The U.S. Science and Technology "Triple Threat": A Regulatory Treatment Plan for the Nation's Addiction to Prescription Opioids

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I. INTRODUCTION

The United States government has demonstrated heightened self-awareness that it is a nation addicted to opioids. "National public health emergency," "unprecedented epidemic," "national crisis"—it has self-declared its state of opioid addiction, the equivalent of the nation introducing itself at a twelve-step meeting with, "I am the U.S., and I am an opioid addict." As the National Institutes on Health ("NIH") summarized:

> Opioid addiction, misuse and overdose is an ongoing and rapidly evolving public health crisis. An estimated 2 million Americans are addicted to opioids, and approximately 25 million suffer daily from chronic pain. Following a rapid increase in rates of opioid pain reliever prescribing, widespread use and misuse of these medications has risen at an alarming rate, giving way to a nation-wide crisis. Heroin use and addiction are now on the rise as some people shift from prescription opioids to their cheaper street relative. For Americans under 50 years of age, drug overdose is the leading cause of death.[1]

Through the Centers for Disease Control and Prevention ("CDC") and other authorities, the U.S. has documented its addiction empirically, and the numbers resonate deafeningly. Some of the sharpest are that the number of annual opioid prescriptions written in the U.S. now roughly equals the number of adults in the U.S. population.[2] There were almost 19,000 overdose deaths in the U.S. in

1. U.S. Dep't of Health & Human Servs., *NIH Opioid Initiative to Help End the Opioid Crisis*, NAT'L INSTS. ON HEALTH, https://www.nih.gov/node/34206 (last updated Dec. 8, 2017).

2. *See* NAT'L CTR. FOR INJURY PREVENTION & CONTROL, CTRS. FOR DISEASE CONTROL & PREVENTION, ANNUAL SURVEILLANCE REPORT OF DRUG-RELATED RISKS AND OUTCOMES: UNITED STATES, 2017, at 9–11 (2017) [hereinafter CDC, ANNUAL

2014 associated with prescription opioids (approximately fifty-two daily), and more than 50,000 in 2015 and 64,000 in 2017—most of which involved opioids.[3] Even more troubling, the number is escalating "faster than ever."[4] In fact, deaths in the U.S. from opioid overdoses now exceed the number of deaths caused by motor vehicle accidents.[5] The pain, suffering, and financial harm attributable to the opioid crisis that individuals, families, and communities throughout the country have endured is vastly more expansive, ongoing, and spreading.[6]

This Article addresses the U.S. government's responsiveness to the opioid crisis thus far, with a focus on achieving true national recovery. After profiling the scope of the U.S. opioid epidemic in Part II, the discussion in Part III centers on government responsiveness to the prescription opioid problem. Key U.S. government agencies have recognized the importance of intra-agency, interdisciplinary (particularly at the nexus areas among government agencies,

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SURVEILLANCE], https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN: IMPROVING PRACTICE THROUGH RECOMMENDATIONS (2017) [hereinafter CDC, PRESCRIBING GUIDELINE], https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (describing some of the risks associated with therapeutic prescription opioid use); Robert M. Califf, Janet Woodcock & Stephen Ostroff, *Special Report: A Proactive Response to Prescription Opioid Abuse*, 374 NEW ENG. J. MED. 1480, 1480 (Apr. 14, 2016) (internal citations omitted), https://www.nejm.org/doi/pdf/10.1056/NEJMsr1601307; *Prescribing Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/prescribing.html (last updated Aug. 30, 2017).

3. Exec. Order. No. 13,784, Establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis, 82 Fed. Reg. 16,283 (Mar. 29, 2017) [hereinafter Commission Exec. Order]; Califf, Woodcock & Ostroff, *supra* note 2, at 1480–81, 85; David A. Kessler, Opinion, *How to Fight the Opioid Crisis*, N.Y. TIMES, (Jan. 10, 2018), https://www.nytimes.com/2018/01/10/opinion/fight-opioid-crisis.html.

4. Kessler, *supra* note 3.

5. Gillian Mohney, *Deaths from Opioid Overdoses Now Higher Than Car Accident Fatalities*, HEALTHLINE (Mar. 30, 2018), https://www.healthline.com/health-news/deaths-from-opioid-overdoses-higher-than-car-accident-fatalities#1 (comparing mortality rates associated with opioid overdoses and vehicle collisions, respectively, in 2016).

6. *See, e.g.*, Commission Exec. Order, *supra* note 3.

biopharmaceutical R&D, and clinical medicine), and government-industry collaboration as essential for national opioid addiction recovery. There are shortcomings, however, that make responsiveness with the levels of efficacy and efficiency so direly needed—what recognition of "national public health emergency" status of the opioid epidemic underscores—questionable.

In Part IV, the Article proposes that the U.S. more fully, directly, and aggressively embrace its legacy of jolting the existing forefront of science forward through a government-academia-industry "triple threat" with the potential of placing the opioid crisis on the nation's continuum of enormous challenges that it has overcome. This continuum spans from splitting the atom to save democratic society during WWII, to landing a man on the moon during the Cold War, to mapping the human genome, and beyond. The Article concludes that, to realize a treatment plan sufficiently responsive to the nation's prescription opioid crisis, the U.S. must utilize the government-academia-industry trilogy as aggressively as it has in the past, with centralized leadership and sufficient funding, to conquer otherwise insurmountable challenges.

II. ADDICTION BY PRESCRIPTION

While stretching to reach the corner of the vaulted ceiling in her client's mid-century living room, Sydney loses her balance, falls off the ladder, and ends up flat on her back, sprawled on the terrazzo floor. Seth, running into Publix Super Market to pick up some baby formula during one of the afternoon showers so typical in Southern Florida, slips in the store aisle and falls on his hip, which will require surgery.

Although fictitious scenarios, Sydney and Seth represent the millions of Americans who use prescription opioids annually for legitimate pain management. "Over the course of a given year, approximately 100 million people in the United States suffer from pain. . . . while the remainder have short-term pain from injuries, illnesses, or medical procedures."[7] Reflective of opioids' highly addictive nature, the number of people who become addicted to them, beginning with legitimate prescription use, is astounding.[8] Moreover,

7. Califf, Woodcock & Ostroff, *supra* note 2, at 1480.

8. *See, e.g.*, CDC, ANNUAL SURVEILLANCE, *supra* note 2, at 13.

that number increases exponentially when patients do not use those prescriptions as written, and, in sync with expansion of the addiction epidemic, when someone other than the person for whom a caregiver writes an opioid prescription uses the drug.[9] As the President's National Commission on Combating Drug Addiction and the Opioid Crisis reports relayed, four out of every five new heroin users first use prescription opioids.[10] Although illicit trade of heroin and fentanyl increasingly feeds the nation's opioid addiction, according to the CDC, "20 percent of patients who receive an initial 10-day prescription for opioids will still be using" (or at least receiving) them after a year.[11]

Current physician opioid-prescribing practices evolved from a 1990s movement to better control pain with assurances from the pharmaceutical industry that patients would not become addicted to prescription opioid pain relievers, and reliance on the same pain medications for decades.[12] Coordination between the U.S. Food and Drug Administration ("FDA") and Drug Enforcement Administration ("DEA")—implementation of the Food Drug and Cosmetic Act and the Controlled Substances Act—to control spillage from prescription opioid use for legitimate pain purposes into uses beyond has failed

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9. *Id.* at 48–49.

10. THE PRESIDENT'S COMM'N ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, FINAL REPORT 28, 117 (2017) [hereinafter COMM'N FINAL REPORT], https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf; THE PRESIDENT'S COMM'N ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, DRAFT INTERIM REPORT 3 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf [hereinafter COMM'N INTERIM REPORT].

11. Katie Thomas & Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, N.Y. TIMES (Sept. 17, 2017), https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html.

12. *See generally* Ronald Melzack, *The Tragedy of Needless Pain*, 262 SCI. AM. 27 (1990) (proposing that morphine taken solely to control pain is not addictive, and that, worldwide, patients are undertreated and suffer unnecessary agony); *see also* Nat'l Institutes on Health, *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last updated Mar. 2018); Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current State, and Future Directions*, 16(5) EXP. CLIN. PSYCHOPHARMACOL. 405 (Oct. 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/pdf/nihms97365.pdf.

miserably.[13] According to the CDC, although from 1999 to 2014 there was no reported change in pain, U.S. sales of prescription opioids almost quadrupled.[14] Moreover, as the FDA recognizes, physicians have been prescribing opioids without a sound knowledge base about them and addiction and, for children, without clinical data.[15]

While U.S. Department of Health and Human Services ("HHS") research on the matter is ongoing, according to preliminary findings, insurers and pharmacy benefit managers have been making opioids more accessible than less addictive prescription alternatives and other non-prescription pain management treatments, such as physical therapy.[16] Market reality is that opioids, especially when available as generic drugs, are cheap relative to safer alternatives. For example, according to analysis by *The New York Times*:

> - "UnitedHealthcare, the nation's largest health insurer, places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a non-opioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first."[17]
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> - "[R]estrictions remain prevalent in Medicare plans, as well. Drug plans covering 33.6 million people include Suboxone, but two-thirds require prior authorization. Even when such requirements do not exist, the out-of-

13. *See generally infra* Section III.C.2.

14. *Infra* Section III.C.2. *See also* CDC, ANNUAL SURVEILLANCE, *supra* note 2.

15. Califf, Woodcock & Ostroff, *supra* note 2.

16. Thomas & Ornstein, *supra* note 11.

17. *Id.* ("The Drug Enforcement Administration places morphine in a higher category than Butrans for risk of abuse and dependence. Addiction experts say that buprenorphine also carries a lower risk of overdose."). Butrans is a pain-relief skin patch that contains buprenorphine, which is generally recognized as a less-risky opioid—including a lower risk of overdose. *See generally Butrans*, PURDUE PHARMA, https://butrans.com/ (last visited Aug. 9, 2018).

> pocket costs of the drugs are often unaffordable . . . ."[18]

- "Only one-third of the people covered [under Medicare prescription drug plans insuring 35.7 million people in the second quarter of 2017], for example, had any access to Butrans. And every drug plan that covered lidocaine patches, which are not addictive but cost more than other generic pain drugs, required that patients get prior approval for them. In contrast, almost every plan covered common opioids and very few required any prior approval."[19]

Moreover, with demand so high, opioids have been extremely profitable for their manufacturers and, accordingly, manufacturers have in turn marketed them aggressively—and, at times, unlawfully. One of the most infamous examples is Purdue Pharma's marketing of OxyContin, which made the company the subject of a 2007 lawsuit for unlawful marketing brought by twenty-seven state attorneys general and resulted in a $20 million settlement.[20] In a separate federal action, Purdue Pharma paid $600 million.[21] Three of its executives pled guilty to misbranding the drug, were ordered to pay $34.5 million, and were sentenced to three years of probation and 400 hours of community service.[22] The DEA case against the McKesson Corporation is another noted example.[23]

Pharmacy benefit managers, drug wholesalers, physicians, and drug manufacturers have become the subjects of myriad legal actions, and those are multiplying.[24] On February 27, 2018, Attorney General

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18. *Id.*

19. *Id.*

20. Laura Strickler, *Drugmakers May Face More Legal Action Over Opioid Epidemic*, CBS NEWS (Sept. 1, 2016, 5:39 PM) https://www.cbsnews.com/news/oxycontin-opioid-drug-makers-legal-action/ (last visited Aug. 19, 2018); *see generally infra* Section III.C.2.

21. Strickler, *supra* note 20.

22. *Id.*

23. *See generally infra* Section III.C.2.

24. *See infra* Section III.C.2. *See also* Lenny Bernstein & Scott Higham, *"We Feel like our System was Hijacked": DEA Agents Say a Huge Opioid Case Ended in*

Jeff Sessions announced a new Justice Department task force dedicated to fighting the opioid epidemic by targeting drug manufacturers and distributors whose overselling of prescription painkillers have fueled the opioid crisis, and assistance to existing state and local lawsuits doing the same.[25]

III. A GOVERNMENT INTERVENTION DIAGNOSIS

The CDC has compiled, and continues to impressively compile, empirical data in an ongoing manner to define the U.S. opioid crisis[26]—a contribution essential for self-awareness and to formulate effective, timely intervention strategies. Acknowledgement of the crisis has triggered a blitzkrieg of national and state programs and funding reactions sprawled among HHS, more than a dozen federal

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a Whimper, WASH. POST (Dec. 17, 2017, 9:31 PM), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html; *60 Minutes: The Biggest Opioid Case in U.S. History* (CBS television broadcast Dec. 17, 2017) [hereinafter *60 Minutes: Biggest Opioid Case*] (interviewing former assistant special agent David Schiller who, having served the agency for more than thirty years, headed the DEA investigation of McKesson); Strickler, *supra* note 20. For updated information on the states' class action, see *Opioid Lawsuits*, CLASSACTION.COM, https://www.classaction.com/opioids/lawsuit/ (last updated Jan. 5, 2018). In addition, "[t]he New York State attorney general's office sent letters last week to the three largest pharmacy benefit managers—CVS Caremark, Express Scripts and OptumRx—asking how they were addressing the crisis." Thomas & Ornstein, *supra* note 11. CVS responded by announcing prescription limits, effective February 1, 2018. *See generally* Press Release, CVS Health, CVS Health Fighting National Opioid Abuse Epidemic with Enterprise Initiatives (Sept. 21, 2017), https://cvshealth.com/newsroom/press-releases/cvs-health-fighting-national-opioid-abuse-epidemic-with-enterprise-initiatives ("This program will include limiting to seven days the supply of opioids dispensed for certain acute prescriptions for patients who are new to therapy; limiting the daily dosage of opioids dispensed based on the strength of the opioid; and requiring the use of immediate-release formulations of opioids before extended-release opioids are dispensed.").

