CITIZEN SCIENCE:
THEORY AND PRACTICE

State Regulation of Biomedical Citizen Science

COLLECTION: BIOMED

ESSAY

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ABSTRACT

Much of the analysis of the public health legal and regulatory mechanisms that potentially apply to biomedical citizen science activities in the United States has focused on the federal government, including US Food & Drug Administration (FDA) and human subjects research requirements. But US state governments have authorities that intersect with, and sometimes extend beyond, federal regulators' powers—such as through state medical practice statutes—and these state authorities might reach certain biomedical citizen science activities. For example, in 2019, California both enacted a "CRISPR law" requiring sellers of gene therapy kits to inform consumers that such kits "are not for self-administration," and through its Department of Consumer Affairs, launched an investigation of a well-known biohacker for "unlicensed practice of medicine" under existing law.

Building on legal analyses of state efforts to regulate establishment science, this essay explores ways that state governments might regulate biomedical citizen science activities and associated bodily autonomy—something that states may become increasingly interested in as biomedical citizen science efforts proliferate and intersect with state efforts to regulate bodily autonomy (for example, in the context of abortion). It also explores implications for those engaged in biomedical citizen science, including the fact that even when state regulatory efforts are not enforced or are successfully challenged, they are important because they can still influence federal policy.

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INTRODUCTION

Interest in biomedical citizen science—also known as biohacking, open science, do-it-yourself (DIY) science, community biology, independent science, non-traditional biology, and non-establishment science (Guerrini et al. 2019)—is growing. This growth may have accelerated in response to the COVID-19 pandemic (Caplan and Bateman-House 2020; Evans 2020; Guerrini et al. 2020; Shah and Jamrozik 2020). For instance, Just One Giant Lab (JOGL), a nonprofit web platform that provides a virtual "laboratory," launched its OpenCOVID-19 initiative in March 2020 that includes projects ranging from efforts to validate mask effectiveness to building ventilators to developing testing (Rasmussen et al. 2020). As another example, several groups have continued to work to create do-it-yourself COVID-19 vaccines (Estep and Church 2020)—with the goal, in the words of such one group, of creating an "open-source" vaccine, "freely-available to all (RadVac)."

Alongside hope (and hype) that biomedical citizen science might further scientific understanding, yield innovations, or provide access where traditional science historically has not, there are important questions about what legal and regulatory mechanisms could and should apply to these activities. In the United States, much of the focus has been on the federal government's authorities. In particular, in the public health context, analyses have focused on the US Food & Drug Administration (FDA), federal human subjects research requirements, and to some extent patent law—and the roles those legal and regulatory regimes can play in mitigating the risks of citizen science while allowing for, and increasing, its potential benefits and ability to produce innovation (Evans BJ 2021; Mehlman 2021; Zettler Guerrini and Sherkow 2019).

This essay observes that state governments have authorities that intersect with federal regulators' powers (beyond the potential for private regulation through state tort law that has been discussed elsewhere [Guerrini et al. 2020]). States may regulate biomedical citizen science through statutes or regulations that the government enforces, such as state medical practice or food and drug statutes, new laws or regulations enacted specifically to regulate citizen science, or general statutes or regulations that, on their face, may have little obvious relationship to citizen science. Such authorities might be able to reach biomedical citizen science activities even in some instances when federal regulators cannot—or when federal regulators do have jurisdiction, but decline to enforce their authorities. Moreover, even when such state regulatory efforts are not enforced, are successfully challenged, or are otherwise limited in direct impact, they can still influence federal policy.

