(UN)SAFE AND (IN)EFFECTIVE: PREEMPTION, DEFERENCE, THE FDA, AND THE OPIOID CRISIS

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ABSTRACT

The Food and Drug Administration ("FDA") is tasked with keeping prescription drugs safe and effective for the American people. The FDA has long enjoyed deference in its decision-making because of the ambiguity in its organic statute, the Federal Food, Drug, and Cosmetic Act ("FDCA"). Gaining FDA approval for prescription drugs, however, is not a rubber stamp that frees a drug manufacturer from liability. Prescription drug manufacturers, such as opioid manufacturers, have been unsuccessful in convincing courts to use the concept of federal preemption and deference—specifically FDA approval and therefore judicial deference to that approval—to shield them from liability from state law claims against the distribution of these drugs. With the fall of *Chevron* deference in June 2024, it is unclear if the FDA will still enjoy the deference it has received, potentially leading to the promulgation of litigation against the FDA for (un)safe and (in)effective drugs. This Note examines the evolution of litigation against prescription drug manufacturers, specifically opioid manufacturers, by analyzing the difficult-to-meet standard of federal preemption under the FDCA. It then examines the history of deference to the FDA under *Chevron* by using the FDA approval and regulation of opioids as a case study. Lastly, it predicts how the overruling of *Chevron* by *Loper Bright Enterprises v. Raimondo* will impact the prescription drug landscape—ranging from circuit splits, to changes in the FDA structure, to even a floodgate of ligation against the FDA itself.

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INTRODUCTION

The FDA is tasked with regulating over twenty-thousand prescription drugs for their safety and effectiveness.[1] Among these thousands of FDA-approved prescription drugs include drugs that treat Alzheimer's Disease, malaria, sickle-cell disease, hypertension, and breast cancer.[2] After approving the drugs initially, the FDA and its staff's job is far from over. They must sift through hundreds of thousands of promotional materials and risk reports to ensure that the drug is still safe and effective.[3] Among the drugs the FDA monitors is a tablet only about seven to ten millimeters in diameter,[4] and responsible for nearly half a million American overdose deaths in the past two decades.[5] This is the prescription opioid crisis.

In 2022, nearly 81.8% of all fatal drug overdoses involved an opioid.[6] Prescription opioids account for more drug overdose deaths than heroin.[7] Between 1999 and 2017, the death toll from illegal and legal opioid use increased six-fold.[8] The nearly 191 million prescriptions for opioids were not a reflection of a decline in the health status of Americans, or the amount of pain Americans report.[9] The rampant misuse of opioids led former President Donald Trump and the acting Secretary of Health and Human Services, Eric D. Hargan, to declare the opioid crisis a public health emergency in 2017.[10] Thousands of lawsuits were instigated against opioid manufacturers, leading Purdue Pharmaceuticals ("Purdue Pharma") to file for bankruptcy in 2019.[11] What caused this epidemic? To understand the

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1. FDA, REGULATED PRODUCTS AND FACILITIES 1 (2020), https://www.fda.gov/media/143704/download [https://perma.cc/HL4U-6T5L].

2. Angelika Batta, Bhupinder Singh Kalra & Raj Khirasaria, *Trends in FDA Drug Approvals over Last 2 Decades: An Observational Study*, 9 J. FAM. MED. PRIM. CARE 105, 107 (2020).

3. *Step 5: FDA Post-Market Drug Safety Monitoring*, FDA (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring [https://perma.cc/S2YL-TDSK].

4. *Label: OxyContin*, NAT'L LIBRARY OF MED. (May 4, 2024), https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bfdfe235-d717-4855-a3c8-a13d26dadede [https://perma.cc/TZ93-4X6R].

5. *Focus on Broadband and Opioids*, FED. COMMC'NS COMM'N, https://www.fcc.gov/reports-research/maps/connect2health/focus-on-opioids.html [https://perma.cc/G6H2-WK6G].

6. *SUDORS Dashboard: Fatal Drug Overdose Data*, CDC (Aug. 23, 2024), https://www.cdc.gov/overdose-prevention/data-research/facts-stats/sudors-dashboard-fatal-overdose-data.html?CDC_AAref_Val=https://www.cdc.gov/drugoverdose/fatal/dashboard/index.html [https://perma.cc/X359-ACG3].

7. *Id.*

8. Sunghee H. Boté, *U.S. Opioid Epidemic: Impact on Public Health and Review of Prescription Drug Monitoring Programs (PDMPs)*, 11 ONLINE J. PUB. HEALTH INFORMATICS e18, e19 (2019).

9. *Id.*

10. *Ongoing Emergencies & Disasters*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 10, 2024 06:01 PM), https://www.cms.gov/about-cms/what-we-do/emergency-response/current-emergencies/ongoing-emergencies [https://perma.cc/LFY2-H45L].

11. William Brangham & Dorothy Hastings, *Purdue Pharma Family Protected from Lawsuits in Exchange for Addiction Treatment Funding*, PBS NEWS HOUR (May 31, 2023, 6:45 PM), https://www.pbs.org/newshour/show/purdue-pharma-family-protected-from-lawsuits-in-exchange-for-

legal theories of these cases, one must understand exactly how opioid use became so prevalent in the United States.

The first synthetic opioids were developed in 1910, but it was not until the late 1980s and early 1990s that the FDA approved long-lasting opioid products, such as Purdue Pharma's oxycodone extended release ("ER") ("OxyContin"), that form the foundation for the crisis.[12] The FDA's 1995 approval of OxyContin was based on six clinical studies with patients that experienced pain such as cancer, lower back inflammation, or osteoarthritis.[13] After OxyContin was approved, Purdue Pharma began aggressively marketing it, spending nearly two hundred million dollars in 2001 to market the drug to physicians, pharmacists, and the general public.[14] Part of Purdue Pharma's marketing strategy included training sales representatives to sell the drug to physicians, who in turn often targeted physicians with high prescription rates of opioids.[15] Purdue even distributed OxyContin plush toys to physicians as a marketing strategy.[16] Purdue also focused on making physicians increase the dosage of OxyContin or "titrating up," when patients who were originally on lower-doses became more tolerant to OxyContin.[17] In 2007, the Attorney General of the United States settled with Purdue Pharma for a whopping six hundred million dollars for misbranding OxyContin with the intent to defraud or mislead (a felony under the FDCA),[18] and since then nearly thousands of lawsuits have been filed against the company,[19] leading to its bankruptcy in 2019.[20]

While Purdue Pharma is liable in perpetuating the opioid crisis, not much attention has surrounded the FDA's role in the predicament. In part,

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addiction-treatment-funding [https://perma.cc/UY9M-LNMA].

12. *Opioid Approval and Monitoring by the U.S. Food and Drug Administration*, *in* PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 359, 360 (Richard J. Bonnie et al. eds., 2017).

13. Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., FDA, to Maggie Hassan, Senator, U.S. Senate, https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf [https://perma.cc/UY2W-V7DV].

14. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221 (2009).

15. *Id.* at 222.

16. *Id.*

17. News Release, The State of New Jersey, Office of the Attorney General, Attorney General Porrino Announces Suit Against Purdue Pharma Alleging Scheme to "Mainstream" Addictive Opioids for Profit, (Oct. 31, 2017), https://nj.gov/oag/newsreleases17/pr20171031a.html [https://perma.cc/W98L-K8DZ].

18. United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 569 (W.D. Va. 2007).

19. See Rebecca Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2302 (2017) for a list of high-profile litigation cases against opioid companies.

20. *See generally in re* Purdue Pharma L.P., 633 B.R. 53 (Bankr. S.D.N.Y.), *vacated sub nom. In re* Purdue Pharma, L.P., 635 B.R. 26 (S.D.N.Y. 2021), *rev'd and remanded sub nom. In re* Purdue Pharma L.P., 69 F.4th 45 (2d Cir. 2023), *aff'd sub nom.*

this is because litigants have been so successful against prescription drug manufacturers, and manufacturers have been unsuccessful at denying liability through legal defenses, like preemption. These defenses often assert that the drug companies are not liable for misleading advertising because the product—and its corresponding label—is FDA approved.[21] In addition, the FDA has long exercised discretion in approving drugs and monitoring their safety and efficacy under its organic statute: the 1938 FDCA because of *Chevron* deference.[22] However, this discretion is now unstable, as *Chevron* was overruled by the Supreme Court's grant of certiorari in two cases that implicate the doctrine and its consolidated decision on those cases in *Loper Bright Enterprises v. Raimondo*.[23]

Part I of this Note examines the history and use of the federal preemption defense by major drug manufacturers under the FDCA. Part II examines the interaction between federal preemption and agency deference, specifically explaining why opioid manufacturers have been so unsuccessful at defending their actions in the opioid crisis through preemption defenses. Part III details the history of *Chevron* deference to the FDA in their approval of prescription drugs, especially the approval of opioids. Lastly, Part IV predicts what may happen to the structure of the FDA since the overturning of *Chevron* and how the absence of *Chevron* will impact the opioid crisis today. The goal of this Note is to analyze how legal doctrines have shaped litigation against FDA-approved prescription drugs and examine the effects of the overruling of *Chevron* on the FDA's ability to approve and regulate prescription drugs, by using the opioid crisis as a case study.