25. Dan Mangan, *Attorney General Jeff Sessions Announces New Opioid Task Force to Target Drug Manufacturers, Distributors Who Fuel Prescription Painkiller Epidemic*, CNBC, https://www.cnbc.com/2018/02/27/attorney-general-jeff-sessions-announces-new-opiod-task-force.html (last updated Feb. 27, 2018, 3:39 PM).

26. *See* CDC, ANNUAL SURVEILLANCE, *supra* note 2; CDC, PRESCRIBING GUIDELINE, *supra* note 2.

agencies, professional medical organizations, and states.[27] In 2016, Congress authorized approximately $1.2 billion to support many of these efforts through the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act, and now has bolstered such initiatives further through $6 billion over the next two years appropriated under the Bipartisan Budget Act of 2018.[28]

Unfortunately, these efforts and associated funding do not amount to the meaningful intervention needed to realistically contain and reverse the ongoing and spreading epidemic: a tightly orchestrated intervention with defined and measurable objective priorities, centralized and accountable leadership, and secured funding sufficient to realize those objectives. As former FDA Commissioner David Kessler, who served under both Presidents George H.W. Bush and Bill Clinton, commented:

> Unfortunately, no one in the federal government has taken the lead to support the testing of new approaches to this epidemic. Such an effort would include new ways to prevent the illicit use of prescription drugs and to establish methods of treating addiction. The President's Commission on Combating Opioid Drug Addiction and the Opioid Crisis has come up with nearly 60 recommendations that are thoughtful and useful, but responsibility falls across so many federal agencies that little progress is likely to result.[29]

27. *See infra* notes 43–46 and accompanying text. *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: OPIOID ABUSE IN THE U.S. AND HHS ACTIONS TO ADDRESS OPIOID-DRUG RELATED OVERDOSES AND DEATHS (Mar. 26, 2015), https://aspe.hhs.gov/system/files/pdf/107956/ib_OpioidInitiative.pdf (surveying actions among the agencies within HHS and primary state actions). The remainder of this Article identifies and discusses myriad such responses to the opioid epidemic. *See generally* Section IV.

28. *See* Bipartisan Budget Act of 2018, Pub. L. 115-123, 132 Stat. 164 (2018); Comprehensive Addiction and Recovery Act of 2016, Pub. L. 114-198, 130 Stat. 695 (2016). *See infra* notes 121–123 and accompanying text.

29. Kessler, *supra* note 3.

A. The Administration's Responsiveness to "Real (Opioid Crisis) News"

Juxtaposed against the reality and severity of the opioid crisis, the Trump Administration's repeated acknowledgements of the epidemic and the dire need for interventions amount to little more than a hollow, haunting echo. The Trump Administration did formulate a National Commission on Combatting Drug Addiction and the Opioid Crisis ("National Commission") and launched its work in July 2016.[30] President Trump also declared the opioid crisis a "national public health emergency" on October 26, 2017 with powerful words that captured the essence of the opioid threat to the nation:

> This epidemic is a national health emergency. . . . Nobody has seen anything like what is going on now. . . . As Americans we cannot allow this to continue. It is time to liberate our communities from this scourge of drug addiction. Never been this way. We can be the generation that ends the opioid epidemic. We can do it.[31]

Yet the President mentioned the opioid epidemic only in passing during his State of the Union address just three months later, and, as former FDA Commissioner Kessler observed on January 14, 2018:

> [T]here is no permanent head of the Drug Enforcement Administration. The president's nominee for "drug czar" to run the White House Office of National Drug Control Policy withdrew from consideration in October and no replacement has been named. The acting chief of staff and general counsel for that office was dismissed [in December 2017].[32]

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30. *See* Commission Exec. Order, *supra* note 3.

31. Dan Merica, *What Trump's Opioid Announcement Means—and Doesn't Mean*, CNN (Oct. 26, 2017, 9:11 PM), http://www.cnn.com/2017/10/26/politics/national-health-emergency-national-disaster/index.html.

32. *Compare President Donald J. Trump's State of the Union Address*, THE WHITE HOUSE (Jan. 30, 2018), https://www.whitehouse.gov/briefings-

Moreover, despite his words capturing the severity of the epidemic, its dire impact on the nation, and the crucial need to contain and reverse the crisis, President Trump's "national public health emergency declaration" fell short of declaring the opioid epidemic a national state of emergency. Such status would have triggered *a source of immediate federal funding relief* under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act") by tapping into funds from the Federal Emergency Management Agency's Disaster Relief Fund.[33] President Trump also has chosen not to use his authority under the Public Health Services Act to provide the immediate, targeted, and secured funding over time needed to combat the crisis as the CDC defines it.[34]

To the contrary, the Administration has engaged in a persistent attack on the Affordable Care Act ("ACA"), infusing a hurricane of uncertainty in the health insurance markets, which translates into higher premiums to buffer against the epidemic.[35] Most notably, the Administration has announced slashing subsidies and state Medicaid funding expansion under the ACA—estimated at $1–2 trillion over ten years—to offset tax cuts, largely directed towards corporate America.[36] As former FDA Commissioner Kessler observed, "[s]teep

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statements/president-donald-j-trumps-state-union-address/ (transcript), *with* Kessler, *supra* note 3.

33. Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 100-707 (1988) (codified as amended at 42 U.S.C. §§ 5121-5207 (2000)). *See generally* Merica, *supra* note 31.

34. *See* Merica, *supra* note 31.

35. Peter Lee, who runs the nation's second largest ACA health care exchange in California, made this point vividly on CNN when interviewed in fall 2017. According to Mr. Lee, the ACA has been working extremely well, but the instability and uncertainty associated with efforts to dismantle key provisions of the ACA, most notably the individual mandate, has jeopardized the law, chilled insurers, and forced them to raise rates to account for uncertainties and associated risks. *Can Obamacare Survive Without Individual Mandate?*, CNN: TRANSCRIPTS (Nov. 16, 2017, 7:30 AM), http://transcripts.cnn.com/TRANSCRIPTS/1711/16/nday.04.html. Mr. Lee emphasized that cost-sharing subsidies have more than offset increases in costs, and the net effect of the individual mandate, the penalties for which have been nominal ("a nudge"), has been to change people's behavior, including Medicaid subscribers, to shop for coverage. *Id.*

36. Abby Goodnough, *Rush to Impose Medicaid Curbs Creates Unease*, N.Y. TIMES, Feb. 11, 2018, at A1, A14; Tammy Lubby, *Not Even the White House Knows How Much It's Cutting Medicaid*, CNN MONEY (May 24, 2017, 12:13 PM),

cuts have been proposed for Medicaid, the largest single insurance program covering opioid addiction treatment, which will further impede access to substance abuse treatment."[37] Moreover, the federal government is adhering to a policy of revenue neutrality (increases and decreases in tax revenue must be coupled with commensurate offsets), and the 2017 Tax Cuts and Jobs Act has been estimated to generate a loss of $1.5 trillion in tax revenue over the next decade.[38] Nevertheless, in early 2018, the Trump Administration declared a commitment to bolstering the U.S. nuclear arsenal and overall military capabilities.[39]

President Trump donated his third-quarter 2017 salary, approximately $100,000, to the HHS to combat the opioid crisis.[40] Some presumably received the gesture as compassionate and

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http://money.cnn.com/2017/05/24/news/economy/medicaid-budget-trump/index.html; *Senate Plan Threatens Health Programs*, CTR. ON BUDGET & POL'Y PRIORITIES (Nov. 9, 2017), https://www.cbpp.org/research/federal-budget/senate-budget-plan-threatens-health-programs.

37. Kessler, *supra* note 3.

38. STAFF OF JOINT COMM. ON TAXATION, REPORT ON ESTIMATED REVENUE EFFECTS OF THE CHAIRMAN'S AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 1, THE "TAX CUTS AND JOBS ACT," SCHEDULED FOR MARKUP BY THE COMMITTEE ON WAYS AND MEANS ON NOVEMBER 6, 2017 (2017), https://www.jct.gov/publications.html?func=startdown&id=5027. Supporters of the tax cuts challenge these estimates under theories that the cuts will stimulate the economy, though such economic responsiveness is subject to undefined time and speculative. Jim Tankersley, *Republicans Sought to Undercut an Unfavorable Analysis of the Tax Plan*, N.Y. TIMES (Dec. 4, 2017), https://www.nytimes.com/2017/12/04/us/politics/republicans-joint-committee-on-taxation-estimate.html.

39. Matthew Yglesias, *Congress Still Isn't Taking the Opioid Crisis Seriously*, VOX (Feb. 9, 2018, 8:00 AM), https://www.vox.com/policy-and-politics/2018/2/9/16991340/opioid-funding-budget-deal. In contrast with the additional $6 billion appropriated to combat the nation's addiction to opioids, the Budget Act of 2018 boosted military spending with an additional $160 billion. *Id.*; *see also* William J. Broad & David E. Sanger, *Trump Plans for Nuclear Arsenal Require $1.2 Trillion, Congressional Review States*, N.Y. TIMES (Oct. 31, 2017), https://www.nytimes.com/2017/10/31/us/politics/trump-nuclear-weapons-arsenal-congressional-budget.html.

40. Christina Wilkie, *Trump Donates Third-Quarter Salary to HHS to Combat Opioid Epidemic*, CNBC (Nov. 30, 2017, 6:55 PM), https://www.cnbc.com/2017/11/30/trump-donates-third-quarter-salary-to-hhs-to-combat-opioid-epidemic.html.

supportive—the interpretation shared by his press secretary, Sarah Huckabee Sanders, when she and colleagues announced the donation.[41] One could forgive the many of the millions of Americans who have been directly impacted by opioid addiction, otherwise have heightened awareness of the crisis, and who are actually engaged in combatting it, if they share a very different interpretation. The President's gesture, in the absence of at least a demand to Congress for a meaningful, national infusion of targeted resources over a block of time on par with the crisis, was empty—if not outright insulting.

B. A Reality Check on Agency Responsiveness

Myriad federal agencies and national professional medical organizations, along with HHS, engage in opioid crisis interventions. Vested entities include the CDC, the Centers for Medicare and Medicaid Services ("CMS"), the Center for Substance Abuse and Treatment ("CSAT"), the DEA, the FDA, the NIH, the National Institute on Drug Abuse ("NIDA"), the Office of National Drug Control Policy ("ONDCP"), and the Substance Abuse and Mental Health Services Administration ("SAMHSA").[42] Professional medical

41. Melanie Arter, *Trump Donates Salary to HHS to Combat Opioid Crisis*, CNS NEWS (Nov. 30, 2017, 8:06 PM), https://www.cnsnews.com/news/article/melanie-arter/trump-donates-salary-hhs-combat-opioid-crisis.

42. *See generally*, *e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ROADMAP TO ADDRESS THE OPIOID EPIDEMIC (2018), https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf; CDC, *Opioid Overdose* (Oct. 23, 2017), https://www.cdc.gov/drugoverdose/; *Medication-Assisted Treatment*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/medication-assisted-treatment (last updated Feb. 7, 2018); Office of Nat'l Drug Control Policy, *The Opioid Crisis*, THE WHITE HOUSE, https://www.whitehouse.gov/ondcp/key-issues/prescription-opioid-misuse/ (last visited Aug. 19, 2018); *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last updated Mar. 2018); Robert M. Califf, Comm'r Food & Drugs, U.S. Food & Drug Admin., FDA Charge to the Committee: FDA Opioid Action Plan and Incorporating the Broader Public Health Impact into the Formal Risk-Benefit Assessment for Opioids (July 6, 2016), https://www.fda.gov/downloads/newsevents/speeches/ucm510139.pdf; Robert W. Patterson, Acting Admin., Dep't of Justice, Department of Justice/Drug Enforcement Administration Press Conference Announcement of New Tools to Address Opioid

organizations that are leading the charge against the crisis include the American Academy of Pain Medicine ("AAPM") and the American Medical Association ("AMA").[43] HHS has assembled an Interagency Pain Research Committee ("IPRC") to promote synergy among federal agencies.[44] The FDA and HHS leadership are seeking collaboration with industry and the medical profession to respond to the opioid epidemic and to advance pain management science and clinical understanding.[45] NIH Director Francis Collins and NIDA Director Nora D. Volkow, after engaging in dialogue with global biopharmaceutical leaders to explore government-industry collaboration, released an initial plan in 2017.[46] Two high priorities emerged: (1) a short-term goal to expand the portfolio of medication options to treat opioid use disorders, prevent and reverse overdoses, and support long-term patient recovery; and (2) a longer-term research and development goal to introduce safe, efficacious non-addictive pain relievers, including non-opioid analgesics.[47]

The HHS and individual agency responsiveness, interagency collaboration, and collaboration among government, the medical profession, industry, and academia are laudable and essential. Nevertheless, these efforts are not enough. Treating, containing, and reversing the opioid crisis are beyond the resources and operating norms of HHS and the government agencies responsible for doing so, as former FDA Commissioner Kessler observed:

Crisis (November 29, 2017), https://www.dea.gov/pr/speeches-testimony/2017t/112917t.pdf.

43. *See, e.g.*, *Opioids Research*, AM. ACAD. PAIN MED., http://www.painmed.org/library/research/opioids/ (last visited Aug. 19, 2018); *Reversing the Opioid Epidemic*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/reversing-opioid-epidemic (last visited Aug. 19, 2018).

