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WHY THE DEA, NOT THE FDA? REVISITING THE REGULATION OF POTENTIALLY-ADDICTIVE SUBSTANCES

BY TALEED EL-SABAWI*

INTRODUCTION

Federal legislative responses to national drug crises in the United States have historically taken a criminal justice approach to addressing problem drug use.[1] This criminal justice approach emphasizes the use of punishment administered by

* J.D., Ph.D. Assistant Professor of Law, Elon University. Thank you to Leo Beletsky, Alex Kreit, Jennifer Oliva, Kelly Dineen, & John Cook for helping me brainstorm and workshop early drafts of this article. Sincerest thanks to Jennifer Carroll, Patricia Perkins, and David Levine for their insight and comments throughout the drafting and editing process. A special thanks to Victoria Corey, Emily B. Chatzky and Clancy Phillips for their invaluable assistance with the research for this article. Finally, a thank to you to NYU's Classical Liberal Institute, its Center of Civil Justice, and the NYU Journal of Law & Business for hosting their conference "The Opioid Conference," and inviting me to present my work.

1. Although at times the criminal justice and punitive approach may seem interchangeable, the criminal justice approach, by my definition, also includes proposals to administer drug treatment through the criminal jus-

criminal justice agencies.[2] Given this focus, few policymakers question why criminal justice agencies like the Drug Enforcement Agency ("DEA") and its grandfather,[3] the Federal Bureau of Narcotics ("FBN"), were deemed the "fixers" of the drug problem.[4] The DEA, a federal agency within the Department of Justice ("DOJ"), was seen so much so as the fixer of problem drug use that it was tasked by Congress to not only oversee the control over the illicit drug supply, but also with oversight over important aspects of the production, distribution, and availability of licit, pharmaceutical substances that are deemed potentially addictive.[5]

In addressing the opioid crisis,[6] Congress has explicitly questioned its historic reliance on a criminal justice approach

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tice system. Some may consider such mandatory treatment punitive, while others may argue that it is still a health solution.

2. *See* Joseph F. Spillane, *The Road to the Harrison Narcotics Act: Drugs and Their Control, 1875–1918*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 1, 7–8 (Jonathon Erlen & Joseph F. Spillane eds., Pharm. Prods. Press 2004) (discussing how the leader of the Narcotics Bureau utilized emotionally-charged narratives so that legislators would believe that those suffering from addiction were deviant persons requiring punishment as the only means to control drug use); *see also* Joseph F. Spillane, *Building a Drug Control Regime, 1919–1930*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 25, 25–61 (Jonathon Erlen & Joseph F. Spillane eds., Pharm. Prods. Press 2004) (discussing how marginalized groups were targeted in the 19th century as deserving punishment); *see generally* EVA BERTRAM ET AL., DRUG WAR POLITICS: THE PRICE OF DENIAL 151–76 (1996); DAVID T. COURTWRIGHT, DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA (enl. ed. 2001) (1982).

3. MATTHEW R. PEMBLETON, CONTAINING ADDICTION: THE FEDERAL BUREAU OF NARCOTICS AND THE ORIGINS OF AMERICA'S GLOBAL WAR ON DRUGS (2017). The FBN also laid down the "global footprint" that would later be the domain of the DEA. *Id.* at 52, 200, 238, 271.

4. Fixers hold a position of power and are consulted by legislators to fix social problems prior to proposing legislative solutions. Consequently, fixers receive large shares of federal and state funding. *See generally* DEBORAH STONE, POLICY PARADOX: THE ART OF POLITICAL DECISION MAKING 224 (3d ed. 2012).

5. *See* 21 U.S.C. §§ 811–32 (2018).

6. The opioid crisis refers to both the high number of opioid overdose deaths and the quadrupling of opioid overdoses since 1998. Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1445–52 (Dec. 30, 2016).

to problem drug use[7] and has instead adopted a more health-oriented approach.[8] In the Comprehensive Addiction and Recovery Act of 2016 ("CARA"),[9] the initial federal legislation enacted as a response to the current opioid crisis, Congress stated the following: "It is the sense of the Congress that decades of experience and research have demonstrated that a fiscally responsible approach to addressing the opioid abuse epidemic and other substance abuse epidemics requires treating such epidemics as a public health emergency emphasizing prevention, treatment, and recovery."[10]

Despite this legislative rhetoric, the DEA, a criminal justice agency,[11] continues to retain the power to make key decisions on the classification of potentially-addictive substances, thereby affecting their manufacture, distribution, and overall availability.[12] While the DEA is statutorily required to defer to

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7. Arrests for nonviolent drug-related offenses have been a key component of the criminal justice approach to drug use. The Comprehensive Addiction and Recovery Act of 2016 required the Government Accountability Office (GAO) to report on the collateral consequences of nonviolent drug-related offenses. Congress requested the report to include information regarding the effects of these consequences on affected persons who try to resume their professional and personal activities. Congress also requested that the report include an explanation of how these consequences remain justifiable. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 401 (130 Stat. 695) 723–24 (2016).

8. *See* Taleed El-Sabawi, *Defining the Opioid Epidemic: Congress, Pressure Groups, and Problem Definition*, 48 U. MEM. L. REV. 1357, 1359–64 (2018).

9. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114–198 (130 Stat. 695) (2016).

10. *Id.* § 708.

11. Part of the mission of the DEA "is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States . . . those organizations and principal members . . . involved in the growing, manufacture, or distribution of controlled substances . . . for illicit traffic in the United States." *DEA Mission Statement*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/mission (last visited Aug. 14, 2019).

12. Namely, under the Controlled Substances Act of 1970, the DEA has the power to schedule a substance, an act which can result in manufacturing quotas, limitations on dispensing, import restrictions and criminal penalties for the unlawful distribution or manufacture of these substances. 21 U.S.C. § 811 *et seq.* (2018). The number of restrictions placed on a substance coincide with the schedule the drug is placed on. The number of schedules range from I–V with schedule I having the greatest restrictions. Theoretically, drugs placed on schedule I have the greatest likelihood for abuse, although "abuse" is not expressly defined in the Act itself, and the scientific

the Food and Drug Administration ("FDA"),[13] a public health agency,[14] at junctions of the decision-making process,[15] the current "split enforcement"[16] scheme laid out in the statutes[17] has not actualized the legislative intent of balancing the medical and scientific considerations with those of law enforcement, tilting the weight of determinations instead to law enforcement criteria and a criminal justice approach to its regulation and enforcement.[18] The current shift in legislative

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basis for substances' classifications can be tenuous at times. *See* GERALD F. UELMEN & VICTOR G. HADDOX, DRUG ABUSE AND THE LAW SOURCEBOOK § 1:10 (West 2003). While these controlled substances are deemed to have a potential for abuse, many of them also have therapeutic or medical benefits. Under current laws, had these substances not had potential for abuse, they would have been regulated by the Food and Drug Administration (FDA) as pharmaceutical drugs or food supplements. *See, e.g.*, *id.* §§ 3:39, 3:104.

13. The statutory mandate requires the DEA to confer with the Health and Human Services (HHS). The FDA is part of HHS and the Secretary of HHS has delegated the authority to consult with the DEA on issues of scheduling to the FDA. Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L., MED. & ETHICS 55, 60 (2003); 21 U.S.C. § 811(b) (2000).

14. *See Oxycontin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers: Hearing Before the Subcomm. on Regulatory Affairs of the Comm. on Gov't Reform*, 109th Cong. 21 (2005) [hereinafter *Oxycontin and Beyond*] (statement of Robert Meyer, Director, Office of Drug Evaluation II, Center for Drug Evaluation and Research, U.S. Food and Drug Administration).