I. WHY PRESCRIPTION DRUG MANUFACTURERS ARE UNSUCCESSFUL IN PREEMPTION DEFENSES: PREEMPTION AND THE FDCA

A. INTRODUCTION TO THE FDA AND PREEMPTION

One of the most common claims in lawsuits against prescription drug manufacturers is that they engaged in deceptive marketing of the drug or that they failed-to-warn the public of certain dangers of their drug.[24] However, in

21. *See infra* Section II; City & Cnty. of S.F. v. Purdue Pharma L.P., 491 F. Supp. 3d 610, 662 (N.D. Cal. 2020).

22. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

23. *See generally* Loper Bright Enters. v. Raimondo, No. 22–451, slip op. (U.S. 2024); Loper Bright Enters., Inc. v. Raimondo, 45 F.4th 359 (D.C. Cir. 2022), *cert. granted in part sub nom.* Loper Bright Enters. v. Raimondo, 143 S. Ct. 2429 (2024); Relentless, Inc. v. United States Dep't of Com., 62 F.4th 621 (1st Cir. 2023), *cert. granted in part sub nom.* Relentless, Inc. v. Dep't of Com., 144 S. Ct. 325 (2023); *see also* Amy Howe, *Supreme Court Likely to Discard Chevron*, SCOTUSBLOG (Jan. 17, 2024, 6:58 PM), https://www.scotusblog.com/2024/01/supreme-court-likely-to-discard-chevron [https://perma.cc/P9LP-J57D].

24. *See* Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*,

response, many drug manufacturers defend their actions by asserting that the drug at issue is FDA-approved.[25] The logic behind the FDA approval defense is as follows: the FDCA,[26] the central governing statute that grants the FDA power, and the corresponding FDA regulations, dictate how the FDA approves labeling, label changes, and sets the standards for governing deceptive marketing for prescription drugs.[27] The concept of federal preemption dictates that state law cannot impose different requirements than federal law.[28] Since state law claims by plaintiffs often allege that a manufacturer failed to warn patients via a drug label about a danger in a drug or that a manufacturer deceptively promoted a drug, manufacturers can use the federal FDA approval of the drug to assert that these state law claims impose different requirements than what is federally required, hence invoking federal preemption.[29] In addition, plaintiffs cannot directly claim that drug manufacturers violated the FDCA, say for misleading marketing or deceptive labeling, because the FDCA does not allow private citizens to enforce the statute; the FDCA does not contain a private right of action. [30]

B. THE LANHAM ACT AS AN AVENUE AROUND PREEMPTION

A popular avenue for plaintiffs seeking to curtail preemption under the FDCA is to instead bring a cause of action under the Lanham Act, a federal statute that governs false and deceptive marketing practices.[31] Specifically, the Lanham Act creates a cause of action against any person who "uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics, [or] qualities . . . of his or her or another person's goods, services, or commercial activities."[32] Its purpose is to protect consumers from unfair competition and to prevent fraud and deception in the marketing of products.[33]

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116 W. VA. L. REV. 1117, 1122–23 (2014).

25. *See generally* Victor E. Schwartz & Christopher E. Appel, *Where's the Beef?: A Guide to Judges on Preemption of State Tort Litigation Involving Branded Drugs*, 89 U. CIN. L. REV. 597 (2021) (outlining that under current law, drug manufacturers can assert that their drug is FDA-approved and that the FDA would reject a change in warning label as a preemption defense against failure-to-warn claims).

26. *See* Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i.

27. See *id.* §§ 351–52 for FDCA drug marketing requirements. The FDA has promulgated its specific requirements regarding labeling in 21 C.F.R. § 201 (2024) and marketing in 21 C.F.R. § 203 (2024).

28. U.S. CONST. art. VI, § 2.

29. *Prescription Drug Defects Leading to Products Liability Lawsuits*, JUSTIA, https://www.justia.com/products-liability/types-of-defective-product-cases/prescription-drugs-containing-product-defects [https://perma.cc/PD87-ACM2].

30. *See* 21 U.S.C. § 337(a).

31. *See* Lanham Act, §§ 15 U.S.C. 1051–1141n.

32. *Id.* § 1125(a)(1).

33. *Id.* § 1127.

Some causes of action brought under the Lanham Act also implicate the FDCA, as both federal statutes govern the advertising, marketing, and handling of drugs.[34] The interplay of the Lanham Act and the FDCA, both federal statutes, raises a question as to whether the FDCA precludes certain causes of action under the Lanham Act if that cause of action is also governed by the FDCA.[35] For example, a plaintiff who brings a claim for deceptive labeling under the Lanham Act may be prevented from doing so if the FDCA governs because the FDCA does not create a private cause of action.

In *POM Wonderful v. Coca-Cola*, the Supreme Court examined the interaction between the FDCA and the Lanham Act in a cause of action for misleading advertising or labeling for a beverage label and determined that the FDCA and the Lanham Act could coexist together because Congress had failed to enact in either statute a provision that would preclude the governance of other federal laws in food and beverage labeling.[36] This was "powerful evidence that Congress did not intend FDA oversight to be the exclusive means."[37]

Although *POM Wonderful* determined that neither the Lanham Act nor the FDCA preclude the other in food and beverage labeling, the Court left open the question as to whether *POM Wonderful* would apply to drug labeling. The Court indicated its hesitancy to apply *POM Wonderful* to other labels approved by the FDA because food and beverage labels, unlike drug labels, are not preapproved by the FDA, and instead are monitored by the FDA post facto through enforcement actions and warning letters.[38] The Court also seemingly suggested that the FDCA may preclude Lanham Act cases involving an affirmative policy decision by an agency.[39]

After *POM Wonderful*, lower courts puzzled at the question of preclusion between the two federal statutes, interpreting the dicta in *POM Wonderful* to mean that, "at a minimum, the Court might find a Lanham Act claim precluded by the FDCA where it turns on the content of a drug label, especially if that drug label were preapproved by the FDA."[40] The Eleventh Circuit commented that because drug approval is a demanding and complicated process, there may be reasons to prevent label challenges that would contradict the FDA or invade its discretion.[41] Some courts draw the line by looking at factors such as whether the drug was new or whether it

34. *See* Rachel Simon, *After the Juice Wars: The Post*-POM Wonderful *Legal Landscape and Its Implications for FDA-Regulated Industries*, 75 FOOD & DRUG L.J. 430, 430–31 (2020).
35. *See id.*
36. POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 113–14 (2014).
37. *Id.* at 114 (citing Wyeth v. Levine, 555 U.S. 555, 575 (2009)).
38. *Id.* at 116.
39. *See id.* at 120.
40. JHP Pharms., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 998 (C.D. Cal. 2014).
41. Belcher Pharms., LLC v. Hospira, Inc., 1 F.4th 1374, 1380 (11th Cir. 2021).

could be lawfully marketed under the FDCA.[42] Today, the application of *POM Wonderful* to other FDCA-covered products, like prescription drugs, lacks a controlling decision from the Court.

C. PREEMPTION IN PRESCRIPTION DRUG LITIGATION

Preemption stems from Article VI, Section II of the Constitution, which states that federal law is "the supreme Law of the Land."[43] There are two general types of preemption: express preemption, when federal law contains explicit preemptive language, and implied preemption, when federal law's structure and purpose necessitates preemption implicitly. Of the implied preemption category, there are two subfields: field preemption, when "Congress has legislated comprehensively to occupy an entire field of regulation, leaving no room for the States to supplement federal law" and conflict, which consists of both impossibility and obstacle preemption.[44] Impossibility preemption occurs "where it is impossible for a private party to comply with both state and federal requirements."[45] Conflict preemption occurs when state law stands in the way of the accomplishment of federal goals.[46] Within all the different types of preemption, "the purpose of Congress is the ultimate touchstone in every pre-emption case,"[47] and there is a "presumption against pre-emption."[48]

Notably, the FDCA contains no express preemption clause for prescription drugs. This is in sharp contrast to the FDCA's Medical Device Amendments ("MDA") that were added to the FDCA in 1976 and clearly write that a State may not, "establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under [federal law] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under" relevant federal law.[49] Under an express preemption clause like the one above, solving preemption problems is straight-forward because preemption is literally written.

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42. Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016); *see* PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 928 (9th Cir. 2010) ("Our decision is consistent with other decisions refusing to allow private actions under the Lanham Act premised on enforcement determinations that the FDA and other regulatory agencies did not themselves make.").

43. U.S. CONST. art VI, § 2.

44. Nw. Cent. Pipeline Corp. v. State Corp. Comm'n of Kan., 489 U.S. 493, 509 (1989).

45. English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990); *see, e.g.*, Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963).

46. CONG. RSCH. SERV., R45825, FEDERAL PREEMPTION: A LEGAL PRIMER 2 (2019).

47. Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

48. *Id.* at n.3.

49. 21 U.S.C. § 360k(a).