44. Mashana Davis, *Identifying Opportunities for Synergy*, INTERAGENCY PAIN RESEARCH PORTFOLIO (May 7, 2014, 11:13 AM), https://paindatabase.nih.gov/content/identifying-opportunities-synergy; *NIH Initiative to Help End the Opioid Crisis*, NAT'L INSTS. ON HEALTH, https://www.nih.gov/opioid-crisis (last visited Aug. 19, 2018); *Interagency Pain Research Coordinating Committee*, https://iprcc.nih.gov/ (last visited Aug. 19, 2018).

45. Califf, Woodcock & Ostroff, *supra* note 2.

46. *See generally* Nora D. Volkow & Francis S. Collins, *The Role of Science in Addressing the Opioid Crisis*, 377 N. ENGL. J. MED. 391 (2017).

47. *Id.* at 393.

> White House czars are largely ineffective because they do not control the agency heads who are legally responsible for carrying out the various congressional mandates of the czars. Historically, the relevant agency heads don't pay much attention to czars. There is a world of difference between someone whose authority is to coordinate and someone who has the true authority to impose change. Moreover, the president's drug control policy office has been more heavily focused on law enforcement than on public health strategies.
>
> The many federal agencies that work on this crisis live largely in their own worlds. Funding for opioid-related activities is under the control of multiple departments, including the Department of Health and Human Services and the Justice Department, both of which are criticized as operating with blinders with respect to coordination and accountability.[48]

C. The Supply Side of the Prescription Opioid Problem

There are several obvious, potential controls on the supply of prescription opioids, which currently enables responsible pain management and feeds the opioid addiction epidemic. The FDA, the market gatekeeper and sentinel for prescription medications, is responsible for determining whether prescription opioids meet safety and efficacy standards, and under what conditions they are market eligible.[49] Physicians, licensed under state law to write the prescriptions, directly make opioids available to patients. To meet prescription demands in accordance with FDA regulations and DEA Aggregate Production Quotas ("APQs"), industry manufactures opioids, and distributors and pharmacies dispense them, in compliance with the DEA's Diversion Control Division ("DCD").[50] DCD's

48. Kessler, *supra* note 3.

49. *See generally* MICHAEL J. MALINOWSKI, HANDBOOK ON BIOTECHNOLOGY LAW, BUSINESS, AND POLICY 127–37 (2016); *see also* 21 U.S.C. §§ 351–360fff-7 (2012) (setting forth the FDA's authority over pharmaceutical products and establishing statutory requirements for various prescription and over-the-counter products).

50. *See infra* notes 51–52 and accompanying text.

mission "is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."[51] The Controlled Substances Act authorizes and mandates that the DEA set APQs:

> When Congress passed the Controlled Substances Act (CSA), the quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling "the quantities of the basic ingredients needed for the manufacture of [controlled substances]." The purpose of quotas are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion. DEA establishes APQs for more than 250 Schedule I and II controlled substances annually.[52]

1. Shackles on the Market Sentinel

The FDA has responded directly to the opioid crisis since the 1990s, and the agency has scaled up its efforts substantially over the last several years as the epidemic has amassed and spun increasingly out of control.[53] For example, the FDA has promoted the market introduction and use of opioids with abuse-deterrent properties—

51. Diversion Control Div., *About Us*, U.S. DRUG ENF'T ADMIN., https://www.deadiversion.usdoj.gov/Inside.html (last visited Aug. 26, 2018).

52. Press Release, U.S. Drug Enf't Admin., DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017 (Oct. 4, 2016), https://www.dea.gov/press-releases/2016/10/04/dea-reduces-amount-opioid-controlled-substances-be-manufactured-2017; *accord* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, 84 Stat. 1236 (1970) (codified as amended at 21 U.S.C. § 801(2012)) (regulating the manufacture, importation, possession, use, and distribution of defined and scheduled substances).

53. *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm (last updated Aug. 6, 2018) [hereinafter FDA, *Timeline*].

notably extended-release ("ER") and long-acting ("LA") opioids.[54] In 2012, the agency introduced a Risk Evaluation and Mitigation Strategies ("REMS") program for ER/LA opioids, which includes voluntary training for prescribers,[55] and issued a draft guidance in 2013, which it finalized in April 2015.[56] Consequently, ER/LA opioids with abuse-deterrent properties and enhanced safety measures (including a stronger FDA post-marketing presence and development of methods to evaluate and mitigate safety issues) have become available since 2015—as of January 2017, the FDA had already approved nine ER opioid analgesics—and with increasing frequency.[57]

In 2016, three FDA physician leaders, Robert M. Califf, Janet Woodcock, and Stephen Ostroff, published a thoughtful, expansive, and proactive opioid intervention strategy in *The New England Journal of Medicine*.[58] In their words,

> We are launching [a] renewed effort in the context of a broad national campaign that includes a major initiative led by the Department of Health and Human Services (HHS) designed to attack the problem from every angle. . . . *[S]imply reinforcing opioid-related activities that are within the FDA's traditional regulatory scope will not suffice to stem the tide*. Instead, we must work more closely with key federal

54. *See* Califf, Woodcock & Ostroff, *supra* note 2, at 1482.

55. The REMS program enhances the post-marketing obligations of manufacturers and requires them to fund continuing medical education ("CME") to raise provider understanding about these products. *Risk Evaluation and Mitigation Strategy (REMS) for Opioid Analgesics*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm (last updated Feb. 27, 2018). As of April 2016, more than 38,000 prescribers had taken part in these programs. Califf, Woodcock & Ostroff, *supra* note 2, at 1482.

56. *See generally* CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE FOR INDUSTRY: ABUSE-DETERRENT OPIOIDS—EVALUATION AND LABELING (2015), https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm334743.pdf.

57. For example, on January 17, 2017, the FDA approved Vantrela ER, which has physical and chemical properties that make intravenous abuse more difficult, though still with some risk of abuse by nasal and oral delivery routes. FDA, *Timeline*, *supra* note 53.

58. *See generally* Califf, Woodcock & Ostroff, *supra* note 2.

> agencies (including many within HHS), the clinical and prescriber communities, and other stakeholders to ensure that all available effective tools are brought to bear on this epidemic and that the evidence base for proper pain management and appropriate opioid use is optimized and translated into practice.[59]

The FDA's primary methodology is to significantly enhance and fully utilize evidence-based medicine in the field of chronic pain treatment:

> The FDA does its best work when high-quality scientific evidence is available to assess the risks and benefits of intended uses of medical products. Unfortunately, the field of chronic pain treatment is strikingly deficient in such evidence . . . .
>
> Recognition of this problem led the FDA, several years ago, to require industry to perform a series of studies on questions that are critical for ensuring safe prescribing. For example, until recently it was believed that opioids' pain-relieving properties would not be time-dependent, but new studies have raised the question of whether opioids continue to be effective or may even increase pain in some patients after several months of use. To explore this question, 1 of the 11 postmarketing studies the FDA is requiring industry to fund is a clinical trial in which participants are randomly assigned to continue opioid therapy or to be weaned from it on a schedule over the course of 1 year of follow-up.[60]

Even before this national campaign announcement, the FDA reached out to the National Academy of Medicine to draw upon evidence-based medicine to improve its "regulatory framework for opioid review, approval, and monitoring."[61] While encouraging and embracing research and development of ER/LA opioids, the agency has mandated that they come with "strict, detailed instructions" and descriptions of their associated risks, and adhere to sufficient ongoing

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59. *Id.* at 1480–81 (emphasis added).

60. *Id.* at 1484.

61. *Id*. at 1482.

monitoring measures.[62] The FDA makes clinical use of ER/LA opioids contingent on exhausting other pain management measures and requires that they "be dispensed in limited quantities."[63]

Beyond ER/LA opioids, the FDA also is collaborating with NIH and industry to develop pain-alleviating medication alternatives that do not have the addictive properties of opioids, and nonpharmacologic approaches to pain treatment. "The FDA has approved nonopioid medications for treatment of various chronic-pain syndromes, including gabapentin (Neurontin), pregabalin (Lyrica), milnacipran (Savella), duloxetine (Cymbalta), and others, and a number of promising development programs are in the pipeline."[64] The FDA also has concentrated resources and expedited review and approval to make medications that can reverse overdose, such as naloxone, available.[65]

When the FDA's physician leaders relayed their proactive intervention strategy, however, they readily acknowledged that a comprehensive, timely solution is beyond the agency's purview:

> *A comprehensive solution to the current opioid crisis goes well beyond the FDA's remit*. . . . Accordingly, we are supporting the CDC's Guideline for Prescribing Opioids for Chronic Pain. . . . We are also supporting the Surgeon General's efforts to engage the clinical community in a concerted approach to curbing inappropriate prescribing and proactively treating opioid addiction, while reinforcing evidence-based approaches to treating pain in a manner that spares the use of opioids. Until clinicians stop prescribing opioids far in excess of clinical need, this crisis will continue unabated.[66]

Although the FDA is the U.S.'s primary market sentinel for prescription opioids, physicians write the prescriptions that provide patients with access, and industry provides the supply. According to the CDC, the latter two have been far from judicious.[67] Deference to

62. *Id.*; *see also supra* notes 55–57 and accompanying text.
63. Califf, Woodcock & Ostroff, *supra* note 2, at 1482.
64. *Id.* at 1483.
65. *Id.*
66. *Id.* at 1484 (emphasis added).
67. *See supra* notes 2–3 and accompanying text.

the practice of medicine and legitimate patient need for pain management stunt the FDA's reach into physician prescribing practices. FDA deference to the practice of medicine is deeply entrenched: "During the twentieth century, FDA pursued a policy of not regulating physicians."[68] For example, in 1925, the Supreme Court unanimously overturned the conviction of a physician for prescribing drugs to addicts in violation of the Harrison Act, a predecessor of the Controlled Substances Act.[69] The Court held, "[o]bviously, direct control of medical practice in the States is beyond the power of the Federal Government."[70]

The agency's authority and market-sentinel responsibilities came into being under the scrutiny of an organized and leery medical profession—a powerful, largely self-regulating presence on both national and state levels.[71] Due primarily to resistance from the medical profession, the U.S. did not expand the FDA's standard for

68. Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 509 (2010); *cf.* Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD & DRUG L.J. 555, 579 (1998) ("Although there are dependable grounds for asserting statutory jurisdiction, FDA must be wary of encroaching on medical practice.") *Cf. also generally* Michael J. Malinowski, *Doctors, Patients, and Pills—A System Popping Under Too Much Physician Discretion? A Law-Policy Prescription to Make Drug Approval More Meaningful in the Delivery of Health Care*, 33 CARDOZO L. REV. 1085 (2012) [hereinafter Malinowski, *Doctors, Patients, and Pills*] (challenging the scope of physician discretion to engage in off-label use of prescription drugs).

69. Comprehensive Drug Abuse Prevention and Control Act, Pub. L. 91-513, 84 Stat. 1236 (1970) (codified as amended at 21 U.S.C. §§ 801–971 (2012)) (regulating the manufacture, importation, possession, use and distribution of defined and scheduled substances); Harrison Narcotics Tax Act, ch. 1, 38 Stat. 785 (1914) (codified as amended at 26 U.S.C. §§ 4702–4900 (2012)) (taxing drugs such as cocaine and morphine that effectively became a prohibition on them).

70. Linder v. United States, 268 U.S. 5, 18 (1925). Although *Linder* subsequently has been mostly overruled or superseded, the Court relied on the case's rationale in *Gonzales v. Oregon*, in which it upheld physician discretion to prescribe FDA-approved drugs in compliance with Oregon's Death with Dignity Act. *See generally* Gonzales v. Oregon, 546 U.S. 243 (2006).

71. *See generally* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (1982) (examining how the roles of doctors, hospitals, health plans, and government programs in patient care have evolved over the last two-and-a-half centuries).

review and approval to include even efficacy until 1962.[72] Moreover, it did so with assurances of maintaining deference to the practice of medicine—for example, continuing to give physicians considerable discretion over the clinical use of approved prescription drugs, including at times expansive off-label uses wholly removed from the clinical data the FDA relied upon to put them on the market.[73] When the FDA Modernization Act of 1997 ("FDAMA")[74] overhauled the agency decades later, Congress reiterated and reinforced this assurance. The House Report that accompanied FDAMA expressly and decisively declared, "FDA has no authority to regulate how physicians prescribe approved drugs in the context of their medical practice. Physicians prescribing off-label uses of approved drugs is not within the jurisdiction of the FDA."[75]

Consistent with this position, the U.S. Supreme Court has protected physician discretion to prescribe, including permissive off-label prescribing. For example, in *Buckman Co. v. Plaintiffs' Legal Committee*,[76] the Court found that "fraud-on-the-FDA" claims challenging off-label promotion were preempted implicitly because they would discourage off-label uses and impede the FDA's obligation to self-restrain from interfering with the medical profession's judgments.[77] The Court also has upheld physicians' discretion to prescribe FDA-approved pain medications, even in a manner that *intentionally ends life* when permitted under state law.[78] In sum, "[p]hysicians hold extraordinary discretion to prescribe drugs that

72. *Id.* at 127–34; *Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm2007256.htm (last updated Feb. 1, 2018) ("Kefauver-Harris Drug Amendments passed in 1962 to ensure drug efficacy and greater drug safety.").

73. *See* Malinowski, *Doctors, Patients, and Pills*, *supra* note 68, at 1104–05.

74. Food and Drug Administration Modernization Act (1997), Pub. L. No. 105-115, 111 Stat. 2296.

75. H.R. REP. NO. 105-310, at 60 (1997).

76. 531 U.S. 341 (2001).

77. *Id.* at 350–51.

