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State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?

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State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?

Lars Noah*

ABSTRACT

In order to prevent further overuse of prescription opioids, states have adopted a variety of strategies. This article summarizes the growing use of prescription drug monitoring programs, crackdowns on “pill mills,” prohibitions on the use of particularly hazardous opioids, limitations on the duration and dosage of prescribed opioids, excise taxes, physician education and patient disclosure requirements, public awareness campaigns, and drug take-back programs. Although occasionally challenged on constitutional grounds, including claims of federal preemption under the Supremacy Clause, discrimination against out-of-state businesses under the dormant Commerce Clause doctrine, and interference with rights of commercial free speech, this article evaluates the possibility that patients might have substantive due process objections against the more aggressive initiatives for unduly burdening a fundamental right of access to narcotic analgesics. In particular, if these regulatory efforts put substantial obstacles in the way of terminally-ill patients seeking palliative care, then states would face a difficult burden of justification.

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*Karl Marx said “Religion is the opiate of the masses.”
I did masses of opiates religiously.*

—Carrie Fisher*

INTRODUCTION

In a recent scholarly article, I criticized the federal response to the prescription opioid crisis as tepid and tardy.¹ Although hardly uniform, states have reacted more aggressively to the problem.² Indeed, several observers have complained that some of the latest state and local initiatives represent overreactions, which may de-

* See Kate Muir, *It’s Carrie Fisher’s Lacerating Wit I’ll Miss; As a Wisecracking Writer, She Earns Her Place Among a Heavenly Hollywood Sisterhood*, TIMES (London), Dec. 30, 2016, Features at 9 (highlighting this quip from Ms. Fisher’s 1987 novel, *Postcards from the Edge*); cf. Catherine Rampell, *Opinion, Was Barr’s Religion Speech a Cry for Help?*, WASH. POST, Oct. 15, 2019, at A27 (“Militant secularism, [the U.S. Attorney General] said, is to blame for the country’s greatest ills, including drug use . . .”).

1. See Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757; see also Mariano-Florentino Cuéllar & Keith N. Humphreys, *The Political Economy of the Opioid Epidemic*, 38 YALE L. & POL’Y REV. (forthcoming 2020); William K. Hubbard, *Editorial, Getting Serious About Opioid Regulation*, 180 JAMA INTERNAL MED. 309, 309 (2020) (“Actions at the federal level to combat the opioid epidemic have been underwhelming.”); Abby Goodnough & Margot Sanger-Katz, *Research Faults F.D.A. on Opioid Oversight*, N.Y. TIMES, Dec. 31, 2019, at A13; Sabrina Tavernise, *New Standards for Painkillers Aim to Stem Overdose Deaths*, N.Y. TIMES, Mar. 16, 2016, at A1 (“The federal government has lagged the states in its response to the opioid epidemic.”).

2. See Barry Meier & Sabrina Tavernise, *States Push to Curb Painkiller Overuse*, N.Y. TIMES, Mar. 12, 2016, at B1 (“[T]he pace of activity in states has grown so intense that experts are having difficulty keeping track. Currently, there are about 375 proposals in state legislatures that would regulate pain clinics and several aspects of prescribing painkillers”); see also *infra* Part I (surveying some of these efforts).

prive legitimate patients of access to drugs that they desperately need.³

This article attempts to assess such complaints and the merits of constitutional objections to restrictive state laws.⁴ It focuses on measures designed to prevent opioid addiction and diversion,⁵ leaving to others an assessment of equally important state and local efforts to help those addicted to opioids, whether by rescuing overdose victims or treating persons with substance use disorders.⁶ Part I of this article offers a snapshot of the different mechanisms

3. See, e.g., George Comerici et al., *Controlling the Swing of the Opioid Pendulum*, 378 NEW ENG. J. MED. 691, 692 (2018) (“We fear that an injudicious approach involving blanket refusals to prescribe opioids and adoption of unreasonable prescribing and dispensing regulations will increase patient suffering.”); Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 1, 45–46, 55–68 (2016); *id.* at 73 (criticizing “the typical use reduction approach embraced by many in the public health and policy community”); Susan A. Glod, *The Other Victims of the Opioid Epidemic*, 376 NEW ENG. J. MED. 2101, 2102 (2017) (bemoaning the “all-or-nothing approach to pain management under which the pendulum has swung from one unsustainable end of the spectrum to the other in the past two decades”); Mark A. Rothstein, Editorial, *The Opioid Crisis and the Need for Compassion in Pain Management*, 107 AM. J. PUB. HEALTH 1253, 1254 (2017) (“Desperately ailing patients who legitimately need medical relief from serious pain should not be the latest unintended victims of societal opioid abuse.”); see also *infra* notes 62, 114–15 (noting more such objections).

4. For a broader treatment of the constitutional questions that arise when states attempt to countermand federal judgments about the availability of therapeutic agents, see Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1.

5. A striking correlation exists between the supply of prescription opioids and fatal overdoses. See Sari Horwitz et al., *Deaths Soared As Pills Proliferated*, WASH. POST, July 18, 2019, at A1 (“The national death rate from opioids was 4.6 deaths per 100,000 residents. But the counties that had the most pills distributed per person experienced more than three times that rate on average.”).

6. See, e.g., Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1, 29–33 (2017) (discussing the widespread adoption of state laws to make the overdose reversal agent naloxone more easily available and immunize those who call for assistance); Andrew M. Parker et al., *State Responses to the Opioid Crisis*, 46 J.L. MED. & ETHICS 367, 371–74 (2018). Schemas favored by some public health aficionados would instead treat these as different varieties of “prevention.” See Melissa McPheeters & Mary K. Bratton, *The Right Hammer for the Right Nail: Public Health Tools in the Struggle Between Pain and Addiction*, 48 U. MEM. L. REV. 1299, 1303 (2018) (“Laws intended to affect initial prescriptions and prescribing patterns are primary prevention. Those laws . . . intended to support the needs of individuals and groups with substance use disorder, with the goal of preventing further negative outcomes, can be classified as ‘tertiary [prevention].’”); see also *id.* at 1303–05, 1353–55 (elaborating on this distinction, and suggesting—along the dimension of available “levers” for pursuing these different forms of prevention—that even interventions aimed at individual physician-patient relationships might appropriately qualify as public health initiatives when viewed in the aggregate).

that states have adopted in trying to prevent the overuse and misuse of prescription opioids. In a few cases, courts have resolved constitutional challenges to these efforts, primarily framed in terms of federal preemption under the Supremacy Clause and the dormant Commerce Clause doctrine. Part II of this article will consider the viability of various substantive due process objections under the Fourteenth Amendment, shifting the focus from the rights asserted by sellers to the rights that users might invoke to the extent that state governments have deprived patients of access to needed pharmaceutical products.

I. SURVEYING THE LANDSCAPE

State legislatures and regulatory officials have adopted a number of measures designed to prevent the overuse, misuse, and abuse of prescription opioids.⁷ Although the sections that follow consider these regulatory efforts in isolation from one another, it bears emphasis that some states have pursued multifaceted approaches,⁸ which increases the prospect of having some meaningful impact on the problem but also complicates any efforts to tease apart the relative contributions of different constituent strategies.⁹ Conversely, forcing prescribers to jump through numerous hoops may discour-

7. Except when focusing on particular state efforts, this article references current compilations of these state laws whenever possible and without attempting to confirm the accuracy of their characterizations. The National Alliance for Model State Drug Laws (NAMSDL), which Congress chartered in 1993, and the National Conference of State Legislatures (NCSL) generally offered the most up-to-date information. For slightly older surveys of state laws related to the opioid crisis, see Nat'l Governors Ass'n, *State Reporting: NGA Compact to Fight Opioid Addiction* (July 17, 2017), <https://bit.ly/2PlmgVy> [<https://perma.cc/5AVF-ETLG>]; and Sonderegger Research Ctr., *State Laws and Other Regulatory Policies Related to Pain Care* (Dec. 31, 2017), <https://bit.ly/2Pm0Yab> [<https://perma.cc/S6L7-DG8J>].

8. See, e.g., McPheeters & Bratton, *supra* note 6, at 1321–25, 1327–29, 1335–37, 1342, 1345–46, 1349–53 (summarizing various steps recently taken in Tennessee); see also Parker et al., *supra* note 6, at 376 (“[S]everal states (including Illinois, Rhode Island, West Virginia, and Connecticut) created comprehensive opioid plans which identify overarching goals and define processes for achieving them.” (footnotes omitted)); *id.* (“States are coalescing around a number of common policy options . . . , but they are also engaged in the process of experimentation.”).

9. See Deborah Dowell et al., *Mandatory Provider Review and Pain Clinic Laws Reduce the Amounts of Opioids Prescribed and Overdose Death Rates*, 35 HEALTH AFF. 1876, 1881 (2016) (“[I]t is not possible to clearly determine whether the combined implementation of the policies or mandated PDMP [prescription drug monitoring program] review drove the observed changes, although pain clinic laws alone appear to have a smaller, if any, effect on overdose deaths.”); Tamara M. Haegerich et al., *What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose*, 145 DRUG & ALCOHOL DEPENDENCE 34, 44 (2014) (“Multiple efforts operating within states

age even entirely appropriate uses of opioids and work to the detriment of patients.

A. Prescription Drug Monitoring Programs Sweep the Nation

Every state now has a prescription drug monitoring program (PDMP), though variations exist in the scope and manner of use of these databases.¹⁰ PDMPs allow prescribers and dispensers to discover whether particular patients previously have filled prescriptions for controlled substances, perhaps after visiting multiple providers (a.k.a. “doctor shopping”).¹¹ In addition, law enforcement officials can use the systems to identify suspicious patterns of prescribing and dispensing by particular health care professionals and facilities.¹² A majority of states now require that providers

that occur in concert with legislation changes have limited the ability to draw causal conclusions about individual state policy effectiveness.”).

10. See Corey S. Davis et al., *Evolution and Convergence of State Laws Governing Controlled Substance Prescription Monitoring Programs, 1998–2011*, 104 AM. J. PUB. HEALTH 1389, 1390–93 (2014) (documenting the central variations); A. Travis Manasco et al., *Characteristics of State Prescription Drug Monitoring Programs: A State-by-State Survey*, 25 PHARMACOEPIDEMOLOGY & DRUG SAFETY 847, 850 (2016) (“[T]here is considerable heterogeneity between state PDMPs in characteristics such as reporting time, data sharing, provider identification, and high-risk patient or prescriber reporting.”); Christine Vestal, *Physicians Check Patients for Use of Addictive Drugs*, WASH. POST, Jan. 16, 2018, at E4. See generally Prescription Drug Monitoring Program Training & Technical Assistance Ctr., *State Profiles*, <https://bit.ly/39bwCz2> [<https://perma.cc/2BRJ-3YUF>] (last visited Feb. 25, 2020).

11. See Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws*, 67 HASTINGS L.J. 1621, 1632 (2016) (“PDMPs are a popular, state-level, legal mechanism that have gained the reputation of having incredible promise for addressing opioid misuse.”); *id.* at 1634–37, 1685–86 (elaborating); *id.* at 1672–76 (reviewing some of the literature on their effectiveness); McPheeters & Bratton, *supra* note 6, at 1316–23 (discussing the central role played by Tennessee’s PDMP in pursuing primary prevention of opioid misuse).

12. See *Pyle v. Woods*, 874 F.3d 1257, 1264–66 (10th Cir. 2017) (affirming the dismissal of Fourth Amendment objections to warrantless searches of Utah’s PDMP); *Lewis v. Superior Court*, 397 P.3d 1011, 1014, 1021–22 (Cal. 2017) (rejecting patient privacy objections asserted by a physician targeted for investigation by the state’s board of medicine); see also Jennifer D. Oliva, *Prescription Drug Policing: The Right to Protected Health Information Privacy Pre- and Post-Carpenter*, 69 DUKE L. REV. 775, 833–53 (2020) (predicting that warrantless searches of these databases by the U.S. Drug Enforcement Administration (DEA) may fare less well against Fourth Amendment objections in the wake of the U.S. Supreme Court’s 2018 decision protecting cell-site location information held by wireless carriers); Devon T. Unger, Note, *Minding Your Meds: Balancing the Needs for Patient Privacy and Law Enforcement in Prescription Drug Monitoring Programs*, 117 W. VA. L. REV. 345, 349–50, 368, 381–83 (2014) (discussing law enforcement uses, and concluding that “patients have a legitimate expectation of privacy in their personally identifiable PDMP data, and the Fourth Amendment requires that law enforcement obtain a warrant before accessing” it).

check their PDMPs before supplying controlled substances to patients.¹³

These databases suffer from well-known limitations. For instance, dispensers may do a poor job of filing reports, or agency employees may fail to promptly upload the reports that they receive.¹⁴ Lack of coordination with adjacent states also means that patients can cross borders to engage in doctor shopping.¹⁵ Nonetheless, when properly implemented and made a prerequisite for prescribing and dispensing, PDMPs plainly help to guard against opioid misuse by patients.¹⁶ A frequently expressed concern about this tool speculates, however, that the prospect of having usage tracked will not simply guard against abuse but also may chill even legitimate prescribing to the detriment of patients in need.¹⁷

13. See NAMSDL, *Prescriber Mandated Use of Prescription Drug Monitoring Programs (PDMP/PMs)—Map* (Jan. 2, 2019), <https://bit.ly/2Pqyn3F> [<https://perma.cc/57QJ-B5EQ>] (counting forty states with such requirements); Vestal, *supra* note 10, at E4 (reporting that these requirements began appearing in 2010 and now exist in 39 states); see also Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 JAMA 891, 892 (2015) (“[PDMP] mandates are a proliferating policy tool.”); *id.* at 891 (“In Kentucky, Tennessee, New York, and Ohio—early adopters of comprehensive use mandates—there were substantial increases in queries and reductions in opioid prescribing following implementation.”); *id.* (“Mandates face significant prescriber opposition across the country.”).