15. For example, Congress has made it clear that the DEA must refer to the Secretary of the Department of HHS for recommendations when scheduling potentially-addictive substances. The Secretary of the Department of HHS operates through the FDA's Center for Drugs and with advice from the FDA Drug Abuse Advisory Committee. 21 U.S.C. § 811(b). Furthermore, the FDA has the veto power over the scheduling recommendations by the DEA. If the FDA does not use the veto power, the DEA proceeds with the scheduling recommendation. *See* JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 24:7 (4th ed. 2019).

16. By "split enforcement" model, I am referring to a term used by Lars Noah to describe the dividing of powers between the FDA and the DEA under the CSA. Noah, *supra* note 13.

17. The primary statute referenced here is the Controlled Substances Act. Controlled Substances Act of 1970, 21 U.S.C. § 801 *et seq.* (1970). The subsequent Amendments to the Act are also referenced. *See* Controlled Substances Act, 21 U.S.C. § 801 (1974), https://www.deadiversion.usdoj.gov/21cfr/21usc/index.html to view each section of the Act and any Amendments since its enactment.

18. For example, if the FDA has not already approved a drug that the DEA wishes to place on Schedule I, the FDA often defers to the DEA's wishes

preference for a health-oriented approach begs the question: Why continue to give such regulatory powers to the DEA and not a public health agency like the FDA?

While such transfer of regulatory powers may seem radical, it becomes less so after an analysis of some often-forgotten FDA history. For at least 20 years prior to the DEA's creation, the FDA regulated and enforced the regulations of illicit sales of non-narcotic drugs, like barbiturates and amphetamines.[19] In 1966, Congress formalized these enforcement powers by creating the Bureau of Drug Abuse Control ("BDAC") within the FDA.[20] However, the BDAC was transferred out of the FDA just two short years later.[21] It was merged with the FBN and

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by following their scheduling recommendations. Noah, *supra* note 13, at 61. Further, the DEA's desire to prosecute drug dealers or persons addicted to the drugs may encourage the agency to label a substance as Schedule I or Schedule II; had the FDA been charged with the determination of scheduling, the priority may instead focus on "the development of a drug potentially valuable in treatment of a legitimate class of users." *Id.* at 61. As such, the differences in agency expertise affect decision-making regarding the scheduling of substances. *See id.* at 60. For example, as Lars Noah notes, the DEA makes many of its scheduling decisions based on the reputation of the active ingredients, without considering how product formulation and dosage affect the risks and benefits of the active ingredient to the user. *Id.* at 61. On the other hand, the FDA commonly considers nuances, like differences in dosage or product formulation, when reviewing new drug applications. *Id.* at 61–62. The DEA's current regulations on drug distribution are based on the drug's schedule without a consideration of the differences between the drugs within a scheduling class, nor do they consider the different "abuse" potential based on the route administration or the particular formulation of the drugs. *Id.* at 61–63. Yet, dosage and product formulation can play a big part in the degree to which a substance is potentially-addictive. *See generally id.* at 60–62.

19. KATHLEEN J. FRYDL, THE DRUG WARS IN AMERICA, 1940–1973 159–65 (Cambridge University Press 2013).

20. S*ee* Interview with Alfred Barnard, HISTORY OF THE U.S. FOOD & DRUG ADMIN., at 17–18 [hereinafter Barnard] (May 14, 1987; June 4, 1987; Mar. 2, 1989), https://www.fda.gov/media/81570/download (discussing when and how he became the Deputy Director of BDAC).

21. John P. Swann, *The FDA and the Practice of Pharmacy: Prescription Drug Regulation Before 1968*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 145, 166; *see also* Interview with Paul A. Pumpian, HISTORY OF THE U.S. FOOD & DRUG ADMIN., at 26 (Jan. 22, 1996), https://www.fda.gov/media/81369/download [hereinafter Pumpian].

then moved to the DOJ.[22] It later became the agency we now know as the DEA.[23]

To some, the BDAC's short-lived existence might suggest that Congress perceived the FDA's enforcement efforts as a failure. Others may correctly point out that FDA Commissioners were eager to get rid of the BDAC when given the opportunity to do so.[24] Why should Congress consider transferring exclusive powers to regulate controlled substances to the FDA, if previous FDA Commissioners lobbied to rid the agency of these powers decades ago?

Building a case for the transfer of regulatory powers from the DEA to the FDA is a subject worthy of a book-length manuscript, but an apt starting point is to gain a deeper understanding of how the DEA, instead of the FDA, ended up with the primary powers to regulate and enforce the regulations on potentially-addictive substances. While other scholars have described the circumstances surrounding this assignment of powers to the DEA,[25] this article extends their research and makes new findings about the circumstances surrounding the transfer of the BDAC, and its power to regulate, to the DEA. Using oral history testimonies from FDA investigators and administrative officials, this Article adds to the historic literature on the allocation of regulatory and enforcement powers over potentially-addictive substances. In doing so, this Article provides

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22. Notably, some officers within the FDA were relieved when the BDAC was ultimately transferred to the DOJ. Interview with Herbert L. Ley, HISTORY OF THE U.S. FOOD & DRUG ADMIN., at 6 (Dec. 15, 1999), https://www.fda.gov/media/80939/download ("I always felt uncomfortable in dealing with BDAC.") [hereinafter Ley]. *See also* Interview with James W. Swanson, HISTORY OF THE U.S. FOOD & DRUG ADMIN., at 55 (June 21–23, 1988), https://www.fda.gov/media/81228/download ("It was a relief for most of us who really didn't like to do that kind of work . . . we were very, very pleased to see it go off in a different direction.") [hereinafter Swanson].

23. *The Early Years*, DRUG ENF'T ADMIN. 12, 26–29, https://www.dea.gov/sites/default/files/2018-05/Early%20Years%20p%2012-29.pdf. While Nixon may be credited with the DEA's creation, legislators and bureaucrats debated for at least a decade as to which agency should regulate potentially-addictive substances. Consequently, the creation of the DEA likely stemmed from recommendations made by commissions during the Kennedy presidency's early years. FRYDL, *supra* note 19, at 363, n. 212.

24. *See* Pumpian, *supra* note 21, at 25, 27; Ley, *supra* note 22; Swanson, *supra* note 22.

25. *See, e.g.*, FRYDL, *supra* note 19; *see also* Swann, supra note 21, at 166.

evidence in support of a contemporary transfer of regulatory power from the DEA to the FDA.

The primary contribution of this Article is that it demonstrates that the removal of the BDAC from the FDA was not due to the BDAC's poor performance or its more regulatory approach to enforcement, but rather in large part due to FBN infiltration into the BDAC and the corruption and criminal justice approach that accompanied the FBN influence. This Article contributes to available literature by emphasizing that the reasons often cited to explain the FDA's short-lived control of the powers over non-narcotic, potentially-addictive drugs are incomplete[26] and that the BDAC's transfer should not be used to argue against the re-assignment of such powers today.

This Article begins by introducing the history of the FBN in an effort to demonstrate how the criminal justice approach was institutionalized within this influential agency. The FBN's approach to its enforcement activities is then contrasted with that of the FDA's field investigators, who paved the way for the creation of the BDAC years later. Section III chronicles the rise and fall of the BDAC based on the accounts of former FDA officials. Section IV concludes with an analysis of why the DEA was ultimately awarded with jurisdiction over the manufacture and distribution of potentially-addictive substances.