78. *See generally* Gonzales v. Oregon, 546 U.S. 243 (2006).

reach pharmacy shelves off label regardless of limits to the scope of clinical data that puts them there."[79]

A related traditional constraint on the FDA is industry sponsors' discretion (recognized as a right of corporate citizens) to shape the scope of the applications for market access they submit to the agency—which invites streamlining applications and supportive clinical research, and then coupling approvals with the pursuit of more expansive market uptake through off-label uses.[80] This practice has perpetuated a dearth of pediatric clinical data for many medications commonly used to treat children, including opioids.[81] While the Best Pharmaceuticals for Children Act ("BPCA") introduced incentives for conducting pediatric studies for products already approved and some funding for the FDA to get studies conducted when product manufacturers refuse,[82] the FDA holds limited authority under the BPCA to mandate them.[83] Fortunately, the Pediatric Research Equity Act ("PREA") has enabled the FDA to require industry sponsors to conduct certain studies to ascertain appropriate medication dosing in children.[84] "Before BPCA and PREA became law, more than 80% of the drugs approved for adult use were being used in children, even though the safety and effectiveness had not been established in

79. Michael J. Malinowski, *Throwing Dirt on Doctor Frankenstein's Grave: Access to Experimental Treatments at the End of Life*, 65 HASTINGS L.J. 615, 636 (2014) [hereinafter Malinowski, *Throwing Dirt*].

80. MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 135–155 (2005) ("No one should rely on a business for impartial evaluation of a product it sells."). Many of these restraints are supported by the wide body of jurisprudence rejecting the Lochner era in American history (1897–1937), during which the Supreme Court, conservative but very judicially active, struck down state business and market regulations based on its own policy conclusions. *See generally* HOWARD GILLMAN, THE CONSTITUTION BESIEGED: THE RISE AND DEMISE OF LOCHNER ERA POLICE POWERS JURISPRUDENCE (1993).

81. Califf, Woodcock & Ostroff, *supra* note 2.

82. Best Pharmaceuticals for Children Act (2007), Pub. L. No. 107-109, 115 Stat. 1408 (codified at 21 U.S.C. § 355a (2012)).

83. Malinowski, *Doctors, Patients, and Pills*, *supra* note 68, at 1125–26.

84. Pediatric Research Equity Act (2007), Pub. L. No. 108-155, 117 Stat. 1936 (codified as amended at 21 U.S.C. § 355c (2012)).

children. [By August 26, 2013,] that number ha[d] been reduced to about 50%."[85]

Still, doctors have continued to prescribed opioids to children without a foundation of pediatric data. As the FDA has observed, "[c]hildren with serious conditions are being treated with opioids in the absence of adequate knowledge about correct indications and dosing."[86] Accordingly, the agency is using its Pediatric Advisory Committee to address the use of opioid medications in children, including compilation of evidence to guide treatment and pediatric labeling for opioids.[87]

The FDA's proactive opioid intervention strategy underscores the importance of physician opioid education, which the agency has been advancing through its REMS CME program. Persistent FDA caution about encroaching on the practice of medicine, however, restrains even this program: "[W]hile FDA has jurisdiction over the pharmaceutical industry, it does not have jurisdiction over the medical profession and, thus, claims not to interfere with the exchange of purely *scientific* information between pharmaceutical manufacturers and doctors."[88] So while the agency mandates ER/LA opioid manufacturers to make CMEs available under the REMS program, physician participation thus far is voluntary—though the FDA supports mandatory education for prescribers.[89]

As the FDA recognizes in its call for collaboration, at least implicitly, given the institution's innate restraints in regulation of the practice of medicine, other federal agencies and the clinical medicine

85. Lynn Yao, *FDA Takes Steps to Encourage Pediatric Drug Studies*, FDA VOICE (Aug. 26, 2013), https://blogs.fda.gov/fdavoice/index.php/tag/pediatric-research-equity-act-prea/.

86. Califf, Woodcock & Ostroff, *supra* note 2, at 1484.

87. *Id.* at 1483–84.

88. Peggy Chen, *Education or Promotion?: Industry-Sponsored Continuing Medical Education (CME) as a Center for the Core/Commercial Speech Debate*, 58 FOOD & DRUG L.J. 473, 473 (2003) (internal citations omitted).

89. "FDA continues to support mandatory education for prescribers, as called for in the 2011 Prescription Drug Abuse Prevention Plan and reemphasized in the 2014 National Drug Control Strategy." Califf, Woodcock & Ostroff, *supra* note 2, at 1482. *Accord* OFFICE OF NAT'L DRUG CONTROL POL'Y, EXEC. OFFICE OF THE PRESIDENT, NATIONAL DRUG CONTROL STRATEGY 72–73 (2014), https://obamawhitehouse.archives.gov/sites/default/files/ndcs_2014.pdf (emphasizing education as a pillar of the strategy).

community are positioned more favorably, jurisdictionally and substantively, to champion mandatory education measures beyond labeling and post-marketing evaluation and safety measures consistent with the REMS program.[90] Measures centered squarely in physician-patient decision-making, such as blanket prescription prior-authorization protocols, are even further beyond the FDA's purview and difficult to realize in a culture of individualized patient care and a legacy of deference to physician-patient decision-making. For example, professional associations representing the clinical community, including the AAPM and the AMA's Opioid Task Force, have raised concerns that "one-size-fits-all" limits, such as those CVS Pharmacy now imposes, could impede individual patient care for treating both opioid use disorder and chronic pain.[91] CVS's limits

90. Califf, Woodcock & Ostroff, *supra* note 2, at 1480–81. The FDA has expanded its jurisdiction to speech beyond labeling and advertising—for example, assertion of jurisdiction over industry-sponsored CME seminars and symposia. *See, e.g.*, Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,075 (Dec. 3, 1997) (urging that providers who develop CME programs do so "independent from the influence of the supporting company" and "disclos[e] relationships between and among the supporting company, provider, presenters, and products discussed that may be relevant to an assessment of the information presented"). Since recognition of drug manufacturers' commercial speech in *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d. 51 (D.D.C. 1998), however, courts have protected commercial speech and widened drug manufacturers' latitude to publicize non-FDA approved uses of pharmaceuticals to doctors provided they include disclaimers. *See generally* Matt Hellman, *Commercial Drug Claims, the FDA, and the First Amendment* (Harv. U. Third Year Paper, 2001), https://dash.harvard.edu/bitstream/handle/1/8852198/Hellman01.pdf. Accordingly, the agency has practiced caution and self-restraint while direct-to-consumer advertising in the U.S. has increased explosively.

91. Susan Scutti & Nadia Kounang, *CVS Will Limit Opioid Prescriptions to 7 Days*, CNN (Sept. 22, 2017), http://www.cnn.com/2017/09/22/health/cvs-prescription-restrictions-opioids-bn/index.html; *cf.* CVS Health, *supra* note 24. For example, the AAPM's position is, "We share concerns voiced by patient and professional groups, and other Federal agencies, that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence." Press Release, Am. Acad. of Pain Med., Statement on CDC Guideline for Prescribing Opioids for Chronic Pain (Mar. 16, 2016), http://www.painmed.org/files/aapm-statement-cdc-guideline-for-prescribing-opioids-for-chronic-pain.pdf; *see also* Califf, Woodcock & Ostroff, *supra* note 2, at 1480 (describing the "difficult balancing act" required for effective regulation that does not limit providers' options to treat patients).

draw upon the CDC prescribing guideline, which favors opioid prescriptions with shorter durations and at lower dosages—a guideline the medical profession has also challenged.[92]

Deference to the practice of medicine and individualized physician-patient decision-making muddles post-marketing surveillance, as do resource limitations for post-market surveillance and enforcement. In response to the Vioxx controversy and FDA withdrawal of ten of its approved drugs for safety concerns between 2000 and March 2006, the Government Accountability Office and the Institute of Medicine evaluated FDA performance and issued scathing reports about the agency's post-marketing surveillance performance.[93]

Congress recognized and addressed the problem through enactment of the Food and Drug Administration Amendments Act of 2007 ("FDAAA").[94] This sweeping legislation, among other measures, called for the FDA to augment premarket clinical studies, enhance its evidentiary standard, and greatly increase post-market communication and observational studies through Sentinel, a national

92. As of February 1, 2018, CVS will: limit opioid prescriptions for patients new to pain therapy to seven days for severe, long-term pain treatment; limit daily dosages based on their strength; and require use of immediate-release formulations before ER/LA opioids. Scutti & Kounang, *supra* note 91.

93. *See generally* INST. OF MED., THE FUTURE OF DRUG SAFETY: ACTION STEPS FOR CONGRESS (2006), https://www.nap.edu/resource/11750/futureofdrugsafety_reportbrief.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESSES (2006), https://www.gao.gov/new.items/d06402.pdf. *Cf.* Michael J. Malinowski, *Government Rx—Back to the Future in Science Funding? The Next Era in Drug Development*, 51 U. LOUISVILLE L. REV. 101, 113–14 (2012) [hereinafter Malinowski, *Government Rx*] (discussing problems with Vioxx, Avandia, and bisphosphonates); Malinowski, *Throwing Dirt*, *supra* note 79, at 635 ("Even with the FDA's portfolio of market failures . . . after several years on the market . . . and scathing evaluations . . . of the FDA's regulatory performance once drugs are on the market, faith in technology endures."); Michael J. Malinowski & Grant G. Gautreaux, *All That Is Gold Does Not Glitter in Human Clinical Research: A Law-Policy Proposal to Brighten the Global "Gold Standard" for Drug Research and Development*, 45 CORNELL INT'L L.J. 185, 188 (2012) ("Recent market controversies in recent years . . . have raised concerns regarding the FDA's performance and trustworthiness in overseeing the nation's pharmaceutical market.").

94. Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended at 21 U.S.C. §§ 301–399i (2012)).

electronic system for medical product safety surveillance.[95] While arguably profound conceptually and theoretically, "FDAAA breathe[d] new life into classic infrastructure regulatory problems by requiring evidence that can only be generated with a massive, networked informational infrastructure that does not yet exist and will have to be financed, built, and administered."[96]

HHS directed the FDA to create Sentinel and launched the initiative in May 2008, the effort advanced beyond "Mini-Sentinel pilot" stage in 2016, and Sentinel is evolving with practicality realizations and adjustments.[97] Beyond finance constraints, a primary obstacle to Sentinel coming into fruition in the foreseeable future, as envisioned, is reliance on and aversions to timely and thorough self-reporting—especially given the intended transparency. In addition to industry proprietary and corporate interests prevalent in our free-market health care system, Sentinel presupposes changing physician culture. "Doctors . . . have an aversion to reporting. For instance, while the Food and Drug Administration relies on physicians to help monitor product safety by alerting the agency to adverse patient reactions, doctors usually do not make such filings, saying they are too busy for the paperwork."[98] Moreover, the uncertainty innate in the art of individualized medicine invites reporting apprehension and hesitation—"physician think," such as, "Perhaps the cause was just my particular patient's drug interactions, lifestyle choices, medical history, or failure to follow orders . . . or perhaps my failure to know as much as I should about this particular drug." Concerns about professional ramifications of not knowing do as well.[99]

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95. *See generally CDER Conversation: The FDA's Sentinel Initiative*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/NewsEvents/ucm586259.htm (last updated Nov. 27, 2017); *see also* Barbara J. Evans, *Authority of the Food and Drug Administration to Require Data Access and Control Use Rights in the Sentinel Data Network*, 65 FOOD & DRUG L.J. 67 (2010); Evans, *supra* note 68, at 425 (describing FDAAA's "paradigm-shifting amendments" that "accept[] that clinical have intrinsic limitations" resulting in a "pragmatic reassessment of their evidentiary value").

96. Evans, *supra* note 68, at 421–22.

97. *See generally CDER Conversation*, *supra* note 95.

98. Barry Meier, *Doctors Who Don't Speak Out*, N.Y. TIMES, Feb. 17, 2013, at SR5.

99. *See, e.g.*, *60 Minutes: Prescription for Trouble* (CBS television broadcast Nov. 14, 2004) (interviewing clinical researchers who published negative data about

2. Opioid Production Beyond Responsible Pain Management

Physicians' broad discretion to prescribe opioids the FDA deems safe and efficacious, and which manufacturers produce and market under FDA oversight, reliance on industry and medical community data, and the sheer volume of data that the DEA must process for decision-making complicate the DEA's exercise of its authority to limit production.[100] When exercising its APQ and DCD authority and responsibilities, the DEA risks placing itself in a precarious position. The agency is subject to accusations from a chorus of the loud, politically influential voices of the medical profession, industry, and patient advocates bellowing that it is impeding the supply of opioids necessary for medically legitimate pain management.[101]

The DEA allegedly caved under such pressures when, in September 2015, it settled the largest opioid-distribution case in U.S. history against the McKesson Corporation. With some 73,000

Vioxx in peer-reviewed literature and were subjected to professional attacks from Merck, the drug's manufacturer).

100. The data the DEA must process to set APQs is voluminous and in a constant state of flux:

> In setting the APQ, DEA considers data from many sources, including estimates of the legitimate medical need; estimates of retail consumption based on prescriptions dispensed; manufacturers' data on actual production, sales, inventory, exports, product development needs, and manufacturing losses; data from DEA's own internal system for tracking controlled substance transactions; and past quota histories.
>
> Once the aggregate quota is set, DEA allocates individual manufacturing and procurement quotas to those companies that apply for it. DEA may revise a company's quota at any time during the year if change is warranted due to increased sales or exports; new manufacturers entering the market; new product development; or product recalls.

Press Release, U.S. Drug Enf't Admin., DEA Proposes Reduction to Amount of Controlled Substances to be Manufactured in 2018 (Aug. 4, 2017), https://www.dea.gov/press-releases/2017/08/04/dea-proposes-reduction-amount-controlled-substances-be-manufactured-2018.