14. See Manasco et al., *supra* note 10, at 849 (finding average lag times of one week or more in twenty-eight states); Stephen W. Patrick et al., *Implementation of Prescription Drug Monitoring Programs Associated with Reductions in Opioid-Related Death Rates*, 35 HEALTH AFF. 1324, 1329–30 (2016) (finding that more frequent (at least weekly) updating improved effectiveness); Jeanmarie Perrone & Lewis S. Nelson, *Medication Reconciliation for Controlled Substances—An “Ideal” Prescription-Drug Monitoring Program*, 366 NEW ENG. J. MED. 2341, 2342 (2012) (“[P]harmacy data entry is time-consuming, and data are uploaded to the prescription database at variable intervals—from immediately or once daily to weekly or monthly. For a PDMP to be most valuable in clinical practice, it must be current, which would require pharmacists to promptly upload information.”).

15. See Richard A. Deyo et al., *Measures Such As Interstate Cooperation Would Improve the Efficacy of Programs to Track Controlled Drug Prescriptions*, 32 HEALTH AFF. 603, 609 (2013) (discussing efforts to link state PDMPs); Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J.L. & MED. 85, 94, 107–08 (2014).

16. See Ian Ayres & Amen Jalal, *The Impact of Prescription Drug Monitoring Programs on U.S. Opioid Prescriptions*, 46 J.L. MED. & ETHICS 387, 389 (2018) (“Our results indicate that PDMPs are not effective in reducing prescription rates unless physicians are required to access the PDMPs prior to prescription.”); *id.* at 390 (reviewing previous studies of this question, and noting their limitations); *id.* at 397 (“PDMPs are only effective if they obligate doctors to check for patient history on the PDMP prior to filling out a prescription.”); Thomas C. Buchmueller & Colleen Carey, *The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare*, AM. ECON. J.: ECON. POL’Y, Feb. 2018, at 77, 109 (same).

17. See Deyo et al., *supra* note 15, at 607 (“Some clinicians and patient advocates believe that prescription monitoring programs have a chilling effect on opioid

B. Shutting Down “Pill Mills” in the Sunshine State

In Florida, so-called pill mills had proliferated, attracting business from opioid customers throughout the country.¹⁸ In 2009, the state legislature began imposing physician ownership and registration requirements alongside various restrictions on the operation of these pain-management clinics.¹⁹ At the same time, it ordered the creation of a PDMP.²⁰ Although neither the first nor the only state to tackle pill mills,²¹ Florida’s efforts have garnered the most atten-

prescribing and adversely affect pain management.”); Haffajee et al., *supra* note 13, at 891–92 (“Although [PDMP use] mandates are not meant to deter opioid prescribing per se, resistant clinicians may simply decline to prescribe opioids”); Perrone & Nelson, *supra* note 14, at 2342 (“There are realistic concerns that a PDMP is burdensome for prescribers and dispensers and may inappropriately reduce the amount of opioid analgesic prescribed.”). *But cf.* Hallam M. Gugelmann & Jeanmarie Perrone, *Can Prescription Drug Monitoring Programs Help Limit Opioid Abuse?*, 306 JAMA 2258, 2258 (2011) (“[T]he targeted use of drug monitoring programs by prescribers does not result in indiscriminately decreased administration of pain medications.”).

18. See Scott Higham et al., *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, WASH. POST, July 17, 2019, at A1 (“During the past two decades, Florida became ground zero for pill mills—pain management clinics that served as fronts for corrupt doctors and drug dealers . . . , advertising their products on billboards by interstate exit ramps.”).

19. See 2009 Fla. Laws ch. 198, §§ 3–4, *repealed and replaced by* 2010 Fla. Laws ch. 211, §§ 3–11 (codified as amended at FLA. STAT. §§ 458.3265, 459.0137, 465.0276); see also Lizette Alvarez, *Florida Shutting “Pill Mill” Clinics: New Laws Curb Illegal Sales of Medicines*, N.Y. TIMES, Sept. 1, 2011, at A1. Clinics operated by specially trained physicians may apply for a certificate of exemption from these rules. See FLA. STAT. § 458.3265(1)(a)(3)(h); see also *State v. Crumbley*, 247 So. 3d 666, 671–72 (Fla. Dist. Ct. App. 2018) (remanding a vagueness challenge for fact-finding in the prosecution of a physician and office manager operating an unlicensed pain-management clinic).

20. See 2009 Fla. Laws ch. 198, § 1 (codified as amended at FLA. STAT. § 893.055); see also Chris Delcher et al., *Abrupt Decline in Oxycodone-Caused Mortality After Implementation of Florida’s Prescription Drug Monitoring Program*, 150 DRUG & ALCOHOL DEPENDENCE 63, 65 (2015) (finding a 25% drop in overdose deaths associated with oxycodone within fourteen months of launch). See generally Ashley Dutko, Note, *Florida’s Fight Against Prescription Drug Abuse: Prescription Drug Monitoring Program*, 34 NOVA L. REV. 739 (2010).

21. See Lainie Rutkow et al., Editorial, *More States Should Regulate Pain Management Clinics to Promote Public Health*, 107 AM. J. PUB. HEALTH 240, 240 (2017) (“[T]hus far only 11 states have enacted specific regulation of pain management clinics.”). For instance, Texas also had targeted pill mills. See 2009 Tex. Gen. Laws ch. 775, § 1 (codified as amended at TEX. OCCUPATIONS CODE ch. 168) (requiring certification of pain management clinics, physician ownership, and that owners be on-site at least one-third of the time and review at least one-third of patient records); Cindy Horswell, “Pill Mills” Skirt Law by Playing Name Game—By Changing Monikers, They Avoid State Scrutiny, HOUS. CHRON., Dec. 29, 2011, at A1 (discussing implementation difficulties); see also McPheeters & Bratton, *supra* note 6, at 1327–32 (discussing Tennessee’s crackdown on pill mills).

tion. Within a few years of passage, researchers documented that these reforms had shown signs of success.²²

A facility qualified as a pain-management clinic subject to the requirements of the Florida statute if, among other things, it had engaged in advertising to the public.²³ Although constitutional objections to the advertising provision appeared to have genuine merit under commercial speech doctrine,²⁴ a federal district court dismissed a facial challenge to the law.²⁵ In doing so, it emphasized that pain-management clinics remained free to advertise so long as they satisfied the registration and other requirements,²⁶ not realizing that one decade earlier the U.S. Supreme Court had invalidated an act of Congress that operated in much the same fashion.²⁷ Most

22. See Alene Kennedy-Hendricks et al., *Opioid Overdose Deaths and Florida's Crackdown on Pill Mills*, 106 AM. J. PUB. HEALTH 291, 295–96 (2016); Lainie Rutkow et al., *Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use*, 175 JAMA INTERNAL MED. 1642, 1643 (2015) (discussing earlier research on this question); *id.* at 1648 (“[I]mplementation of Florida’s PDMP and pill mill law was associated with modest decreases in opioid use and prescribing among patients and providers with high levels of opioid use at baseline relative to Georgia, a comparison state.”); Timothy W. Martin & Arian Campo-Flores, *New Front Opens in Florida Pill War—Crackdown on Pain Clinics Selling Oxycodone Makes Headway, but Addicts Now Crowd Pharmacies*, WALL ST. J., Mar. 8, 2012, at A6 (“In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011, according to [DEA] data.”); see also Tatyana Lyapustina et al., *Effect of a “Pill Mill” Law on Opioid Prescribing and Utilization: The Case of Texas*, 159 DRUG & ALCOHOL DEPENDENCE 190, 195–96 (2016) (finding that the Texas law worked); Rutkow et al., *supra* note 21, at 243 (concluding that pill mill laws “fill an important gap with their unique targeting of high-risk prescribing environments while minimizing impact on legitimate users”).

23. See FLA. STAT. § 458.3265(1)(a)(1)(c)(I) (2019).

24. See Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31, 89 n.234 (2011); *id.* at 67 (“[O]utright prohibitions designed to dampen demand (or to serve other collateral purposes) [are] vulnerable to constitutional invalidation, while more limited restrictions or disclosure requirements designed to guard against potentially misleading promotional messages would seem to survive.”).

25. See *P.R.A. v. Armstrong*, No. 4:10cv414-RH/CAS, 2012 WL 13034006, at *1–2 (N.D. Fla. Aug. 7, 2012).

26. See *id.* at *2 (“The statutes do not prohibit the plaintiffs from advertising. The statutes instead use advertising as a means of identifying pain-management clinics that must register.”).

27. See Noah, *supra* note 24, at 51–65 (discussing *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002)); *id.* at 54–57 (explaining that the challenged provision “posed an unconstitutional conditions problem insofar as it had predicated the availability of an exception to an existing legal requirement on the waiver of First Amendment rights”); see also Lars Noah, *Does the U.S. Constitution Constrain State Products Liability Doctrine?*, 92 TEMP. L. REV. 189, 210 (2019) (explaining that a state law “impos[ing] special burdens on companies when they advertise—whether or not the advertisements contained any misleading claims . . . —plainly

other state pill mill laws do not use advertising as a trigger for their various restrictions on the operation of these facilities.²⁸

C. *Trying to Ban a Hydrocodone Product in Massachusetts*

In 2013, the U.S. Food and Drug Administration (FDA) approved a new drug application submitted by Zogenix, Inc. for an extended-release hydrocodone product (Zohydro ER®) intended for patients with chronic severe pain that failed to respond to alternative treatment.²⁹ Less than six months later, the Commonwealth of Massachusetts acted to prevent any sales of this drug,³⁰ which prompted the manufacturer to lodge various constitutional objections.³¹

Within a month, a federal district court sided with Zogenix, issuing a preliminary injunction against the Commonwealth.³² Judge Rya Zobel concluded that the congressional statute governing the approval of new drugs impliedly preempted the state's action.³³ She ruled that a prohibition on the sale of an FDA-ap-

singles out for unfavorable treatment defendants that engage in commercial speech" in a manner now forbidden by the Supreme Court).

28. See Rutkow et al., *supra* note 21, at 241 tbl.1 (listing only Georgia and Kentucky as also using definitions tied to advertising).

29. See Matthew Perrone, *FDA Unexpectedly OK's New Hydrocodone Option*, BOS. GLOBE, Oct. 26, 2013, at B5.

30. See Bradley J. Fikes, *Massachusetts Bans Painkiller Zohydro ER; Zogenix Takes Issue with Action, Which Applies to All Pure-Hydrocodone Drugs*, SAN DIEGO UNION-TRIB., Mar. 29, 2014, at C1; see also Jon Kamp, *New Painkiller Sparks Abuse Concern*, WALL ST. J., May 24, 2014, at A3 ("Lawmakers in Ohio and New York recently proposed measures that would effectively ban Zohydro by classifying it as a drug akin to heroin or LSD.").

31. See Travis Andersen, *Patrick Asks Ban on Drug Be Upheld; but Painkiller Zohydro Was Approved by FDA*, BOS. GLOBE, Apr. 12, 2014, at B2; Brady Dennis, *U.S. Judge Set to Rule on Drug Firm's Suit Against Massachusetts over Painkiller Ban*, WASH. POST, Apr. 14, 2014, at A4.

32. See Brady Dennis, *Judge Voids Ban on Painkiller in Mass.*, WASH. POST, Apr. 16, 2014, at A3; Milton J. Valencia, *US Judge Blocks State Ban on Opiate; Critics Say Zohydro Could Be Misused*, BOS. GLOBE, Apr. 16, 2014, at B1.

33. *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014). The court declined to reach the plaintiff's other constitutional arguments. See *id.* at *2 n.2. The objection premised on the dormant Commerce Clause doctrine seemed at least slightly misplaced because, as it turned out, the financial consequences of Commonwealth's prohibition would have fallen most heavily on an in-state company. See Yvonne Abraham, *Fighting, Then Fueling, Drug Abuse*, BOS. GLOBE, Apr. 10, 2014, at A1 ("Out front in all of this controversy has been a company called Zogenix, out of San Diego. But Zogenix has only a license to market the drug. The actual outfit behind Zohydro is a Waltham company named Alkermes Zogenix markets the drug and takes heat from critics, but Alkermes owns Zohydro, manufactures it, and stands to make mountains of money from it."). Moreover, the emergency regulation applied to all extended-release pure hydrocodone products that lacked abuse-resistant features, whether

proved product in a particular state probably would frustrate accomplishment of federal purposes, which she understood as “mak[ing] drugs available to promote . . . the public health.”³⁴ As I have explained previously, the court’s “obstacle” preemption analysis made absolutely no sense.³⁵ Nonetheless, if Judge Zobel had instead assessed the apparent conflict between state and federal law using the U.S. Supreme Court’s newly expansive approach to the “impossibility” prong of conflict preemption,³⁶ then she undoubtedly would have reached the same conclusion.

sold by a local or foreign manufacturer, though Zogenix objected that (at least initially) only Zohydro fell into this narrowly defined class. Nothing, however, suggested that this public health regulation served merely as a pretext to favor local interests. In contrast, imagine that Connecticut (home of the companies’ chief rival Purdue Pharma) had taken a similar step. For more on the dormant Commerce Clause doctrine in this context, see Noah, *supra* note 4, at 35–42.