I.
Federal Drug Enforcement Pre-BDAC

A. *The FBN and Narcotics Regulation*

In 1914, the Harrison Narcotics Tax Act ("Harrison Tax Act") was enacted by Congress to regulate the sale and distribution of opiates.[27] Upon its passage, the Harrison Tax Act was viewed by the medical industry as a tax measure designed to create a recordkeeping and licensing system that accounted for the dispensing of narcotic medications.[28] The Harrison

26. *See* discussion *infra* Section III.A.

27. Harrison Narcotic Act, ch. 1, 38 Stat. 785 (1914).

28. Rufus G. King, *The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick*, 62 Yale L.J. 736, 737 (1953). Those in the medical industry actively lobbied, forming the National Drug Trade Conference ("NDTC") to lobby for federal legislation. In doing so, drug manufacturers, physicians, and pharmacists were all active participants in the defining of the drug problems during the time. David F. Musto, The American Disease:

Tax Act was enacted pursuant to Congress' power to tax and spend,[29] so the Bureau of Internal Revenue ("BIR")[30], a tax agency and not a public health agency, was assigned to enforce the law. Responsibilities for enforcement were first given to the Commissioner of Internal Revenue and then to the Narcotics Division, which was not created until 1921.[31] While a health agency may have been better equipped to enforce the Harrison Tax Act, giving such powers to the nation's public health agency, the Public Health Service,[32] could have undermined Congress' reliance on the power to tax and spend if the Harrison Tax Act were to be challenged as an unconstitutional exercise of federal power. Moreover, although the Bureau of Chemistry (the predecessor to the FDA) was in existence, its regulation of drugs was in its nascent phase.[33]

In sum, while the placement of the regulation of narcotics within a tax agency seems unusual, the BIR was arguably the most logical choice to enforce the Harrison Tax Act. Moreover, Congress' decision to award such powers to the BIR over health agencies was likely not motivated by any consideration of the merits of such agencies' health approach to addressing narcotics use. The decision to appoint the BIR was, instead, motivated by constitutional considerations regarding the separation of powers, and the resulting criminal justice approach that developed due to the BIR's enforcement was an unplanned consequence of such appointment. In fact, the institutionalization of the criminal justice approach that began with the BIR's enforcement of the Harrison Tax Act did not come to

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ORIGINS OF NARCOTIC CONTROL 54–55 (Oxford Univ. Press 3rd ed. 1999) (1973); *see also* El-Sabawi, *supra* note 8, at 1389–401. The Harrison Tax Act was also a response to national and international concern over the import and export of narcotics. *See* David F. Musto, *Opium, Cocaine and Marijuana in American History*, 265 SCI. AM. 40, 43–44 (1991).

29. U.S. CONST. art. I, § 8.

30. The BIR is the predecessor to the Internal Revenue Service.

31. Harrison Narcotic Act, ch. 1, § 10, 38 Stat. 785, 789 (1914).

32. In 1912, the nation's public health agency was the Public Health Service ("PHS"). *History*, U.S. PUB. HEALTH SERV., https://www.usphs.gov/aboutus/history.aspx (last visited Aug. 19, 2019).

33. *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-i-1906-food-and-drugs-act-and-its-enforcement (last updated Apr. 24, 2019).

fruition until the BIR was charged with policing the prohibited the sale of alcohol during the prohibition era.[34]

The nation's prohibition laws—which outlawed the sale of alcohol—were also enacted pursuant to Congress' constitutional power to tax and spend[35] and the nation's tax agency, the BIR, was therefore tasked with the enforcement of prohibition laws, along with the Harrison Tax Act.[36] The BIR's Bureau of Prohibition[37] was notorious for reinforcing the Temperance Movement's narrative of deviancy and for capitalizing on a culture of fear.[38] In 1927, the BIR transferred the Narcotics Division into the Bureau of Prohibition,[39] further linking the two divisions. The same tactics that were used by its new parent agency in its enforcement of the prohibition laws were adopted by the Narcotics Division in its enforcement of narcot-

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34. *See* LISA MCGIRR, THE WAR ON ALCOHOL: PROHIBITION AND THE RISE OF THE AMERICAN STATE 212–13 (2015).

35. National Prohibition Act, Pub. L. No. 66-66, 41 Stat. 305 (1919). Of note, is the fact that "[p]rohibition was implemented through the taxing power of the federal government." MUSTO, *supra* note 28, at 46.

36. National Prohibition Act § 5.

37. When the National Prohibition Act passed, a new branch of the BIR was formed. LAURENCE F. SCHMECKEBIER, THE BUREAU OF PROHIBITION: ITS HISTORY, ACTIVITIES AND ORGANIZATION 7 (1929). This Prohibition Unit was initially responsible for the enforcement of Prohibition laws, but it often passed on enforcement responsibilities to State Prohibition Directors. *Id.* The Prohibition Unit, which was originally under the control of the Assistant Secretary of the Collection of Revenues,was transferred to the Assistant Secretary of Customs, Coast Guard, and Prohibition in 1925. *Id.* at 9. This shift was made "out of a desire to obtain better enforcement of the law." *Id.* at 10. This shift reorganized the operations of the Prohibition Unit. *See id.* at 10–13. By 1927, H.R. 10729 became law and the Bureau of Prohibition was formed within the Treasury Department. *Id.* at 20. According to the agent manuals, the Bureau of Prohibition's agents were responsible for "gathering, correlating, filing, and dissemination of information not strictly local in character, covering violations of the national prohibition act and the related states [and] to investigate fully all those violations of the national prohibition act and related statutes not specifically entrusted to the several administrators and to the customs force." *See Welcome to the Agency*, HISTORY OF THE PROHIBITION BUREAU, https://prohibitionbureauhistory.omeka.net/exhibits/show/the-prohibition-bureau/1920/agency (last visited Aug. 24, 2019). No changes were made to the Unit until March 3, 1927. SCHMECKEBIER, *supra*, at 154.

38. *See generally* MCGIRR, *supra* note 34.

39. *Records of the Drug Enforcement Administration*, NAT'L ARCHIVES, https://www.archives.gov/research/guide-fed-records/groups/170.html (last visited Jan. 16, 2020).

ics regulations.[40] After its merger with the Federal Narcotics Control Board, the Narcotics Division became its own bureau, called the Bureau of Narcotics ("FBN"). Despite its transfer, the FBN continued its use of the Bureau of Prohibition's rhetoric to define a criminal class and to establish the FBN as its police.[41]

The culture of punishment that came to dominate the FBN, and later the DEA, endured in part because of its longtime leader, Harry J. Anslinger. President Herbert Hoover appointed Harry J. Anslinger as Commissioner of the FBN, a position Anslinger held for over three decades.[42] Commissioner Anslinger transferred to the FBN from the Bureau of Prohibition, which was soon to be dissolved due in part to its ineffective enforcement of the nation's prohibition laws.[43] Anslinger was intent on preventing the FBN from succumbing to the same fate as the Bureau of Prohibition and spent much of his career convincing legislators, bureaucrats, and the public that narcotics and marijuana were a threat to public safety, that these drugs should be feared, and that the FBN could protect the nation from their perils.[44] As historian Lisa McGirr describes, "A stalwart supporter of the antiliquor crusade, Anslinger brought its moral fervor and Manichaean outlook to his new mission . . . . [A]t the helm of the new Federal Bureau of Narcotics Anslinger applied this same harsh treatment to drug violators more successfully, urging judges to 'jail offenders, then throw away the keys.' "[45] Throughout his tenure, Anslinger's rhetoric laid the foundation for the FBN's criminal

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40. *Id.*

41. As Rufus G. King notes, the courts helped aid the Narcotics Bureau, and its predecessor the Narcotics Division, in this criminal justice interpretation. King, *supra* note 28, at 738.