It is worth clarifying the scope of this essay at the outset. First, it focuses on statutes and regulations—in other words, requirements with the force of law—that are enforced by state governments. The potential application of state tort law to biomedical citizen science activities, while an important issue, is generally outside the scope of this essay because tort law is enforced through lawsuits brought by private parties, not governments (Guerrini et al. 2020). Second, local governments, such as cities or states, may already be, or may become, interested in regulating biomedical citizen science or bodily autonomy, just as states are. For example, in recent years, cities such as Denver, Santa Cruz, Oakland, and Ann Arbor, have been some of the first government bodies in the United States to take steps to decriminalize the possession and use of certain psychedelics (Marks 2020; Marlan 2019; Zettler 2021). However, this essay focuses primarily on requirements enforced by state, rather than local, governments, and the resulting intersection of state and federal authorities.

FEDERAL AND STATE POWER

As a preliminary matter, it is helpful to consider the reach, and limits, of the authority of US states. The Tenth Amendment of the US Constitution provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States."[1] Under the Tenth Amendment, and US states' so-called police powers, states generally have wide latitude to protect people's health, safety, and welfare. It is these police powers that enable states to enact many statutes potentially relevant to biomedical citizen science communities, such as laws defining and regulating the practice of medicine.

At the same time, the US Constitution gives the federal government quite broad powers of its own, such as the power to regulate interstate commerce. And states are not free to eliminate federal requirements, even under their police powers (Zettler 2017). Accordingly, if a state law were to pass a law purporting to permit pharmaceutical companies to sell new drugs in interstate commerce without FDA approval, that would not change the fact that those companies are required, under federal law, to obtain FDA approval before engaging in such conduct.

Moreover, under the US Constitution, federal law is the "supreme Law of the Land."[2] This means where federal and state law conflict, federal law preempts state law, and the state law is without effect (Lewis 2020; Noah 2016; Sharkey 2015; Zettler 2017). There are several theories under which a court can conclude that federal law preempts state law. "Express preemption" occurs when the federal

statute at issue includes explicit language indicating that Congress intended to displace relevant state law. A court might also conclude that a federal statute lacking such an express provision preempts state law under several theories of implied preemption. Implied "field preemption" occurs when Congress intended the federal government to wholly occupy an area of regulation, though courts are often reluctant to find field preemption in the context of biomedical regulation absent some connection to foreign commerce (such as when state law purports to allow the importation of drugs lacking FDA approval) (Zettler 2017). Implied "conflict preemption" occurs either when it is impossible for parties to comply with both state and federal law (known as "impossibility preemption"), or when compliance is technically possible, but state law poses an obstacle to the full execution of the purposes of federal law (known as "obstacle preemption"). Importantly, courts are the ultimate arbiters of whether any particular law is preempted. That is, preemption is not automatic—a party must successfully challenge a state law on one of these preemption theories for a state law to be struck down.

OPTIONS FOR STATE REGULATION OF BIOMEDICAL CITIZEN SCIENCE

Against this background, this section considers three examples of ways that states might regulate biomedical citizen science—medicine- or public health-related statutes or regulations, such as state medical practice statutes or state food and drug statutes; newly enacted statutes or regulations specifically designed to regulate aspects of biomedical citizen science; and general statutes or regulations, such as consumer protection laws, that may seem at first glance unrelated to citizen science—and explores the lessons that might be learned from each.

MEDICAL PRACTICE AND STATE FOOD AND DRUG REQUIREMENTS

One means for states to regulate certain biomedical citizen science activities may be under laws motivated by health or public health concerns, such as medical practice and state food and drug statutes. These laws might allow states to reach conduct that federal regulators, like FDA, may not be able reach under their existing authority. For example, distributing instructions for making an epinephrine autoinjector at home—without distributing any materials for the product—generally falls outside of FDA jurisdiction, because FDA typically regulates products (Guerrini, Sherkow, and Zettler 2021). Such conduct, however, might constitute the unlicensed practice of medicine under state statutes, which typically define medical practice to include prescribing or providing treatments for diseases or conditions, like severe allergic reactions (Zettler 2017). To be fair, state medical boards are often responsible for bringing enforcement actions against those engaged in the unlicensed practice of medicine, and concerns that state medical boards may rarely take enforcement actions in other contexts have been raised (McIntosh T et al. 2021). Additionally, state medical boards, as a practical matter, may be limited in their ability to discover relevant biomedical citizen science activities, and when activities are limited to providing information, as with the epinephrine autoinjector example, courts might judge those activities to have some constitutional protection.[3] But state use of medical practice statutes to reach biomedical citizen science is not purely speculative—there is at least one example of a state doing so. In 2019, California's Department of Consumer Affairs launched an investigation of a well-known biohacker for "unlicensed practice of medicine" (though the investigation that did not lead to any enforcement action) (Brown 2019).