101. *Cf.* Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. 114-145, 130 Stat. 354 (2016) (codified at 21 U.S.C. § 823–24 (2012 & Supp. 2017)); *see also infra* note 110 and accompanying text.

employees, thirty drug warehouses across the nation, and revenue of almost $200 billion annually, McKesson is America's fifth-largest public corporation and its top drug distributor.[102] At the time of the investigation, McKesson was a second-time offender: the company had paid a $13.25 million fine in 2008 for "failing to report hundreds of suspicious hydrocodone orders from Internet pharmacies—even after being warned by the DEA three years earlier that is was shipping excessive amounts of Vicodin."[103] As part of this previous settlement, McKesson also pledged to temporarily suspend distribution of narcotics from two of its centers and to enhance its system to responsibly monitor and report suspicious drug orders.[104] According to the DEA, however, McKesson reverted to its previous behavior within two years and filled unusually large, frequent orders placed by pharmacies, some of which knowingly supplied drug rings.[105] McKesson allegedly "raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[106]

After 2 years of aggressive investigation, David Schiller, head of the DEA team that investigated McKesson and an agent with some three decades of experience, and colleagues believed that the case was strong enough to support revocation of registrations to distribute controlled substances at multiple McKesson drug warehouses, a fine of $1 billion or more, and criminal prosecution.[107] Rather, according to the terms of the settlement, McKesson promised to be more diligent about diversion of its pills to street use, and agreed to temporarily suspend controlled substance shipments to four of its distribution centers and pay a $150 million fine.[108] The latter was "only about $50 million more than the compensation [in 2016] for McKesson board chairman and chief executive John H. Hammergren, the nation's third-highest-paid chief executive."[109]

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102. Bernstein & Higham, *supra* note 24; *60 Minutes: Biggest Opioid Case*, *supra* note 24.

103. Bernstein & Higham, *supra* note 24.

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

These political pressures and influences also resulted in the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 ("Access Act") quietly becoming law on April 19, 2016—in the midst of a frenzy of national media attention on the opioid crisis as the deadliest drug epidemic in U.S. history.[110] The legislation, which greatly diminished the DEA's ability to freeze suspicious shipments from drug companies under the pretext of making opioids available to patients, did not itself draw attention until October 2017, when *60 Minutes* and the *Washington Post* reported the findings of their joint investigation of the Access Act.[111] U.S. Representative Tom Marino, whom President Trump had nominated to head the ONDCP (to serve as the nation's "drug czar"), who had invested years pushing the Access Act through Congress, and who wrote the version of the legislation that ultimately became law, withdrew his nomination two days later.[112]

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110. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 354 (codified at 21 U.S.C. §§ 823–824 (2012 & Supp. 2017)). *See generally* Peter Baker, *Tom Marino, Drug Czar Nominee, Withdraws in Latest Setback for Trump's Opioid Fight*, N.Y. TIMES (Oct. 17, 2017), https://www.nytimes.com/2017/10/17/us/politics/trump-says-drug-czar-nominee-tom-marino-withdraws-from-consideration.html; Anne Gearan et al., *Trump Says Drug Czar Nominee Tom Marino is Withdrawing After Washington Post/"60 Minutes" Investigation*, WASH. POST (Oct. 17, 2017), https://www.washingtonpost.com/news/post-politics/wp/2017/10/17/trump-says-drug-czar-nominee-tom-marino-is-withdrawing-after-washington-post60-minutes-investigation/; Amber Phillips, *A Cheat Sheet to the Investigation That Cost Rep. Tom Marino the Nomination to Be Drug Czar*, WASH. POST (Oct. 17, 2017), https://www.washingtonpost.com/news/the-fix/wp/2017/10/17/a-cheat-sheet-to-the-investigation-that-cost-tom-marino-the-job-as-drug-czar/. Both the House and Senate have introduced legislation to repeal the Marino-crafted legislation, but efforts continue to linger. *See generally* A Bill to Repeal the Amendments Made to the Controlled Substances Act by the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, S. 1960, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/1960; To Repeal the Amendments Made to the Controlled Substances Act by the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, H.R. 4084, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/house-bill/4084.

111. *See generally* Baker, *supra* note 110; Gearan et al., *supra* note 110; Phillips, *supra* note 110.

112. Phillips, *supra* note 110.

The federal government's failure to meet its responsibilities to control the nation's supply and distribution of prescription opioids has forced the states to attempt to do so. While Congress has been investigating "how drug distributors . . . sent 780 million pills over six years in West Virginia—433 doses for every man, woman, and child in the state," and more than 20.8 million pills over ten years in a coal mining town with just 3,191 residents and two pharmacies (6,500 prescription painkillers per person), states have been taking action.[113] As of December 2017, forty-one state attorneys general had joined forces to sue the opioid industry.[114]

Moreover, although the DEA has set APQs to cut prescription opioid production significantly in 2018,[115] the effort is arguably futile given the impact of a similar measure in 2017[116] and the millions of people already addicted. As former Commissioner Kessler commented, "when the agency cracks down on one form of the drug, opioid addicts move to other forms to sustain their addiction. Playing Whac-a-Mole is hardly a strategy."[117]

IV. A NATIONAL PRESCRIPTION OPIOID TREATMENT PLAN

The U.S., in a state of political division, is grappling with debate over myriad issues, including the ACA, Medicaid funding, and health care in general.[118] Nevertheless, there is resounding consensus that the nation's opioid crisis is an epidemic and building, it must be contained,

113. Bernstein & Higham, *supra* note 24; Gabe Gutierrez et al., *This Tiny West Virginia Town is Awash in Prescription Painkillers*, NBC NEWS (Feb. 2, 2018), https://www.msn.com/en-us/news/us/this-tiny-west-virginia-town-is-awash-in-prescription-painkillers/ar-BBIAlK3?li=AA4ZnC.

114. Bernstein and Higham, *supra* note 24.

115. *See* Alicia Ault, *DEA Proposes Significant Cuts to Opioid Production in 2018*, MEDSCAPE (Aug. 10, 2017), https://www.medscape.com/viewarticle/884055.

116. U.S. Drug Enf't Admin., *supra* note 52.

117. Kessler, *supra* note 3.

118. *See* David Ignatius, *One Nation, Divided Under Trump, with Perilous Consequences*, WASH. POST (Dec. 28, 2017), https://www.washingtonpost.com/opinions/trumps-divisiveness-puts-america-at-risk/2017/12/28/6cd5b738-ec11-11e7-9f92-10a2203f6c8d_story.html; Chuck Todd, Mark Murray & Carrie Dann, *A Nation Divided Under Trump*, NBC NEWS (Nov. 21, 2017), https://www.nbcnews.com/politics/first-read/nation-divided-under-trump-n822811.

and that time is of the essence.[119] As President Trump, the National Commission, and a plethora of government agencies have recognized, the scale of this public health emergency, in terms of its ongoing and escalating impact on human health and treatment complexities, poses a government challenge on par with some of the greatest this nation has ever confronted.[120]

Acknowledging the pervasiveness and dire consequences of the opioid crisis, which observers have empirically documented beyond question, without funding an intervention on scale with the problem is arguably the cruelest form of government hypocrisy. While Congress authorized over $181 million each year to fight the opioid epidemic under the Comprehensive Addiction and Recovery Act of 2016, it scattered the funding and subjected it to annual renewals.[121] Similarly, Congress's "responsiveness" to the problem through the 21st Century Cures Act opioid provisions, enacted during the Obama Administration's final hours—the administration's "curtain call" legislation—will, at most, make only some contributions. The Cures Act bundles the opioid crisis with curing cancer and a blitzkrieg of other expansive health care missions, accompanied by relaxation of biopharmaceutical regulations, without enough secured funding over time to realistically accomplish them meaningfully under the Trump Administration.[122] The pattern lingers: the appropriation of an

119. *See generally supra* Part III.

120. *See, e.g.*, *supra* note 31 and accompanying text; COMM'N FINAL REPORT, *supra* note 10; COMM'N INTERIM REPORT, *supra* note 10.

121. *See generally* Comprehensive Addiction and Recovery Act of 2016, Pub. L. 114-198, 130 Stat. 695 (2016).

122. *See generally* 21st Century Cures Act, Pub. L. 114-255, 103 Stat. 1033 (2016). The Act contains provisions that Roll back regulations of the biopharmaceutical industry, and much of its funding is subject to annual appropriations:

> The catch was that while the regulatory rollback that so rankled some Democrats is guaranteed, the research funding is not. It will have to be appropriated each year. Even worse in Democrats' eyes, it will be paid for in part by raiding more than $3 billion from Obamacare's Prevention and Public Health Fund, which pays for anti-smoking campaigns and other preventive health efforts.

additional $6 billion over two years under the Budget Act of 2018 is a vague and insufficient response to an increasingly defined and deadly opioid epidemic.[123]

Those trained in law and policy are versed in the significance of precedent, and the importance of drawing from history and experience—to avoid past mistakes and to garner insights to meet present challenges—is a notion broadly instilled and shared. The U.S. experience, dating from the middle of the last century and robust in the present one, is that government, industry, and academia, when melded into a focused force—a triple threat—introduces the potential to jolt science application forward from its status quo to overcome ominous public health and other societal challenges, with benefits well beyond. The following discussion first summarizes this experience, and then draws upon it to propose a law and policy treatment plan capable of meeting the nation's pressing opioid crisis challenge.

A. The U.S. Science and Technology Triple Threat Legacy

The U.S. has faced and overcome extraordinary challenges, including saving democratic society from annihilation during WWII, by intervening aggressively to advance science and technology. The U.S. entered WWII without much of a standing army and with enormous fear that the Nazis could and would develop an atomic bomb.[124] The U.S. built the former and quelled the latter through

> Biden and other supporters told concerned Democrats that the Obamacare money would disappear anyway with the repeal of the health law.

Sarah Karlin-Smith et al., *Biden's Farewell Gift: Cancer Moonshot Helps Pass $6.3 Billion Research Bill*, POLITICO (Dec. 7, 2016, 5:22 PM), http://www.politico.com/story/2016/12/joe-biden-cancer-moonshot-bill-232342.

123. *See generally* Bipartisan Budget Act of 2018, Pub. L. 115-123, 132 Stat. 164 (2018); *see also* Paige Winfield Cunningham, *The Health 202: Congress Is Poised to Invest More Dollars in the Opioid Crisis*, WASH. POST: POWERPOST (Feb. 8, 2018), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/02/08/the-health-202-congress-is-poised-to-invest-more-dollars-in-the-opioid-crisis/5a7b434830fb041c3c7d769b/; Yglesias, *supra* note 39, and accompanying text.

124. U.S. DEP'T OF ENERGY, DOE/MA-0001-01/99, THE MANHATTAN PROJECT: MAKING THE ATOMIC BOMB vii (1999), http://www.energy.gov/sites/prod/files/edg/media/Making_Atomic_Bomb.pdf.

determined intervention that harnessed and orchestrated the resources of government, academia, and industry—a triple threat strategy—to accomplish both, and it became a legacy of utilizing this triple threat methodology to jolt science and technology forward to overcome defined and daunting challenges.[125]

The Manhattan Project ("MP") was a massive, hands-on, federal government undertaking with a defined research and development mission and under daunting time pressure.[126] The U.S. accomplished its mission by orchestrating the establishment of laboratories across the nation, an army of researchers, and direct industry involvement—most notably Dupont—under defined, focused government direction.[127] The U.S. emerged from WWII with established, expansive, and ongoing relationships with industry and academia, while industry and academia largely shifted back to their separate science-technology tracks and cultures.[128] Beyond undertaking expansive direct government research, the U.S. continued to invest substantially in both academic and industry science and technology during the Cold War era—industry research through the military-industrial complex and academic research through federal grant funding allocated by peer review.[129] This investment fueled the nation's global economic and academic competitiveness, military

125. *See generally* Malinowski, *Government Rx*, *supra* note 93.

126. *See generally The Manhattan Project*, U.S. HISTORY, http://www.ushistory.org/us/51f.asp (last visited Sept. 2, 2018); *see also generally* THE MANHATTAN PROJECT: THE BIRTH OF THE ATOMIC BOMB IN THE WORDS OF ITS CREATORS, EYEWITNESSES, AND HISTORIANS 294–313 (Cynthia C. Kelly ed., 2007) [hereinafter THE BIRTH OF THE ATOMIC BOMB]; U.S. DEP'T OF ENERGY, *supra* note 124.

127. RICHARD RHODES, THE MAKING OF THE ATOMIC BOMB 431 (1986); U.S. DEP'T OF ENERGY, *supra* note 124, at 28–29. While industry culture in research already was anchored in application, "[g]iven the absolute priority of the war effort, the usual academic tasks of universities were largely displaced for the duration." ROGER L. GEIGER, RESEARCH & RELEVANT KNOWLEDGE 7 (2d ed. 2004). The precedent of federal research grant funding, including "administrative overhead," was established: "The basic relationship between the federal government and universities for conducting wartime research was governed by contracts negotiated according to the principle of no-loss and no-gain. Universities were reimbursed for the direct costs they incurred and also given some allowance for overhead." *Id*. at 6.

128. *See generally* GEIGER, *supra* note 127.