42. *The Early Years*, *supra* note 23, at 16.

43. Rebecca Carroll, *Under the Influence: Harry Anslinger's Role in Shaping America's Drug Policy*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 61, 61 (Jonathon Erlen & Joseph F. Spillane eds., Pharm. Prods. Press 2004); *see also* Sidney J. Spaeth, *The Twenty-First Amendment and State Control over Intoxicating Liquor: Accommodating the Federal Interest*, 79 CAL. L. REV. 161, 179 (1991).

44. Much has been written about Anslinger's strategic and rhetorical skills. *See, e.g.*, DOUGLAS VALENTINE, THE STRENGTH OF THE WOLF: THE SECRET HISTORY OF AMERICA'S WAR ON DRUGS 50–65 (2004); Carroll, *supra* note 43, at 66; PEMBLETON, *supra* note 3.

45. MCGIRR, *supra* note 34, at 217.

justice approach by characterizing those addicted to narcotics and those who sold narcotics as "deviants."[46]

The culture that Anslinger created within the FBN would have such a lasting effect that decades later, it influenced how DEA agents would come to define their primary duties.[47] As a consequence of Anslinger's branding of the FBN as a criminal justice agency, the FBN neglected its duties of enforcement and monitoring of the dispensing of potentially-addictive pharmaceutical narcotics.[48] Rather than devoting resources to the oversight of manufacturers, distributors, and providers of pharmaceutical narcotics, the FBN chose to focus its resources on headline-worthy drug busts involving international crime rings.[49] When the nation was faced with new synthetic drug problems caused by non-narcotic, potentially-addictive substances that had medical use,[50] the FBN steadfastly argued that its primary purpose was to target criminal enterprises and not to police the misuse of otherwise licit substances.[51] Commissioner Anslinger repeatedly urged Congress to delegate the regulation of potentially-addictive, non-narcotic pharmaceutical substances, like barbiturates, to another federal agency.[52]

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46. *See* EDWIN M. SCHUR, CRIMES WITHOUT VICTIMS 138–45 (1965) (providing an in-depth discussion of the social and policy ramifications of categorizing drug users as deviants); *see also* MERRILL SINGER & J. BRYAN PAGE, THE SOCIAL VALUE OF DRUG ADDICTS: THE USES OF THE USELESS 159–69 (2014). Much of Anslinger's negative depiction of drug users was racially charged. *See* Douglas A. Berman, *Leveraging Marijuana Reform to Enhance Expungement Practices*, 30 FED. SENT'G REP., no. 4–5, Apr./June 2018, at 231, 305–16 (2018).

47. *See* PEMBLETON, *supra* note 3, at 112 (citing JAMES Q. WILSON, THE INVESTIGATORS: MANAGING FBI AND NARCOTICS AGENTS 22, 42 (1978)).

48. FRYDL, *supra* note 19, at 282.

49. *Id.*

50. For an overview of the growth of amphetamine use, see UELMEN & HADDOX, *supra* note 12, § 3:39. For a discussion on steroids, see *id.* § 3:148. For a discussion of hallucinogens, see *id.* § 3:104; *see also* PEMBLETON, *supra* note 3, at 278–79.

51. *See generally* LISA N. SACCO, CONG. RESEARCH SERV., R43749, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS 1, 3–5 (2014).

52. For example, when testifying in front of Congress in 1955 on Traffic in, and Control of, Narcotics, Barbiturates, and Amphetamines, Anslinger explicitly stated that he did not believe that barbiturates should be handled by the Treasury Department and that there was a "tremendous difference" between heroin addicts and persons who use barbiturates. *Traffic in, and Control of Narcotics, Barbiturates, and Amphetamines: Hearing Before the Subcomm. on*

As historian Matthew Pembleton notes, "the FBN had important regulatory functions, but it was first and foremost a police agency, and that, too, shaped how it saw the drug problem. In short, the FBN was a hammer, so everything looked like a nail."[53]

While the true reasons for the FBN's staunch refusal to accept responsibility for the regulation and enforcement of potentially-addictive, non-narcotic substances are debatable, some scholars suggest that Anslinger refused to take on these new drugs because of his close relationships with the pharmaceutical companies that manufactured them.[54]

B. *FDA and the Regulation of Other Potentially-Addictive Drugs*

For nearly two decades, Congress continued debating over which agency should be tasked with the oversight of new potentially-addictive, non-narcotic substances.[55] Some legislators argued that it was duplicative to create another government agency to oversee the regulation of potentially-addictive, non-narcotic substances when the FBN was already responsible for the regulation of narcotics.[56] But Anslinger and the FBN were powerful forces with which to reckon, and so the regulation of these new synthetic, potentially-addictive drugs remained unassigned.[57]

FDA investigators stepped in to fill the void, going undercover to investigate the illicit distribution of stimulants, amphetamines, and barbiturates, among other "dangerous drugs."[58] Unlike the FBN, the FDA began as an agriculture di-

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Narcotics of the H. Comm. on Ways & Means, 84th Cong. 1114 (1955) (statement of Harry Anslinger, Commissioner, Bureau of Narcotics); *see also* FRYDL, *supra* note 19, at 166.

53. PEMBLETON, *supra* note 3, at 33.

54. *See, e.g.*, *id.* at 278.

55. FRYDL, *supra* note 19, at 271–88.

56. *See generally* SACCO, *supra* note 51; *see also* FRYDL, *supra* note 19, at 159.

57. FRYDL, *supra* note 19, at 159

58. Interview with Henry P. Roberts, Former Director, Food & Drug Admin., at 14 (June 20, 2006), https://www.fda.gov/media/81593/download; Interview with Charles W. (Bill) Sedgwick, Former Director, Food & Drug Admin., at 20 (June 21, 2006), https://www.fda.gov/media/86282/download; *see also* Swanson, *supra* note 22, at 54; Interview with Alfred Barnard, Director, Bureau of Reg. Compliance, Food & Drug Admin., at 50 (May 14, 1987; June 4, 1987; Mar. 2, 1989), https://www.fda.gov/media/81570/download [hereinafter Barnard].

vision within the U.S. Patent Office in 1847; after a number of name changes and administrative shuffles, it became the Food and Drug Administration in 1930.[59] The FDA was created as a public health agency charged with ensuring the safety and efficacy of drugs.[60] While the FDA had been granted the powers to regulate food and drugs incrementally prior to 1938,[61] the Federal Food, Drug, and Cosmetic ("FDC") Act of 1938, and its amendments, are largely cited as the source of the FDA's modern powers to regulate drugs.[62]

The FDA first began regulating potentially-addictive, non-narcotic drugs, including amphetamines, barbiturates, and sulfa drugs under the FDC.[63] The FDC required that drugs carry labels that notified consumers that they were safe for

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59. In 1890, the agency was named the Division of Chemistry. It was changed again in 1901 to the Bureau of Chemistry. Soon after, in 1927, the name was again changed to the United States Food, Drug and Insecticide Administration. Three years later, the name was shortened to its current name, the U.S. Food and Drug Administration. Of note, the FDA was originally housed in the U.S. Department of Agriculture, but, in 1940, the FDA was transferred to the Federal Security Agency, a newly formed agency. In 1953, the agency was renamed to the Department of Health Education and Welfare and then in 1979, the Department of Health and Human Services. *See History of FDA's Internal Organization*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), https://www.fda.gov/about-fda/history-fdas-fight-consumer-protection-and-public-health/history-fdas-internal-organization.

60. *See generally Oxycontin and Beyond*, *supra* note 14.

