or appropriate action will be taken against those involved." Nevada yielded to this threat and, on October 9, removed its directive to stop using the tests (http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Resources/Removal%20of%20Directive%20to%20Discontinue%20Use%20of%20Antigen%20POC_10.09.2020.pdf).

HHS highlighted that Nevada questioned the false positives, but not the false negatives, as if this were a flaw in Nevada's analysis. False negatives are a serious concern when screening for and controlling infectious disease. False negative results tell people who have the disease that they do not have it, which might lead them to continue contacts that expose others to a potentially deadly disease. False positives, on the other hand, seem to err on the side of caution. After all, what could be the harm of needlessly quarantining healthy people for a couple of weeks, just to make sure?

When caving to HHS's threat on October 9, Nevada explained why false positives matter. In a nursing home or other congregate living facility, false positives consign vulnerable-but-healthy people to be moved into wards with known COVID-19 cases. Once there, people who were falsely positive can become truly infected and, possibly, die. Nevada was trying to protect its elderly and vulnerable patients from that fate. HHS ordered them to stop.

HHS asserted it could do so under the Public Readiness and Emergency Preparedness – or PREP – Act of 2005. The PREP Act authorizes the Secretary of HHS to provide liability protection to manufacturers, health care providers, and other "covered persons" when they are responding to a declared public health emergency. The Secretary grants this protection by publishing a declaration in the Federal Register, which recommends covered countermeasures (activities to address the emergency, such as manufacturing or administering tests) that will receive this immunity from lawsuits.

Protecting against liability is all the PREP Act does. It is not a general public health law. To trigger the federal government's more general public health powers during an emergency, the Secretary must make a separate determination under Section 319 of the Public Health Service Act, which Secretary Alex Azar did on January 31 (https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx). The PREP Act declaration appeared in the Federal Register on March 17 (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-

readiness-and-emergency-preparedness-act-for-medical-countermeasures), with amendments in April (https://www.federalregister.gov/documents/2020/04/15/2020-08040/amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical), June (https://www.federalregister.gov/documents/2020/06/08/2020-12465/second-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for), and August (https://www.federalregister.gov/documents/2020/08/24/2020-18542/third-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical).

HHS's October 8 letter made a sweeping statement that "PREP Act coverage preempts any state or local provision of law or legal requirement that prohibits … licensed health-care practitioners from administering or prescribing FDA-authorized COVID-19 tests …" It cited a May HHS Advisory Opinion (https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf) as its authority. There are several problems with this argument: The Advisory Opinion dealt with unrelated subject matter, contained a major factual inaccuracy — it assumed that the March PREP Act declaration authorized pharmacists to administer COVID-19 tests when, in fact, this was done in a later HHS guidance document (https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf) — and acknowledged that, as an opinion, its advice was legally non-binding.

Therein lies the rub: The PREP Act preempts state law only if the state law is different from or in conflict with a federal *requirement* (https://www.law.cornell.edu/uscode/text/42/247d-6d). If there is no federal requirement, there can be no preemption. Guidance documents, by definition, are non-binding and cannot establish federal legal duties or requirements. The Supreme Court settled years ago that federal guidance documents do not preempt state law (https://www.supremecourt.gov/opinions/08pdf/06-1249.pdf). Neither do non-binding Advisory Opinions that accord preemptive effect to non-binding guidance documents.

In the Nevada case, HHS used an August 31 guidance document (https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf) to announce its policy on PREP Act coverage for COVID-19 screening tests at nursing homes and assisted-living, long-term care, and other congregate facilities. This guidance discussed the kinds of FDA-authorized COVID tests that Nevada's public health officials found wanting. Yet states are free to do whatever they think best in response to non-binding federal guidance documents.

By using guidance documents, HHS failed to trigger the PREP Act's preemption provision. Guidance documents let agencies act swiftly, which is useful in an emergency, but they do not establish federal legal requirements that can preempt state law.

The PREP Act foresaw this problem and specifically mentions interim final rules — binding federal regulations that go into effect at once — for emergency situations where the usual process for making new regulations would take too long. And yet, HHS chose to fight the COVID-19 pandemic with guidance documents.

The PREP Act *could* preempt Nevada's actions if the Food, Drug, and Cosmetic Act established a federal requirement that is different from or in conflict with what Nevada did. But while the FDA has for decades described its role as to decide which medical products will be available for physicians to

order or prescribe, it carefully avoids regulating medical practice, which is a traditional state responsibility. In fact, section 1006 of the Food, Drug, and Cosmetic Act expressly bars the FDA from interfering with physicians' best judgment in deciding whether a given medical device is in the patient's best interest.

