

# Continuous Reproductive Surveillance

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**Abstract:** The *Dobbs* opinion emphasizes that the state's interest in the fetus extends to "all stages of development." This essay briefly explores whether state legislators, agencies, and courts could use the "all stages of development" language to expand reproductive surveillance by using novel developments in consumer health technologies to augment those efforts.

In the shadow of *Dobbs v. Jackson Women's Health Organization*, many have lamented a return to life before *Roe v. Wade*. Yet, while some courts and state legislatures march reproductive rights backward, technology continues its relentless progress forward. Indeed, the United States looks different than in 1973 when *Roe* was decided, but in some ways, it is still mired in its past. Generalized reproductive surveillance and control remain, especially against marginalized communities.<sup>1</sup> Digital trails, including Google searches, have been used to prosecute suspicious miscarriages, even before *Dobbs*.<sup>2</sup> Consumer health technologies create new risks as restrictions target earlier stages of gestation.<sup>3</sup> The Internet, social media, and an inescapably digital economy mixed with the predictive power of large datasets offer additional avenues for pregnancy identification and monitoring yet to be explored at scale.<sup>4</sup> And if history is a guide, those most at risk for augmented surveillance and enforcement in the future will be those who have long experienced the disproportionate effects of systemic racism and classism regardless of the Supreme Court's formal position on abortion.<sup>5</sup>

Looming in the periphery of these observations is not simply whether modern technologies can identify a pregnancy.<sup>6</sup> A more difficult hypothetical is: will state governments use these tools to promote their expanded interest in the fetus, which the *Dobbs* opinion emphasizes repeatedly encompasses "all stages of development?"<sup>7</sup> Unfortunately, whether and how a state could do so is somewhat ambiguous from both a legal and technological standpoint. In this essay,

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we briefly explore whether state legislators, agencies, and courts could use the “all stages of development” language as a vehicle to expand reproductive surveillance in the name of public health, perhaps with the assistance of consumer technologies. We then turn to a legal argument against these measures and conclude with commentary on the utility of considering such extreme hypotheticals in the fight to achieve reproductive justice.

Consider a thought experiment based on real legal and scientific developments to frame the discussion. Say a fictional state legislature seeks to define life as beginning at fertilization and to protect those fertilized eggs with “the same laws protecting other human beings.”<sup>8</sup> However, fertilization is not a point that any

While extending this logic to continuous reproductive surveillance might seem unthinkable at first, the law already tolerates invasive systematic monitoring programs as a requirement to obtain certain medications. One example at the federal level is the Risk Evaluation and Mitigation Strategy (REMS)<sup>13</sup> for Isotretinoin — a drug used to treat severe acne. Isotretinoin causes severe congenital malformations.<sup>14</sup> To help reduce fetal exposure to Isotretinoin, the Food and Drug Administration (FDA) requires patients who can become pregnant to take mitigation steps monitored by a centralized system, regardless of dose or duration. Before initiating treatment, a patient must have two negative pregnancy tests at specified intervals, one negative test every month during treatment, and

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*in vivo* medical test can establish. While we can identify ovulation and the period shortly after the placenta begins developing (after implantation), the point at which the sperm meets the egg remains elusive.<sup>9</sup> However, recent research reveals that digital self-monitors — like the Oura Ring, a commercially available consumer wearable — may be able to detect pregnancy significantly earlier than any existing urine- or hormone-based pregnancy test through continuous temperature monitoring.<sup>10</sup> In this hypothetical, the fictional state seeks to require a continuous temperature monitor to protect its interest in the fetus at all stages of development, beginning as close to the point of fertilization as technologically achievable.