34. *Zogenix*, 2014 WL 1454696, at *2 (“The FDA endorsed Zohydro ER’s safety and effectiveness when it approved the drug. . . . If the Commonwealth were able to countermand the FDA’s determinations and substitute its own requirements, it would undermine the FDA’s ability to make drugs available to promote and protect the public health.”). Judge Zobel never suggested finding implied conflict preemption premised instead on an impossibility of dual compliance, and she distinguished cases that had rejected an implied preemption defense to inadequate warning claims in tort litigation: “Here, the obstruction is clearer because the drug Massachusetts wants Zogenix to adopt—Zohydro ER with an ‘abuse-resistant formulation’—has not been approved Zogenix would be required to return to the FDA and seek approval of a drug different from the one the FDA has already deemed safe.” *Id.* Whether or not this purpose animates the FDA’s organic statute, Judge Zobel correctly considered issues of access for legitimate patients in assessing the other factors relevant to deciding whether to grant preliminary relief. *See id.* (“As to the equities, although the ban may prevent someone from misusing the drug, the ban prevents all in need of its special attributes from receiving the pain relief Zohydro ER offers. For the same reason, the injunction is in the public interest.”).

35. *See* Noah, *supra* note 4, at 8–12.

36. *See id.* at 27–35; *see also* *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 490–93 (2013) (holding that FDA restrictions on the labeling of generic drugs made compliance with additional state requirements impossible); *cf.* *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679–80 (2019) (holding that judges rather than jurors should decide whether a company had offered clear evidence that the FDA would have rejected an enhanced warning statement). Contrast the FDA’s controversial recent decision to approve Dsuvia® (sufentanil), which far surpasses fentanyl in potency but apparently happened at the behest of the U.S. military. *See* Lenny Bernstein, *Stronger Than Fentanyl, Opioid Gets FDA Approval*, WASH. POST, Nov. 3, 2018, at A3. In light of this federal interest, any state effort to restrict its use might well raise obstacle preemption objections. Similarly, because the FDA imposed stringent access restrictions under its risk evaluation and mitigation strategy (REMS) authority when it approved Dsuvia, *see* Noah, *supra* note 1, at 780 & n.109, the sponsor would not enjoy the power to unilaterally modify its labeling. Indeed, now that the FDA has imposed REMS requirements on most opioids, *see id.* at 781–83, conflict preemption might operate more strongly than it does for other brand-name drugs. *Cf.* Patricia J. Zettler, *Pharmaceutical Federal-*

Rather than continue litigating the case, officials in Massachusetts decided to issue new rules that focused instead on the behavior of medical professionals licensed by the state: before prescribing Zohydro, physicians would, among others things, have to check patient records for any evidence of substance abuse, and they then would have to prepare a letter of medical necessity—attesting, for instance, that other pain management treatments had failed—without which pharmacists could not dispense the drug.³⁷ In an amended complaint, Zogenix characterized these new rules as amounting to “a *de facto* prohibition,” and the federal district court found even some of these more limited restrictions problematic.³⁸

Judge Zobel explained that the letter of medical necessity requirement suffered from various ambiguities and could mean that, contrary to the labeling approved by the FDA, physicians should use Zohydro only as a last resort.³⁹ Finding a probability of implied preemption because such an interpretation would frustrate the federal decision to make this drug available for health professionals to use whenever they deemed it appropriate, she preliminarily enjoined enforcement of this rule pending clarification from the defendants.⁴⁰ Judge Zobel also, however, summarily rejected an equal protection claim asserted by Zogenix, which had alleged that the defendants lacked any rational basis for singling out their drug from all of the other long-acting opioids.⁴¹ Less than two months

ism, 92 IND. L.J. 845, 874–75 (2017) (focusing, however, on the obstacle rather than impossibility prong of conflict preemption in making this point).

37. See Milton J. Valencia, *State Limits Use of Potent Painkiller; Addiction Concerns Raised on Zohydro*, BOS. GLOBE, Apr. 23, 2014, at B1; see also Zettler, *supra* note 36, at 873 & n.189 (elaborating on the practice restrictions imposed in Massachusetts, and noting that Vermont had promulgated similar rules).

38. See *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610, at *3–5 (D. Mass. July 8, 2014), *vacated in part*, 2014 WL 4273251 (D. Mass. Aug. 28, 2014).

39. See *id.* at *4.

40. See *id.* at *5. Strangely, apart from finding a probability of success on the merits, Judge Zobel said nothing about the other three prerequisites for granting preliminary relief even though her brief discussion of these factors when initially enjoining the outright prohibition would hardly apply with equal force to the prescribing restrictions. As for the company’s challenge to a related state rule that allowed only licensed pharmacists to handle Zohydro (thereby barring pharmacy technicians or interns from doing so), she found insufficient evidence to justify a preliminary injunction on grounds of preemption. See *id.* (concluding that Zogenix had failed to “provide sufficient detail that pharmacies will not carry Zohydro”).

41. See *id.* at *2 n.3 (explaining that the Supreme Court has reserved “class-of-one” equal protection claims for situations where clear standards exist against which to measure individual departures made by regulatory classifications rather than discretionary judgments that depend on particularized assessments). Judge Zobel also again declined to reach the plaintiff’s Contract Clause and dormant Commerce Clause objections. See *id.* (calling these “undeveloped arguments”);

later, after the defendants issued revised rules clarifying what should appear in the medical necessity letter, she vacated her previous order: instead of having to declare that other pain management options had “failed,” now physicians simply would have to refer to the “inadequa[cy]” of alternatives for a particular patient, which essentially mimicked the FDA-approved labeling and therefore avoided implied preemption.⁴²

Even more so than her preemption analysis when preliminarily enjoining the outright ban, Judge Zobel offered a questionable explanation of how the prescribing and dispensing restrictions might conflict with federal law. She properly conceded that uncertainty about how state officials might interpret these rules made it difficult to discern whether they genuinely would frustrate federal purposes.⁴³ Even absent such contingency, however (in short, let us assume that Massachusetts unmistakably had narrowed the circumstances of use or otherwise imposed conditions on prescribing above and beyond those of federal law), the restrictions on use would not create nearly the same conflict as had the original blanket prohibition.

No doubt, as Judge Zobel explained, a tradition of state regulation of the medical profession does not exclude the possibility of

see also *Zogenix, Inc. v. Baker*, No. 14-11689-RWZ, 2015 WL 1206354, at *4–8 (D. Mass. Mar. 17, 2015) (declining to dismiss the plaintiff’s third amended complaint insofar as it again claimed implied preemption of the pharmacist-only handling restrictions, but granting the defendants’ motion to dismiss the equal protection, Contract Clause, and dormant Commerce Clause objections to that rule). Even if *Zogenix* lacked a valid equal protection objection, the state’s decision to single out this product might buttress substantive due process claims asserted by patients. *See infra* note 111 and accompanying text; *cf.* *Eisenstadt v. Baird*, 405 U.S. 438, 447–55 (1972) (invalidating a Massachusetts law that had prohibited the distribution of contraceptives only to unmarried individuals as irrational under the Equal Protection Clause).

42. *See Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 4273251, at *2–3 (D. Mass. Aug. 28, 2014). The Massachusetts regulation applicable solely to the use of single ingredient extended-release hydrocodone products lacking abuse-deterrent features (i.e., *Zohydro*) also requires that physicians query the state’s PDMP, discuss risks and benefits with patients, and enter into treatment agreements that address issues such as drug screening. *See* 243 MASS. CODE REGS. 2.07(25) (2019). It seems odd that officials chose not to apply such requirements to all Schedule II opioids, but the differential treatment plainly would discourage ever selecting this particular drug for a patient, so perhaps it continued to operate as a *de facto* prohibition even after the state watered down the language governing medical necessity letters. *Cf.* Christopher M. Jones et al., *Addressing Prescription Opioid Overdose: Data Support a Comprehensive Policy Approach*, 312 JAMA 1733, 1734 (2014) (critiquing the state’s rules for “[s]jingling out” *Zohydro* in this fashion).

43. *See Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610, at *5 (D. Mass. July 8, 2014).

preemptive federal involvement in the field.⁴⁴ She failed to recognize, however, that Congress repeatedly had offered assurances that the FDA's authority to license therapeutic products would not interfere with the practice of medicine.⁴⁵ Such legislative guidance seemingly renders obstacle preemption inapt,⁴⁶ unless, of course, a state rule purporting to regulate prescribing or dispensing in fact represented a veiled prohibition on use of an approved product.⁴⁷ In spite of its setbacks in the litigation, the Massachusetts Department of Public Health could find some solace in the fact that the FDA subsequently approved abuse-resistant versions of the drug.⁴⁸

D. *Capping the Number and Strength of Pills Dispensed*

The opioid crisis emerged at least in part from irresponsible prescribing by physicians.⁴⁹ Of course, the medical staff affiliated

44. See *id.* at *4.

45. See Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 166–67 n.74, 173 (2004); see also *id.* at 155 (“Congress repeatedly has announced its intention that federal officials take care not to interfere with the practice of medicine.”); *id.* at 171, 175–76, 180, 191 n.179 (explaining that the FDA and the DEA defer to state decisions about who enjoys prescribing privileges). That article addressed the flipside of the problem considered here—namely, asking whether the Constitution might bar restrictive federal decisions in connection with therapeutic product licensure for posing an affront to state primacy in regulating health professionals.

46. See *id.* at 166 (“[C]ourts have cited this provision [appearing in the Medicare statute] as evidence that Congress did not intend to preempt state laws related to the delivery of health care services to the elderly or the disabled.”); *cf. id.* at 167–68 (conceding that the inclusion of a “savings” clause would have done so more clearly).

47. *Cf. Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636 (2013) (“A State may not evade the pre-emptive force of federal law by resorting to creative statutory interpretation or description at odds with the statute’s intended operation and effect.”).

48. See Bradley J. Fikes, *Painkiller Unit Sold for \$100M Upfront; San Diego-Based Zogenix to Use Proceeds for Other Drug Trials*, SAN DIEGO UNION-TRIB., Mar. 11, 2015, at C1; see also Lisa Girion, *Powerful Painkiller Approved*, L.A. TIMES, Nov. 21, 2014, at A8 (reporting that Purdue Pharma, the manufacturer of OxyContin® (extended-release oxycodone), had secured FDA approval for its abuse-resistant extended-release hydrocodone product Hysingla ER®).

49. See Michael L. Barnett et al., *Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use*, 376 NEW ENG. J. MED. 663, 664 (2017) (“It is frequently argued that the prescribing behavior of physicians has been a driver of the opioid epidemic.”); Gillian A. Beauchamp et al., *Moving Beyond Misuse and Diversion: The Urgent Need to Consider the Role of Iatrogenic Addiction in the Current Opioid Epidemic*, 104 AM. J. PUB. HEALTH 2023, 2023 (2014) (“[A] similar phenomenon occurred in the 19th and early 20th centuries, when opioids were prescribed liberally and indiscriminately for all types of pain.”); Jones et al., *supra* note 42, at 1734 (“[S]tudies have identified inappropriate opioid prescribing—generally by a small percentage of prescribing clinicians—as a major contributor to the increase in morbidity and mortality.”).

with pill mills must have known that they had become nothing better than drug dealers serving recreational users and other individuals already suffering from opioid use disorder. One can trace the wave of new addicts, however, to law-abiding physicians struggling to treat serious pain in legitimate patients but engaging in sometimes inexplicable patterns of prescribing.⁵⁰

In 2016, the U.S. Centers for Disease Control and Prevention (CDC) issued guidelines to address opioid prescribing.⁵¹ Among other things, the agency urged primary care physicians to use these narcotics sparingly, recommending instead the selection of non-opioid analgesics and non-drug modalities such as physical therapy; it also called for limiting first-time prescriptions for acute pain to seven days as well as a maximum daily dose of 90 milligram morphine equivalents (MMEs) for chronic pain patients on long-term prescriptions.⁵² The CDC's effort appears to have had an impact,⁵³ in part thanks to state decisions to codify parts of these guidelines.⁵⁴

50. See Noah, *supra* note 1, at 759, 762–64.

51. See Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 315 JAMA 1624 (2016).

52. See *id.* at 1638 box 5; see also Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374 NEW ENG. J. MED. 1501, 1503 (2016) (“When prescribing opioids, the rule of thumb is to ‘start low and go slow.’”); *id.* (“Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”). An affiliated entity, the U.S. Preventive Health Services Task Force, recently issued proposed recommendations that call upon primary care physicians to routinely ask their patients about illicit drug use. See Jan Hoffman, *Task Force Advises That All Adult Patients Be Screened for Drug Abuse*, N.Y. TIMES, Aug. 14, 2019, at A19.