129. Malinowski, *Government Rx*, *supra* note 93, at 106–07.

strength, and space program for decades.[130] President Eisenhower thoughtfully reflected upon this rite of passage for the U.S. government, its implications, and the future of science and technology in his January 17, 1961, farewell address:

> [R]esearch has become central; it also becomes more formalized, complex, and costly. A steadily increasing share is conducted for, by, or at the direction of, the Federal government. . . . The prospect of domination of the nation's scholars by Federal employment, project allocations, and the power of money is ever present — and is gravely to be regarded.
>
> Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific-technological elite.
>
> It is the task of statesmanship to mold, to balance, and to integrate these and other forces, new and old, within the principles of our democratic system—ever aiming toward the supreme goals of our free society.[131]

After decades of building prosperity, and in spite of enormous ongoing investment in science and technology, economic crisis overwhelmed the U.S. by the end of the 1970s.[132] The Vietnam War, Watergate scandal, and resignation of President Nixon shook faith in the U.S. government domestically and abroad.[133] Economically, the country faced double-digit unemployment, a severe oil shortage necessitated harsh rationing and caused prices at the pump to skyrocket, and foreign competitors, which had taken the lead in the automobile and other sectors once the U.S.'s domain globally, posed a

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130. *Id.* at 108–09.

131. President Dwight D. Eisenhower, Farewell Radio and Television Address to the American People (Jan. 17, 1961), http://www.presidency.ucsb.edu/ws/index.php?pid=12086&st=farewell&st1=.

132. *See generally* DOMINIC SANDBROOK, MAD AS HELL: THE CRISIS OF THE 1970S AND THE RISE OF THE POPULIST RIGHT (2012).

133. *Id.*

competitive threat overall.[134] The failures of both big government and big business exasperated the public.[135] Demands for more research and development and economic stimulus grew deafening and shouted Congress into action.[136]

Congress responded in the spirit of the MP by undertaking a grand science research-and-development triple-threat experiment: the introduction of U.S. federal technology transfer law and policy, which Congress jumpstarted through legislation in 1980.[137] The core strategy was to free science and technology innovation financed with federal funding, which was lingering in a state of research institution purgatory,[138] by giving it away on the condition that it be applied commercially—thereby stimulating the economy on national, state, and local levels.[139] Although the initiative originally targeted only

134. *See generally* MEG JACOBS, PANIC AT THE PUMP: THE ENERGY CRISIS AND THE TRANSFORMATION OF AMERICAN POLITICS IN THE 1970S (2017). *See also* ALAN S. BLINDER, INFLATION: CAUSES AND EFFECTS 270–71 (1982); MICHAEL S. SHERRY, IN THE SHADOW OF WAR: THE UNITED STATES SINCE THE 1930S 329–31 (1995).

135. *See generally* SANDBROOK, *supra* note 132; JACOBS, *supra* note 134.

136. Malinowski, *Government Rx*, *supra* note 93, at 106–07.

137. The primary pieces of legislation, both enacted in 1980, are the Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–212 (2012)) [hereinafter Bayh-Dole], and the Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–3724 (2012)) [hereinafter Stevenson-Wydler]. Later, Congress added to these Acts to expand R&D opportunities. For a full discussion of U.S. technology transfer law and policy, *see generally* MALINOWSKI, *supra* note 49, at 69–77.

138. U.S. GOV'T ACCOUNTABILITY OFFICE, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 2–3 (1998) [hereinafter GAO, TECHNOLOGY TRANSFER] ("At the time, fewer than 5 percent of the 28,000 patents being held by federal agencies had been licensed, compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention."); Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 153–54 (2006); James Stuart, *The Academic-Industrial Complex: A Warning to Universities*, 75 U. COLO. L. REV. 1011, 1033–34 (2004) ("Whereas the major principle in the decades after World War II was that technology owned by the government was for 'everyone's benefit,' supporters of the [Bayh-Dole] Act claimed that this policy effectively rendered government-owned technology for 'nobody's benefit.' It simply gathered dust in government repositories.").

139. "The legislative intent of Bayh-Dole" and Stevenson-Wydler "was, through reform of patent policy related to government-sponsored research: (1) to

small businesses, the U.S. expanded it during the 1980s to include all commercial ventures and to bestow complementary research and development opportunities to government agencies and researchers.[140]

This grand, triple-threat experiment enabled the formation of an entire vibrant biotechnology sector in less time than it takes to develop a single innovative new prescription drug, and it launched a global genomics revolution with the U.S. dually positioned as its detonator and epicenter.[141] On the footing of this accomplishment, the U.S. then utilized its triple-threat strategy to undertake the Human Genome Project ("HGP")—an initiative that fully embraced the core methodology used to accomplish its MP predecessor. Like the MP, the HGP had a defined mission that necessitated intense, triple-threat collaborations and crisp, focused government leadership to accomplish decisive, tangible objectives.[142] Essential for credibility, Congress securely funded the HGP over a block of time—$3 billion (FY1991 dollars) for up to fifteen years.[143] Moreover, the U.S. placed the HGP

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enable and encourage universities, not-for-profit corporations, and small businesses to patent and commercialize their federally-funded inventions and (2) to allow federal agencies to grant exclusive licenses for their technology to provide more incentive to businesses." Malinowski, *Government Rx*, *supra* note 93, at 108; GAO, TECHNOLOGY TRANSFER, *supra* note 138, at 3. As the NIH explained, the collective goal of these Acts "is to promote economic development, enhance U.S. competitiveness, and benefit the public by encouraging the commercialization of technologies that would otherwise not be developed into products due to lack of incentives." U.S. DEP'T OF HEALTH & HUMAN SERVS., NAT'L INSTS. ON HEALTH, NIH RESPONSE TO THE CONFERENCE REPORT REQUEST FOR A PLAN TO ENSURE TAXPAYERS' INTERESTS ARE PROTECTED 4 (2001), https://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf.

140. MALINOWSKI, *supra* note 49, at 69–77.

141. *Id.* at xxiii–xxx.

142. HGP centered on achieving three technical goals: to produce (1) physical maps of large chromosome regions to enable direct study of DNA structure in search of genes, (2) genetic linkage maps to study chromosome regions, and (3) substantial DNA sequence information to enable correlation of DNA changes with alterations in biological function. *Id.* at 13; Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. REG. 163, 190 (1996).

143. Nat'l Institutes on Health, *Human Genome Project Completion: Frequently Asked Questions*, NAT'L HUMAN GENOME RESEARCH INST., https://www.genome.gov/11006943/human-genome-project-completion-frequently-asked-questions/ (last updated Oct. 30, 2010). A noted distinction is that President

on a bedrock of federal technology transfer law and policy and government-academia-industry collaboration, which served as an expansive battleground for a genomics revolution.[144] The HGP was a global phenomenon, for it transcended borders as well as disciplines from its inception:

> [T]he immediate impact of HGP was to instill a profound focus in the international science community not experienced since the Manhattan Project. The science community and research institutions were heavily influenced by a guaranteed flow of considerable U.S. federal grant funding for more than a decade. An additional draw was the direct commitment of two major U.S. federal agencies (NIH and the Department of Energy, DOE), and the same from global counterparts through the Wellcome Trust and other countries' complementary programs. Another was an unprecedented international network focused on human genetics during an era of intense internet communication that has and continues to rise in volume exponentially.[145]

The HGP was an enormous undertaking—a proverbial "white elephant"—when launched in 1990 and years into the project, for very little of the essential enabling technology, especially the bioinformatics capabilities so crucial to its success, existed at the time.[146] In 1997, approximately the half-way point in HGP's originally anticipated fifteen-year duration, ninety percent of the project's budget

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Franklin D. Roosevelt moved forward with the MP in 1941 under a thickly piled shroud of secrecy—maintained remarkably well until completed four years later and in spite of some 100,000 people working on it. Nat'l Constitution Ctr., *On This Day, FDR Approves Funding the Manhattan Project*, CONST. DAILY (Oct. 9, 2017), https://constitutioncenter.org/blog/on-this-day-fdr-approves-funding-the-manhattan-project. For secrecy, and to ensure necessary funding shielded from Congressional intrusion, the executive branch financed the project through discretionary funds. *Id.* "In all, the United States spent an estimated $2 billion on a project that employed more than 120,000 people to build a nuclear weapon." *Id.*

144. MALINOWSKI, *supra* note 49, at 1–14.

145. *Id.* at 13 (citation omitted).

146. Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 JURIMETRICS J. 23, 23–26 (2000).

had been spent to accurately sequence just 2.68% of the human genome.[147] Yet through government and industry competition and collaboration, researchers completed the HGP ahead of schedule and under budget—somewhat of a phenomenon in "government work."[148] The accomplishment was simply remarkable, as President Clinton observed when he announced completion of a preliminary draft:

> We are here to celebrate the completion of the first survey of the entire human genome. Without a doubt, this is the most important, most wondrous map ever produced by humankind. . . . More than 1,000 researchers across six nations have revealed nearly all 3 billion letters of our miraculous genetic code. I congratulate all of you on this stunning and humbling achievement.
>
> Today's announcement represents more than just an epic-making triumph of science and reason. After all, when Galileo discovered he could use the tools of mathematics and mechanics to understand the motion of

147. *See* Juan Enriquez & Ray Goldberg, *Transforming Life, Transforming Business: The Life-Science Revolution*, HARV. BUS. REV., Mar.–Apr. 2000 at 95 (noting that advances in genetic research are setting off an industrial convergence), https://hbr.org/2000/03/transforming-life-transforming-business-the-life-science-revolution.

148. As the Human Genome Research Institute summarized

> In 1990, Congress established funding for the Human Genome Project and set a target completion date of 2005. Although estimates suggested that the project would cost a total of $3 billion over this period, the project ended up costing less than expected, about $2.7 billion in FY 1991 dollars. Additionally, the project is being completed more than two years ahead of schedule.

Nat'l Institutes on Health, *supra* note 143. *See generally* MICHAEL A. FORTUN, CELERA GENOMICS: THE RACE FOR THE HUMAN GENOME PROJECT, *in* ENCYCLOPEDIA OF THE HUMAN GENOME (2006); Press Release, Nat'l Human Genome Research Institute, International Consortium Completes Human Genome Project (Apr. 14, 2003), http://www.genome.gov/11006929; *see also generally* 409 NATURE 745 (2001) (issue dedicated to the release of a draft map of the human genome); 291 SCIENCE 1145 (2001) (issue entitled "The Human Genome"). Pushed to the finish line by Celera Genomics, a commercial competitor formed in 1998 to pick up with the work accomplished by the government effort at that point, all in the public domain, and challenge it in a race to complete the genome sequencing.

> celestial bodies, he felt, in the words of one eminent researcher, "that he had learned the language in which God created the universe."
>
> Today, we are learning the language in which God created life. . . . Genome science will have a real impact on all our lives—and even more, on the lives of our children. It will revolutionize the diagnosis, prevention and treatment of most, if not all, human diseases.[149]

The combined impact of the technology transfer and HGP triple-threat initiatives has been profound—for the advancement of technology research and development, economically, and increasingly for the improvement of human health. Pharmaceuticals are the past, while biopharmaceuticals are the very real present and future.[150] Advancement of genomic science is translating into clinical human health benefits, such as a proliferation of quality, clinically meaningful genetic screening to enhance preventive care, to improve diagnoses, and to make much more informed and better choices among treatment options.[151] Today's patients live in an era of biopharmaceuticals and biologics that intervene in disease pathways rather than just take away symptoms, and treatments such as immunotherapies.[152] The advent of genomics in clinical care has just begun, and the potential to improve human health appears limited only by imagination, determination, time, and health care resources, though the latter is increasingly daunting.[153]

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149. Press Release, The White House, Remarks Made by the President, Prime Minister Tony Blair of England (via satellite), Dr. Francis Collins, Director of the National Human Genome Research Institute, and Dr. Craig Venter, President and Chief Scientific Officer, Celera Genomics Corporation, on the Completion of the First Survey of the Entire Human Genome Project (June 26, 2000), http://www.genome.gov/10001356.

150. MALINOWSKI, *supra* note 49, at xxi–xxix.

151. KAREN JEGALIAN, NAT'L HUMAN GENOME RESEARCH INST., NIH PUB. NO. 00-4873, GENETICS: THE FUTURE OF MEDICINE (2005), https://www.genome.gov/pages/educationkit/images/nhgri.pdf.

152. MALINOWSKI, *supra* note 49, at xxiii–xxix.

153. *See id.* at xxi–xxii (noting that the "future for genomic medicine is bright"). Juxtaposing the U.S.'s wrangling over the ACA and health care costs with the cost of innovative biologics that are the means to treat life-threatening and otherwise seriously life-debilitating diseases for which no sufficient treatments exist

B. An Opioid Addiction and Pain Pathway Project Proposal

In the midst of pervasive divisiveness within the U.S., there is profound consensus that the nation's opioid epidemic demands bold government intervention on a critical basis.[154] The opioid epidemic has been escalating and raging for years, it is out of control and has been so for years, and time is of the essence.[155] As former FDA Commissioner Kessler observed in this context, times of crisis are opportunities for change—for example, the precarious state of U.S. health care finance drove passage of the ACA, despite its muddle of ambiguities, uncertainties, and the hawkish opposition it triggered.[156] The health care finance situation is even more dire now, however, as costs have continued to climb, and existing funding for federal and state programs is in jeopardy.[157]

The dire state and scope of the opioid epidemic and the nation's public health demands a federal government response that, consistent with the HGP,[158] *transcends any presidential administration*, especially the present one.[159] The national public health emergency

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is beyond sobering. At annual costs that may exceed $45,000 for a course of treatment, biologics threaten to further overwhelm health care systems. *See* Lacie Glover, *Why Are Biologic Drugs So Costly? A Look at How Biologics are Made, How Much they Cost and Why*, U.S. NEWS (Feb. 6, 2015, 12:40 PM), http://health.usnews.com/health-news/health-wellness/articles/2015/02/06/why-are-biologic-drugs-so-costly. "According to pharmacy benefits giant Express Scripts, even though only 2 percent of the population uses biologic drugs, biologics account for 40 percent of prescription drug spending in the U.S." *Id.*

154. *Cf. supra* note 106 and accompanying text (discussing the disappointing results of the Government's case against McKesson). *See also* Kessler, *supra* note 3 ("Most people agree that the federal government should tackle public health crises, and there is a particular consensus about the current epidemic involving opioids.").