The fact that the FDA authorizes emergency use of a COVID-related countermeasure in no way implies that the FDA has established a federal requirement that physicians *must* use it. Nevada's directive that certain tests were too inaccurate to use in congregate care facilities was not different from or in conflict with any "requirement applicable to the covered countermeasure … under the Federal Food, Drug, and Cosmetic Act (https://www.law.cornell.edu/uscode/text/42/247d-6d)."

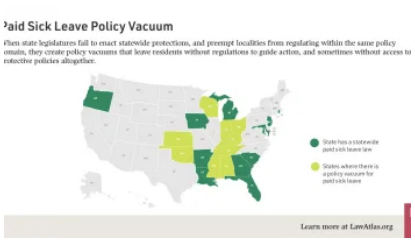
HHS's recent interference with Nevada's public health directive was an inappropriate exercise of the federal power to preempt state laws, yet another misstep placing vulnerable lives at risk.

Barbara J. Evans, Ph.D., J.D., LL.M., is Professor of Law and Stephen C. O'Connell Chair at the University of Florida Levin College of Law and Professor of Engineering at UF's Wertheim College of Engineering. evans@law.ufl.edu (mailto:evans@law.ufl.edu)

Ellen Wright Clayton, J.D., M.D., is Craig-Weaver Professor of Pediatrics, Professor of Law, and Professor of Health Policy at Vanderbilt University Medical Center and the Vanderbilt University School of Law.

Views expressed are authors' personal views and not views of their institutions or funders.

(https://blog.petrieflom.law.harvard.edu/2020/12/21/covid-public-health-preemption/)



(https://blog.petrieflom.law.harvard.edu/2020/03/16/preemp

(https://blog.petrieflom.law.harvard.edu/2020/06/01/mexico-global-responses-covid19/)

COVID-19 Unmasks Issues Around Public Health Preemption (https://blog.petrieflom.law.harvard.edu/2020/12/21/covid-public-health-preemption/)

tion-paid-leave-and-the-health-of-america/)
Preemption, Paid Leave, and the Health of America (https://blog.petrieflom.law.harvard.edu/2020/03/16/preemption-paid-leave-and-the-health-of-america/)

Human Rights at Risk During the Response to the COVID-19 Pandemic in Mexico (https://blog.petrieflom.law.harvard.edu/2020/06/01/mexico-global-responses-covid19/)

alex azar (https://blog.petrieflom.law.harvard.edu/tag/alex-azar/)

coronavirus (https://blog.petrieflom.law.harvard.edu/tag/coronavirus/)

coronavirus pandemic (https://blog.petrieflom.law.harvard.edu/tag/coronavirus-pandemic/)

COVID-19 (https://blog.petrieflom.law.harvard.edu/tag/covid-19/)

covid-19 testing (https://blog.petrieflom.law.harvard.edu/tag/covid-19-testing/)

COVID19 (https://blog.petrieflom.law.harvard.edu/tag/covid19/)

health and human services (https://blog.petrieflom.law.harvard.edu/tag/health-and-human-services/)

HHS (https://blog.petrieflom.law.harvard.edu/tag/hhs/)

Nevada (https://blog.petrieflom.law.harvard.edu/tag/nevada/)

Preemption (https://blog.petrieflom.law.harvard.edu/tag/preemption/)

PREP act (https://blog.petrieflom.law.harvard.edu/tag/prep-act/)

THE PETRIE-FLOM CENTER STAFF (HTTPS://BLOG.PETRIEFLOM.LAW.HARVARD.EDU/AUTHOR/PETRIEFLOM/)

The Petrie-Flom Center staff often posts updates, announcements, and guests posts on behalf of others.

LEAVE A REPLY

You must be logged in (https://blog.petrieflom.law.harvard.edu/wp-login.php?redirect_to=https%3A%2F%2Fblog.petrieflom.law.harvard.edu%2F2020%2F10%2F22%2Ffederal-covid19-response-nevada-preemption%2F) to post a comment.

This site uses Akismet to reduce spam. Learn how your comment data is processed (https://akismet.com/privacy/).

‹ Compulsory Licensing for Pharmaceuticals in the EU: A Reality Check (https://blog.petrieflom.law.harvard.edu/2020/10/21/compulsory-licensing-eu-pharma/)

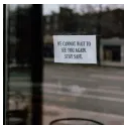
Black Men Carry the Cost of Police Violence › (https://blog.petrieflom.law.harvard.edu/2020/10/22/racism-police-violence-black-men/)

Search...