Field preemption has often been ruled out by the courts regarding prescription drug litigation. In response to suits brought against drug companies for tort law claims, such as failure to warn or deceptive marketing, drug companies began to assert impossibility preemption as a defense in the early 2000s. The FDA, through amicus curiae briefs, supported the drug companies' preemption claims, as evident in the United States's amicus curiae brief in *Riegel v. Medtronic*,[50] as well as in the 2001 case *Motus v. Pfizer*. In *Motus v. Pfizer*, a plaintiff, on behalf of her decedent, sued the drug company, Pfizer, for failing to warn that taking the drug Zoloft may increase the risk of suicide; in turn, Pfizer asserted a preemption defense, claiming that placing a suicide warning on the package would frustrate the congressional purpose of the FDCA.[51] The district court ultimately rejected Pfizer's preemption argument.[52] Pfizer then appealed to the Ninth Circuit.[53]

In the Ninth Circuit, the FDA wrote an amicus curiae brief supporting Pfizer's preemption argument. The FDA argued that the plaintiff's failure-to-warn claim for Zoloft should be preempted because state and federal law conflicted. The FDA pointed out that the FDA itself considered and rejected that Zoloft and other similar antidepressant drugs caused suicide,[54] and thus would disapprove the warning because the causal relationship between suicide and Zoloft was not supported by science.[55] The Ninth Circuit did not reach the preemption argument upon review, dismissing the case for other reasons,[56] yet the FDA's actions in the case hinted at its strong desire to ensure that federal law reigned supreme.

D. THE 2006 FDA AMENDMENTS: SETTING THE STANDARD FOR PREEMPTION

In 2006, the FDA amended its regulations of prescription drug labeling, appearing to declare its intent to preempt state law tort claims in the preamble.[57] The preamble acknowledged the long history of prescription drug labeling, in which the FDA set the "floor"—the minimum safety standards—while state law was free to set the "ceiling," meaning states were

50. *See* Brief for the United States as Amici Curiae Supporting Respondent, at 20–30, Riegel v. Medtronic, Inc., 552 U.S. 312 (2007) (No. 06–179).

51. Motus v. Pfizer Inc., 127 F. Supp. 2d 1085, 1086–87 (C.D. Cal. 2000).

52. *Id.* at 1101.

53. Brief of Appellant, Motus v. Pfizer, Inc. (Roerig Div.) at 1, 358 F.3d 659 (9th Cir. 2004) (No. 02-55498), 2002 WL 32303086.

54. Amicus Brief for the United States In Support of the Defendant-Appellee and Cross-Appellant at 13, Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498).

55. *Id.* at 17.

56. Motus v. Pfizer Inc., (Roerig Div.), 358 F.3d 659, 660 (9th Cir. 2004).

57. *See* 21 C.F.R. §§ 201, 314, 601 (2024) for FDA regulations of prescription drug labeling.

free to supplement the FDA minimum safety standards with their own safety standards that go beyond the FDA's.[58] The FDA then seemingly put an end to this historic understanding by declaring that, "[i]n fact, FDA interprets the act to establish both a 'floor' and a 'ceiling.' "[59]

The FDA indicated that the more stringent standards that state laws imposed were pressuring drug companies to place more speculative risks on warning labels, thus diluting a physician's attention to the more established risks.[60] The FDA also mentioned that excessive warnings may discourage patient use of safe and effective products.[61] Lastly, the FDA wrote that state laws were not experts in drug policy use and that state law would require "lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public," which ultimately is the central role of the FDA.[62]

1. Judicial Reaction to the 2006 Preamble

Because the FDA had issued a statement of their intent at preemption in 2006, the FDA presumably wanted courts to defer to its view that state law claims were now preempted.[63] Yet, there were some problems, as the preamble did not "expressly preempt," because it was not added to the text of the FDCA. However, the preamble could have theoretically added force to an argument of implied preemption, more specifically conflict preemption ("impossibility preemption") or field preemption. If courts deferred to the FDA's interpretation of the FDCA's preemptive effect, that would suggest that the FDCA, which is a federal law, impossibly conflicts with a differing state law. Courts could have also interpreted the preamble to suggest that the differing state law would frustrate the Congressional purpose of enacting the FDCA, as pointed out above.[64] Ultimately, however, the legal force of the preamble stems from an interpretation by an agency—the FDCA—and if preemption were to apply, the courts would have to decide not only whether or not to defer to that interpretation, but also how much deference the

58. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935. (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601 (2024)).

59. *Id.* ("Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.").

60. *Id.*

61. *Id.*

62. *Id.*

63. *See id.*

64. *See id.* ("FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.").

interpretation merits.

Some courts merited substantial deference to the FDA's preamble. Just after the FDA released its preamble, a district court judge in the Eastern District of Pennsylvania ruled that the FDCA impliedly preempted state law failure-to-warn claims in *Colacicco v. Aptex*.[65] However, in the 2000 case *Wyeth v. Levine*,[66] the Supreme Court ruled that the 2006 preamble only deserved a lower type of deference, *Auer* deference, because the preamble was not made with the force of law.[67] The Court found that the FDA's preamble was not consistent with prior Congressional purpose and the FDA's prior position, all of which viewed state litigation as supplemental means of regulating the prescription drug industry.[68] Thus, the Court in *Wyeth* effectively destroyed any meaningful legal effect of the 2006 preamble.

E. *ALBRECHT*: THE MODERN PREEMPTION LANDSCAPE

In 2019, the Court revisited the issue of preemption in state law claims for prescription drugs, this time in the case *Merck Sharp & Dohme Corp. v. Albrecht*.[69] The plaintiffs were more than five hundred individuals who took the prescription drug, Fosamax, which treats and prevents osteoporosis in postmenopausal women, and developed femoral fractures.[70] Their suits were consolidated into a multi-district litigation in which they alleged Merck failed to warn them of the risk of femoral fractures from taking Fosamax.[71] Merck argued in response that the plaintiffs' claims were preempted because even though FDA regulations would have allowed Merck to edit Fosamax's warning label while it was on the market, Merck claimed the FDA would not have approved the addition of the warning to the label.[72]

In the 9-0 decision, the Court held that the clear evidence standard governs impossibility preemption defenses in failure-to-warn cases, meaning clear evidence "requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning."[73] Additionally, the Court determined that judges, rather than juries, should decide a

65. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 525 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *cert. granted, judgment vacated*, 556 U.S. 1101 (2009).
66. Wyeth v. Levine, 555 U.S. 555, 559 (2009).
67. See *infra* Section II.A for a discussion of both *Chevron* and *Auer* deference.
68. *Wyeth*, 555 U.S. at 578–79.
69. *See* Merck Sharp & Dohme Corp. v. Albrecht, No. 17–290 (U.S. 2019).
70. *Id*. at 1.
71. *Id.*
72. *Id.*
73. *Id.* at 2.

contested issue about an agency's decision.[74]

The Court then remanded the case to the Third Circuit, to consider the case again by treating the preemption issue as a question of law instead of fact, and for the appellate court to comply with the clear evidence standard.[75]

II. AN ANALYSIS OF THE INTERACTION BETWEEN PREEMPTION AND DEFERENCE

Lower courts have since struggled to apply the standards from both *Wyeth* and *Merck* to the facts. This is of no surprise, since *Merck* left open questions, such as, how much discretion would judges actually have in deciding preemption issues? Was preemption only met for failure-to-warn cases if the defendant could meet the clear evidence standard? If judges were the ones ultimately deciding preemption issues as *Merck* dictated, did a judge have leeway in determining impossibility preemption defenses?

Some lower courts have disregarded the clear evidence standard in their analysis, instead deciding impossibility preemption on the judge's own discretion. For example, the FDA's rule of sameness dictated that generic drug manufacturers were not able to unilaterally change their labels without the brand-name manufacturer also changing their labels.[76] Thus, when a generic drug manufacturer raised an impossibility preemption defense, a court could not analyze the issue under the clear evidence standard because the generic drug company could not present a label change proposition to the FDA in the first place. Judges thus decided impossibility preemption defenses at their own discretion, without regard to whether the drug company actually submitted a revised warning label to the FDA and whether the FDA, fully informed, rejected the warning label.[77] New legislation has since been introduced to allow generic drug manufacturers the same avenue to change their labels. [78]

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74. *Id.* at 3.

75. *Id.*

76. *See* U.S. FOOD & DRUG ADMIN., SUPPLEMENTAL APPLICATIONS PROPOSING LABELING CHANGES FOR APPROVED DRUGS AND BIOLOGICAL PRODUCTS 5 (2013) ("Generic drugs are generally required to have the same labeling as the reference listed drug and are not currently permitted to independently change labeling to include new safety-related information that does not conform to the approved labeling of the reference listed drug.").

77. *See* Polt v. Sandoz, Inc., 462 F. Supp. 3d 557, 565 (E.D. Pa. 2020) (rejecting a failure to warn claim against a generic drug manufacturer "because it was impossible for Sandoz to both change the label to make it adequate under state law and comply with FDA regulations requiring the generic manufacturer's label to be identical to the brand-name manufacturer's label").