53. See Amy S.B. Bohnert et al., *Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention’s 2016 Opioid Guideline*, 169 ANNALS INTERNAL MED. 367, 374 (2018); cf. Wenjia Zhu et al., *Initial Opioid Prescriptions Among U.S. Commercially Insured Patients, 2012–2017*, 380 NEW ENG. J. MED. 1043, 1047 (2019) (“Notably, these downward trends began long before the release of the CDC guidelines in March 2016 (or even the draft guidelines in December 2015), indicating that the CDC guidelines were not the sole precipitating force behind the declines”); Joel Achenbach et al., *An Onslaught of Pills, Hundreds of Thousands of Deaths: Who Is Accountable?*, WASH. POST, July 21, 2019, at A1 (“Prescription opioid overdoses have claimed the lives of more than 200,000 people in the United States since 1996. A crackdown on indiscriminate doctors and pharmacists—commonly known as pill mills—as well as tighter prescription guidelines by the medical community have helped drive down the number of overdoses due to prescription drugs.”).

54. See Allison Petersen et al., *State Legislative Responses to the Opioid Crisis: Leading Examples*, J. HEALTH & LIFE SCI. L., Feb. 2018, at 30, 35 (“Several states have utilized the CDC’s Guidelines as a model for their own efforts to battle the problem.”). Such guidelines may, of course, influence practice patterns through other less direct routes: health insurers have used them to justify restrictions on reimbursement, and they may help to define the standard of appropriate care for

Two years after its failed initial effort to block the use of Zohydro, Massachusetts imposed restrictions on the prescribing of essentially all opioid analgesics.⁵⁵ Inspired by the CDC's guidelines, the Commonwealth decided to limit the duration of initial prescriptions to seven days.⁵⁶ Since then, approximately two-thirds of the states in this country have imposed opioid prescribing limitations of some sort.⁵⁷ Initial prescriptions—at least for acute pain—may range from as little as three days in a few states to as much as two weeks in others.⁵⁸ Eight of these jurisdictions impose tighter

purposes of state disciplinary board proceedings as well as medical malpractice litigation. See John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421, 422–23 (1994); *id.* at 442–43 (“Third-party users including courts, insurers, regulators, and policy makers should recognize the tenuous nature of parameter development and the substantial tensions tied to competing interests as these guidelines are constructed.”); Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 416–29, 462–63 (2002) (discussing guideline development and use in malpractice litigation).

55. See Parker et al., *supra* note 6, at 369 (“Massachusetts . . . set a seven day policy for new prescriptions, which has become the most common benchmark nationwide”); see also *id.* at 376 (calling these laws “low-cost options . . . involv[ing] only legislation and a minimal amount of implementation or regulation”). Although frequently credited as the first state to take this step, one set of researchers noted that Iowa and Vermont had done so before 2012. See Ellen Meara et al., *State Legal Restrictions and Prescription-Opioid Use Among Disabled Adults*, 375 NEW ENG. J. MED. 44, 48 (2016).

56. See MASS. GEN. LAWS ch. 94C, § 19D(a) (2019); see also *id.* § 19D(b) (specifying the circumstances that would allow prescribers to deviate from this restriction). Three years later, however, Massachusetts had witnessed fairly disappointing results. See Felice J. Freyer, *State Progress on Opioids Uneven*, BOS. GLOBE, May 16, 2019, at B1 (reporting only slight declines in overdose deaths to that point).

57. See NCSL, *Prescribing Policies: States Confront Opioid Overdose Epidemic* (Oct. 31, 2018), <https://bit.ly/37Sv7EI> [<https://perma.cc/5K7P-8DH7>] (“[A]t least 33 states have enacted legislation related to opioid prescription limits.”) [hereinafter “NCLS Prescribing Policies (Oct. 2018 compilation)”]; see also *id.* (“Rather than setting opioid prescription limits in statute, a few state laws direct or authorize other entities to do so (such as New Hampshire, Ohio, Oregon, Vermont, Virginia, Washington and Wisconsin). These entities may include the department of health/state health official, or provider regulatory boards”); *id.* (under the “Table: Legislation” tab) (detailing the laws enacted in each state as of April 4, 2018); Corey S. Davis et al., *Laws Limiting the Prescribing or Dispensing of Opioids for Acute Pain in the United States: A National Systematic Legal Review*, 194 DRUG & ALCOHOL DEPENDENCE 166, 169–70 (2019). Perhaps as importantly, some states repealed their intractable pain treatment acts, which had created safe harbors for health care professionals when prescribing opioids. See Dineen, *supra* note 3, at 56; McPheeters & Bratton, *supra* note 6, at 1311–12 (discussing the operation and fate of Tennessee’s statute).

58. See NCLS Prescribing Policies (Oct. 2018 compilation), *supra* note 57 (under the “State Action” tab) (“Most of this legislation limits first-time opioid prescriptions to a certain number of days’ supply—seven days is most common, though some laws set limits at three, five or 14 days.”); *cf. id.* (“Maryland’s law

restrictions on opioid prescriptions for minors.⁵⁹ Also taking a cue from the CDC's guidelines, a few states have capped maximum allowable dosages,⁶⁰ which effectively prohibits the use of any opioids approved by the FDA for chronic pain patients if the individual dosage sizes exceed such a daily maximum.

Although preliminary research credits these restrictions with reductions in opioid overuse and addiction,⁶¹ some physician

requires providers to prescribe the lowest effective dose of an opioid for a quantity that is not greater than that needed for the expected duration of pain.”). Oklahoma recently adopted a seven-day prescribing limit for adults with acute pain that also required selection of the lowest effective dose of an immediate-release version. See OKLA. STAT. tit. 63, § 2-309i(A) (2019).

59. See NCLS Prescribing Policies (Oct. 2018 compilation), *supra* note 57 (under the “State Action” tab) (“Alaska, Connecticut, Indiana, Louisiana, Massachusetts, Nebraska, Pennsylvania and West Virginia also set limits specifically for minors. These laws set limits for any opioid prescription (versus [only] the initial opioid prescription for adults) and may also specify other requirements, such as discussing opioid risks with the minor and parent or guardian.”).

60. See *id.* (“In a few cases, states also set dosage limits . . .”); *id.* (under the “Table: Legislation” tab) (showing daily dosage caps of 30 MMEs in Rhode Island; 90 MMEs in Arizona and Nevada; and 100 MMEs in Maine); see also 2019 Tenn. Pub. Acts ch. 124, § 8 (codified at TENN. CODE § 63-1-164(b)) (“[A] healthcare practitioner shall not treat a patient with more than a three-day supply of an opioid and shall not treat a patient with an opioid dosage that exceeds a total of one hundred eighty (180) morphine milligram equivalent dose.”); Sara E. Heins, *Morphine Equivalent Daily Dose (MEDD) Policies* (June 1, 2017), <https://bit.ly/2VooPu2> [<https://perma.cc/K7JD-65KA>] (under the “Profiles” tab). One state acted years before the CDC issued its guidelines. See Barry Meier, *Tightening the Lid on Pain Prescriptions*, N.Y. TIMES, Apr. 9, 2012, at A1 (reporting that, in the state of Washington, “lawmakers last year imposed new requirements on doctors to refer patients taking high dosages of opioids [defined as 120 MME] . . . for evaluation by a pain specialist if their underlying condition is not improving,” codifying largely ignored guidelines that a state panel had issued four years earlier); see also David N. Juurlink et al., *Improving Opioid Prescribing: The New York City Recommendations*, 309 JAMA 879, 880 (2013) (discussing guidelines issued for city emergency departments, comparing those used in Washington).

61. See Callie Ferguson, *Maine Leads Nation in Decline of Prescription Opioid Sales, Report Finds*, BANGOR DAILY NEWS (ME), June 19, 2018, available on LexisNexis (“Maine led the pack because it was one of several states to pass a bill in 2016 aimed at curbing the amount of opioids that doctors can prescribe to patients, the report [from Avalere Health] stated. States that passed more aggressive laws saw greater declines.”); Carolyn Y. Johnson, *Opioid Prescriptions Fell 10% Last Year, Study Says*, WASH. POST, Apr. 20, 2018, at A14 (“The volume of prescription opioids given out by pharmacists has been decreasing since 2011, but this was the most dramatic drop yet, as measured by the equivalent morphine dose of all the opioids prescribed in a given year. The trend suggests that public outrage over the opioid epidemic and regulatory, legislative, clinical and commercial measures have begun to curb their use by physicians and patients.”); see also Steven B. Porter et al., Letter, *Association of Florida House Bill 21 with Postoperative Opioid Prescribing for Acute Pain at a Single Institution*, 155 JAMA SURGERY 263 (2020); cf. Meara et al., *supra* note 55, at 47–49 (reviewing laws adopted between 2006 and 2012, including quantitative prescribing limits in two states, but finding no significant impacts in the population studied); *id.* at 50 (“[L]egislative restrictions showed

groups complained that the inflexibility of such policies has adversely affected legitimate patients.⁶² In 2019, the CDC and the FDA responded by issuing clarifications about the 2016 guidelines and the prescribing information that accompanies particular products, cautioning physicians that abruptly cutting off—or too rapidly tapering patients already taking high doses—might trigger withdrawal symptoms and even suicide.⁶³ Even if state legislators and regulators take this caveat seriously, it will require some time before existing mandates get revised accordingly. If they fail to do

no measurable association with the percentage of [disabled Medicare] beneficiaries filling prescriptions that yield high daily opioid doses or the percentage treated for nonfatal prescription-opioid overdose.”); Parker et al., *supra* note 6, at 369 (“Because these policies were enacted quite recently, their effectiveness has not yet been thoroughly examined.”).

62. See Jan Hoffman & Abby Goodnough, *Rule Led to Big Drop in Opioid Prescriptions; Too Big, Some Doctors Say*, N.Y. TIMES, Mar. 7, 2019, at A16; see also Daniel P. Alford, *Opioid Prescribing for Chronic Pain—Achieving the Right Balance Through Education*, 374 NEW ENG. J. MED. 301, 302 (2016) (“[S]uch blunt approaches will also limit access to opioids for patients who are benefiting or may potentially benefit from them. . . . These regulations will lead some clinicians to refuse to prescribe opioids even when they’re indicated, seeing it as too risky or too much work.”); Kao-Ping Chua et al., *Opioid Prescribing Limits for Acute Pain: Potential Problems with Design and Implementation*, 321 JAMA 643, 643 (2019) (bemoaning “the failure of these limits to account for the heterogeneity in prescribing and pain needs among individual patients”); Stefan G. Kertesz & Adam J. Gordon, *A Crisis of Opioids and the Limits of Prescription Control: United States*, 114 ADDICTION 169, 172–73 (2018) (complaining about the “weaponization” of the CDC’s guidelines); Parker et al., *supra* note 6, at 369 (“States have faced some resistance from physicians’ groups in implementing these policies [limiting opioid prescriptions]. Leaders of organizations including the American Medical Association and the Maryland Society of Addiction Medicine have voiced opposition.”); Zhu et al., *supra* note 53, at 1050 (“[L]arge numbers of providers have responded to the opioid crisis by ceasing to prescribe opioids to patients who had not used opioids, rather than prescribing opioids when indicated but at safer doses and durations.”).

63. See Deborah Dowell et al., *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENG. J. MED. 2285, 2286–87 (2019); Abby Goodnough, *Caution Urged in Scaling Back Opioids*, N.Y. TIMES, Oct. 11, 2019, at A15; Sally Satel, *Opinion, Pain Patients Get Relief from Regulation*, WALL ST. J., Apr. 15, 2019, at A17; see also Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L. REV. 961, 961–68, 1001–10 (2019) (emphasizing the suicide risk); Deborah Dowell & Tamara M. Haegerich, *Editorial, Changing the Conversation About Opioid Tapering*, 167 ANNALS INTERNAL MED. 208, 208 (2017) (explaining that the CDC had not supported “involuntary or precipitous tapering”).

so,⁶⁴ however, then the previously discussed implied preemption arguments might enjoy greater traction.⁶⁵

E. Imposing a Surcharge on Opioid Sales in New York

In 2018, the New York legislature enacted the Opioid Stewardship Act.⁶⁶ By imposing surcharges on the sale of opioids, the state sought to collect \$100 million annually.⁶⁷ The statute prohibited companies from passing these charges on to their customers through price increases,⁶⁸ though it failed to specify the territorial reach of this prohibition. Although the funds would also support prevention efforts, including operation of the state's PDMP, the law sought primarily to fund treatment and other responses to opioid addiction.⁶⁹

Members of the industry promptly lodged various constitutional objections to the statute. A federal district court held that

64. Cf. Lev Facher, *Painful Change; Oregon's Plan to Cut off Coverage of Opioid Painkillers for Some Medicaid Patients Is Prompting a National Debate*, BOS. GLOBE, Aug. 20, 2018, at B9 ("State officials are considering a first-in-the-nation proposal that would end coverage of opioids for many chronic pain patients who . . . are enrolled in Oregon's Medicaid program. Over just 12 months, beginning in 2020, they would see their opioid doses tapered to zero.").

65. See *supra* notes 36–47 and accompanying text. Separately, the DEA adopted a rule more than a decade ago to allow limited circumvention of the statutory prohibition on refills for Schedule II drugs by letting patients receive three 30-day prescriptions at a single visit. See *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 Fed. Reg. 64,921, 64,930 (Nov. 19, 2007) (codified at 21 C.F.R. § 1306.12(b)). To the extent that it did so in order to facilitate patient access, state laws that now impose greater restrictions arguably frustrate the purposes of federal law (notwithstanding the CDC's seemingly stricter advisory guidelines, which do not qualify as binding federal law).