61. In 1848, Congress passed the Drug Importation Act, which required U.S. Customs Service to conduct inspections drugs imported into the United States. From 1880 to 1905, more than one-hundred food and drug bills were introduced to Congress. By 1906, the first ever Food and Drug Act passed, prohibiting interstate commerce of both adulterated and misbranded foods, drinks, and drugs. A seminal Supreme Court, *U.S. v. Johnson* was decided in 1911, determining that the 1906 Act only prohibited misleading and false statement about the identity or the ingredients of a drug. In response, Congress enacted the Sherley Amendment in 1912 to prohibit the labeling of medicines with false therapeutic claims. Ultimately, by 1933, the FDA recommended that the Food and Drugs Act of 1906 be completely revised, a battle lasting five years to implement. *Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history (last updated Jan. 31, 2018).

62. O'REILLY & VAN TASSEL, *supra* note 15, at 3.

63. *See* Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938); *see also* John P. Swann, *Drug Abuse Control Under FDA, 1938–1968*, 112 PUB. HEALTH REP. 83, 83 (1997) (discussing how the 1938 regulations "stipulated that certain drugs . . . had such a potential for misuse or abuse that they

use.[64] The FDA determined that due to their potential for misuse, amphetamines, barbiturates and sulfa drugs could not be labeled as safe for use when self-medicating.[65] Rather, they could only be safely used under the management of a physician or dentist.[66] This distinction between self-medication and physician management was the first differentiation between over-the-counter ("OTC") and prescription medication.[67]

Beginning in the late 1930s, the FDA began to enforce this interpretation of the FDC by investigating illegal OTC sales of medication that should otherwise have only been dispensed with a prescription.[68] This enforcement accelerated after the Supreme Court confirmed FDA jurisdiction over retail pharmacies in 1948.[69] FDA investigators were responsible for the conviction of more than 2,300 persons and firms for illicit drug sales from the 1950s to the mid-1960s.[70] The investigators' work was described by some FDA personnel as "criminal work," even though field investigators may not have perceived it as such.[71] One common example of such work is what is referred to as "truck stop work."[72] Truck stop work required FDA

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simply could not be labeled safe self-medication."). As such, the Durham–Humphrey Amendment of 1951 was enacted. *Id.*

64. *See* 52 Stat. 1040.

65. Swann, *supra* note 63.

66. *Id.*

67. *Id.* The distinction between prescription and over the counter use was further reinforced by the Durham–Humphrey Amendment of 1951. *Id.*

68. *See* John P. Swann, *The FDA and the Practice of Pharmacy: Prescription Drug Regulation Before 1968*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 145, 155 (Jonathon Erlen & Joseph F. Spillane eds., Pharm. Prods. Press 2004). *See also* Interview with Edward Wilkens for first hand discussion of a FDA investigators' experience with this, in 1958, HISTORY OF THE FOOD & DRUG ADMIN., at 28–40 (Apr. 20, 2004), https://www.fda.gov/media/80970/download [hereinafter Wilkens].

69. United States v. Sullivan, 332 U.S. 689 (1948) (holding that the FDA also had jurisdiction over pharmacies, allowing the agency to investigate the illegal sales of pharmaceutical drugs—including amphetamines and barbiturates—occurring in pharmacies); *see also* Swann, *supra* note 68 at 158.

70. Swann, *supra* note 63, at 84.

71. *See* Wilkens, *supra* note 68, at 81; *see also* Interview with James Ritz, HISTORY OF THE U.S. FOOD & DRUG ADMIN., at 28 (May 9, 2001), https://www.fda.gov/media/81584/download ("Of course, there were always people in FDA doing criminal work.").

72. *See* FRYDL, *supra* note 19, at 192–98; *see also* Wilkens, *supra* note 68, at 37–41 (describing the illicit trafficking of pharmaceutical amphetamines at truck stops).

field investigators to go undercover to attempt to purchase prescription drugs without a prescription.[73] As one FDA investigator describes, "I found myself working all day making inspections of oil mills and warehouses and cornmeal plants, and then working half the night trying to make illegal drug buys from pharmacies and truck stops and individual operators."[74]

With only 200 investigators to oversee transactions at 50,000 retail drug stores, however, the FDA was understaffed to properly investigate illicit pharmaceutical sales amidst the growing drug crisis.[75] FDA investigators used evidence obtained during their fieldwork to demonstrate to Congress the scope of the nation's drug problem, while demonstrating their capabilities for enforcement despite their limited resources.[76] While FDA investigators and their unit supervisors may have wanted Congress to formalize their investigations in a legislative delegation of enforcement powers, the FDA Commissioner Paul Dunbar (1944–1951) did not want the responsibility of policing the illicit traffic of amphetamines and barbiturates.[77] His field investigators had been policing the illicit distribution of non-narcotic drugs for nearly three decades[78], but the FDA's field investigators would not have a legislative advocate until his successor, George Larrick (1954–1965), was appointed as FDA Commissioner.[79] While FDA investigators were increasing their enforcement activity, the FBN was experiencing turmoil.[80] The discord at the FBN combined with the FDA's enforcement activity paved the way for the creation of the BDAC within the FDA.

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73. *See* FRYDL, *supra* note 19, at 192–98.
74. Swanson, *supra* note 22, at 28.
75. Swann, *supra* note 68 at 160.
76. *See* Swanson, *supra* note 22, at 40–41.
77. *See* FRYDL, *supra* note 19, at 166–67.
78. Swann, *supra* note 68 at 155.
79. Commissioner Larrick lobbied for the assignment of criminal powers to the FDA, as well as the rights to asset forfeiture. *See* FRYDL, *supra* note 19, at 271.
80. Wilkens, *supra* note 68, at 66.

II.
THE RISE & FALL OF THE BDAC

A. *The Creation of the BDAC*

In the early 1960s, Henry Anslinger reached his mandatory retirement age and reluctantly retired.[81] Anslinger's successor was not well-equipped to handle the changing public opinion on drug use accompanying the cultural changes occurring during the 1960s, nor did he have "the force of personality nor the political acumen necessary to corral the rambunctious agency and guide it through its many crises."[82] Moreover, national attention shifted to concerns about the recreational use of non-narcotic drugs, like LSD, barbiturates, and amphetamines: drugs outside the jurisdiction of the FBN.[83] The FBN continued to resist additional enforcement duties, and its parent agency, the Department of Treasury,[84] similarly did not want to be associated with this increase in regulatory power.[85] Historian Kathleen Frydl argues that the Department of Treasury was "[b]eset by complaints and challenges to the legitimacy" of its new power to tax the income of American's absent a war and did not want the additional challenges that might arise with the expansion of its powers to regulate all potentially-addictive substances.[86]

Further, legislators were already inclined to treat amphetamines and barbiturates differently than narcotics because those addicted to narcotics were portrayed as "inner city blacks," while other drug users were often described as "white" and "middle class."[87] For example, during a hearing before the Subcommittee on Narcotics, Representative Frank Karsten explicitly asked Anslinger about these differences by stating,

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81. Despite his retirement, Anslinger tried to stay active in American drug policy, but had limited success in maintaining his influence. *See* PEMBLETON, *supra* note 3, at 272–95. Some scholars argue that Anslinger was forced to retire by the Kennedy Administration. *See* FRYDL, *supra* note 19, at 243.

82. *See* PEMBLETON, *supra* note 3, at 273.

83. *See* Swann, *supra* note 63, at 85.

84. *See Drug Enforcement Agency History: The Early Years*, U.S. DEP'T OF JUSTICE, https://www.dea.gov/sites/default/files/2018-05/Early%20Years%20p%2012-29.pdf (last visited Feb. 1, 2020).