Beyond prohibiting unlicensed practice of medicine, medical practice statutes and regulations can also govern how medical care is provided—such as through imposing restrictions on the prescribing or dispensing of drugs—and sometimes states use medical practice requirements as avenues to regulate socially contested issues involving bodily autonomy. When such state regulatory efforts restrict access to health care, they may push more people to become interested in non-establishment routes to obtaining their care, such as through biomedical citizen science. For example, even before the Supreme Court's June 2022 decision in *Dobbs v. Jackson Women's Health Organization* that eliminated a right to abortion grounded in the US Constitution,[4] numerous states had restricted access to medication abortion through medical practice statutes (Zettler and Sarpatwari 2022). And now, after *Dobbs*, many states are implementing near-complete bans on abortion, often through prohibiting any person, including physicians, from providing another person abortion procedures or medications (Cohen, Donley, and Rebouche 2023). Alongside these legal developments, interest in self-managed abortion and DIY manufacturing of abortion medications seems to be increasing (Regalado 2022; Four Thieves 2022) It is easy to imagine that states seeking to limit abortion access will look to use general prohibitions on providing abortion care to limit biomedical citizen science activities in that space as well—and similar things may occur in other areas of health care where states act to limit the availability of drugs or health care through establishment routes.

Another possibility would be that states would rely on their state food and drug laws to reach certain biomedical citizen science activities. These state laws generally mirror

requirements that also exist in the Federal Food, Drug, and Cosmetic Act. But the terms of the Federal Food, Drug, and Cosmetic act are such that FDA's jurisdiction is often limited to things that have been distributed across state lines, or that contain a component or ingredient that has crossed state lines at some point (Hutt et al. 2022). Thus, state food and drug acts might allow states to reach certain intrastate conduct that falls outside FDA's purview, such as biomedical citizen science with plant-based drug products that could be made and distributed wholly intrastate.

That said, purely intrastate conduct may be rare and, thus, in contrast to state medical practice statutes, state food and drug acts may only rarely allow states to reach activities that FDA cannot already regulate. Perhaps more importantly, then, states might be interested in regulating pursuant to their state food and drug statutes in instances where FDA is declining to enforce its requirements or when a state is working with FDA. For example, many transcranial direct current stimulation (tDCS) products—products that provide a low level of electrical current to the brain, and are described as both treating disease and enhancing wellness or performance—likely fall within FDA's device jurisdiction (Wexler 2015; Zettler 2016). But FDA has not clearly and publicly asserted authority over the products, nor has it taken significant steps to enforce its own device requirements on those distributing the products. California's Department of Health, however, investigated, and ultimately took enforcement action against, a distributor of kits for people to build their own tDCS devices after an FDA official alerted California to concerns about the company (Wexler 2015).

REQUIREMENTS SPECIFIC TO BIOMEDICAL CITIZEN SCIENCE

In addition to relying on existing laws or regulations related to health or public health concerns, states also might enact new laws, or state agencies might issue new regulations, directly aimed at biomedical citizen science activities. One possibility is that states would do this in response to concerns about biomedical citizen science, in an effort to reign in concerning activities. Again, this possibility is not speculative. In 2019, California enacted a "CRISPR law" requiring sellers of gene therapy kits to inform consumers that such kits "are not for self-administration."[5] In another example, albeit not one related to *biomedical* citizen science, in 2017, Wyoming enacted a statute that imposed criminal penalties for entering "open land," without permission, to collect data,[6] reportedly in response to citizen scientists collecting water samples on open lands and showing that certain bodies of water were contaminated with *e. coli* bacteria (Keller 2017). Although a federal court ultimately struck down the law after it was challenged,[7] the law is, nevertheless, an example of state interest in regulating through a statute specifically enacted to address citizen science.