155. *See supra* notes 1–6 and accompanying text.

156. *See generally* Robert M. Sade, *The Health Care Reform Law (PPACA): Controversies in Ethics and Policy*, 40(3) J.L. MED. & ETHICS 523, 523–24 (2012).

157. *See supra* notes 35–37 and accompanying text.

158. *See supra* notes 142–153 and accompanying text.

159. The Roosevelt Administration accomplished the MP through enormous executive branch discretionary funding to ensure tight orchestration, adequate resources, and secrecy—a cloak to protect the project from Congressional intrusion during a world war, and during a very different (pre-Pentagon Papers and Watergate scandal) time in the history of the American presidency. *See generally The Manhattan Project*, *supra* note 126; THE BIRTH OF THE ATOMIC BOMB, *supra* note

that the opioid epidemic poses beckons a Congressional response, and federal and state public health policing and *parens patriae* powers provide the authority to do so.[160] Congress must sufficiently and securely fund a national, multifaceted legislative response with defined direction and leadership that builds upon ongoing initiatives and draws from the U.S.'s science and technology triple-threat legacy of overcoming similarly ominous challenges through advancement of science and technology. Through a legislative mandate to which agency and HHS heads are held administratively accountable, Congress must designate centralized leadership, similar to the leadership that NIH Director Francis Collins provided as head of the HGP.[161] The administrative head or heads designated should "have explicit, unambiguous authority over [opioid epidemic recovery and containment] programs, now in the hands of many others, and see to it that we effectively treat those who are addicted and prevent the next generation from becoming addicted."[162]

NIH and her sister agencies shifting funding from their annual budgets to prioritize opioid strategies and to advance pain pathway science and technology also is commendable and necessary. However, it is not enough. An undeniable reality is that meeting the challenge posed by the ongoing opioid crisis in the timeframe this national public health emergency demands will cost the nation tens of billions of dollars beyond existing federal agency operating budgets and ongoing health care funding. Other realities, however, are that the

126. The nation's response to the opioid crisis must take the form of a legislative mandate superimposed over the idiosyncrasies and subjectivities of a sitting president.

160. *See generally* James Hodge, Jr., *Implementing Modern Public Health Goals Through Government: An Examination of New Federalism and Public Health Law*, 14 J. CONTEMP. HEALTH L. & POL'Y 93 (1997). Federal police powers are based in the Commerce Clause, and States' police powers are grounded in the Constitution's reservation of power and rights to them under the Tenth Amendment. *See* U.S. CONST. art. I, sec. 8, cl. 3; U.S. CONST. amend. X. The Constitutional checks on these powers, requiring government interventions to be sufficiently compelling, are due process under, respectively the Fifth and Fourteenth Amendments, and individual rights under the First Amendment. *See* U.S. CONST. amends. I, V, XIV. *See also* SANDRA H. JOHNSON ET AL., BIOETHICS AND LAW IN A NUTSHELL, 273–277, 280–285 (2d ed. 2016). *Cf. infra* notes 177–179 and accompanying text (comparing aspects of this Article's proposal to other congressional interventions into health care).

161. *Cf. generally* VICTOR K. MCELHENY, DRAWING THE MAP OF LIFE (2010).

162. Kessler, *supra* note 3.

consequences of opioid addiction already have cost the nation much more financially, they are continuing to do so, and that cost is rising as the epidemic is amassing.[163] Immensely more significant than the financial costs, the opioid addiction epidemic has and continues to consume lives that the federal and state governments have a public health duty to protect—as the U.S. directly acknowledged when it officially declared the opioid epidemic a public health emergency.[164]

The following discussion proposes such a treatment plan—an Addiction and Pain Pathway Project ("APPP"). The APPP primary objectives would be: (1) to advance pain-pathway science and technology research and development consistent with the triple-threat methodology of the MP and the HGP; and (2) to contain the supply side of the prescription opioid problem. The methodology proposed for the latter involves introducing meaningful controls on prescribing, production, and distribution practices realized by a combination of legislative mandates and federal funding targeted to meet them.

1. Proposed Pain Pathway Science and Technology R&D Objective

The nation anxiously awaits an infusion of deeper understanding and innovative treatment alternatives for addiction and pain management. The APPP could jolt addiction and pain-pathway science and technology forward consistent with the advances in atomic and nuclear science realized through the MP and in genomics realized through the HGP.[165] NIH, well-versed in triple-threat science and

163. *Id.*

164. *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (Oct. 26, 2017), https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf (official declaration of Acting Secretary Eric D. Hargan that the opioid crisis constitutes a public health emergency); *accord* Press Release, U.S. Dep't of Health and Human Servs., HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis (Oct. 26, 2017), https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

165. *Peaceful Nuclear Innovations*, ATOMIC HERITAGE FOUND. (June 5, 2014), https://www.atomicheritage.org/history/peaceful-nuclear-innovations; *see also generally* 291 SCIENCE 1145 (2001) (issue entitled "The Human Genome"); 409 NATURE 745 (2001) (issue dedicated to the release of a draft map of the human genome).

technology research-and-development methodology through HGP and decades of federal technology transfer experience, is pursuing industry collaboration through its Opioid Initiative.[166] According to the FDA, "[t]he pharmaceutical industry has shown significant interest in developing abuse-deterrent opioid formulations and the field is progressing rapidly."[167]

Congress should enact legislation to launch APPP with a research-and-development component modeled after the HGP that aggressively utilizes technology transfer law and policy—meaning full integration of government, academic, and industry resources.[168] Moreover, given ongoing progress in the field and pervasive, immediate patient need, Congress should frontload the outcomes timeline and budget accordingly. The commitment and stability of substantial research-and-development funding over time to achieve targeted goals through collaboration among government, academia, and industry positioned both MP and HGP for success; that success was extraordinary, and it jolted the relevant science and technology forward to overcome ominous challenges.[169] Both initiatives created focused, collaborative science research-and-development epicenters for government, academia, and industry.

Such a research-and-development component would require generous and sound funding, additional incentives, and assurances to prove persuasive enough to draw the critical mass of industry involvement necessary to advance pain pathway research and development on a level commensurate with ongoing public health need. Biopharmaceutical research and development in particular is extraordinarily risk-intensive and accompanied by a lengthy

166. NIH's initiative includes "working with FDA and private sector experts to draft a plan for a formal partnership to advance specific pharmacological treatments for pain and addiction." U.S. Dep't of Health & Human Servs., *NIH Opioid Initiative to Help End the Opioid Crisis*, NAT'L INSTITUTES ON HEALTH, https://www.nih.gov/node/34206 (last visited Jan. 9, 2018). In 2017, NIH convened a series of meetings with experts from across government, industry, and academia to determine the pharmacological areas that could be best addressed through a public-private partnership. *Id.*

167. Califf, Woodock & Ostroff, *supra* note 2, at 1483.

168. *See supra* notes 142–144.

169. *See generally supra* Section IV.A.

timeline.[170] Industry has become accustomed to acquiring federally-funded basic, and even some advanced, research-innovation outcomes through decades of experience with federal technology transfer law and policy.[171] Industry decisions to make research-and-development commitments are zero-sum in that they inevitably entail opportunity costs, and technology transfer generates an ongoing plethora of opportunity alternatives.

Moreover, multinational biopharmaceutical companies, many with tens of thousands of employees, are, at times, as bureaucratic as small countries.[172] Top executives are cognizant of their potentially brief "shelf lives" in those positions.[173] Containing taxes and profitability for investors are priorities and fiduciary responsibilities.[174] Opioid manufacturing, in part *because of* their

170. *See* Malinowski, *Government Rx*, *supra* note 93, at 109–110.

171. *See* MALINOWSKI, *supra* note 49, at 69–77.

172. Consider how the multinational pharmaceutical sector adhered to its traditional, largely chemistry-based research and development until, in the late 1990s, it realized that its portfolio of drug products was falling off patent protection and its pipeline for new products was running dry. *See* Michael J. Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development*, 2 HOUS. J. HEALTH L. & POL'Y 31, 34–35 (2002). Fortunately for the pharmaceutical industry, it was able to buy up biotech from that maturing sector, resulting in today's combined biopharmaceuticals focus in drug development. *Id.* Centralization of review of all new drugs, whether based primarily in biology or chemistry, within the Center for Drug Evaluation and Research ("CDER") beginning in 2004, confirmed that pharmaceutical R&D and biotech had integrated extensively. Michael J. Malinowski & Grant G. Gautreaux, *Drug Development-Stuck in A State of Puberty?: Regulatory Reform of Human Clinical Research to Raise Responsiveness to the Reality of Human Variability*, 56 ST. LOUIS U. L.J. 363, 389 (2012). *See* Press Release, U.S. Food & Drug Admin., FDA Completes Final Phase of Planning for Consolidation of Certain Products from CBER to CDER (Mar. 17, 2003), http://www3.scienceblog.com/community/older/archives/M/2/fda1387.htm. In 2016, the biotechnology industry's trade organization, the Biotechnology Industry Organization, changed its name to the Biotechnology Innovation Organization. *See generally* BIOTECHNOLOGY INNOVATION ORGANIZATION ("BIO"), http://www.bio.org (last visited Oct. 13, 2018).

173. The author relies on his observation working for the Massachusetts Biotechnology Council from 1997 to 1998, and industry interactions and observations thereafter.

174. *Id.*

highly addictive nature, has proven a profitable business.[175] Those in the biopharmaceutical industry responsible for the opioid supply, and who are major contributors to and beneficiaries of the crisis, have demonstrated enormous influence.[176]

As an added expression of commitment to incentivize industry, Congress should build upon agency self-initiatives and provisions in the Addiction and Recovery Act, Cures Act, and Budget Act of 2018 that prioritize opioid crisis funding. Specifically, the APPP should include provisions that *further and more specifically* mandate that federal agencies prioritize opioid-crisis responsiveness and pain-pathway science and technology when funding grant applications and entering into Cooperative Research and Development Agreements with industry.[177] Congress also should add provisions that direct the FDA to use familiar industry incentives within its purview, such as the fast track for innovative new drugs, to prioritize and advance APPP's objectives. Congress also should add a market exclusivity to the some fifteen it has authorized the FDA to issue focused on industry responsiveness to the opioid crisis.[178] Finally, Congress should consider introducing tax incentives such as those used to promote research and development of orphan (small disease group) drugs, and

175. Consider, for example, the financial success of the McKesson Corporation. *See supra* notes 102–109 and accompanying text.

176. Consider Congress's quiet passage of the Access Act in the midst of media attention on the severity of the nation's opioid crisis. *See supra* notes 110–112 and accompanying text.

177. The APPP should encompass and enhance initiatives such as the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, a progeny of HGP. *See generally* U.S. Dep't of Health & Human Servs., *What is the Brain Initiative?*, NAT'L INSTS. ON HEALTH, https://www.braininitiative.nih.gov/ (last visited Oct. 13, 2018); *see also* Courtney Humphries, *Mapping the Way to a Brain Survey*, HARV. MAG. (July–Aug. 2013), https://harvardmagazine.com/2013/07/mapping-the-way-to-a-brain-survey.

178. MALINOWSKI, *supra* note 49, at 158–69. Market exclusivities coupled with other commercial incentives, such as tax breaks, streamlined review and approval, and expedited FDA responsiveness, have successfully incentivized the development of orphan drugs, generic drugs, the completion of pediatric studies, and beyond. *See generally id.* at 127–69.

an opioid "new public health" counterpart to the National Vaccine Injury Program as an additional incentive, given its past success.[179]

2. Proposed Supply-Side Provisions

Even if such a project realizes the goal of pain-treatment alternatives to addictive opioids, the timeframe from bench research to market approval of innovative biopharmaceuticals exceeds a decade by most estimates,[180] while the opioid epidemic is ongoing, catastrophic, and spreading. Prescription opioids with addictive properties certainly are going to remain in the portfolio of prescription medications to manage pain for the foreseeable future—as they should,

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179. *See* Orphan Drug Act, Pub. L. No. 97-414, § 2(a), 96 Stat. 2049 (2000) (codified as amended at 21 U.S.C. § 360bb); MALINOWSKI, *supra* note 49, at 167–69; *see also generally* Mark D. Shtilerman, *Pharmaceutical Inventions: A Proposal for Risk-Sensitive Rewards*, 46 IDEA 337, 337–39 (2006). The new public health movement centers on scientific understanding about the determinants of health and responsive, more utilitarian law and policy interventions based on this level of understanding. *See generally* Lindsay F. Wiley, *Rethinking the New Public Health*, 69 WASH. & LEE L. REV. 207 (2012); *see also* Hodge, *supra* note 160.

180. Malinowski, *Government Rx*, *supra* note 93, at 109; Malinowski, *Throwing Dirt*, *supra* note 79, at 659. According to industry, new drugs cost over $1.2 billion to approve and take more than 15 years to produce, with an extraordinary failure rate—greater than 80% for drug candidates that actually reach the stage of human clinical trials. *See* Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 235 (2013); Steve Morgan et al., *The Cost of Drug Development: A Systematic Review*, 100 HEALTH POL'Y 4, 14–16 (2011). It is important to note, however, that this cost number takes into account the expense of drug failures (the numbers are comingled into averages and medians), and it is calculated based upon proprietary data *self-reported by industry* to the Tufts Center for the Study of Drug Development, and on industry-sponsored research. *See generally* Tufts Ctr. for the Study of Drug Dev., *Sponsored Research*, TUFTS UNIV., http://csdd.tufts.edu/sponsored_research (last visited Oct. 13, 2018). Also, individual new drug cost estimates vary widely, and those on the biologics forefront (for example, biologics, including biosimilars and interchangeable drugs) are much more expensive to develop, manufacture, and deliver (often injections, and with potentially much greater side effects) in patient care. *See* MALINOWSKI, *supra* note 49, at 164–65; Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012), https://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/ ("The average drug developed by a major pharmaceutical company costs at least $4 billion, and it can be as much as $11 billion.").

given legitimate patient needs. There is no denying, however, that prescription opioids have been, and are, a (if not *the*) primary factor feeding the epidemic,[181] and that they are likely to continue to do so for the foreseeable future.