85. PEMBLETON, *supra* note 3, at 273.

86. FRYDL, *supra* note 19, at 159.

87. *Id.* at 158.

"[t]here would be a great difference between a man who has been taking two sleeping pills every night for 15 years, and a heroin addict. There is a great difference in the two?"[88] To that, Anslinger replied, "[t]here would be a *tremendous* difference."[89]

Congress' willingness to differentiate between narcotic and non-narcotic use was complemented by support from the 1963 President's Advisory Commission on Narcotics and Drug Abuse. The Commission reported on the FDA's accomplishments, despite their meager resources, and suggested that the FDA receive additional appropriations to continue its fight against the illicit sales of potentially-addictive non-narcotic drugs.[90] The FDA's fieldwork, combined with the FBN's refusal to accept new responsibilities, led to the enactment of the Drug Abuse Control Amendments of 1965.[91] The purpose of the Drug Abuse Control Amendments was to protect "the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs."[92] Under the Drug Abuse Control Amendments, a new division was created within the FDA: the BDAC.[93] While FDA field investigators of illicit OTC sales had already assumed responsibility for the control of the distribution of non-narcotic drugs,[94] the creation of the BDAC legitimized their operations and granted them new powers. The BDAC was awarded the power to regulate all potentially-addictive, non-narcotic drugs and was given additional appropriations, offices, and investigators.[95] The BDAC officers were also permitted to carry firearms, make arrests,

88. Statement of Harry Anslinger, *supra* note 52.

89. *Id.* (emphasis added).

90. *See* Swann, *supra* note 63, at 84.

91. *See* Interview with Maurice D. Kinslow, HISTORY OF THE FOOD AND DRUG ADMIN., at 11–13 (Sept. 16, 18, 1982), https://www.fda.gov/media/81024/download [hereinafter Kinslow]. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, 79 Stat. 226 (1965).

92. *Id.* at 227.

93. *See* Joseph D Lohman & Robert M. Carter, *University Training Program for Agents of the Bureau of Drug Abuse Control*, 57 J. CRIM. L. & CRIMINOLOGY 526, 526–27 (1967).

94. *See* Wilkens, *supra* note 68, at 28–29.

95. Swann, *supra* note 63, at 85.

and serve search warrants, powers normally reserved for criminal enforcement agencies.[96]

FDA investigators with field experience investigating OTC sales were sent to Berkeley, California to take courses on criminal investigation.[97] Because this was the FDA's first assignment of criminal powers[98], FDA officials turned to FBN officials for guidance. The BDAC also recruited law enforcement officers, including those from the FBN, to join their ranks.[99] Unbeknownst to FDA officials, however, many of the FBN agents that applied to transfer to the BDAC were under investigation for corruption.[100] The FBN, eager to get rid of its "unattractive people," withheld evidence of the agents' corruption from the BDAC officials.[101] Many of these FBN agents were hired by the BDAC with promotion and some entered into leadership positions.[102]

Despite seeking law enforcement expertise by consulting with the FBN, in 1966, the FDA appointed John Finlater as director. Finlater was an experienced manager who did not have a law enforcement background.[103] He hoped to bring a fresh approach to enforcement, one that was more aligned with the purpose of protecting public health.[104] He defined his approach as a "statistical-psychological-educational" approach that did not center around the deviancy of the drug user.[105] It also emphasized collaboration with state and local law enforcement,[106] a feature that was more typical of the regulatory approach used by the FDA's pre-BDAC field investiga-

96. *Id.*

97. Wilkens, *supra* note 68, at 42–43.

98. Some FDA investigators felt that these criminal enforcement powers were much needed due to the dangers encountered during their investigations. See e.g. Swanson, *supra* note 22, at 31.

99. *Id.* at 43; *see also* PEMBLETON, *supra* note 3, at 280.

100. Wilkens, *supra* note 68, at 66–67; *see also* Interview with Francis J. Flaherty, HISTORY OF THE U.S. FOOD & DRUG ADMIN., at 8 (June 14, 2000), https://www.fda.gov/media/81557/download [hereinafter Flaherty].

101. Flaherty, *supra* note 100; *see also* Wilkens, *supra* note 68, at 61–62.

102. *See* Flaherty, *supra* note 100.

103. Pumpian, *supra* note 21, at 27.

104. Finlater's approach also focused on drug traffickers' behavior rather than punishing the drug users. PEMBLETON, *supra* note 3, at 280; *see also* VALENTINE, *supra* note 44, at 381.

105. PEMBLETON, *supra* note 3, at 280.

106. *Id.*; *see also* VALENTINE, *supra* note 44, at 381.

tors.[107] Finlater's approach included addressing the demand for drugs, alongside the supply. Alfred Barnard, the former Deputy Director of the BDAC, who had been recruited to assist Finlater form the agency, created a Division of Drug Studies and Statistics to explore the factors that led to the demand for drugs.[108] "I was more interested in really looking into the basic problems that lead to drug abuse as opposed to just making cases and putting peddlers in jail,"[109] Barnard explained.

B. *The Unraveling of the BDAC*

While this new approach was complementary to the regulatory approach used by FDA-turned-BDAC-investigators ("FDAers"), it clashed with the former FBN officers' punitive approach.[110] While the FDAers were much more focused on protocols, processes, and procedures (a regulatory approach to enforcement), former FBN officers were more likely to ignore protocol, engage in entrapment, or otherwise take ethically questionable shortcuts to accomplish their objects.[111] This behavior may have been encouraged while these officers were at the FBN through the implementation of arrest quotas, which required FBN officers to reach a minimum number of arrests within a specified time period.[112] The pressure to meet these quotas helped create an FBN culture that played fast and loose with the rules, and while no such quota system existed at the BDAC, the FBN's culture was still embedded in the practices of the former FBN officers,[113] as was the rowdiness and corruption that accompanied them.[114] As a former Director of Product Surveillance and Approval of the New Jersey District recounts:

> [T]hey may not have been taking bribes, but like I said, they were entrapping people, they were probably taking some money. You know, they'd bust into a place to arrest people, and there'd be a thousand,

107. Pumpian, *supra* note 21, at 41.
108. Barnard, *supra* note 20, at 62.
109. *Id.*
110. *See* FRYDL, *supra* note 19, at 171.
111. *See* Wilkens, *supra* note 68, at 56–60.
112. *Id.* at 57–58.
113. *Id.* at 55–57.
114. *Id.* at 69. ("[T]hey were a wild bunch, a real wild bunch.").

> $100,000 laying around on the bed.[115]. . . [T]hey used to tell us stories, and they'd tell us stories out of the BDAC class, the federal guys, where they'd break into these places and find these huge amounts of money and huge amounts of drugs there. And when you see, especially with the city guys were getting paid like $20,000 a year or something, and they'd go in and there's tons of money laying around, so they were really exposed to the biggest temptation you can imagine, and it's hard to pass up. Nobody knew how much money was there. You know, they could grab a bundle of it and nobody would know, and they did; a lot of them did.[116]

The former FBN officers' behaviors made the FDAers uncomfortable.[117] As the former Director of the Bureau of Regulatory Compliance recalled, "Initially, we had a pretty good operation. When they went into Narco, it became a different situation."[118]

As more FBN officers began migrating from the struggling FBN to the BDAC, the FDA's culture of regulatory enforcement became overshadowed by the FBN's culture.[119] Despite poor reputations with U.S. Attorney's Office and FDA investigators, the former FBN officers touted their experience and took over the ranks of the BDAC.[120] "These Bureau of Narcotics guys, who knew nothing about FDA or nothing about our cases, were in charge," explained a former Chief Agent of the New York Field Office.[121]

As the former FBN officers grew in number, many FDAers requested transfers and left the BDAC.[122] While these FDAers had liked—even loved—the work that they were doing, they

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115. *Id.* at 68.

