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Fostering states as laboratories

thehill.com/opinion/healthcare/519191-we-should-promote-the-use-of-states-as-laboratories

Myrisha S. Lewis, opinion contributor

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By Myrisha S. Lewis, opinion contributor — 10/01/20 07:00 PM EDT

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As the COVID-19 pandemic has evolved in the United States, state and local actions continue to stand in stark contrast to the federal government's. While the federal response has been characterized as a dispute between scientific facts and political preferences, many states are showing us the way forward. After the pandemic is over, as America continues innovating and resolving jurisdictional and practical challenges related to health care and medicine, including innovative therapies that straddle the line between state and federal jurisdiction, we should consider increasing the role of state governments.

During the coronavirus pandemic, states have played important roles in the absence of federal leadership during this pandemic, including through the use of contact tracing, masking requirements, quarantines, and frequent public health briefings. States' historically significant health care roles have become smaller with the expansion of the many operating divisions of the U.S. Department of Health and Human Services. Yet, despite the primacy of federal law in areas like drug regulation, states' longstanding powers

shape medicine practice through the licensing of health professionals, medical malpractice law, and products liability regimes. States also have the advantage of being closer to patients, although they certainly need more funding and aid in various forms.

States often complement the federal government's actions or inactions. Several states used budgetary allocations or even created specific agencies to fund stem cell research after the federal funding ban announced during President George W. Bush's administration. Some states have also enacted legislation related to informed consent and human subjects protection. Other states, including Texas and Florida, have been criticized for their markets in stem cell treatments, which still exist in the absence of federal regulation. Each of these states, and many others, can benefit from a more cooperative, shared federal-state regulatory system.

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Before the pandemic, at a gathering of former FDA Chief Counsels, one former Chief Counsel noted (at 48:27) the challenges of emerging technologies for the agency, including the “jurisdictional and practical challenges of selling gene therapy” and how that related to the agency's current statutory authorizations. States and the federal government already cooperate in many areas, including Medicaid, governmental responses to infectious disease, and food regulation. A more cooperative framework for innovative therapies could improve regulatory transparency, increase oversight, and facilitate the discovery of adverse effects.

Political and social views in each state will continue to carry weight in medicine and innovation regulation. States also face many of the same challenges as the federal government, such as funding shortages, the possibility of regulatory capture by interested entities, and political influences on decision-making. Yet increasing the states' role through a more cooperative framework could improve the diversity of viewpoints in the regulatory system in a meaningful way.

Political scientists and lawyers often quote former Supreme Court Justice Louis Brandeis' “states as laboratories” line from *New State Ice Co. v. Liebmann*: “It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.” In the COVID-19 context, states are certainly operating in a way that fulfills that metaphor. Numerous lessons and changes are stemming from the pandemic, such as improvements in access to and coverage of telehealth when the public and the public health system shift back to focusing on non-COVID-19 concerns, the expertise and work of state health actors may be worth leaning on in other health care situations as well.

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