78. *See* MODERN Labeling Act of 2020, H.R. 5668, 116th Cong. (2020). In 2013, the FDA began considering revising the "rule of sameness" regarding labeling for prescription generic drugs. The revised rules would make it so that generic drug manufacturers would be able to change their drug labels unilaterally, no matter if the name-brand manufacturers of the same drug also changed the label. This was formally introduced as the MODERN Labeling Act of 2019. The bill passed in the House of Representatives but is still pending in the Senate. *See also* Mitchell Russell Stern, Note, *An Adverse*

Some have emphasized the importance of flexibility and pragmatism in judges interpreting the clear evidence standard, as it avoids the possibility that drug manufacturers would "pursue unnecessary FDA rulings that formally reject every conceivable warning change simply to obtain a surefire preemption defense where the agency has made its position clear by telling the manufacturer to 'hold off' or that the science 'does not provide a clear path forward' for a labeling change."[79] Lastly, flexibility in interpreting the clear evidence standard also allows the FDA to avoid reviewing unnecessary warning labeling changes, hence allowing the agency to free up resources that would have been devoted to reviewing those label changes.[80]

A. A PRIMER ON AGENCY DEFERENCE

Under the landmark, but now defunct case, *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, the Court set the standard for agency deference.[81] The first step in applying the doctrine is determining "whether Congress has directly spoken to the precise question at issue"[82] using the "traditional tools of statutory construction."[83] If courts find that the statutory language is ambiguous, courts will then defer to an agency's interpretation of the statute so long as that interpretation is reasonable.[84] The touchstone of the *Chevron* doctrine is congressional intent, meaning that the application of the doctrine assumes that Congress, either implicitly (i.e., through statutory ambiguity) or explicitly (i.e., through express delegation of power to the agency to enact its own regulations), meant to delegate its powers to the agency. [85] Since *Chevron*'s adoption, the Court however slowly curtailed the doctrine, making courts perform an inquiry into congressional intent to delegate legal authority and the agency's use of that legal authority (often called step zero),[86] until *Chevron*'s eventual overruling in *Loper Bright* in

Reaction: FDA Regulation of Generic Drug Labeling, 90 N.Y.U. L. REV. 2154, 2174–75 (2015) https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-90-6-Note-Stern.pdf [https://perma.cc/LF8E-TVKE] (discussing the problems with the potential FDA rule changes, such as leading to labeling confusing differences between generic and name-brand drugs, increasing unnecessary warnings so that manufacturers have a defense against tort liability, and violating the Hatch-Waxman Act by potentially making generic drugs more expensive as generic drug manufacturers become exposed to tort liability).

79. Schwartz & Appel, *supra* note 25, at 620–21 (citing case record in Merck Sharp & Dohme Corp. v. Albrecht, No. 17–290, slip op. at 4–5 (U.S. 2019)).

80. *Id.* at 621.

81. Chevron, U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–45 (1984).

82. *Id.* at 842.

83. *Id.* at n.9.

84. *Id.* at 843–44.

85. *Id.* at 843–44 ("The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.").

86. United States v. Mead Corp., 533 U.S. 218, 229–31 (2001).

June 2024.[87]

Despite *Chevron*'s overruling, Courts will still defer to an agency's interpretation of their own regulations, as long as it is reasonable under *Auer* deference, which comes from the seminal case, *Auer v. Robbins*.[88] Nearly fifteen years later, the Court modified the Auer test in *Kisor v. Wilkie*.[89] *Kisor* determined that a federal court must defer to an agency's interpretation of its own regulation only after a federal court has determined that (1) the regulation is genuinely ambiguous, (2) the agency's interpretation of the regulation is reasonable, and (3) the agency's interpretation meets minimum thresholds to warrant *Auer* deference.[90]

Lastly, there is *Skidmore* deference, which is the lowest level of deference owed to agency interpretations.[91] *Skidmore* deference is invoked when an agency makes an interpretation through more informal procedures that perhaps do not have the force of law, such as opinion letters and enforcement guidelines.[92] The Court will then look at "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements."[93]

In recent years, the Supreme Court has identified yet another avenue in agency interpretation: the major questions doctrine. The major questions doctrine was brought to light in *West Virginia v. Environmental Protection Agency*, in which Chief Justice Roberts wrote:

> Precedent teaches that there are "extraordinary cases" in which the "history and the breadth of the authority that [the agency] has asserted," and the "economic and political significance" of that assertion, provide a "reason to hesitate before concluding that Congress" meant to confer such authority. Under this body of law, known as the major questions doctrine, given both separation of powers principles and a practical understanding of legislative intent, the agency must point to "clear congressional authorization" for the authority it claims.[94]

The idea, therefore, behind the major questions doctrine is that Congress presumably would not intend to delegate such large issues to

87. *See id*. at 218–19 (holding that an agency interpretation embodied in a formal regulation is not alone a dispositive factor in meriting deference, rather, courts should also look to whether Congress intended to delegate power to the agency, either explicitly or implicitly, in light of the specific circumstances).

88. Auer v. Robbins, 519 U.S. 452, 457–58 (1997).

89. Kisor v. Wilkie, No. 18–15, slip op. (U.S. 2019).

90. *Id.* at 2.

91. Skidmore v. Swift & Co., 323 U.S. 134 (1944).

92. *See id*. at 139–40.

93. *Id.* at 140.

94. West Virginia v. EPA, No. 20–1530, slip op. at 4 (U.S. 2022) (citing FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159–60 (2000); Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 324 (2014).

agencies absent clear authority.

B. *CHEVRON* GONE: *LOPER BRIGHT V. RAIMONDO*

In June 2024, the Court overruled *Chevron* in *Loper Bright v. Raimondo*, a case in which plaintiffs challenged the National Marine Fisheries Service ("NMFS") regulation that mandated Atlantic herring fishery fund costs for required on-board observers as contrary to the statutory authorization in the Magnuson-Stevens Fishery Conservation and Management Act ("MSA").[95] Chief Justice Roberts, writing for the majority, overruled *Chevron*, citing the Framers' intention to place the final interpretation of laws within the province of the courts,[96] the Administrative Procedure Act ("APA")'s mandate that courts decide the relevant questions of law arising from agency actions,[97] the fixed meaning of statutes,[98] and an agency's lack of "special competence" in resolving statutory ambiguities.[99] Now, courts need not defer to an agency interpretation of law because of ambiguity, but instead must independently judge whether an agency acted within its statutory authority.[100]

C. THE INTERACTION BETWEEN DEFERENCE AND PREEMPTION

1. Preemption and Deference in Opioid Lawsuits

Defendants in opioid litigation are well aware of the principles of preemption and agency deference as a means to escape liability for state-law tort claims. In *City and County of San Francisco v. Purdue Pharma*, the defendants, including Purdue Pharma, argued that the Controlled Substance Act ("CSA") preempted the City of San Francisco's state law claims through implied preemption, more specifically, obstacle preemption.[101] Specifically, the defendants argued that the City's claims posed an obstacle to the objective of the CSA because under the CSA, the Drug Enforcement Agency ("DEA") had an obligation not to interfere with the lawful dispensing of prescription opioids and it was Congress's goal to foster beneficial use of opioid medications.[102]

The Court held that there was no positive conflict between the CSA and the City's claims, as the City's claims of preventing unlawful diversion of opioids were consistent with the DEA's policy statement on dispensing

95. Loper Bright Enters. v. Raimondo, No. 22–451, slip op. at 2–3 (U.S. 2024).
96. *Id.* at 7.
97. *Id.* at 14; *see also* 5 U.S.C. § 706.
98. *Loper Bright Enters.*, slip op. at 22.
99. *Id.* at 23.
100. *Id.* at 35.
101. City & Cnty. of S.F. v. Purdue Pharma L.P., 491 F. Supp. 3d 610, 662 (N.D. Cal. 2020).
102. *Id.*

controlled substances and the CSA's goals of " 'foster[ing] the beneficial use of those medications,' and ensuring 'no interference with the dispensing' of lawfully prescribed opioids."[103]

The defendants also asserted implied preemption as to the marketing claims in which the City alleged that the defendants engaged in acts that violate California's False Advertising Law ("FAL").[104] The defendants argued that the FDCA preempted such marketing claims because the City's claims were based on the idea that the defendants were falsely advertising opioids as safe and effective, yet the FDA approved opioids as safe and effective. In addition, defendants asserted that the FDA approved four of the nine alleged misrepresentations on the label.[105] Therefore, the FDCA, by way of the FDA's decision to approve opioids, preempted the City's state law allegations that opioids were not safe and effective.[106]

The district court rejected the first claim, reasoning that the safety and effectiveness of the opioids was not "crucial" to the City's state law cause of action, meaning that none of the alleged misrepresentations contradict the FDA's position that opioids were safe and effective for use.[107] Namely, the Court ruled that the nine alleged misrepresentations, which included claims that risk of addiction from chronic opioid therapy is low, were centralized around the premise that Purdue Pharma had engaged in a marketing scheme to promulgate false misrepresentations about opioid use, which was a much broader claim than a claim that opioids were not safe and effective.[108] The Court wrote, "There is no preemptive conflict between the City's state law claims and the FDCA, because federal law does not permit marketing schemes comprised of falsehoods and omissions to promote prescription drugs."[109]

The defendants also argued that the marketing and promotional materials ware consistent with FDA-approved labeling, suggesting that the FDCA preempts any challenges to the consistent marketing materials.[110] Again, the Court rejected the defendants' claim, writing that the alleged falsehoods went beyond what was consistent with FDA-approved labels.[111] Gleaning from this case, courts seem to be hesitant to accept preemption defenses when claims are premised on state law claims that exist

103. *Id.* at 663 (citing Gonzales v. Raich, 545 U.S. 1, 4 (2005)).
104. *Id.* at 665.
105. *Id.*
106. *See id.*
107. *Id.*
108. *Id.*
109. *Id.*
110. *Id*. at 666.
111. *Id*.

independently of the FDCA, as well as claims which are not dependent on specific statements made by the FDA (such as if the drug was "safe and effective").