116. *Id.* at 69.

117. *See id.* at 60–61. "He had all these diamond rings on, you know, like you see in the movies. Where did all these diamond rings, diamond pins, where do these guys get their money, you know?" *Id.* at 61.

118. Barnard, *supra* note 20, at 18.

119. "[T]hey kind of took over this FDA bureau." Flaherty, *supra* note 100, at 9.

120. *See* Wilkens, *supra* note 68, at 62.

121. *Id.*

122. *Id.* at 64–66; *see also* Flaherty, *supra* note 100; Barnard, *supra* note 20; Pumpian, *supra* note 21.

found the new environment untenable.[123] As the Chief Agent of the New York Field Office later testified:

> Anyway, it was a disappointment, the agency, to me, the 18 months or whatever I was in there, because it wasn't, in my mind, an FDA type agency. We were overwhelmed, overtaken at the headquarters level and the field level and the agent level with these other people with different standards, different ways of operating. Not that that was bad, but different credibility, different ethics, and it was more than I could handle. So I'm so lucky that I got out of there with a promotion. I mean, if I got out of there laterally, I would have been happy.[124]

In 1968, only two short years after its creation, the BDAC was transferred out of the FDA and with it went the FDA's status as the primary enforcer of regulations on potentially-addictive, non-narcotic substances.[125] President Johnson merged the BDAC with the FBN through an executive order[126] at the recommendation of FDA Commissioner Goddard.[127] Together, the agencies were transferred to the DOJ, forming the Bureau of Narcotics and Dangerous Drugs ("BNDD").[128] FBN leadership was not happy about the merger, as its Director considered it a decrease in stature,[129] and Congress was split over whether to support or override the President's merger plan.[130] Representative Thomas Hale Boggs, an ally of the FBN Commissioner, proposed a resolution to override the Presi-

123. Wilkens, *supra* note 68, at 66.

124. *Id.* at 70–71.

125. *See* Swann, *supra* note 63, at 86.

126. Reorganization Plan No. 1 of 1968, *reprinted in* 82 Stat. 1367, 1368 (1968).

127. Goddard had been informed by the FDA's Director of the Office of Legislative and Governmental Affairs that President Kennedy's White House Conference on Narcotic and Drug Abuse had recommended that the BDAC be transferred to the DOJ. Because Goddard wanted to get rid of the BDAC, he used the information to support his request for its transfer. *See* Pumpian, *supra* note 21, at 25.

128. *Id.*; *see also* DRUG ENF'T ADMIN., THE DEA YEARS 30, 30 (2018), https://www.dea.gov/sites/default/files/2018-07/1970-1975%20p%2030-39.pdf.

129. Pumpian, *supra* note 21, at 27.

130. *Id.* at 28. As Pumpian explained, the Commissioner of the Bureau of Narcotics worked together with Representative Thomas Hale Boggs to attempt to block the merger. *Id.* at 27–28.

dent's reorganization order, which was defeated by only ten votes.[131] Legislators voiced skepticism over whether the DOJ was equipped to handle licit regulation, with some wondering if the merger was "an overreaction to crime in the streets, an enforcement kind of attitude."[132] After the merger, attempts were made to preserve some of the FDAers' regulatory approach by appointing former BDAC Director, John Finlater, as an associate director of the BNDD.[133] However, after John Ingersoll, a former street cop, was named as director of BNDD, the BNDD's adoption of a criminal justice approach, over a regulatory approach, was imminent.[134]

In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970[135] to address "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances."[136] Title II of the Controlled Substances Act ("CSA") created a scheduling system to classify controlled substances,[137] based on the level of dangerousness, their potential for addiction, and their "legitimate medical value."[138] Upon enactment, the CSA was enforced by BNDD.[139] Although Congress provided some guidance on the scheduling scheme in CSA, it also "insisted that the Attorney General request and abide by recommendations from the Secretary of Health and Human Services (HHS) when revising the schedule."[140] Theoretically, this was Con-

131. *Id.* at 27–29. Frydl suggests that the near-passage of the resolution could have been attributed to backlash of President Johnson's announcement a few days earlier that he would not be seeking re-election. FRYDL, *supra* note 19, at 285.

132. *Id.* at 287 (citing JOHN FINLATER, THE DRUGGED NATION: A "NARC'S" STORY 22 (New York: Simon & Schuster, 1973)).

133. Henry L. Giordano, a commissioner of the FBN, was appointed as the co-associate director with Finlater. Each co-associate director believed that he would be later selected to act as sole director, but neither co-associate director was selected to be director. DOUGLAS VALENTINE, STRENGTH OF THE PACK: THE PERSONALITIES, POLITICS AND ESPIONAGE INTRIGUES THAT SHAPED THE DEA 2–5 (2009).

134. Pumpian, *supra* note 21, at 29.

135. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91–513, 84 Stat. 1236.

136. 21 U.S.C. § 801(2) (1970).

137. THE DEA YEARS, *supra* note 128, at 31.

138. *Id.*

139. *Id.*

140. Noah, *supra* note 13, at 58.

gress' attempt to balance a criminal justice approach with a more-scientific health approach.[141] Yet, the powers delegated to the FDA, vis-à-vis HHS, paled in comparison to those given to the BNDD.[142] This imbalance of power was later compounded by President Nixon's creation of his own "police force," the DEA.[143]

The BNDD was subsumed into the DEA in June of 1973.[144] Nixon's election platform included the promise to strengthen federal enforcement of laws regulating illicit drug trafficking, and the DEA was the vehicle through which Nixon planned to accomplish this campaign promise.[145] While a more health-oriented treatment approach had gained support during the late 1960s and early 1970s within the Executive branch,[146] the creation of the DEA symbolized a "choice in favor of enforcement, and exclusively enforcement."[147] By creating the DEA and awarding it with primary jurisdiction over potentially-addictive substances, the President endorsed and institutionalized the FBN's criminal justice approach over the FDA's regulatory, health-oriented approach.

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141. Congress requires the DEA to request recommendations from the Secretary of the Department of Health and Human Services (HHS) when scheduling potentially-addictive substances. The Secretary of the Department of HHS operates through the FDA's Center for Drugs and with advice from the FDA Drug Abuse Advisory Committee. 21 U.S.C. § 811(b) (2018). Furthermore, the FDA has veto power over the scheduling recommendations made by the DEA. If the FDA does not use the veto power, the DEA proceeds with the scheduling recommendation. O'REILLY & VAN TASSEL, *supra* note 15; 21 C.F.R. § 14.100(c)(6) (2019).

142. *Compare* THE DEA YEARS, *supra* note 128, at 30–34 (discussing BNDD authority and power in the early 1970s), *with* discussion *supra* note 141 (explaining the role of the HHS).

143. EDWARD JAY EPSTEIN, AGENCY OF FEAR: OPIATES AND POLITICAL POWER IN AMERICA 216 (Verso 1990) ("The White House finally succeeded in 1972 in creating a private police force in the form of the Office of Drug Abuse Law Enforcement.").

144. Reorganization Plan No. 2 of 1973, Pub. L. No. 93-253, § 1, 87 Stat. 1091 (1973).

145. *See* FRYDYL, *supra* note 19, at 363.

146. *See* MICHAEL MASSING, THE FIX 86 (1998) (discussing Nixon's appointment of Jaffe). As a means to enforce the Controlled Substances Act, in July of 1973, President Nixon created the DEA. SACCO, *supra* note 51, at 6–7.