While state requirements that exceed or add to federal requirements, like California's CRISPR law, might be preempted in certain circumstances or struck down for other reasons as was the case with Wyoming's law, state and federal regulation can and do coexist in numerous circumstances (Zettler 2017). Moreover, sometimes states' imposition of stricter or additional requirements, whether those laws are successfully challenged as preempted or not, seems to motivate federal regulators or lawmakers to likewise explore stricter policies. For example, in 2004, California enacted requirements stricter than those at the federal level with respect to supply chain security for pharmaceuticals, which seemed to lead to changes to federal law, enacted in 2013, to give FDA more authority in this space (Zettler 2017).

A second possibility is that states would seek to enact laws that open the door wider to biomedical citizen science, in ways federal regulators have not expressly done. There is a long history of state efforts to be more permissive than the federal government, albeit in areas that may not be conventionally understood to be about biomedical citizen science. For example, California passed the first "medical marijuana" state law in 1996, and now dozens of states have such laws, with adult-use or recreational marijuana laws also spreading at the state level (Zettler 2017). In the past few years, states and cities also have started to pass, or consider, similar laws for certain psychedelics (Smith and Applebaum 2021). As noted above, these state laws that are more permissive than federal law cannot eliminate federal requirements—it remains federally illegal throughout the United States to possess cannabis, for example. Notably, however, while federal law has not changed to formally permit cannabis possession, state laws have driven the federal government to exercise its discretion not to enforce federal prohibitions in certain circumstances, and spurred proposals to change federal law.[8]

Indeed, beyond influencing federal regulators' enforcement choices, more permissive state laws can drive Congress to change federal law, just as more restrictive state laws have done. Terminally and seriously ill patients have, for decades, had a pathway under FDA regulations for receiving unapproved drugs outside clinical trials for treatment purposes, known as expanded access. Although FDA authorizes the overwhelming majority of the expanded access requests it receives (~99%) and often within days or hours (Fernandez Lynch et al. 2020), in 2014, Colorado passed the first "right to try" law purporting to create a pathway for drug companies to distribute, and terminally ill

patients in Colorado to access, unapproved drugs without FDA's authorization. Between 2014 and 2018, 40 more states passed such laws, but as with cannabis, these laws could not, and did not, eliminate the federal requirement for FDA authorization of non-trial preapproval access. In May 2018, however, Congress amended the Federal Food, Drug, and Cosmetic Act to create a federal "right to try" pathway. Although both ethicists and patient advocacy groups have been critical of the "right to try" pathway for numerous reasons (Bateman-House and Robertson 2018; Fernandez Lynch et al. 2020), the "right to try" story does demonstrate how state laws more permissive than federal law, even though they cannot actually eliminate federal requirements, have the potential to ultimately lead to changes in federal law.

GENERAL REQUIREMENTS NOT MOTIVATED BY HEALTH OR BIOMEDICAL CITIZEN SCIENCE CONCERNS

Although perhaps a less obvious option than medical practice, state food and drug, or citizen science-specific requirements, states also might turn to general statutes or regulations already on the books to regulate biomedical citizen science. For instance, states might employ general consumer protection laws to reach biomedical citizen science activities, to the extent products are being sold to consumers without evidence of effectiveness. New York, among other states, has relied on consumer protection law to take action against stem cell clinics marketing unproven interventions (Richardson 2019).