66. See 2018 N.Y. Laws ch. 57, pt. NN; see also Sara Randazz, *Opioid Companies Fight New Tax*, WALL ST. J., Nov. 20, 2018, at A2 ("More than a dozen other states have considered some form of opioid tax in the 2018 legislative session, but only New York's has become a law, according to the National Conference of State Legislatures."). Minnesota subsequently passed a similar law. See Torey van Oot, *Fees from Drugmakers Will Fund Opioid Fight*, MINN. STAR TRIB. (MN), May 21, 2019, at 1A (reporting that the largest manufacturers of opioids initially would pay more than \$300,000 annually into a special fund to support prevention and treatment programs).

67. See N.Y. PUBLIC HEALTH LAW § 3323(3) (McKinney 2019). Manufacturers and distributors would have their ratable shares calculated on the basis of morphine milligram equivalents that they sold rather than as a percentage of sales price. See *id.* § 3323(5).

68. See *id.* § 3323(2). The law would sunset after six years. See 2018 N.Y. Laws ch. 57, pt. NN, § 5.

69. See N.Y. STATE FINANCE LAW § 97-aaaaa(4) (McKinney 2019). After all, by barring companies from passing along the charges to patients, the law could not have reduced the use of these drugs by making them less affordable, though, given the way that it calculated surcharges, it may have driven lower cost generic formulations from the market.

the pass-through prohibition ran afoul of the dormant Commerce Clause doctrine.⁷⁰ It recognized that the law, by making it prohibitively expensive for generic drug manufacturers to continue selling in New York, “could well *reduce* the availability of opioid medications for those who need them.”⁷¹ The decision prompted the state legislature to replace the surcharge with an excise tax designed to generate the same funds.⁷² Although patients with drug benefit coverage typically would not show much sensitivity to changes in prices, their health insurers often do,⁷³ while other purchasers—both legitimate and illegitimate—might turn to entirely illicit opioids in the face of escalating prices for the FDA-approved prescription products.⁷⁴

70. See *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 261–63 (S.D.N.Y. 2018) (explaining that it either had an impermissible extraterritorial reach or, if the prohibition applied only to sales within the state of New York, it would discriminate against out-of-state buyers, effectively forcing them to subsidize benefits for residents of New York), *app. pending* (2d Cir.); see also *id.* at 265 (declining to reach the plaintiffs’ other constitutional objections).

71. *Id.* at 266. Although OxyContin and other brand-name opioids attract most of the attention, they account for only a tiny fraction of the opioids prescribed in this country. See Aaron C. Davis et al., *Makers of Generics Had Key Role in Drug Crisis, Records Show*, WASH. POST, July 28, 2019, at A1 (“[R]ecords show that by 2006, as the death rate accelerated, a handful of obscure generic-drug manufacturers were selling the bulk of opioid pills flooding the country.”).

72. See 2019 N.Y. Laws ch. 59, pt. XX (to be codified as N.Y. TAX LAW §§ 497–499). Separately, the attorney general of New York and other public entities have pursued lawsuits against the industry in hopes of securing sizeable settlements that may get earmarked for similar purposes. See Roni Caryn Rabin, *Opioid Barons Stashed Assets, N.Y. Suit Says*, N.Y. TIMES, Mar. 29, 2019, at A1; see also Jan Hoffman, *As Opioid Case Moves to Trial, Stage Is Set for a Landmark Ruling*, N.Y. TIMES, Oct. 21, 2019, at B2 (reporting that there are “now more than 2,300” public entity lawsuits, adding that the consolidated “federal opioid litigation is being called the most complex in American legal history”). As I have explained in commenting to the press, this strikes me as unproductive (though potentially lucrative!) scapegoating. See Harriet Ryan, *Washington City Sues OxyContin Drugmaker; Everett, Hit Hard by Opioid Addiction, Alleges That Purdue Pharma Ignored Criminal Trafficking*, L.A. TIMES, Jan. 20, 2017, at A1; Mitch Smith & Monica Davey, *With Overdoses on Rise, Cities and Counties Look for Someone to Blame*, N.Y. TIMES, Dec. 22, 2017, at A18 (“Critics say the litigation is a sideshow in the opioid debate—a chance for lawyers to make money and politicians to make headlines—rather than a lasting solution in the overwhelming crisis . . .”). In other respects, however, the pending state and local litigation falls beyond the scope of this article.

73. See Katie Thomas & Charles Ornstein, *Insurers Putting Cost over Safety with Painkillers*, N.Y. TIMES, Sept. 18, 2017, at A1 (reporting that drug benefit plans prefer reimbursing for the use of cheaper drugs even if they pose a greater risk of addiction).

74. Cf. Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 MARQ. INTELL. PROP. L. REV. 161, 178 (2015) (noting that “price reductions for opioid analgesics might further expand the black market” for diverted prescription products); Anna Wilde Mathews &

F. *Miscellaneous Other Prevention Strategies*

A few states have mandated that prescribers enter into treatment agreements with at least some of their pain patients,⁷⁵ and these contracts may call for periodic urine testing. Normally, suspicionless drug testing would confront serious constitutional problems,⁷⁶ but here it gets framed as a condition of access typically implemented by private actors.⁷⁷ Such laws seek to reduce the risk of misuse either because the added burden created by such mandates makes health professionals hesitate or because the agreements usefully engage patients in minimizing inappropriate use.⁷⁸ In a related vein, at least ten states have called for co-prescribing of the overdose reversal agent naloxone (e.g., the nasal spray Narcan®) whenever patients receive high doses of opioids,⁷⁹ which at

Leila Abboud, *FDA Approves Generic OxyContin; Teva, Endo Get Clearance After Agreeing to Implement Abuse-Reduction Programs*, WALL ST. J., Mar. 24, 2004, at A3 (“Law-enforcement officials have long been concerned about the potential for a bigger, cheaper, less well-controlled supply once [generic] versions of OxyContin are marketed by multiple companies.”).

75. See, e.g., ARK. CODE ANN. § 20-7-707(a)(2) (West 2019); FLA. STAT. § 456.44(3)(c) (2019); MASS. GEN. LAWS ch. 94C, § 18A(b) (2019); N.J. STAT. ANN. § 24:21-15.2(e)&(g) (West 2019); OKLA. STAT. tit. 63, § 2-309i(E) (2019); see also Michelle Andrews, *When Patients Have to Sign “Pain Contracts,”* WASH. POST, Apr. 5, 2011, at E4.

76. Cf. *Ferguson v. City of Charleston*, 532 U.S. 67, 77–86 (2001) (holding unconstitutional a public hospital’s program of disclosing to police urine test results of pregnant patients that had indicated prenatal cocaine exposure).

77. Cf. Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 234–36, 238 (2007) (discussing requirements that patients undergo regular pregnancy testing and agree to other steps if they wish to access prescription drugs known to cause serious birth defects); *id.* at 252–54, 257–58 & n.104 (explaining the nature of the “unconstitutional conditions” problem arguably posed by such programs).

78. See Joanna L. Starrels et al., *Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients with Chronic Pain*, 152 ANNALS INTERNAL MED. 712, 717–18 (2010); cf. Mark Collen, *Opioid Drug Contracts and Random Drug Testing for People with Chronic Pain—Think Twice*, 37 J.L. MED. & ETHICS 841, 844 (2009) (objecting that this approach amounts to “heavy-handed medicine”); Daniel S. Goldberg & Ben Rich, *Pharmacovigilance and the Plight of Chronic Pain Patients: In Pursuit of a Realistic and Responsible Ethic of Care*, 11 IND. HEALTH L. REV. 83, 102–22 (2014) (reviewing and critiquing the use of opioid contracts).

79. See Christine Vestal, *New Naloxone Laws in U.S. Seek to Stop Overdoses; Doctors on Board with Initiatives*, PITT. POST-GAZETTE (PA), May 5, 2019, at A4 (noting the recent passage of such laws in Arizona, California, Florida, New Mexico, Ohio, Rhode Island, Vermont, Virginia and Washington); see also Terry DeMio, *Doctors Must Pitch Naloxone*, CIN. ENQUIRER (OH), May 7, 2019, at A4 (reporting on a new rule from the State Medical Board of Ohio that requires a discussion of naloxone with chronic pain patients when initially prescribing high-dose opioids).

the very least might help to underscore the seriousness of the risks associated with the latter.⁸⁰

States and localities have launched campaigns to educate health care professionals as well as the public.⁸¹ A few states have imposed specialized training requirements for anyone wishing to prescribe opioids, mandating that they devote several hours to subjects such as pain management and addiction.⁸² Other states have added coverage of such topics to their generally applicable rules for continuing medical education (CME).⁸³ A few states also require

80. See Alexander Y. Walley, Editorial, *Mainstreaming Naloxone Through Coprescription to Patients Receiving Long-Term Opioid Therapy for Chronic Pain*, 165 ANNALS INTERNAL MED. 292, 292 (2016) (“Receiving a naloxone rescue kit may have served as tangible reinforcement of overdose prevention messages, though this warrants further study.”); Vestal, *supra* note 79, at A4 (quoting Dr. Andrew Kolodny, the director of Physicians for Responsible Opioid Prescribing, to this effect); see also Ayres & Jalal, *supra* note 16, at 388 (“[T]he impact of other opioid-related policies operates on prescriptions through more indirect channels such as awareness amongst doctors of the extent, urgency and consequences of the misuse and abuse of prescription opioids.”); *id.* at 398 (elaborating on this point).

81. See, e.g., FLA. STAT. § 893.30 (2019); see also Parker et al., *supra* note 6, at 370 (“At least 37 states have a public education campaign specific to the opioid epidemic, and more are developing such programs.”); *id.* (“The evidence regarding the effectiveness of antidrug education initiatives is mixed, at best. Studies indicate that many prevention campaigns do not have a significant impact.”). One interesting initiative, which had the local medical examiner’s office send letters to prescribers when one of their patients died, apparently made an impression on recipients. See Jason N. Doctor et al., *Opioid Prescribing Decreases After Learning of a Patient’s Fatal Overdose*, 361 SCIENCE 588, 588–89 (2018); Margot Sanger-Katz, *Cheap Way to Fight Misuse of Drugs? Stern Letter to Doctor*, N.Y. TIMES, Sept. 7, 2018, at A20; see also Felice J. Freyer, *Doctors Warned on Scripts; US Attorney Cites Opioid Practices*, BOS. GLOBE, Nov. 30, 2018, at B1 (reporting similar initiatives taken by federal prosecutors in Massachusetts and Georgia, though sending letters with a more accusatory tone).

82. See, e.g., MASS. GEN. LAWS. ch. 94C, § 18(e) (2019); N.Y. PUB. HEALTH LAW § 3309-a(3) (McKinney 2019) (requiring three hours of such training every three years); OR. REV. STAT. § 413.590 (2019); N.M. CODE R. § 16.10.14.11(B) (LexisNexis 2019) (requiring physicians with DEA registrations to take five hours of CME on these subjects every three years); see also CAL. BUS. & PROF. CODE § 2190.5(a) (West 2019) (requiring it of essentially all physicians and surgeons); Corey S. Davis & Derek Carr, *Physician Continuing Education to Reduce Opioid Misuse, Abuse, and Overdose: Many Opportunities, Few Requirements*, 163 DRUG & ALCOHOL DEPENDENCE 100, 102–04 (2016) (surveying the range of requirements around the country); *id.* at 105 (“Physicians currently receive minimal, if any, training on pain management, the proper prescribing of controlled substances, and the identification and treatment of substance use disorder.”); NCLS Prescribing Policies (Oct. 2018 compilation), *supra* note 57 (under the “State Action” tab) (“States have also created requirements for training or education for providers related to opioids, such as training in prescribing controlled substances, pain management and identifying substance use disorders.”).

83. See, e.g., CONN. GEN. STAT. § 20-10b(b)(3)(B) (2019); see also Parker et al., *supra* note 6, at 370 (“Only five states require that all physicians receive CME on pain management. Eight more apply such requirements to those licensed to

that physicians disclose to their patients certain risks associated with prescription opioids and recommendations for safe storage in the home.⁸⁴

Lastly, localities have promoted drug take-back programs—for instance, by installing secure drop-boxes at police stations—in part to get surplus opioids out of people’s medicine cabinets and guard against the risk of diversion.⁸⁵ One county in California obligated manufacturers of any type of drug product to establish a program to take back and safely dispose of unused supplies.⁸⁶ In rejecting the industry’s dormant Commerce Clause challenge, a federal appellate court emphasized the relatively trivial financial burden imposed by this ordinance: at most, it would cost little more than 0.1% of the revenues generated by those companies in that county.⁸⁷ In practice, however, these programs have hardly made a dent in our still plentiful supply of prescription opioid products.⁸⁸

prescribe or dispense controlled substances This leaves a significant number of states with minimal or no required pain management education.”).