147. FRYDYL, *supra* note 19, at 364.

III.
WHY THE DEA AND NOT THE FDA?

Some scholars have claimed that the BDAC was short lived because the work it did often overlapped with the FBN.[148] Many illicit drug traffickers sold narcotics along with other potentially-addictive substances, resulting in the BDAC and the FBN investigating the same persons.[149] Scholars have also argued that the BDAC was transferred out of the FDA because the scope of enforcement necessary to quell the nation's drug problem was more than the FDA could handle and that the FDA was ill-equipped to handle responsibilities that were required to enforce the CSA.[150] Their arguments are supported by the lack of buy-in of FDA leadership evidenced by FDA Commissioner Goddard's unwillingness to fight to keep the BDAC.[151] Taken at face value, these arguments beg the question: Why should Congress consider shifting the powers of enforcement from the DEA to the FDA?

The evidence presented in this Article challenges the aforementioned explanations, by arguing that oral history testimony demonstrates the following key findings. A faction within the FDA wanted the powers at issue and executed its duties in a manner that convinced Congress to institutionalize those duties.[152] When the BDAC was created and the FDA's jurisdiction was institutionalized, the BDAC continued to perform well, "steal[ing]" headlines from the FBN[153] and making "splashy busts."[154] Given these facts, why would the FDA Commissioner lobby for these powers only to advocate for their reassignment two years later?

Former FDA Commissioner Larrick and his successor, former Commissioner Goddard, reported being uncomfortable with the riskiness of undercover work.[155] Commissioner Larrick was said to have set up the BDAC as an independent

148. *See, e.g.*, *id.* at 159.
149. Swann, *supra* note 68 at 166.
150. *Id. See, e.g.,* FRYDL, *supra* note 19, at 122.
151. Swann, *supra* note 68 at 150.
152. *See* discussion *supra* Section II.A.
153. PEMBLETON, *supra* note 3, at 280–81.
154. VALENTINE, *supra* note 44, at 381.
155. *See* Kinslow, *supra* note 91, at 13–14; Ley, *supra* note 22, at 6–7.

agency[156] "set up for the plucking."[157] Perhaps, Commissioner Larrick did so because he was aware that the FBN's demise was forthcoming[158] and that Attorney General Robert Kennedy had expressed interest in absorbing the FBN into the DOJ.[159]

FDA leadership may have also been hesitant to fight to keep the BDAC because of its high profile clashes with FBN leadership that generated negative publicity for the FDA. During FDA Commissioner Goddard's tenure, FDA leadership was under scrutiny for its public disagreement with the FBN over the harmful effects of marijuana, with FBN officials insisting on using Prohibition Era rhetoric to describe marijuana use and the FDA questioning the scientific basis for the FBN's claims.[160] This disagreement culminated in a call for FDA Commissioner Goddard to resign over his comments that alcohol was likely more harmful than marijuana.[161] The negative press coverage of the marijuana disagreement was compounded by coverage of birth-defects caused by an FDA-approved drug called thalidomide. The thalidomide tragedy led to questions of FDA competence in regulating dangerous drugs.[162] Moreover, the BDAC was not without its own controversy. Commissioner Goddard worried about the "reaction to agents being killed" and potential damage to the FDA's image as a "scientific agency."[163] The Commissioner's concerns were particularly warranted given the corruption of former FBN officers detailed above. Shortly after the BDAC merged with the FBN, BNDD leadership purged itself of "dirty agents."[164] FBN officials had been aware of the internal investigations within the FBN that prompted the transfer of its unsavory agents to the BDAC, and, once it was merged with the BDAC, these former FBN officials used that information to fire thirty-two agents on suspicions of corruption.[165] BNDD leaders then in-

156. Flaherty, *supra* note 100, at 7.

157. Swanson, *supra* note 22; *see also* Pumpian, *supra* note 21, at 25.

158. *See* VALENTINE, *supra* note 44, at 455–56 (discussing how the FBN was becoming obsolete).

159. AG Kennedy later changed his mind about wanting the FBN. *See* FRYDL, *supra* note 19, at 264–68.

160. *See* PEMBLETON, *supra* note 3, at 281–82.

161. *Id.* at 281.

162. FRYDL, *supra* note 19, at 245.

163. Pumpian, *supra* note 21, at 25.

164. PEMBLETON, *supra* note 3, at 283.

165. Wilkens, *supra* note 68 at 66–68.

vited the Central Intelligence Agency to conduct an investigation into the scope of the corruption.[166]

In sum, the evidence reviewed in this section suggests that our prior understanding of the circumstances surrounding the transfer of the BDAC from the FDA to the DOJ are incomplete. The evidence reviewed supplements the historic record by proving that despite contrary indications by FDA leadership, a faction within the FDA wanted the powers to investigate illicit sales of potentially-addictive substances. The evidence presented disputes theories that the FDA lost its position as primary enforcer because the FDA was ineffective at its duties. Moreover, this article demonstrates that when the FDA was enforcing the regulations on potentially-addictive substances, it did so using a regulatory rather than a criminal justice approach—an approach that may be more in-line with current efforts to utilize a public health approach in addressing problem drug use related to the ongoing opioid crisis. Finally, this Article provides a new theory to explain how the FDA lost some of its powers to regulate these potentially-addictive substances to the DEA—one that suggests that the downfall of the BDAC can be attributed to the willful sabotage by FBN leaders and accompanied by an infiltration of FBN officers into the BDAC. It was not that the FDA's regulatory approach was not the most effective in addressing the illicit sales of potentially-addictive substance, but rather that the FBN's criminal justice approach displaced the FDA's regulatory approach and led to the demise of the BDAC.

Since Congress has reconsidered the use of the criminal justice approach to address problem drug use, it should also revisit its reliance on a criminal justice agency to regulate and enforce the regulation of potentially-addictive substances. The FDA has a history of regulating potentially-addictive substances. Even after the powers of enforcement were taken away from the FDA vis-à-vis the transfer of the BDAC, the FDA continued to express a desire to at least regulate a facet of illicit

166. *Id.*

distribution.[167] While the FDA is by no means perfect,[168] it is an agency that prioritizes public health over punishment, a necessity for the implementation of a public health approach to the opioid crisis and the crises that will likely follow.

167. The FDA's efforts to regulate illicit distribution of potentially-addictive drugs resulted in a D.C. court decision maintaining that Congress had delegated those powers to the DEA. The court concluded that, "Congress intended to create two complementary institutional checks, [the FDA and the DEA] on the production and marketing of new drugs." The public policy arguments made by the FDA to control the distribution of a controlled substance did not outweigh the deliberate Congressional separation of the powers of the DEA and the FDA. American Pharmaceutical Ass'n v. Weinberger, 377 F. Supp. 824 (D.D.C. 1974).

168. This is not to say that FDA's current reviews of potential risks and benefits of drugs is not without its flaws. FDA's decision-making process has been criticized as being too clinical (or individualistic) (*see* Noah, *supra* note 13, at 55–74), as needing to include more of a consideration of population or public health in determining risks and benefits (*see, e.g.*, Micah L. Berman, Taleed El-Sabawi & Peter G. Shields, *Risk Assessment for Tobacco Regulation*, 5 TOBACCO REG. SCI. 36, 36–49 (2019)), and as relying too heavily on placebo-controlled clinical trials (*see generally* SUZANNE WHITE JUNOD, FDA AND CLINICAL DRUG TRIALS: A SHORT HISTORY, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/110437/download). And, in 2005, the FDA came under congressional scrutiny for regulation of OxyContin, a potentially-addictive opioid. *Oxycontin and Beyond*, *supra* note 14.