The concepts of preemption and deference in litigation against opioid manufacturers leave many unanswered questions. For example, if a court were to find that a plaintiff's claims were premised on the safety and effectiveness of opioids, to what extent, if at all, would courts defer to the FDA's official position that these drugs were truly safe and effective, hence possibly preempting such a claim? In addition, what level of deference would a court use: without *Chevron*, could it still use *Auer*, or possibly *Skidmore*? Or would a court decide it was a major question?

These are questions that have yet to be answered and might not be very important, as plaintiffs have been successful in crafting their lawsuits against drug manufacturers to avoid implicating preemption and therefore avoiding the topic of deference.[112] Because *Chevron* has been overruled, the shift of litigation against drug manufacturers to litigation against the *FDA itself* is impending, as courts no longer must defer to the FDA's position that a drug is safe and effective, thereby giving plaintiffs a way to challenge the FDA's actions directly.

III. SAFE AND EFFECTIVE UNDER THE FDCA: DEFERRING TO THE FDA ON THE APPROVAL AND REGULATION OF OPIOIDS UNDER *CHEVRON*

A. AN OVERVIEW OF THE FDCA AND NEW DRUG APPROVAL: STATUTORY AMBIGUITY

The 1938 FDCA, titled under 21 U.S.C., created the Food and Drug Administration under 21 U.S.C. § 393, to regulate the production and sale of drugs, devices, food, and cosmetics in the United States.[113] The goal of the FDA in regulating drugs is deceptively simple: to promote and protect the public health by ensuring that "human and veterinary drugs are safe and effective."[114] However, what exactly do the words "safe and effective" mean? The FDCA, the FDA's organic statute, repeats the word safe or some version of the word safe (i.e., safety) nearly 855 times in its text, and the word effective (or effectively) 661 times, yet provides no clear definition as to what these words actually mean, beyond writing that the term safe "has

112. *See* Catherine M. Sharkey, *The Opioid Litigation: The FDA is MIA*, 124 DICK. L. REV. 669, 681 (2020).

113. *See* 21 U.S.C. § 393; *see also* AGATA DABROWSKA & SUSAN THAUL, CONG. RSCH. SERV., 7-5700, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 1 (2018).

114. 21 U.S.C. § 393(b)(2)(B).

reference to the health of man or animal."[115] Merriam-Webster Dictionary defines the word safe as "free from harm or risk;" "secure from threat of danger, harm, or loss;" or "obsolete, of mental or moral faculties."[116] Effective is defined as "producing a decided, decisive, or desired effect."[117]

One of the preliminary steps in getting a drug on the market is for the FDA to approve a new-drug application ("NDA"). The FDCA directs the FDA to deny a NDA when the applicant fails to include adequate testing that shows the result is safe and effective, the tests show that the drug is not safe and effective, when there is insufficient information that the drug is safe based on the NDA, when there is substantial evidence that the drug is consistent with its purported effects, among other provisions.[118] The FDCA further defines "substantial evidence" of a drug's effectiveness as:

> [E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.[119]

The standard for substantial evidence leaves open the question about the quantity and quality of evidence needed to establish effectiveness.[120] In fact, reading further into § 355(d)(7), Congress makes it clear that the Health Secretary should ultimately use a risk benefit framework.[121] The FDA stated that it interprets effectiveness to require "two adequate and well-controlled studies, each convincing on its own," and will also consider a single study with confirmatory evidence.[122] However, what constitutes adequate, well-controlled and confirmatory evidence will also depend on the discretion of the FDA.[123] The FDA has defined adequate well-controlled studies in their

115. *Id.* § 321(u).

116. *Safe*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/safe [https://perma.cc/7MPT-8HUK].

117. *Effective*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/effective [https://perma.cc/745H-6K2M].

118. 21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.125 (2024).

119. 21 U.S.C. § 355(d)(7).

120. U.S. DEPT. OF HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS 2–3, 6 (1998), https://www.fda.gov/media/71655/download [https://perma.cc/JVR6-V767].

121. *See* 21 U.S.C. § 355(d)(7) ("The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decision-making, and the communication of the benefits and risks of new drugs.").

122. U.S. DEPT. OF HEALTH & HUM. SERVS., *supra* note 120, at 3 (citing Final Decision on Benylin, 44 Fed. Reg. 51512, 518 (Aug. 31, 1979); Warner-Lambert Co. v. Heckler, 787 F.2d 147 (3d Cir. 1986)).

123. *Id.* at 4.

own regulations.[124] Ultimately, Congress meant for the FDCA provisions regarding NDAs to read as general guidelines allowing the FDA to fill them in through its own regulations.

The FDCA "is a purposefully broad delegation of discretionary powers, delegated by Congress,"[125] and Congress intended to rely on the FDA's expertise in filling in the details from its broad delegation.[126] In the absence of direct guidance from Congress in the FDCA as to what "safe" and "effective" actually mean in order to approve a NDA, besides the broad standard of substantial evidence, which requires some form of study, the FDA has considerable discretion to approve and deny new drugs.[127] Currently, the FDA has defined neither safety nor effectiveness in their guidance, rules, or statutes.[128] In the end, the FDA writes that approving a NDA depends on an "informed judgment" call and a "case-specific determination" for the reviewing committee to decide.[129]

B. CAN SAFE AND EFFECTIVE UNDER THE FDCA BE CHALLENGED IN THE ABSENCE OF *CHEVRON*?

When it was still good law, *Chevron* deference only applied when the organic statute was ambiguous.[130] Even though Congress intended the FDA to have broad discretion when granting NDAs, as detailed above, the language of safe and effective is ultimately ambiguous, meaning that Congress did not speak clearly on the issue, hence triggering *Chevron* deference for the FDA's drug approval process. it is likely that with *Chevron*'s fall, plaintiffs could challenge the FDA's decision-making ability. In fact, even when *Chevron* was intact, plaintiffs began to challenge the FDA's ability to approve and regulate drugs.

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124. See 21 C.F.R. § 314.126 (2024) for further requirements for adequate and well-controlled studies.

125. JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 6:1 (4th. ed. 2023).

126. *See* Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901, 902 (2008).

127. *See also* 21 U.S.C. § 355(d)(7).

128. Niskanen Ctr., Public Interest Comment on Benefit-Risk Assessments in Drug Regulatory Decision-Making, (Oct. 19, 2017), at 4, https://www.niskanencenter.org/wp-content/uploads/old_uploads/2017/10/Comments-Benefit-Risk-Assessments-FDA.pdf [https://perma.cc/KH6V-AXZH].

129. U.S. DEPT. OF HEALTH & HUM. SERVS., BENEFIT-RISK ASSESSMENT FOR NEW DRUG AND BIOLOGICAL PRODUCTS 3–4 (Oct. 2023), https://www.fda.gov/media/152544/download [https://perma.cc/C3E8-REMY]; *see also Step 4: FDA Drug Review*, FDA (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review [https://perma.cc/AU9P-QNTS].

130. *See supra* Section II.A.

C. *FDA v. Brown & Williamson Tobacco Corp.*: *Chevron* and the FDA

In *FDA v. Brown & Williamson Tobacco Corp.*, tobacco manufacturers, retailers, and advertisers, challenged the FDA's ability to regulate tobacco products.[131] More specifically, the FDA attempted to regulate sales of tobacco products to children and minors to prevent tobacco addiction.[132] This was accomplished by the 1996 rule, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," in which the FDA banned the sale of cigarettes and smokeless tobacco products to all people under eighteen years old.[133] Tobacco manufacturers, retailers, and advertisers then challenged the FDA regulations, claiming that the FDA did not have jurisdiction to regulate tobacco products and that the FDA was outside of its statutory authority.[134]

In a 5-4 opinion, Justice Kagan wrote for the majority, asserting that while tobacco could be considered a drug and cigarettes could be considered a combination of a drug and a device within the statutory authority of the FDA, the FDA ultimately could not regulate tobacco products because doing so would force the FDA to ban such products, which was contrary to Congressional intent.[135] The Court first highlighted that the statutory interpretation question of the FDCA as to whether the FDA could regulate tobacco products is governed by *Chevron* because it involved an agency construction of its organic statute.[136] However, the Court stopped at *Chevron* Step 1,[137] because it found that Congress had already spoken on the issue of whether the FDA could regulate tobacco products, and therefore the statute was not ambiguous.[138]

The Court's reasoning for denying the FDA deference stemmed from

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131. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 (2000).
132. *Id.* at 128.
133. *Id.* at 127–28.
134. *Id.* at 129–30. More specifically, the plaintiffs argued that the FDA was exceeding its authority granted by 21 U.S.C. § 360j(e), which reads:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—
> (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or
> (B) upon such other conditions as the Secretary may prescribe in such regulation,
> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360j(e).
135. *Brown & Williamson Tobacco*, 529 U.S. at 136–138.
136. *Id.* at 132.
137. See *supra* Section II.A for *Chevron* Step 1.
138. *Brown & Williamson Tobacco*, 529 U.S. at 132.