84. See, e.g., NEB. REV. STAT. § 28-473 (2019); 21 R.I. GEN. LAWS § 28-3.18(q) (2019); TENN. CODE ANN. § 63-1-164(a)(4)(A) (2019) (also requiring that women of child-bearing age receive information about neonatal abstinence syndrome); N.H. CODE ADMIN. R. Med. 501.02(i)(3)(A) (LexisNexis 2019). Other states require disclosures only when prescribing opioids to minors under certain circumstances. See MASS. GEN. LAWS ch. 94C, § 19D(a) (2019); OHIO REV. CODE ANN. § 3719.061 (West 2019); S.C. CODE ANN. § 44-53-363 (2019). Still other states require that patients receive prominent written warnings upon dispensing by pharmacists. See, e.g., COLO. REV. STAT. § 12-42.5-121(3) (2019); HAW. REV. STAT. § 329-39.5 (2019).

85. See Parker et al., *supra* note 6, at 371. The DEA has promoted local efforts to take back controlled substances. See Disposal of Controlled Substances, 79 Fed. Reg. 53,520, 53,567–69 (Sept. 9, 2014) (codified at 21 C.F.R. pt. 1317(B)). In 2018, a pair of states mandated that the industry create such programs applicable to all drugs. See N.Y. PUB. HEALTH LAW § 291 (McKinney 2019); WASH. REV. CODE § 69.48.030 (2019).

86. See Abby Sewell, *Firms Fight Drug Disposal Plan; The Industry Resists a Proposal Requiring It to Pay to Collect Unused Medications*, L.A. TIMES, Mar. 28, 2016, at B1 (reporting that other municipalities in the state had followed the lead of Alameda County, adding that the ordinances aim to reduce contamination of the water supply as well as the abuse of prescription drugs).

87. See Pharm. Research & Mfrs. Am. v. Cnty. of Alameda, 768 F.3d 1037, 1045 (9th Cir. 2014) (“The county compares the cost of running the disposal program (\$530,000–\$1,200,000 per year) to the manufacturers’ revenue-stream in Alameda County (approximately \$950 million per year) to conclude that the burden is minimal.”); see also Bob Egelko, *Top Court OKs Drug Disposal Measure; Firms Must Bear Cost in Alameda County; County Can Make Manufacturers Pay for Discarded Drugs*, S.F. CHRON., May 27, 2015, at D1 (explaining that other countries have long imposed similar requirements).

88. See Kathleen L. Egan et al., *From Dispensed to Disposed: Evaluating the Effectiveness of Disposal Programs Through a Comparison with Prescription Drug Monitoring Program Data*, 43 AM. J. DRUG & ALCOHOL ABUSE 69, 74–75 (2017); Parker et al., *supra* note 6, at 371 (concluding that “take-back programs are un-

II. STEERING CLEAR OF FOURTEENTH AMENDMENT OBSTACLES

Previous sections have touched on preemption under the Supremacy Clause and the dormant Commerce Clause doctrine as potentially limiting state initiatives to combat the prescription opioid crisis. This Part considers other potential constitutional obstacles—namely, those arising under the Fourteenth Amendment. Putting aside its incorporation of First Amendment rights against the states, which gives sellers possible commercial speech objections,⁸⁹ the Fourteenth Amendment shifts the focus to the potential rights of buyers. Although many of the previously discussed initiatives would in no sense burden whatever fundamental rights patients enjoy, some of the more restrictive state laws might unduly intrude on interests protected by the U.S. Constitution.

I could find only a single scholarly article that even hinted at such possible constitutional objections to recent state initiatives responding to the prescription opioid crisis.⁹⁰ Strangely, this group of authors focused on the arguable rights that physicians enjoy as distinct from those of their patients, though they noted that these would redound to the benefit of the latter group,⁹¹ and they repeatedly emphasized the “extremely unusual” nature of these governmental restrictions on medical practice.⁹² Drawing on a decidedly unrepresentative smattering of lower court decisions related to the

likely to significantly reduce the prescription opioid supply”); *cf.* Dineen, *supra* note 3, at 74 (applauding even such admittedly “modest” efforts).

89. *See supra* notes 24–27 and accompanying text (discussing such objections to aspects of Florida’s crackdown on pill mills).

90. *See* Nathan Guevremont et al., *Physician Autonomy and the Opioid Crisis*, 46 J.L. MED. & ETHICS 203, 207–10 (2018) (discussing recent restrictions in five states); *see also id.* at 207 (“The [opioid] prescription limits are unusual in that they are binding and specific, contrasting with typical practice guidelines, which tend to be general and advisory.”); *id.* at 208 (“[T]he [prescribing] guidelines are unusually detailed and specific.”). The three authors, all affiliated with the Yale Law School, included a student (as the lead author), an adjunct instructor, and a research fellow.

91. *See id.* at 215 (arguing that the restrictions work “at the expense of physician autonomy, whose goal, ultimately, is to allow the physician to assure the best treatment of the individual patient”); *id.* at 216 (“[T]hese efforts could be more narrowly tailored, impose less on the autonomy of physician decision-making, and do less damage to those patients for whom opioid prescriptions are medically indicated.”).

92. *Id.* at 210; *see also id.* at 203 (arguing that laws applicable to opioid use “curtail physician autonomy to a greater degree than in almost any other area of medical practice”); *id.* at 204 (“[I]t is one of the few areas in which legislatures have interfered with physician self-regulation.”); *id.* (“[W]hen it comes to opioids state legislatures increasingly have abandoned the historical norm of physician self-regulation.”).

use of abortifacient drugs,⁹³ compelled physician speech, and restrictions on questioning patients about gun ownership,⁹⁴ these authors ultimately invoked the limited judicial recognition of constitutional safeguards in this context only to buttress their broader conclusion that policymakers should let the medical community get its own house in order rather than threaten the autonomy of physicians to use opioids as they see fit.⁹⁵ Their half-hearted constitutional analysis strikes me as weak,⁹⁶ and I find even less merit in their affiliated policy arguments.⁹⁷ The sections that follow will offer a more serious assessment of possible Fourteenth Amendment objections.

93. For instance, the authors focused on a 2013 decision invalidating an Oklahoma law that had prohibited the off-label use of the abortifacient drug Mifeprex® (mifepristone) or the ulcer drug Cytotec® (misoprostol). *See id.* at 212 (discussing *Cline v. Okla. Coalition Reprod. Justice*, 313 P.3d 253, 262 (Okla. 2013)). In fact, that court had invalidated the law one year earlier, the U.S. Supreme Court granted certiorari but certified questions about statute's coverage back to the Oklahoma Supreme Court, the cited opinion answered those questions in a manner that then prompted the Court to dismiss certiorari as improvidently granted, 571 U.S. 985 (2013). The state legislature revisited the issue one year later, but the Oklahoma Supreme Court ultimately invalidated that effort as well. *See infra* note 136. Apart from the authors' failure to discuss the parts of this convoluted history available to them at the time, they entirely failed to mention that a pair of federal appellate courts already had held otherwise in reviewing challenges to similar state laws. *See Noah, supra* note 4, at 18 n.69 (citing decisions from the U.S. Courts of Appeals for the Fifth and Sixth Circuits).

94. *See Guevremont et al., supra* note 90, at 211–13; *see also id.* at 215 (“Constitutional and statutory challenges may be available Laws requiring physician speech in this context may find close analogues in similar laws in the abortion context and raise First Amendment concerns. Other potential sources of law may be state and/or federal constitutional privacy doctrines”).

95. *See id.* at 214–16.

96. *See Noah, supra* note 45, at 158–71; *see also id.* at 168 (“Congress has chosen to leave matters of medicine to the states, which in turn have chosen to leave these matters largely to professional self-regulation. Nothing in the Constitution requires that doctors be given such a wide berth.”); *id.* at 193 (“[E]fforts to protect patients by limiting the distribution of hazardous prescription drugs should not founder on an exaggerated preoccupation with the rights of either states or physicians.”).

97. *See Noah, supra* note 1, at 766–84; *see also Noah, supra* note 54, at 391–95, 402–06, 438–42 (discussing the difficulties that physicians encounter in accessing and acting upon clinically relevant evidence); Gina Kolata, *10 Medical Myths That Everyone Should Stop Believing*, N.Y. TIMES, July 2, 2019, at D5 (“[R]esearchers recently discovered that nearly 400 routine practices were flatly contradicted by studies published in leading journals. Of more than 3,000 studies [that they reviewed] . . . , more than one of 10 amounted to a ‘medical reversal’: a conclusion opposite of what had been conventional wisdom among doctors.”). In fact, the medical profession has gotten a free pass from lawmakers for far too long, so the crackdown on the irresponsible prescribing of opioids strikes me as a long overdue come-uppance for physicians that might usefully usher in closer scrutiny of their practices in other areas.

A. *Varied Aspects of Substantive Due Process*

More than forty years ago, one early version of a PDMP got assailed under the Fourteenth Amendment. In *Whalen v. Roe*,⁹⁸ the U.S. Supreme Court rejected a substantive due process challenge to New York legislation that had required the use of triplicate prescription forms (with a copy sent to state officials) for purposes of monitoring the use of Schedule II drugs.⁹⁹ The plaintiffs had claimed, among other things, that the centralized reporting requirement would interfere with patients' privacy-based rights to make independent decisions about the use of drugs.¹⁰⁰ The Court held that the reporting mechanism imposed no serious burden on such choices.¹⁰¹

In further explaining this decision, Justice Stevens remarked: "Although the State no doubt could prohibit entirely the use of particular Schedule II drugs, it has not done so. This case is therefore unlike those in which the Court held that a total prohibition of certain conduct was an impermissible deprivation of liberty."¹⁰² Does this language suggest that a state could altogether bar access to a drug without any particularly good reason, as implied by the first sentence quoted above; or did the Court instead recognize that a state might well have good reasons for doing so, as implied by reading the second sentence quoted above as a limitation on the first and in view of the fact that, by definition, Schedule II drugs carry a high potential for abuse?¹⁰³ Only rarely have courts or commentators referenced this passage from *Whalen*, much less tried to make sense of it.¹⁰⁴

98. *Whalen v. Roe*, 429 U.S. 589 (1977).

99. *See id.* at 597–604.

100. *See id.* at 598–600.

101. *See id.* at 602–04; *id.* at 606 ("[T]his record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment."). *But cf.* *Thornburgh v. Am. Coll. Obstetricians & Gynecologists*, 476 U.S. 747, 766–68 (1986) (crediting concerns that a state requirement for reports about abortion procedures might chill patients who feared public disclosure of this sensitive information).

102. *Whalen*, 429 U.S. at 603 (footnote omitted); *see also id.* at 603 n.30 ("It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions.").

103. *See* Elizabeth G. Patterson, *Health Care Choice and the Constitution: Reconciling Privacy and Public Health*, 42 RUTGERS L. REV. 1, 29–30 n.149 (1989) ("[T]his dictum appears to reflect a perception that the public interest behind such a prohibition would be strong, rather than that the right to privacy would not be implicated."); *see also Whalen*, 429 U.S. at 592–93 ("Our concern is limited to Schedule II which includes the most dangerous of the legitimate drugs.").

104. *See, e.g., Borucki v. Ryan*, 827 F.2d 836, 841 n.7 (1st Cir. 1987); *Lewis v. Superior Court*, 397 P.3d 1011, 1019 (Cal. 2017); *State v. Wiedeman*, 835 N.W.2d 698, 709 (Neb. 2013); *Doe v. Axelrod*, 527 N.Y.S.2d 385, 401 (App. Div. 1988);

Two decades later, in its physician-assisted suicide decisions, the U.S. Supreme Court rejected the argument that either physicians or patients enjoyed a fundamental right of access to pharmaceuticals for uses not approved by the FDA.¹⁰⁵ It seemed, however, that five of the Justices would have recognized a right to obtain medication for palliative purposes even if the use of such drugs might hasten death,¹⁰⁶ which at least suggests the possibility of a comparable right of access for patients without a terminal illness if appropriate use of the drugs would not pose any risk of fatality.¹⁰⁷ That possible extension aside, a slim majority at the time evidently felt that terminally-ill patients enjoyed a fundamental right of access to opioid analgesics.¹⁰⁸

Margaret B. Hoppin, Note, *Overly Intimate Surveillance: Why Emergent Public Health Surveillance Programs Deserve Strict Scrutiny Under the Fourteenth Amendment*, 87 N.Y.U. L. REV. 1950, 1968 & n.89 (2012); see also B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 304 (2007) (recognizing that “the Court’s statements about outlawing certain drugs were pure dicta”); Note, *Last Resorts and Fundamental Rights: The Substantive Due Process Implications of Prohibitions on Medical Marijuana*, 118 HARV. L. REV. 1985, 1996 n.61 (2005) (suggesting why “this point should be treated with care”).

105. See *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (concluding that the claimed right was neither “deeply rooted in this Nation’s history and tradition” nor “implicit in the concept of ordered liberty”); *id.* at 735 (holding that the state’s prohibition survived review under the rational basis test); see also *Vacco v. Quill*, 521 U.S. 793, 800–01, 808–09 (1997) (rejecting an equal protection challenge to a New York statute that prohibited anyone from assisting suicide notwithstanding the fact that another statute had authorized competent patients to decline resuscitation efforts); Lars Noah, *Turn the Beat Around?: Deactivating Implanted Cardiac-Assist Devices*, 39 WM. MITCHELL L. REV. 1229, 1260–67 (2013) (discussing these decisions and patient requests to discontinue the use of life-sustaining medical devices).