The immediate answer to whether an effort like this could withstand legal challenge is unclear, but public health law may provide some justification. Typically, the government does not have the authority to force citizens to forgo bodily integrity and autonomy, even for the protection of others.<sup>11</sup> Instead, public health mandates often incentivize people to adopt the government’s desired measures. For example, while the state cannot force vaccinations upon residents, parents are incentivized to inoculate their children through restrictions on school attendance if they are unvaccinated without a statutory exemption.<sup>12</sup>

one following the last dose, conducted by an approved (CLIA-certified) laboratory. Among other stipulations, the REMS requires that patients use two forms of contraception from an enumerated list, which are also entered into the REMS website every month and validated by the prescriber, along with a monthly quiz and attestation.<sup>15</sup>

The Isotretinoin REMS shows that a scheme designed to effectuate continuous reproductive surveillance of the type we contemplate in this essay already exists and is acceptable as a balanced compromise to ensure access to an important but nevertheless fetal-harming (in this case, teratogenic) medication. As a result, it is important to probe whether states could use a program like this as a template for expanded control and monitoring in other circumstances, augmented by advancements in reproductive science and consumer technology. With this in mind, we can add specificity to our thought experiment using the example of methotrexate — a drug commonly used for rheumatoid arthritis. Methotrexate is also an abortifacient.<sup>16</sup> As a result, pharmacists have refused to fill prescriptions in states prohibiting abortion or creating sufficient ambiguity about liability.<sup>17</sup> In our fictional scenario, a state defining life as beginning at fertilization could propose that the methotrexate patient use a

wearable capable of continuous temperature monitoring. Such continuous monitoring through a consumer wearable could further the state's interest in protecting the fetus. And, for states that criminalize abortion at the earliest stages or outlaw it completely — or even seek fetal personhood — these data may be critical for physicians and pharmacists wary of prosecution due to prescribing and dispensing fetal-harming medication. Thus, a state could frame such a requirement as a tailored protective measure that furthers all interests while still enabling access to dangerous medications.

Importantly, this would go beyond FDA requirements for dispensing methotrexate.<sup>18</sup> The degree to which a state can introduce additional safety measures is somewhat unclear, highly fact-specific, and currently in flux.<sup>19</sup> The state would almost certainly categorize compulsory reproductive surveillance as an extra precaution to prevent harm, an interest it would likely assert is well within its police power authority.<sup>20</sup> To bolster their claim of authority, the state could also frame the law as one that regulates the practice of medicine and the distribution of medications through pharmacies, which has historically been included within the police power.<sup>21</sup> The question then is whether the compulsory reproductive surveillance is in conflict with the FDA's approval of a drug as safe and effective for public use.

As a general matter, under the Supremacy Clause, federal law will preempt state law if federal and state laws conflict.<sup>22</sup> Setting aside criminal law concerns, an outright ban on medication the FDA has approved for sale is a relatively clear conflict and, as a result, unlikely to survive a preemption challenge. However, courts may accept additional state protections under the auspices of safety and could consider the state measure in line with congressional and FDA objectives of protecting the public from preventable harm caused by drugs approved for public use.

Some case law supports a state's power to impose protective measures beyond those required by the FDA. For example, Massachusetts attempted to limit access to Zohydro, an opioid analgesic drug that is an extended-release (ER) formulation of hydrocodone (Zohydro ER).<sup>23</sup> While the drug was FDA-approved, the approval was controversial.<sup>24</sup> Massachusetts initially banned prescribing and dispensing Zohydro ER, but a district court enjoined this law as a matter of implied obstacle preemption, because the ban “interposed its own conclusion about Zohydro ER's safety and effectiveness,” contravening the FDA's congressionally granted authority.<sup>25</sup> Implied obstacle preemption occurs where the state law “stands as an obstacle to the accomplishment and execution of the full purposes

and objectives of Congress.”<sup>26</sup> Massachusetts then adjusted its strategy to focus on the traditional areas of state authority, regulating — but not prohibiting — the prescription and dispensing of the drug through mandated procedural steps and limiting who is authorized to dispense it. While the district court did note the possibility that the drug manufacturer could prove the regulations operated as an unlawful barrier to access, the court said the additional safety regulations were not facially invalid under obstacle preemption.<sup>27</sup>

In a subsequent case, the Supreme Court clarified that Congress preserved state law in its authorizing statutes for the FDA, especially for prescription drugs. In *Wyeth v. Levine*, the Court noted that when the state acts within traditional realms of police power authority, the presumption is that “the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>28</sup> Consequently, the Court held that FDA approval of a drug and its label did not provide a shield to tort claims under state law.<sup>29</sup> If both the state and federal requirements can be met, the preemption claim is much weaker.<sup>30</sup> Therefore, state laws related to fetal protection may not be deemed in conflict with — and, as a result, preempted by — federal law. Viewed in this light, the FDA may create a floor, but the Court will not necessarily assume it creates a ceiling for drug safety measures. And it is the ceiling that creates new cause for alarm in a post-*Dobbs* world.