the FDA's position regarding the danger of tobacco products.[139] The FDA, after examining numerous studies and data, determined that tobacco products are "dangerous to health" (i.e., fundamentally unsafe and ineffective) when used in the manner prescribed.[140] But, the FDCA only allows products to be marketed if the FDA determines that they are safe and effective.[141] Because the FDA's position was that tobacco products were unsafe, the Court concluded that the FDA would be mandated by the text of the FDCA to ban all tobacco related products, as the FDA could not approve the sale and marketing of products under its current position that tobacco products are unsafe.[142] Banning tobacco products would be contrary to the intent of Congress, which "has foreclosed the removal of tobacco products from the market," through its various legislation.[143] Additionally, the Court referenced that Congress had considered and rejected bills in the past granting the FDA jurisdiction over tobacco.[144]

Armed with what the Court thought was clear Congressional intent against the FDA's ability to regulate tobacco products, the Court declined to defer to the FDA's position that tobacco regulation was safe within the meaning of the FDCA.[145] The FDA attempted to claim that tobacco was unsafe according to the general meaning of the word, but safe within the meaning of the FDCA because banning tobacco completely would result in extreme withdrawal symptoms for those who were addicted.[146] The Court disagreed, writing that the FDCA required that the safety and effectiveness requirement concerned only the drug or device itself, and did not concern the

139. *Id.* at 134–35.

140. *Id.*

141. *Id.* at 134–36. The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). The statute goes on to define two provisions that would make a product adulterated or misbranded, "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof" or "[u]nless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary for the protection of users." *Id.* §§ 352(j), (f)(1). Because the FDA had such a strong position regarding the danger of tobacco products, the Court concluded that the FDA could not allow tobacco products to be sold and marketed because they would be misbranded, against the FDCA. *See Brown & Williamson Tobacco*, 529 U.S. at 135–36.

142. *Id.* at 135–36.

143. *Id.* at 137. See also the six pieces of regulations Congress had promulgated concerning tobacco products, all of which stop short of a ban: Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. No. 89-92, 79 Stat. 282 (1965); Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub .L. No. 102-321, § 202, 106 Stat. 323, 394 (1992).

144. *Brown & Williamson Tobacco*, 529 U.S. at 144.

145. *Id.* at 139.

146. *Id.*

effects of banning a product from the market.[147]

D. A MODERN-DAY ANALYSIS OF *BROWN & WILLIAMSON*, EVEN WITHOUT *CHEVRON* DEFERENCE, THE COURT GRANTS CONSIDERABLE DEFERENCE TO THE FDA

Brown & Williamson's applicability to the current challenge of the FDA's ability to approve NDAs and regulate drugs on the market presents an interesting issue. The Court was only able to ignore the FDA's interpretation that tobacco was a "safe" product because the question at hand failed *Chevron* Step 1.[148] Because the Court found that Congress had specifically denied FDA's ability to regulate tobacco, Congress spoke clearly that it did not want the FDA to regulate tobacco, and therefore the Court did not owe deference to the FDA's interpretation in the case that tobacco was actually a safe product within the meaning of the FDCA.

Interestingly, however, part of the Court's reasoning was circular in and of itself. As explained above, the Court wrote that, among other provisions, that the FDCA did not allow the FDA to regulate tobacco because the FDCA would mandate the FDA to ban tobacco (as it was the FDA's position that it was unsafe), which is contrary to Congressional intent.[149] However, how did the Court determine that tobacco was unsafe to arrive at this conclusion? The Court actually, and perhaps without realizing, deferred to the FDA's position that tobacco itself was unsafe. The Court did not look to analyze studies on tobacco correlation with cancer to arrive at the position that tobacco was unsafe. Instead, it deferred to the FDA's interpretation, even quoting various FDA positions in the opinion, to conclude that tobacco as a product was unsafe.[150] Without realizing it, the Court performed a *Chevron*-like analysis on the safety and effectiveness of tobacco by deferring to the FDA's scientific position on the safety and effectiveness of tobacco.

Brown & Williamson therefore hints that the Justices do provide ample consideration to the FDA's position on the intrinsic safety and effectiveness of products, provided by the FDA's *scientific* interpretation of the product, despite rejecting the FDA's *legal* interpretation that the product was actually

147. *Id.* at 140.

148. *Id.* at 135–36.

149. *Id.* at 143.

150. It was the FDA's position that "tobacco products are unsafe, dangerous, and cause great pain and suffering from illness." *Id.* at 121. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents**,** 61 Fed. Reg. 44396, 4412 (Aug. 28, 1996). The dissent countered the majority's point by pointing out that cancer drugs are also dangerous, but the FDA would not ban them. *Brown & Williamson Tobacco*, 529 U.S. at 177 (Breyer, J. dissenting). The Court wrote in response that for certain patients the therapeutic benefits outweigh the risks of the harm, whereas "[a]s the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect." *Id.* at 142.

"safe" within the meaning of the FDCA. This notion that courts still may be able to defer to the FDA's scientific opinion on a drug, even though the courts may not owe deference to the FDA's legal position, may prove to be useful for courts who make future decisions under *Loper Bright*.

IV. THE FALL OF *CHEVRON* AND ITS EFFECT ON THE FDA'S APPROVAL OF OPIOIDS AND LIABILITY IN THE OPIOID CRISIS

A. THE FDA'S POTENTIAL LIABILITY

In *Brown & Williamson*, the Court deferred to the FDA's scientific position that tobacco products are fundamentally unsafe to determine that the FDA did not have jurisdiction to regulate tobacco. The FDA lists in 21 C.F.R § 216.24 drug products that are withdrawn or removed from the market for reasons of safety or effectiveness.[151] Many common opioids are not on that list. The FDA began approving opioids, such as morphine ("MS Contin") and ER OxyContin in the late 1980s and 1990s using the same methodology as it would approve other drugs.[152] I will focus my analysis on OxyContin, since it remains at the center of many opioid crises to this day.

The FDA only approves new drugs if they are "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling."[153] Purdue Pharma had manufactured shorter-release opioids before the release of ER OxyContin. The main selling point of OxyContin was that it would require fewer doses, which Purdue claimed would reduce the drug's potential for abuse.[154] The original label for OxyContin that garnered FDA approval emphasized this point: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug;" "iatrogenic 'addiction' to opioids legitimately used in the management of pain is very rare."[155] The 1995 OxyContin label also indicates that the drug is used for "the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days."[156] The FDA granted this approval based on six clinical trials of patients with moderate to severe pain, including cancer pain and low back

151. 21 C.F.R. § 216.24 (2024).

152. *See Opioid Approval and Monitoring by the U.S. Food and Drug Administration*, *supra* note 12.

153. 21 U.S.C. § 355(d)(1).

154. Cherkaouia Kibaly, Jacob A. Alderete, Steven H. Liu, Hazem S. Nasef, Ping-Yee Law, Christopher J. Evans & Catherine M. Cahill, *Oxycodone in the Opioid Epidemic: High 'Liking', 'Wanting', and Abuse Liability*, 41 CELLULAR & MOLECULAR NEUROBIOLOGY 899, 903 (2021).

155. *1995 OxyContin Label*, JUDGE FOR YOURSELVES, https://www.judgeforyourselves.info/wp-content/uploads/2021/04/1995-OxyContin-label-1.pdf [https://perma.cc/7XRZ-B6XE]; *see also* Purdue Pharma L.P. v. Kentucky, 704 F.3d 208, 211 (2d Cir. 2013).

156. *1995 OxyContin Label*, *supra* note 155.

pain.[157] A 2003 study by the Government Accountability Office ("GAO") wrote that the FDA was led to believe that the controlled-release formulation of OxyContin would reduce the potential for abuse, hence why it approved the language on the label.[158] The FDA, though including a label warning against crushing up OxyContin, apparently did not recognize that OxyContin could also be dissolved in water and injected.[159] Whether or not the FDA properly approved OxyContin under the FDCA is up for debate.[160] Yet, under the statutory framework analyzed above, which grants the FDA considerable discretion in approving which drugs are safe and effective, the FDA seemed to properly adhere to the text of the FDCA because it based its decision on the FDCA's required risk-benefit analysis and also grounded its approval of OxyContin in clinical trials.[161]

After OxyContin's FDA approval, however, abuse of the drug became rampant. Part of the reason for the widespread abuse was due to OxyContin's aggressive marketing tactics, which included targeting physicians to prescribe OxyContin for noncancer pain and encouraging physicians to prescribe higher doses.[162] The FDA in response, as obligated by their duties under the FDCA to prevent misleading labeling and advertising, placed a black-box level label (the highest level of warning) on OxyContin.[163]

B. THE FALL OF *CHEVRON* AND ITS IMPACT ON LITIGATION AGAINST THE FDA

As covered in Section II,[164] drug manufacturers' defense that plaintiffs' claims are preempted because of the FDA's position that opioids are safe and effective does not seem to merit much deference in court. Claims that drug

157. Letter from Janet Woodcock, *supra* note 13.

158. U.S. GOV'T ACCOUNTABILITY OFF., GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM 9 (2003).

159. *Id.*

160. *See* Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS 743, 744–45 (2020) (arguing that the FDA did not properly enforce the FDCA under OxyContin's labeling because the FDA approved a label that was too broad).