As the FDA observed, regulating the supply of prescription opioids must balance "two complementary principles: that the United States must deal aggressively with opioid misuse and addiction, and at the same time, that it must protect the well-being of people experiencing the devastating effects of acute or chronic pain."[182] Regulators must achieve balance with the input of patient advocacy groups, such as the National Cancer Coalition, and the medical profession, but Congress must grant the FDA the authority to cleanly strike and enforce that balance. Along with the FDA's authority, Congress must act without further delay to elevate DEA and DOJ authority to regulate physician opioid prescription practices and opioid manufacturing. Moreover, in the APPP, Congress must legislatively mandate that these agencies do so with specificity, fund them accordingly so that they are able, and hold them accountable.

Prohibitions on encroachment on the practice of medicine constrain the federal government from effectively managing prescription opioid use.[183] The number of annual opioid prescriptions written in the U.S. now roughly equals the number of adults in the U.S. population.[184] These restrictions on the federal government are relics of a bygone era of medicine—one predating the proliferation of managed care, the commercialization of medicine, aggressive patient consumerism, and direct-to-consumer marketing by biopharmaceutical companies by decades.[185] They undermine the FDA, the mission of which is to keep watch over the prescription drug market, to the point that addiction to opioids has engulfed the nation. This legacy embodies deference to the states and trust in them to license and police the practice of medicine within their jurisdictions, though states investigate and discipline physicians for allegations of

181. *See supra* note 3 and accompanying text.

182. Califf, Woodcock & Ostroff, *supra* note 2, at 1480.

183. *See supra* notes 68–79 and accompanying text.

184. CDC, ANNUAL SURVEILLANCE, *supra* note 2, at 9–11. *See also* Califf, Woodcock & Ostroff, *supra* note 2, at 1480.

185. *See supra* notes 68–76 and accompanying text.

professional misconduct through medical boards and proceedings—which the medical profession conveniently controls.[186]

The medical profession's influence over policy, as codified legislation and decades of case law demonstrate, bolstered by the biopharmaceutical industry's protection of physicians' discretion to prescribe FDA-approved medicines and patient demands, may damn the nation to continue to drag the cumbersome, antiquated legacy of prescription deference along in contemporary medicine. Nevertheless, as former Commissioner Kessler recognized, "[i]n times of crisis, major change can happen[,]"[187] and we are in the midst of a chronic, escalating opioid crisis obviously beyond existing governmental means.[188] The opportunity for government and medical profession intervention has been more than ample over the last several years—some would argue decades—and the numbers are self-explanatory. Obviously, neither the federal government nor the states have proven effective at checking opioid prescription practices, and the medical profession has proven itself incapable of self-restraint. Although the FDAAA enhanced the FDA's muscle and reach, entrenched legal restraints, norms, and resource limitations—the same impediments and post-marketing performance insufficiencies that inspired enactment of the FDAAA in the first place—continue to stymie both.[189]

The medical profession, which generally opposes practice guidelines because it views them as encroachments on physician discretion, has challenged the CDC guideline for prescribing opioids in favor of education.[190] In fact, the nation needs both. The APPP should include provisions to coordinate and bolster them, and it should authorize federal agencies to make opioid guidelines mandatory and enforceable—for example, by conditioning state participation in Medicaid, Medicare, and other government health-related programs on implementation. Perhaps as another condition on participation in government health-related programs, Congress should also require states to impose opioid and addiction competency mandates on physicians in accordance with federal criteria as a prerequisite for

186. *See* STARR, *supra* note 71, at 21–29, 40–59, 102–12.

187. Kessler, *supra* note 3.

188. *See supra* Part III.

189. *See generally* Evans, *supra* note 68.

190. *See supra* note 91 and accompanying text.

prescribing opioids within their jurisdictions. Consistent with other raging epidemics, the opioid epidemic does not respect state borders. Addiction and profits ensure the mobility of both patients and pills—another factor that makes the opioid epidemic truly a *national* public health crisis. Under the Health Insurance Portability and Accountability Act, the federal government requires all physicians to be proficient in medical privacy to protect the rights of their patients.[191] Similarly, the federal government should require all physicians to be proficient about the opioids they prescribe to protect the *lives* of their patients. At the present time, multiple agencies beyond the CDC, including the FDA, the NIDA, the SAMHSA, and the Office of the Surgeon General, are responsible for physician education.[192] The FDA's opioid strategy emphasizes physician education, in part, because this approach is much less susceptible to political and legal challenges than directly regulating prescription practices.[193] In our free-market, deference-to-physicians health care system, reliance on medical education as a solution to a public health dilemma on the scale of the opioid epidemic is highly suspect. In fact, restraints on the FDA in an age of heightened biopharmaceutical innovation and pervasive marketing arguably have bestowed the biopharmaceutical industry with the most influential "education" podium.[194] As Dr. Marcia Angell, former *New England Journal of Medicine* editor-in-chief and author of *The Truth About Drug Companies*, has observed, drug companies are in the business of selling biopharmaceuticals and making profits for their investors—not the enterprise of objective, unbiased medical education.[195]

Effectively regulating physician opioid prescription practices certainly would augment the importance of DEA and DOJ regulation of opioid production. Opioid manufacturing facilities are scaled-up to meet opioid epidemic supply demands, and meeting those demands has

191. Health Insurance Portability and Accountability Act, Pub. L. 104–191, 110 Stat. 1936 (1996).

192. Califf, Woodcock & Ostroff, *supra* note 2, at 1480; Kessler, *supra* note 3.

193. *See supra* notes 88–89 and accompanying text.

194. MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 135–55 (2005); Malinowski, *Doctors, Patients, and Pills*, *supra* note 68, at 1089–99.

195. ANGELL, *supra* note 194, at 135 ("No one should rely on a business for impartial evaluation of a product it sells.").

proven extraordinarily profitable.[196] The APPP should include provisions to mandate federal regulation and enforcement at a heightened level. The political influences that have impeded progress by allowing the epidemic to gorge on uncontrolled supply, however, have proven daunting.[197] Reminiscent of the nation's wrangle with the tobacco industry, necessity has compelled the states to battle the opioid addiction beast, amassed under the federal government's watch, in a litigation forum.[198] On February 27, 2018, Attorney General Sessions announced intentions to file federal counterparts to these state actions, and also to potentially help them directly.[199] The Federal government brought *and settled* the McKesson case, however.[200] The APPP should include a provision to ensure that the states are supported in their legal actions and complementary legislative initiatives, and that the support is substantial and reliable over time.

3. Federal Mandates and Support of State Initiatives

Although there is no practicable grassroots solution to the opioid crisis, the epidemic is taking place on state soil, where primary regulation of the practice of medicine and patient treatment resides and has resided for decades.[201] Moreover, states hold extensive public health and safety powers, and they have demonstrated effective ingenuity in grappling with the crisis.[202]

The APPP or any other federal intervention must wholly utilize and promote state initiatives through targeted grant funding—mandates that are much more direct, fully defined, fully funded, and centrally orchestrated than those under the Addiction and Recovery

196. *See supra* notes 102–109 and accompanying text (discussing the McKesson case); *supra* notes 20–22 and accompanying text (discussing Purdue Pharma litigation).

197. *See, e.g.*, *supra* notes 102–109 (discussing the McKesson case); *supra* notes 110–112 (discussing the industry-influenced Access Act).

198. Bernstein & Higham, *supra* note 24.

199. *See supra* note 25 and accompanying text.

200. *See supra* notes 102–109 and accompanying text.

201. *See supra* note 186 and accompanying text.

202. *See supra* note 160 and accompanying text; *see also* Wiley, *supra* note 179.

Act, the Cures Act, and the Budget Act of 2018.[203] First and foremost, through grant and Medicaid funding, the federal government must support treatment facilities and rehabilitation programs that meet national criteria developed under the APPP and fund the establishment of new ones. Given the pervasiveness of the opioid epidemic in rural areas, Congress should immediately remove the Social Security Administration's prohibition on allocating federal funding to state-sponsored mental-health and substance-abuse-disorder residential treatment facilities with more than sixteen beds under the provision of Medicaid law referred to as the "institute for mental disease" exclusion.[204]

Federal intervention also should mandate funding for states' prescription drug-monitoring programs ("PDMPs") that meet national criteria modeled on the most effective state PDMPs at the time APPP is implemented as a condition for participation in Medicaid and other federal health-related programs, and Congress should provide grant funding to enable compliance. Moreover, the federal government should facilitate coordination among them, as it has done in other contexts for years—such as the National Practitioner Data Bank ("NPDB") and the Health Integrity and Protection Data Bank ("HIPDB").[205]

Some jurisdictions that the opioid epidemic has particularly devastated, such as Buffalo, New York, and Stafford Country, New Hampshire, have introduced drug courts that couple prosecution of addicts with closely supervised treatment, recovery, and rehabilitation

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203. *See supra* note 28 and accompanying text.

204. *See* 42 U.S.C. §§ 290bb-1(e), 1396d(i) (2012). Congress included this exclusion in the Social Security Amendments Act of 1965, which created Medicare and Medicaid, to leave the responsibility and burden of funding mental health services on state governments. Pub. L. 89-97, § 121(a), 79 Stat. 286, 343–50. *See also generally* LEGAL ACTION CTR., THE MEDICAID IMD EXCLUSION: AN OVERVIEW OF OPPORTUNITIES FOR REFORM (n.d.), https://lac.org/wp-content/uploads/2014/07/IMD_exclusion_fact_sheet.pdf.

205. *See* 45 C.F.R. § 60.1 (2017); *cf.* George F. Indest III, *National Practitioner Data Bank (NPDB) Update*, THE HEALTH L. FIRM, https://www.thehealthlawfirm.com/resources/health-law-articles-and-documents/national-practitioner-data-bank.html (last visited Oct. 13, 2018) (noting that the Affordable Care Act eliminated the HIPDB and merged it with the NPDB).

programs.[206] Some regional medical centers, such as East Tennessee Children's Hospital, have established neonatal intensive care units to treat neonatal abstinence syndrome involving opioid withdrawal—an epidemic within the opioid epidemic.[207] Philadelphia, inspired by the success of Canadian programs such as Vancouver's, is considering establishment of safe injection sites to prevent overdose deaths and to connect addicts with treatment.[208] The federal opioid crisis intervention should include grant funding for such state and community programs that meet criteria drawn from need and experience successes. Exploratory innovative initiatives should be eligible for federal grant funding as well, perhaps in the form of federal matching funds, to promote ongoing novel, creative, community, and state-based "boots on the ground" opioid addiction problem solving.

V. CONCLUSION

The U.S. is addicted to opioids, it has been for many years, and the crisis has amassed and spun increasingly out of control.[209] The scope and severity of the addiction, which the CDC has documented beyond question, poses a national public health emergency that national and state governments have recognized, and which millions of citizens—whose numbers are compounding—have experienced.[210] Federal agencies such as the FDA, the nation's market gatekeeper for

206. Chris Cuomo, *Inside with Chris Cuomo: SOS New Hampshire* (CNN television broadcast Oct. 20, 2017). CNN Reporter Chris Cuomo investigated and reported on New Hampshire's efforts to grapple with the heightened opioid crisis within its borders, including introduction of an innovative drug court. *Id.*

207. *See generally* PAUL D. WINCHESTER, NEONATAL ABSTINENCE SYNDROME (2012), https://www.in.gov/attorneygeneral/files/(edit)Winchester_Neonatal_Abstinence_and_Opiate_Prescriptions._12_13_2012_pt.pdf. *See also* ABC News, *Nightline: Drug-Dependent Infants Detox at Tenn. NICU*, YOUTUBE (July 11, 2012, 3:43 PM), https://www.youtube.com/watch?v=2eP5EnFSG0c.

208. Elana Gordon, *What's Next for "Safe Injection" Sites in Philadelphia?*, NAT'L PUB. RADIO (Jan. 24, 2018), https://www.npr.org/sections/health-shots/2018/01/24/580255140/whats-next-for-safe-injection-sites-in-philadelphia.

209. *See supra* notes 1–6 and accompanying text.

210. *See, e.g.*, Merica, *supra* note 31 and accompanying text (reporting on President Trump's recognition and declaration of the crisis as a national public health emergency).

prescription drugs, have expended an enormous amount of energy and effort to respond to the opioid crisis while the problem has ballooned into an ominous national epidemic.[211]

This Article has proposed a federal government intervention, under centralized responsibility and leadership, with three tangible objectives. These objectives are to (1) advance pain-pathway science and technology through research and development, (2) control the supply side of prescription opioid use, and (3) bolster state initiatives through targeted grant funding and mandates tied to participation in the federal government's health-related programs.

In the words of former FDA Commissioner David Kessler, "Without centralizing responsibility and finding the right leadership, many of our citizens will be lost."[212] In fact, millions already have been, many millions more are struggling to find their way, and countless more will continue to join them indefinitely unless the U.S. rises to meet its public health and moral responsibilities. Full acknowledgement of the opioid epidemic without commensurate action and the funding to make it meaningful is the hollowest, cruelest form of government hypocrisy.

211. *See supra* Part III.

212. Kessler, *supra* note 3.