106. See, e.g., *Glucksberg*, 521 U.S. at 792 (Breyer, J., concurring in the judgment) (suggesting that the Court might hold it unconstitutional “were state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life”).

107. See Beth Packman Weinman, *Freedom from Pain: Establishing a Constitutional Right to Pain Relief*, 24 J. LEGAL MED. 495, 528 (2003) (“While [Justice Breyer] does not explicitly state that barriers to adequate pain treatment in nonterminal patients also would potentially represent a constitutional violation, such a conclusion seems implicit in his reasoning.”); *id.* at 529 (“It seems logical to imply from Justice Stevens’ argument that he would support a constitutional right to pain treatment that does not hasten death for nonterminal pain.”); see also John A. Robertson, *Embryo Culture and the “Culture of Life”: Constitutional Issues in the Embryonic Stem Cell Debate*, 2006 U. CHI. LEGAL F. 1, 10 (“[T]he right to use safe and effective medical treatments could also be grounded in liberty rights to be free of pain or disability.”).

108. See Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care*, 337 NEW ENG. J. MED. 1234, 1234–35 (1997); Yale Kamisar, *On the Meaning and Impact of the Physician-Assisted Suicide Cases*, 82 MINN. L. REV. 895, 908–09 (1998). Subsequent decisions also reflect a

B. Judging When Burdens Become Undue

The U.S. Supreme Court increasingly evaluates substantive due process claims by asking whether a challenged state action poses an “undue burden” to the exercise of a fundamental right.¹⁰⁹ Certain state and local initiatives, such as public education campaigns and drug take-back programs, obviously pose no burden on continued access by legitimate patients, but these sorts of efforts also seem likely to have little or no impact on the opioid crisis. At the other extreme, outright bans would erect substantial obstacles to access, though the effort to do so in Massachusetts had targeted only a single opioid product, which left any number of substitutes available.¹¹⁰ For the most part, however, states have not taken draconian steps such as banning individual drugs, preferring instead more nuanced measures that focus on the behavior of prescribers and dispensers. Nonetheless, laws that single out opioids as a class while ignoring similarly situated drugs (for instance, others listed in Schedule II) arguably impose undue burdens on the rights of patients;¹¹¹ minimum rationality tolerates underinclusiveness, but heightened forms of scrutiny would demand some justification for this differential treatment.¹¹² In this respect, contrast PDMP

more flexible approach to recognizing fundamental rights. See Kenji Yoshino, *A New Birth of Freedom?: Obergefell v. Hodges*, 129 HARV. L. REV. 147, 148 (2015) (calling the Court’s same-sex marriage decision “a game changer for substantive due process jurisprudence”). Although the membership of the Court has changed in the meantime, which might herald a return to the grudging approach reflected in *Glucksberg*, a willingness to find a constitutional right of access to palliative care at least for the terminally-ill may survive.

109. See Pamela S. Karlan, *Undue Burdens and Potential Opportunities in Voting Rights and Abortion Law*, 93 IND. L.J. 139, 145–51 (2018) (arguing that this form of balancing has in practice come to resemble rational basis scrutiny); *id.* at 155–56 (adding that the Supreme Court’s latest abortion decision gave the test more teeth); Mary Ziegler, *Rethinking an Undue Burden: Whole Woman’s Health’s New Approach to Fundamental Rights*, 85 TENN. L. REV. 461, 488–502, 511–15 (2018) (same). *But cf.* *June Med. Servs., L.L.C. v. Gee*, 905 F.3d 787, 805–15 (5th Cir. 2018) (rejecting a facial challenge to Louisiana’s admitting privileges requirement applicable to both surgical and medication abortions), *cert. granted*, 140 S. Ct. 35 (No. 18-1323 Oct. 4, 2019).

110. See Noah, *supra* note 4, at 58 (conceding that “Zohydro hardly qualifies as a life-saving drug, and patients in severe pain would still have any number of long-acting opioid analgesic substitutes available to them”); *see also supra* note 42 (noting the objection to singling out just one opioid).

111. *Cf.* Kate L. Fetrow, Note, *Taking Abortion Rights Seriously: Toward a Holistic Undue Burden Jurisprudence*, 70 STAN. L. REV. 319, 338–39, 343–44, 352–53, 356–59, 362 (2018) (arguing that the regulation of comparable medical procedures should serve as the baseline for assessing the constitutionality of state-enforced restrictions).

112. See Lars Noah, *When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?*, 85 GEO. WASH. L. REV. 1462, 1465–68 (2017).

databases, which generally do not target only narcotic analgesics even if the opioid crisis inspired more states to adopt more demanding requirements, with pill mill laws and prescribing restrictions, which single out these drugs.¹¹³

Most of the prescribing restrictions adopted by states sweep across the entire range of FDA-approved narcotic analgesics, and they have prompted objections about sacrificing the needs of those for whom opioids may offer the only effective form of treatment for their pain.¹¹⁴ As one physician put it: “Trying to correct prescription drug abuse by targeting the number of prescriptions is similar to trying to decrease automobile accidents by reducing the number of cars; it may have some effect, but it will leave many walking.”¹¹⁵ Conversely, some of these laws apply only to acute pain,¹¹⁶ chronic nonmalignant pain,¹¹⁷ or otherwise explicitly carve out palliative

113. See Dineen, *supra* note 63, at 974–75, 999–1001, 1005; *id.* at 996 (“State prescribing laws and regulations singled out opioid prescribing for chronic pain, while ignoring completely the palpable harms of other drug classes and practices that left significant numbers of pills available for diversion.”); Guevremont et al., *supra* note 90, at 214 (objecting to “opioid exceptionalism,” pointing out that “stimulants have not been widely singled out for prescription limitations”).

114. See Guevremont et al., *supra* note 90, at 207 (“Some physicians have argued that such ‘hard limits’ [on opioid prescribing] prevent them from adequately addressing individual patients’ needs.”); Joel Achenbach & Lenny Bernstein, *Pain Patients Frustrated by a Crackdown*, WASH. POST, Sept. 11, 2019, at A1; Stephanie Armour, *Opioid Curbs Face Patients’ Pushback*, WALL ST. J., Apr. 27, 2018, at A3 (“Patient groups and health providers are increasingly challenging the limits that have been placed on prescription opioids in the name of combating the epidemic.”); Jan Hoffman, *His Patients in Pain, a Doctor Must Limit Their Use of Opioids*, N.Y. TIMES, Mar. 17, 2016, at A1; Terrence McCoy, “Unintended Consequences,” WASH. POST, June 3, 2018, at A1 (“The correction has been so rapid, and so excruciating for some patients, that a growing number of doctors, health experts and patient advocates are expressing alarm . . .”).

115. Frankie M. Griffin, *Prescription Opioids in Arkansas: Finding Legislative Balance*, 68 ARK. L. REV. 913, 915 (2016); see also *id.* at 958 (elaborating); Kurt Kroenke & Andrea Cheville, *Management of Chronic Pain in the Aftermath of the Opioid Backlash*, 317 JAMA 2365, 2365 (2017) (“[M]any patients respond better to one analgesic than another Given the small analgesic effect on average of most pain drugs, the few classes of analgesic options, and the frequent need for combination therapy, eliminating any class of analgesics from the current menu is undesirable.”); *id.* at 2366 (“Imperfect treatments do not justify therapeutic nihilism. A broad menu of partially effective treatment options maximizes the chances of achieving at least partial amelioration of chronic pain.”); *supra* notes 3 & 62 (referencing other commentators who have lodged similar objections).

116. See, e.g., FLA. STAT. § 456.44(5)(a) (2019); OKLA. STAT. tit. 63, § 2-309i(A) (2019).

117. See, e.g., FLA. STAT. § 456.44(3)(c) (2019); MASS. GEN. LAWS ch. 94C, § 18A(b) (2019). Genuine doubts exist about their comparative effectiveness in these patients. See, e.g., Jason W. Busse et al., *Opioids for Chronic Noncancer Pain: A Systematic Review and Meta-Analysis*, 320 JAMA 2448, 2456–57 (2018) (reviewing studies done on the question, and concluding that opioids appeared to offer no advantages over other drugs used in treating chronic pain). The authors

care for terminally-ill patients,¹¹⁸ which makes them better tailored though still raises concerns about potentially chilling even plainly defensible uses of opioids.

The freedom to make choices about medical interventions seems to differ constitutionally from other purchasing decisions in the marketplace of consumer goods and services.¹¹⁹ Lower courts have rejected claims of a constitutional right of access to potentially life-saving drugs not (yet) approved by the FDA,¹²⁰ much less to drugs not even undergoing clinical trials in the hopes of eventually securing a license from the agency.¹²¹ What, however, about pa-

did conclude that, “[c]ompared with placebo, opioids were associated with . . . small improvements in pain, physical functioning, and sleep quality.” *Id.* at 2456. In other words, trial subjects treated with opioids reported doing only marginally better (and in only some respects, though worse in others) than those subjects given dummy pills! Somewhat remarkably, one commentator recently touted this review article as finding “small but statistically significant improvements in pain, sleep quality, and physical function with the use of chronic opioid therapy (COT) in some groups,” Dineen, *supra* note 63, at 970–71 (meaning what groups, pain sufferers who otherwise would try to just tough it out?!), and she even complained that “the media widely reported that the study showed that opioids do not help at all,” *id.* at 971. Let us not forget that the prescription opioid crisis emerged in part because of misunderstandings about some flimsy findings that had appeared in the published medical literature. See Noah, *supra* note 1, at 759 & n.13.

118. See, e.g., OKLA. STAT. tit. 63, § 2-309i(H) (2019); TENN. CODE § 63-1-164(e)(1) (2019); see also NCLS Prescribing Policies (Oct. 2018 compilation), *supra* note 57 (under the “State Action” tab) (“Nearly half the states with limits specify that they apply to treating acute pain, and most states set exceptions for chronic pain treatment. In addition to exceptions for chronic pain, most laws also exempt treatment for cancer and palliative care from prescription limits.”).

119. See *Whalen v. Roe*, 429 U.S. 589, 603 (1977) (“Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication.”); Hill, *supra* note 104, at 305–13, 329–32, 341–45 (discussing the Court’s treatment of autonomy in making choices about medical care); Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1827 (2007) (“[T]o impose a substantial burden on the patient’s right to protect her life through medical procedures, the government should have to show that it has an extremely powerful reason for burdening the right and that the burden is genuinely necessary because the government’s goals can’t be achieved in less burdensome ways.” (footnote omitted)).

120. See *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 701, 711–13 (D.C. Cir. 2007) (en banc) (investigational drugs that have successfully completed Phase I trials for terminally-ill patients without any other options); *id.* at 701 (“We do not address the broader question of whether access to medicine might ever implicate fundamental rights.”); *CareToLive v. von Eschenbach*, 525 F. Supp. 2d 952, 965–66 (S.D. Ohio 2007) (rejecting constitutional objections to the FDA’s delay in approving an active cellular immunotherapy (Provenge®) for metastatic prostate cancer).

121. See, e.g., *Raich v. Gonzales*, 500 F.3d 850, 864–66 (9th Cir. 2007) (marijuana); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (amygdalin); *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) (same); *Pearson v. McCaffrey*, 139 F. Supp. 2d 113, 123 (D.D.C. 2001) (marijuana).

tients seeking access to a federally licensed narcotic analgesic for approved uses in a state that has decided to restrict its use; would that not substantially interfere with the rights of patients to make sometimes profound or sensitive decisions about the course of their medical care?

Two decades ago, the U.S. Supreme Court held that a state could not ban one of two recognized methods of late-term abortion without including an exception when necessary to protect a woman's health,¹²² while only seven years later it decided that Congress could do just that.¹²³ Although such medical procedures do not undergo any form of federal licensure,¹²⁴ this pair of decisions might help to explain what makes state restrictions on the use of an FDA-approved opioid problematic. If the agency has not approved a particular analgesic (or it has withdrawn such an approval), then generally no one in the country can secure access to it;¹²⁵ if, however, the agency has issued a license but one state acts to disregard it, then persons in that state (and only that state) cannot take advantage of an opioid even though it has received official sanction. In short, upon FDA approval of a drug the baseline shifts from non-availability to availability for pain patients, which a particular state's restrictions then would unsettle in a way that interfered with their freedom to make potentially critical medical choices.

The act of federal licensure, even if not enough to trigger implied preemption under the Supremacy Clause, seems to make the

122. See *Stenberg v. Carhart*, 530 U.S. 914, 930–38 (2000); see also *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 327–28, 331 (2006) (holding that a state restriction on minors' access to abortion required a health exception); Hill, *supra* note 104, at 310, 319–20, 322–25 (finding a more limited recognition of this exception in the Court's subsequent rejection of a challenge to the federal prohibition on late-term abortions); Volokh, *supra* note 119, at 1826 (“Postviability abortions cannot be distinguished on the ground that they involve the woman's reproductive choice. After viability, the time for that choice has passed, and the right to get a therapeutic abortion is a consequence of the woman's medical self-defense right, not her abortion-as-choice right.”). Commentators invoking the health exception required by the Supreme Court for abortion restrictions do so in order to claim a substantive due process right of terminally-ill patients without other options to access *investigational* drugs; surely such a constitutional claim more readily embraces a right of access to therapeutic products that already have received FDA approval.

123. See *Gonzales v. Carhart*, 550 U.S. 124, 161–67 (2007) (upholding the federal prohibition on “partial-birth” abortions even though it lacked a maternal health exception).