161. See 21 U.S.C. § 355 for the specific requirements indicated by the FDCA for approval of new drugs.

162. Kibaly et al., *supra* note 154, at 903–04; *see also* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 158, at 4, 6–7.

163. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 158, at 34. *See also* 21 C.F.R. § 314.80 (2024) for the requirement of post marketing reporting of adverse drug experiences. The FDA has multiple avenues for reporting dangers in drugs after approval, including the FDA Adverse Event Reporting System, the MedWatch program, and mandatory reporting of adverse events. *Postmarketing Surveillance Programs*, FDA (Apr. 2, 2020), https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs [https://perma.cc/NFX3-LQDG]. The FDA also monitors prescription drug advertising to ensure that labels and promotional materials adhere to the general text at the time of approval. *See* 21 C.F.R. § 202 (2024); *see also* 21 U.S.C. § 352 (granting the FDA broad latitude to monitor false or misleading labels).

164. *See supra* Section II.

companies lawfully marketed and sold opioids because the FDA approved them as safe and effective only succeed if the company can show "clear evidence" that they informed the FDA of the reasons for labeling changes and the FDA would not approve it. However, without *Chevron*, plaintiffs no longer need to worry about preemption defenses. Instead, plaintiffs can simply allege that a drug itself is not safe and effective within the meaning of those words, and courts do not have to defer to the FDA's position on safety and effectiveness even with the ambiguity in what safe and effective means.

The ramifications of the fall of *Chevron* potentially destroy the ability of defendants in opioid suits to craft preemption arguments. The usual defense for drug companies entails some sort of preemption argument, like the argument used in *City & County of San Francisco*, in which the defendants argued that that the state law claims for failure to warn or misleading advertising were preempted by federal law because the companies were simply promoting a drug that the FDA has already deemed safe and effective.[165] Now, courts will no longer have to defer to the FDA's position on safety and effectiveness.[166] However, this may not actually have much of a practical effect. As explained in Section II, the courts that have addressed preemption arguments in opioid litigation cases are more likely to dispense of the preemption defense, often due to the specific way in which plaintiffs allege that defendants violate state law.[167]

I predict, therefore, that we will only see a small uptick in the amount of litigation against drug manufacturers, and in turn, a small decrease in the use of preemption defenses by drug companies. Instead, however, the demise of *Chevron* threatens the very premise of FDA decision-making completely because courts will no longer have to defer to the FDA's expertise for drug approval. Ultimately, this could mean a large increase in the amount of litigation challenging FDA approval of not only opioids, but also other prescription drugs, which would place courts in the decision-making seat for drug approval.

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165. *See* City & Cnty. of S.F. v. Purdue Pharma L.P., 491 F. Supp. 3d 610, 665 (N.D. Cal. 2020); *In re* Nat'l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1380 (J.P.M.L. 2017).

166. *See supra* Section III.

167. See Sharkey, *supra* note 112, at 681 for a discussion on why courts have avoided invoking federal preemption in opioid lawsuits:

> One explanation is that plaintiffs have strategically framed their causes of action so as to avoid federal preemption, and courts have narrowly construed the domain of federal preemption to apply to failure-to-warn (and design defect) product liability claims. In other words, where courts have addressed the federal preemption defense, the brevity of their discussion is a function of their finding that the bulk of claims fall outside the scope of the preemption defense.

1. Changes in Deference in the Prescription Drug Landscape: *Alliance for Hippocratic Medicine v. FDA*

Courts have long deferred to the FDA's interpretation of prescription drugs under the FDCA, often only reviewing the FDA's actions under the arbitrary and capricious standard of review.[168] However, in recent years, especially after *Dobbs*,[169] courts have been less likely to defer to agency positions. In *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*,[170] the plaintiffs challenged FDA approval of the drug mifepristone—which induces chemical abortions under various claims, including that the FDA violated the FDCA because of its approval of mifepristone.[171] Specifically, the plaintiffs alleged that the FDA violated the FDCA when it approved mifepristone to be used under conditions that were not consistent with the exact protocols implemented during clinical trials.[172] The FDCA mandates that the FDA must deny a NDA if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,"[173] and if "the results of such tests show that such drug is unsafe for use under such conditions."[174] Because the plaintiffs alleged that procedures used in clinical trials, such as requiring a woman to receive an ultrasound to exclude an ectopic pregnancy, were not conditions mandated for use in the FDA's approval of mifepristone, the FDA's approach conflicted with the requirements of the FDCA and defied sound scientific policy.

The Fifth Circuit agreed with the district court's reasoning that the FDA's actions were not the product of reasoned decision-making,[175] expanding on the district court's holding by clarifying that because the FDA did not base their decision to loosen mifepristone safety protocols on studies

168. *See, e.g.*, Novartis Pharm. Corp. v. Leavitt, 435 F.3d 344, 349, 352 (D.C. Cir. 2006) (deferring to the FDA's interpretation of 21 U.S.C. § 352(e) that the FDA could designate an interim name and citing Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 883 (D.C. Cir. 2004)); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 (D.C. Cir. 1998) (for the proposition that courts defer to the FDA for interpretation of the FDCA); *see also* U.S. v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 397 (E.D. N.Y. 1995), *aff'd*, 72 F.3d 285 (2d Cir. 1995) (holding that "food" in the FDCA 21 U.S.C. § 321(g)(1)(C) and 321(f)(1) is ambiguous and because Congress had not spoken on whether a nasal gel is a food, the Court defers to the FDA's interpretation).

169. *See* Dobbs v. Jackson Women's Health Org., No. 19–1392, slip op. at 49–50 (U.S. 2022).

170. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507 (N.D. Tex. 2023), *aff'd in part, vacated in part*, 78 F.4th 210 (5th Cir. 2023), *cert. granted sub nom.* Food & Drug Admin. v. All. for Hippocratic Med., 217 L. Ed. 2d 285 (Dec. 13, 2023), *cert. granted sub nom.* FDA v. All. for Hippocratic Med., 217 L. Ed. 2d 285 (Dec. 13, 2023).

171. Plaintiffs' Reply Brief in Support of Their Motion for Preliminary Injunction at 17, All. for Hippocratic Med. v. FDA, No. 2:22-cv-00223-Z (N.D. Tex. 2023).

172. *Id.* at 18.

173. 21 U.S.C. § 355(d).

174. *Id.*

175. *All. for Hippocratic Med.*, 78 F.4th 210, 246 (5th Cir. 2023).

that show the cumulative effect of loosening those protocols on mifepristone's safety and effectiveness, the FDA's actions were arbitrary and capricious.[176] In effect, the Fifth Circuit second-guessed the FDA's determination that mifepristone was still safe and effective by refusing to defer to the FDA's expertise that mifepristone was still safe and effective, instead scrutinizing the FDA's evidence behind its position..[177] Although the Supreme Court granted certiorari, the case was dismissed on standing grounds, leaving the question as to whether the Court would side with the FDA open.[178]

Alliance for Hippocratic Medicine is significant because it exhibited the ability for courts to use procedural grounds—the arbitrary and capricious standard of review—to bypass deference to the FDA to instead look to whether the FDA provided adequate rationale to make a reasoned decision.[179] The FDA claimed that it routinely approved drugs with conditions of use that differ from clinical trial protocols and that the agency based its decision to approve mifepristone on their scientific discretion.[180] Both the district court and the Fifth Circuit used arbitrary and capricious review to scrutinize the FDA's actions, holding that the discrepancy between clinical trial conditions and conditions for use when mifepristone entered the market was *not* a product of reasoned decision-making.[181] In addition, both courts ruled that by not accounting for the differences, the FDA failed to consider an important part of the problem with the drug mifepristone.[182] The courts, by effectuating arbitrary and capricious review, decided the case solely on what *the courts* thought reasoned decision-making should result in and ruled that the FDA's scientific discretion was not enough to amount to the approval of mifepristone.[183] By doing so, the courts effectively undermined the FDA's scientific decision-making abilities on what is safe and effective. Therefore, even before *Chevron* was fully overruled, courts curtailed the concept of deference under arbitrary and capricious review.