MOST POPULAR

(https://blog.petrieflom.law.harvard.edu/2020/09/15/covid19-vaccine-mandate-compulsory/) Why a COVID-19 Vaccine Shouldn't be Mandatory (https://blog.petrieflom.law.harvard.edu/2020/09/15/covid19-vaccine-mandate-compulsory/)
by Dorit Reiss (https://blog.petrieflom.law.harvard.edu/author/doritreiss/)

(https://blog.petrieflom.law.harvard.edu/2017/12/08/islam-and-the-beginning-of-human-life/) Islam and the Beginning of Human Life (https://blog.petrieflom.law.harvard.edu/2017/12/08/islam-and-the-beginning-of-human-life/)
by ylenfest (https://blog.petrieflom.law.harvard.edu/author/ylenfest/)



(https://blog.petrieflom.law.harvard.edu/2020/11/30/covid-vaccine-eua-mandate-business/) Under an EUA, Can Businesses Require Employees and Customers to Get Vaccinated? (https://blog.petrieflom.law.harvard.edu/2020/11/30/covid-vaccine-eua-mandate-business/)
by Dorit Reiss (https://blog.petrieflom.law.harvard.edu/author/doritreiss/)

(https://blog.petrieflom.law.harvard.edu/2020/08/27/moderna-covid19-vaccine-government-funding/) How Does Moderna's COVID-19 Vaccine Work, and Who Is Funding Its Development? (https://blog.petrieflom.law.harvard.edu/2020/08/27/moderna-covid19-vaccine-government-funding/)
by The Petrie-Flom Center Staff (https://blog.petrieflom.law.harvard.edu/author/petrieflom/)

(https://blog.petrieflom.law.harvard.edu/2020/04/14/coronavirus-negligence-liability-for-covid-19-transmission/) Coronavirus Negligence: Liability for COVID-19 Transmission (https://blog.petrieflom.law.harvard.edu/2020/04/14/coronavirus-negligence-liability-for-covid-19-transmission/)
by Shelly Simana (https://blog.petrieflom.law.harvard.edu/author/ssimana/)

GET OUR NEWSLETTER

SUBSCRIBE NOW (HTTP://PETRIEFLOM.WPENGINE.COM/SIGN-UP-FOR-THE-PETRIE-FLOM-CENTER-

HOT TOPICS

Select Category

ARCHIVES

Select Month

POWERED BY

(http://petrieflom.law.harvard.edu/)

PAGES

About Bill of Health (https://blog.petrieflom.law.harvard.edu/about/)

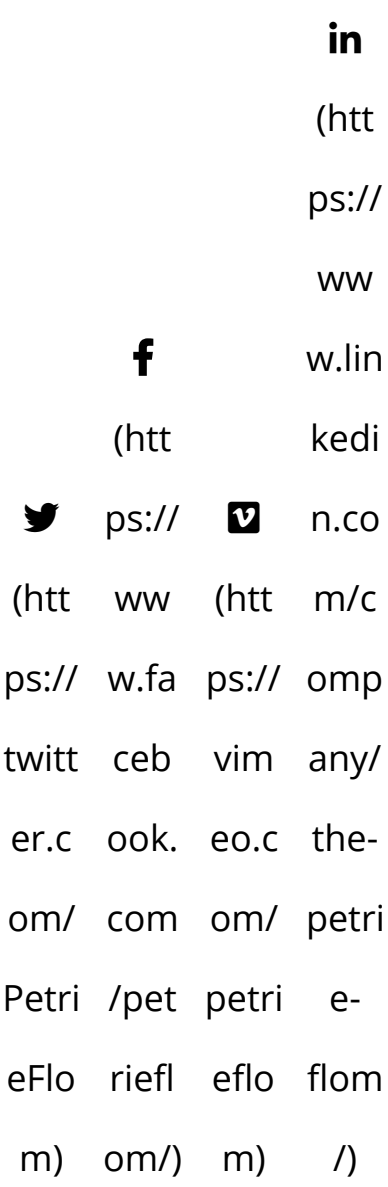
Policies (https://blog.petrieflom.law.harvard.edu/policies/)

Symposia (https://blog.petrieflom.law.harvard.edu/symposia/)

SIGN UP FOR OUR NEWSLETTER

SUBSCRIBE (HTTP://PETRIEFLOM.WPENGINE.COM/SIGN-UP-FOR-THE-PETRIE-FLOM-CENTER-NEWSLETTER/)

FOLLOW US


(https://www.linkedin.com/company/the-petrie-eflom/)
(https://www.facebook.com/petrieflom/)
(https://vimeo.com/petrieflom)
(https://twitter.com/PetrieFlom)