124. See Noah, *supra* note 54, at 447–49.

125. Similarly, once Congress banned partial birth abortion, Nebraska presumably could resurrect its earlier prohibition (carrying more draconian penalties than imposed under federal law) without running afoul of the Fourteenth Amendment.

state's burden of justification nearly impossible in the event that some form of heightened scrutiny applies.¹²⁶ Under what circumstances might a state have a substantial (much less a compelling) interest in limiting access to a drug that the FDA approved?¹²⁷ Indeed, the FDA's approval decision suggests that depriving legitimate patients of access would represent something of a hardship to them.¹²⁸ On the other side of the constitutional ledger, serious questions exist about the efficacy of the various initiatives that states have taken in this area,¹²⁹ which would not matter under the

126. Cf. Sarah Ricks, *The New French Abortion Pill: The Moral Property of Women*, 1 *YALE J.L. & FEMINISM* 75, 90–92, 99 (1989) (arguing that FDA approval of the abortifacient mifepristone would make it impossible for individual states seeking to prohibit use of the drug to invoke safety rationales if challenged as burdening the right to privacy).

127. If courts could freely disregard the FDA's risk-benefit judgment, then, because prescription opioids invariably carry a risk of serious side effects, state officials wanting to restrict access to a pharmaceutical product could simply point to the risk labeling approved by the agency as the basis for asserting a safety rationale for their action.

128. Cf. Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 *BROOK. L. REV.* 839, 855 (2009) (warning of “the twin dangers of tunnel-vision (risk-utility judged solely from a [tort] plaintiff’s perspective) and preference aggregation (risk-utility evaluated from a societal perspective), both of which might unduly sacrifice the needs of a minority of patients for whom the risk-utility balance differs from either the particular victim or the norm” (footnote omitted)); *id.* at 872–73 (illustrating with the infamous teratogen thalidomide). Critics sometimes devalue pain relievers as nontherapeutic agents. *See id.* at 865 (“[A]re powerful analgesics properly dismissed as merely ‘lifestyle’ drugs? Contraceptives sometimes get trivialized in this fashion.”); *id.* at 866 (“In the final analysis, all drugs are, to one degree or another, lifestyle drugs.”). If, however, some patients could not tolerate any of the alternatives, *see id.* at 849 & n.39, 855–56 (explaining the flaws in assuming therapeutic substitutability), then a state prohibition would deprive them of access to palliative care in seeming contravention of the Supreme Court’s guidance in the physician-assisted suicide cases, *see supra* note 107 and accompanying text; *see also* *Stenberg v. Carhart*, 530 U.S. 914, 934 (2000) (“A rarely used treatment might be necessary to treat a rarely occurring disease that could strike anyone—the State cannot prohibit a person from obtaining treatment simply by pointing out that most people do not need it.”).

129. *See, e.g.*, Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 *AM. J. PUB. HEALTH* 182, 183 (2018) (cautioning that “an exclusive focus on opioid supply hampers effective responses”); Haegerich et al., *supra* note 9, at 45 (concluding in 2014 that “overall the quality of evidence for the effectiveness of the reviewed [prevention] strategies is low”); Allison L. Pitt et al., *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic*, 108 *AM. J. PUB. HEALTH* 1394, 1398 (2018) (“We found that policies that expand addiction treatment or directly mitigate harmful effects of addiction (e.g., overdose, infection) are immediately and uniformly beneficial Policies that reduce the prescription opioid supply may generate both benefits and harms (at least in the short term)”); *id.* at 1399 (“[A]lthough our base case analysis found that reduced chronic pain prescribing did not reduce addiction-related deaths over 5 or 10 years, it reduces incidence of opioid addiction and would eventually reduce deaths.”); *see also supra* note 16 and accompanying

forgiving test of minimum rationality but becomes increasingly relevant as one climbs the tiers of constitutional scrutiny.¹³⁰

In 2000, the FDA approved the controversial abortifacient drug mifepristone (Mifeprex®).¹³¹ Several states decided to impose restrictions on use of this drug,¹³² which triggered challenges in the courts.¹³³ Insofar as these states simply mandated strict adherence to the directions for use specified in the labeling approved by the FDA, even though the agency itself does not do so,¹³⁴ they at least managed to avoid a direct confrontation with the federal li-

text (discussing research on PDMPs); *supra* note 22 and accompanying text (discussing research on pill mill laws); *supra* note 61 and accompanying text (discussing research on prescribing restrictions).

130. See *FCC v. Beach Comm'n's, Inc.*, 508 U.S. 307, 315 (1993) (explaining that only on minimum rationality review may a legislative choice “be based on rational speculation unsupported by evidence or empirical data”); Richard H. Fallon, Jr., *Strict Judicial Scrutiny*, 54 *UCLA L. REV.* 1267, 1273 (2007); Roy G. Spece, Jr. & David Yokum, *Scrutinizing Strict Scrutiny*, 40 *Vt. L. REV.* 285, 310–11 (2015).

131. See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 *WAKE FOREST L. REV.* 571, 571–90 (2001); see also Elizabeth Lawrence, *Women Explore Online Options for Abortion*, *USA TODAY*, June 26, 2019, at 1A (“Medication abortion before eight weeks’ gestation accounted for 24.6% of all abortions in the USA in 2015, according to the latest figures from the [CDC]. The FDA said taking the combination of pills in the first trimester has a success rate of 95% to 99%.”).

132. See Laurah J. Samuels, Note, *Mifepristone Protocol Legislation—The Anti-Choice Movement’s Disingenuous Method of Attack on the Reproductive Rights of Women and How Courts Should Respond*, 26 *COLUM. J. GENDER & L.* 316, 325–30 (2014) (discussing statutes from Arizona, North Dakota, Ohio, Oklahoma, and Texas).

133. See Noah, *supra* note 4, at 18–19 n.69 (citing split decisions among the various lower federal courts and one state supreme court that have confronted the issue, and noting that “[t]hese challenges claimed an undue burden on the abortion decision but did not raise any preemption arguments”); cf. *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292 (2016) (invalidating restrictions in a Texas statute, which required that abortion providers work in a facility on par with an ambulatory surgical center and have admitting privileges at a nearby hospital, as undue burdens); *id.* at 2315 (“The record makes clear that the surgical-center requirement provides no benefit when complications arise in the context of an abortion produced through medication.”); *supra* note 109 (noting that the Court recently granted certiorari to review a challenge to a similar statute in Louisiana).

134. See Marc Kaufman, *Death After Abortion Pill Reignites Safety Debate; Opponents Renew Drive to Ban Drug Woman Took*, *WASH. POST*, Nov. 3, 2003, at A3; see also Eric A. Schaff et al., *Vaginal Misoprostol Administered 1, 2, or 3 Days After Mifepristone for Early Medical Abortion*, 284 *JAMA* 1948, 1952 (2000) (“A regimen that requires misoprostol to be given in an office setting 2 days after mifepristone, followed by 4 hours of observation, . . . is unnecessarily restrictive and creates scheduling and additional cost barriers to women.”); Sarah Lueck, *Groups Offer Abortion-Drug Variations*, *WALL ST. J.*, Oct. 30, 2000, at B2. See generally Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 *AM. J.L. & MED.* 361, 397–99 (2002) (discussing the FDA’s recognition of the legitimacy of “off-label” use).

censing decision. After the agency revised the drug's labeling in order to facilitate readier access,¹³⁵ however, states that continued to bar any deviations from the now obsolete original directions for use should fare poorly in the courts.¹³⁶

To the extent that the prescription opioid epidemic came about through irresponsible off-label use,¹³⁷ states might consider imposing restrictions on these Schedule II drugs similar to those tried with mifepristone.¹³⁸ Apart from sometimes narrow indications for usage, however, the approved labeling for most opioids allows for a fair amount of flexibility,¹³⁹ but such a move would, for instance, bar much of the growing and arguably inappropriate use in adoles-

135. See Sabrina Tavernise, *New F.D.A. Rules Will Ease Access to Abortion Pill*, N.Y. TIMES, Mar. 31, 2016, at A1. One day later, a state reacted by mandating continued adherence to the now obsolete older protocol. See Erik Eckholm, *Arizona Governor Signs Abortion Bill That Skirts F.D.A. Decision*, N.Y. TIMES, Apr. 2, 2016, at A8.

136. See *Okla. Coalition Reprod. Justice v. Cline*, 441 P.3d 1145, 1153–61 (Okla. 2019) (invalidating such a statute as posing an undue burden on the abortion right). If, however, the U.S. Supreme Court backpedals on women's freedom to terminate a pregnancy, then the Supremacy Clause may become an increasingly important tool in the face of growing restrictions imposed by the states:

To the extent that recent Supreme Court cases have reinvigorated implied preemption in cases where state law stands as an "obstacle" to the achievement of federal purposes, one could argue that any state efforts to prohibit or restrict distribution of mifepristone would create an impermissible conflict with federal law. After all, the Clinton administration actively encouraged the introduction of mifepristone in the U.S. market, and it took some unprecedented steps to facilitate FDA approval. It would not necessarily matter that the new administration fails to share the goals that inspired the agency's earlier licensing decision.

Noah, *supra* note 131, at 601 (footnote omitted).

137. See Katie Thomas, *Doubts Raised About Off-Label Use of a Painkiller*, N.Y. TIMES, May 14, 2014, at B1 ("The F.D.A. approved [sublingual fentanyl spray] Subsys only for cancer patients who are already using round-the-clock painkillers, and warned that it should be prescribed only by oncologists and pain specialists. But just 1 percent of prescriptions are written by oncologists About half of the prescriptions were written by pain specialists, and a wide range of doctors prescribed the rest, including general practice physicians, neurologists and even dentists and podiatrists."). Apart from its narrowly drawn indications statement, the approved labeling for Subsys also explicitly contraindicated most other uses. See Stacey A. Tovino, *Fraud, Abuse, and Opioids*, 67 U. KAN. L. REV. 901, 909 (2019); see also Denise Grady, *U.S. Warns of Dangers from Patch Used for Pain*, N.Y. TIMES, July 16, 2005, at A10 (same for Duragesic® and other transdermal fentanyl patches).

138. Cf. Noah, *supra* note 1, at 783 (recommending that Congress do so); *id.* at 784 (conceding that "such a move would no doubt infuriate many physicians and the powerful associations that represent their interests").

139. See *In re Opioid Litig.*, No. 400000/2017, 2018 WL 3115102, at *10 (N.Y. Sup. Ct. June 18, 2018) (explaining that, in response to a citizen petition filed by Physicians for Responsible Opioid Prescribing in 2012, "the FDA declined to recommend a daily maximum dose or the maximum duration of opioid treatment").

cent patients.¹⁴⁰ Any patients thereby deprived of access to drugs would have to surmount the fact that the FDA had not approved a particular opioid for use in their condition,¹⁴¹ while those patients for whom the agency decided that the benefits might justify the risks would continue to enjoy relatively unfettered access. In contrast, state laws that interfere with access to opioids by patients unmistakably contemplated in the labeled indications would unduly burden their ability to exercise a fundamental right of access.

CONCLUSION

In order to prevent further overuse of prescription opioids, states have adopted a variety of strategies. Modest responses, which should not raise any serious constitutional questions, include physician education and patient disclosure requirements, public awareness campaigns, excise taxes, and drug take-back programs. More aggressive initiatives include mandatory queries of PDMPs by prescribers and dispensers, restrictions on the operation of pain-management clinics, prohibitions on the use of particularly hazardous opioids, and limitations on prescription duration and dosage. Although these seem to have a better chance of success, the over- and underinclusiveness of such laws makes them vulnerable to substantive due process challenges. In particular, if these regulatory efforts put substantial obstacles in the way of terminally-ill patients seeking palliative care, then states would face a difficult burden of justification. Chronic pain patients deprived of access to opioid analgesics approved for sale by federal regulators also might have valid constitutional objections to state laws that sweep too broadly,

140. See Joel D. Hudgins et al., *Trends in Opioid Prescribing for Adolescents and Young Adults in Ambulatory Care Settings*, 143 *PEDIATRICS* e20181578, at 6 (2019) (“[A]dolescents and young adults are at high risk for opioid misuse and abuse after exposure from medical treatment, and a number of studies indicate that the opioid epidemic disproportionately affects young people.”); see also Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain: Misconceptions and Mitigation Strategies*, 374 *NEW ENG. J. MED.* 1253, 1257 (2016) (“[I]n adolescents, the risks and benefits of prescribing opioids for pain management need to be even more carefully weighed than in adults.”); Catherine Saint Louis, *F.D.A. Approval of OxyContin Use for Children Continues to Draw Scrutiny*, *N.Y. TIMES*, Oct. 9, 2015, at A20 (reporting that the agency allowed the addition of a narrow indication for use in adolescents conditioned on the submission of postmarket data on patterns of use).

141. In fact, growing restrictions on opioids have reportedly caused an increase in the dangerous off-label use of non-narcotic drugs in some chronic pain patients. See Sheila Kaplan, *Curtailing Opioids, Not Back Pain*, *N.Y. TIMES*, July 31, 2018, at D1 (discussing epidural injections of steroids such as Depo-Medrol® (methylprednisone acetate)).

especially to the extent that these efforts do not effectively reduce the overdose rates.