Criminal law provides another example of where general state laws might be employed to reach biomedical citizen science activities, if the government were motivated to do so. For example, in 2015, a person was indicted in Massachusetts for encouraging another person to die by suicide.[9] Although some states have laws that expressly address encouraging another person to die by suicide, Massachusetts did not have such an express law. Instead, the government asserted that the defendant, through verbally encouraging the other person to die by suicide, engaged in "wanton or reckless conduct" and thus was guilty of involuntary manslaughter, even though she was not present when the death actually occurred.[9] It is conceivable that a similar theory of involuntary manslaughter could be applied to certain biomedical citizen science activities if, for example, one person encouraged another to try an experimental, and ultimately deadly, intervention, when they knew or should have known the intervention was likely to cause the other person harm. (Likewise, one could imagine tort lawsuits brough by the injured person, or their family, in such circumstances; however, as noted above, the focus of this essay is on government-enforced requirements.)

IMPLICATIONS FOR BIOMEDICAL CITIZEN SCIENCE

At a minimum, those engaged in biomedical citizen science in the United States should be aware that federal regulators are not the only regulators that might have authority over their activities. States governments may also have power to regulate at least some biomedical citizen science activities, as they have power to regulate aspects of establishment science. In other words, just as federalism is a fixture in the legal and regulatory structures for establishment science and health care (Wiley et al 2021), so too should it be understood to be part of the regulatory landscape for biomedical citizen science.

As biomedical citizen science continues to grow, including in contested spaces of bodily autonomy like abortion and patients' abilities to access unapproved interventions for serious or terminal illness, states might become more interested in regulating in the biomedical citizen science space, in ways both more strict and more permissive than federal law. This state interest, in turn, could play an important role in shaping federal policy (Zettler 2017). Increased state interest might be something some in citizen science communities will welcome, particularly if citizen science communities feel better able to influence policies at the state level (Trejo M et al 2021). State oversight, however, also might contribute to confusion about what requirements do and do not apply to citizen science activities. Moreover, engagement with state regulators, who may not have significant scientific expertise in relevant areas, might not have the same informational and scientific benefits for citizen science communities as engagement with expert regulators like FDA might (Guerrini, Pearlman, and Zettler 2021).

CONCLUSIONS

US state governments might be able to reach many of the same, and in some circumstances different, biomedical citizen science activities as the US federal government might be able to reach. States might become increasingly interested in regulating in this space, as aspects of biomedical citizen science intersect with contested social questions about bodily autonomy. Additionally, state efforts, even when they are successfully challenged, not enforced, or otherwise not directly impacting biomedical

citizen science activities, have the potential to influence federal policy. Thus, state efforts might have an important role in shaping both biomedical citizen science communities and the federal regulatory regimes that ultimately govern them.

NOTES

1 US Const. amend. X.

2 US Const. art. VI cl. 2.

3 A recent court decision concluded that legal advice, provided by people who are not licensed to practice law, may be speech protected by the First Amendment. *Upsolve, Inc. v. James* (May 24, 2022 S.D.N.Y.). This decision might—or might not—signal that states may face challenges in the future if they bring enforcement actions against people unlicensed to practice to medicine solely for providing medical advice.

4 *Dobbs v Jackson Women's Health Organization*, _ US _ (June 24, 2022).

5 Cal. Bus. & Prof. Code Ann. § 22949.50 (2020).

6 Wyo. Stat. Ann. § 6-3-414.

7 A federal district court concluded that the Wyoming law was a content-based restriction on speech and expression, because it only prohibited those interested in data collection from entering open lands, and the law was not sufficiently narrowly tailored to avoid violating people's First Amendment rights under the US Constitution. *W. Watersheds Project v. Michael*, 353 F. Supp. 3d 1176 (D. Wyo. 2018).

8 See, for example, Marijuana Opportunity Reinvestment and Expungement Act, H.R. 3617, 117th Congress (2021–2022).

9 *Com. v. Carter*, 52 N.E.3d 1054 (2016).

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