It is not a foregone conclusion that the regime we propose in our hypothetical would survive legal challenges. While states are actively litigating the FDA's authority in the context of medication abortion at the time of writing,<sup>31</sup> plausible legal arguments counter increased intrusions into the reproductive lives of citizens in anti-abortion states. Congressional intent is central to preemption analysis, and in recent years, Congress has sought to expand the FDA's authority rather than limit it.<sup>32</sup> This includes areas where states have traditionally played a prominent or even primary role, such as regulating drug compounding.<sup>33</sup> The distinction between federal authority to regulate products and state authority to regulate the practice of medicine no longer appears to be the critical question, and, as Professor Patricia Zettler has demonstrated, this line has long been blurred.<sup>34</sup> Conflicting state laws have been struck down under preemption, even with claims that they are within the traditional sphere of police power.<sup>35</sup> As Professor Zettler observes, courts have been willing to look beyond how states explicitly frame their arguments about state police power to get at the “underlying intent of the regulatory efforts” and reach conclusions that they are implicitly “intended

to challenge particular aspects of the FDA's scheme." Thus, *Wyeth* may be more accurately considered an outlier, with subsequent cases avoiding the case or narrowing its holding.<sup>36</sup> A key element of these results is that Congress authorized the FDA to evaluate the risks and benefits of medications and determine what, if any, safety measures are needed in an effort to achieve national uniformity.

Hypothetical state efforts to restrict access to medications such as methotrexate unless allowing for continuous reproductive surveillance would undoubtedly frustrate national uniformity and create conflict with the FDA's assessment of risks and benefits. The conflict arises not merely with the FDA's authority to *protect* public health but also its Congressional mandate to *advance* public health through access to safe and effective drugs and devices.<sup>37</sup> For example, when the FDA enacts REMS restrictions, they have done so because Congress tasked the agency with exclusive authority to strike the appropriate balance between restrictions necessary to ensure safety and avoid undue burdens on patients and health care systems.<sup>38</sup> In other words, the existence (or absence) of a REMS or similar safety precaution results from a calculus that lies solely with the FDA, and state efforts to go beyond those restrictions may be preempted.

In the context of reproductive surveillance, states may use their expanded authority to act in the interests of the fetus to argue that a new weighing of risks and benefits is warranted. But while a more expansive state authority to regulate in the interest of the fetus may be new, the risks to that fetus from previously evaluated drugs are not. Congress explicitly requires the FDA to consider the risks and benefits and, in doing so, has even made additional requirements specifically in the interest of the fetus. The isotretinoin example proves this point. By not requiring more precautions for other medications, such as methotrexate, the FDA has decided in its risk-benefit calculus that more protections are unwarranted. Unfortunately, the Court has also previously held that legal drugs can be used for illegal purposes and, as a result, states may create additional policies for criminal investigation.<sup>39</sup> Which argument would prevail post-*Dobbs* world and with the introduction of criminalization is an open question.

We conclude by observing that reproductive surveillance's present incarnation is an evolution of its past but is rapidly taking on new forms. While it is impossible to discuss the full array of legal and technical considerations relevant to those changes in this essay, anticipating potential abuses and considering solutions, even for what may seem like unlikely or extreme scenarios, will be critical to preserving rights

and working toward reproductive justice. The federal or state government may require reproductive surveillance because it already does in some limited circumstances — even when the individual has no intention of becoming pregnant. So exploring the limits of that power is not catastrophizing but rather a way to think comprehensively about the challenges ahead.

#### Note

The authors have no conflicts to disclose.

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