However, the absence of *Chevron* threatens administrative decisions

176. *Id.*
177. *See id.*
178. FDA v. All. for Hippocratic Med., No. 23–235, slip op. 2 (U.S. 2024).
179. *Id.*
180. Reply Brief for the Federal Petitioners at 41–43, All. for Hippocratic Med. v. FDA, No. 23-10362 (5th Cir. 2023).
181. *All. for Hippocratic Med.*, 78 F.4th at 246; *All. for Hippocratic Med.*, 668 F. Supp. 3d 556 (N.D. Tex. 2023).
182. *All. for Hippocratic Med.*, 668 F. Supp at 550; *All. for Hippocratic Med.*, 78 F.4th at 246 ("The cumulative effect of the 2016 Amendments is unquestionably an important aspect of the problem; indeed, that was the whole point of FDA's action. Because FDA failed to seek data on the cumulative effect, and failed to explain why it did not, its decision to approve the amendments was likely arbitrary and capricious.").
183. *All. for Hippocratic Med.*, 668 F. Supp at 556; *All. for Hippocratic Med.*, 78 F.4th at 246.

even beyond those that are arbitrary and capricious. Now, judges do not have to defer to even the most reasoned decisions. It is no secret that the FDA has been subject to scrutiny in the past regarding its regulatory decisions.[184] A simple Google search reveals the FDA's failures—from failing to implement safety standards for spinach growth,[185] to failing to respond to complaints about contamination in breathing machines,[186] to relying on manipulated or mishandled data in approving a drug for a rare childhood condition[187]—the FDA has been far from perfect in its ability to regulate food, drugs, and devices. The demise of *Chevron* will only place further pressure on the FDA, as litigants can challenge the very basis of what makes a drug "safe" and "effective." There are of course pros and cons to this approach. On one hand, as explained in the Introduction, the opioid crisis caused and continues to cause millions of deaths, in part because of the FDA's approval of the broad labeling of OxyContin, coupled with the FDA's inability to monitor and respond to Purdue Pharma's misleading advertising.[188] On the other hand, the FDA, using the available evidence and its scientific discretion, did approve OxyContin because opioids are effective for pain management for certain patients. This was not like *Brown & Williamson*, in which the FDA believed that there were no therapeutic benefits to the drug at hand, rather, opioids are documented to alleviate pain. There have already been plenty of lawsuits that have held companies liable for their failure-to-warn and misleading marketing, therefore, if courts second-guess the FDA's expertise, the demise of *Chevron* could lead to circuit splits, or even the removal of

184. *See, e.g.*, Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 957 (2007); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 492–95 (2008).

185. Helena Bottemiller Evich, *The FDA's Food Failure*, POLITICO (Apr. 8, 2022, 05:00 AM), https://politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards [https://perma.cc/MMF6-RH5V].

186. Debbie Cenziper, Michael D. Sallah & Michael Korsh, *Millions of People Used Tainted Breathing Machines. The FDA Failed to Use Its Power to Protect Them.*, PROPUBLICA (Dec. 7, 2023, 5:30 AM), https://www.propublica.org/article/how-the-fda-failed-to-protect-millions-of-people-tainted-breathing-machines [https://perma.cc/LC9A-XR6F].

187. The Editorial Board, Opinion, *This Drug Will Save Children's Lives. It Costs $2 Million.*, N.Y. TIMES (Aug. 13, 2019), https://www.nytimes.com/2019/08/13/opinion/novartis-drug-cost.html [https://perma.cc/3ELV-GZHJ].

188. The FDA is responsible for monitoring false and misleading advertising for prescription drugs and does so via 21 U.S.C. §§ 351, 352 (21 C.F.R. § 202 (2024)). The FDA released "warning letters" to Purdue Pharma related to the misleading advertisements, such as leaving out serious safety risks and promoting it for uses beyond FDA approval. *Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention*, FDA (July 10, 2024), https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose [https://perma.cc/F3T6-THUG]. Although the Food and Drug Administration Amendments Act (FDAAA), passed in 2007, authorized the FDA to "*order* labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of the drug", the FDA did not do so. U.S. DEPT. OF HEALTH AND HUM. SERVS., GUIDANCE FOR INDUSTRY: SAFETY LABELING CHANGES—IMPLEMENTATION OF SECTION 505(O)(4) OF THE FD&C ACT 3 (2013), https://www.fda.gov/media/116594/download [https://perma.cc/N2P4-F8EC].

opioid products from the market.

C. FOUR EFFECTS ON THE FDA AND THE OPIOID CRISIS DUE TO THE FALL OF *CHEVRON*

For the purposes of this Note, I will focus on the effects of the overruling of *Chevron* on the FDA and the opioid crisis in particular.[189] The opioid crisis is unique in that the litigation against opioid manufacturers has been so successful that the overturning of *Chevron* will not floodgate litigation against the companies themselves, as those doors have already been opened.[190] Preemption defenses related to the FDA simply are less likely to succeed in opioid litigation, meaning that courts do not have to defer to any federal agency interpretation and can focus on liability for opioid manufacturers under state law claims.[191] Therefore, the fall of *Chevron* will not have a major effect on increasing the number of lawsuits against opioid manufacturers. Rather, overturning *Chevron* shifts the burden of litigation from drug companies, like Purdue Pharma, to the FDA itself. This effect will be noticeable and pronounced.

1. Circuit Split

One of the effects overruling *Chevron* will have on opioid litigation will be circuit splits throughout the nation. Some courts will be persuaded by opioids' ability to help those in severe pain, while others will be deterred by the chronic opioid addiction that has plagued the nation. This may lead to certain states allowing the FDA approval of opioids to stand, whereas in others states where opioids are not deemed safe and effective, opioids will be removed from distribution. This has occurred in the past: for example, courts have split on whether to apply *Chevron* deference to major issues, which results in different substantive outcomes in each of the respective courts.[192] However, in general, circuit courts have adhered to premises of *Chevron*, especially for relatively straightforward issues. Deference to the FDA to determine safety and effectiveness is a mostly straightforward issue; "[t]he FDA is the agency charged with implementing the Food, Drug and

189. *See, e.g.*, Christopher J. Walker, *Attacking* Auer *and* Chevron *Deference: A Literature Review*, 16 GEO. J.L. & PUB. POL'Y 103, 112–15 (2018).

190. *See supra* Section II.

191. *Id.*

192. See, e.g., Scenic America, Inc. v. U.S. Dep't of Transp., 836 F.3d 42, 56–57 (D.C. Cir. 2016); contra Meadow Green-Wildcat Corp. v. Hathaway, 936 F.2d 601, 604–05 (1st Cir. 1991) for a circuit split related to whether an agency's interpretation of a contract merits *Chevron*'s deference; Ibarra v. Holder, 736 F.3d 903, 918 (10th Cir. 2013), contra Florez v. Holder, 779 F.3d 207, 213 (2d Cir. 2015); Mondragon-Gonzalez v. U.S. Att'y Gen., 884 F.3d 155, 159 (3d Cir. 2018) for whether the Board of Immigrant Appeals' interpretation of the crime of child abuse under the Immigration and Nationality Act is entitled to *Chevron* deference. *See also* Jennifer Safstrom, *An Analysis of the Applications and Implications of* Chevron *Deference in Immigration*, 34 GEO. IMMIGR. L.J. 53, 55 (2019).

Cosmetic Act as amended. Its judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us." [193]

Since the FDA's discretion to decide safety and effectiveness has been relatively uncontested, the fall of *Chevron* will have a major shock on the national regulation of prescription drugs. No longer will the FDA be able to monitor the safety and effectiveness of prescription drugs nationally. In the extreme, we may return to a pre-FDA world, in which drugs are not centrally monitored, operating instead on a buyer beware model or relying on state law to fill in the gaps. In a more likely scenario, the FDA's approval of a drug would only be challenged if a litigant decides to challenge the approval in court, leading to prevalent circuit splits about a drug's safety and effectiveness. For example, imagine that a plaintiff brings suit against the FDA in the Third Circuit and the Third Circuit rules against FDA approval, but a different plaintiff brings a similar suit in the Fourth Circuit, and the Fourth Circuit rules in favor of the FDA. This will create two different precedents on opioids that impact a person's access to the drug in neighboring states. This uncertainty in a drug's safety promulgated by the circuit splits may ultimately lead to less confidence from the American public in the drug itself.

2. The FDA Loses Its Flexibility to Determine Safety and Effectiveness as Science Progresses

As Justice Scalia expressed in his 1989 speech, *Judicial Deference to Administrative Interpretations of Law*, when courts solve ambiguities, they solve them "for ever and ever" with only statutory amendments changing or clarifying meaning.[194] When courts decide issues of agency statutory interpretation, agencies, like the FDA, will lose the ability to interpret the safety and effectiveness of new drugs considering new scientific evidence. For example, if a court rules that there is evidence that opioids are not safe and effective because of the FDA's failure to mandate that the drug be used under its clinical study conditions (like in the mifepristone case), yet later new scientific evidence indicates that opioids are safe and effective when used in conjunction with X product even in spite of the FDA's failure to mandate use under the clinical study conditions, a court would have trouble overruling its original holding in light of that new evidence. This is because a court would have already made an initial determination of what the FDCA mandates to approve a new drug—that is, that the drug must be used in real life under the same clinical study conditions in order to be safe and

193. Schering Corp. v. FDA, 51 F.3d 390, 399 (3rd Cir. 1995).

194. Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 517–18 (1989).

effective.[195] The bottom line is that if opioids were not used post-approval under those same clinical conditions, opioids do not meet the statutory criteria for drug approval.

Contrast that with the approach of the FDA, in which "safe and effective" under the FDCA has a range of interpretations. Under what was *Chevron*, the FDA had the statutory authority to consider new evidence and make new determinations about the safety and effectiveness of drugs as long as the interpretation was reasonable, which meant it could respond to new scientific evidence that would show that the drug is still safe and effective when used with X product, despite not being used under the same conditions as in the clinical trials. Ultimately, the FDA now loses its flexibility as an agency to respond to new scientific evidence because it no longer enjoys deference to its decision-making skills about the nature of safety and effectiveness.

3. The FDA May Be Forced to Become More Transparent

Without *Chevron*, the FDA will be forced to become more transparent and thorough about why and how it takes certain actions. As indicated in *Alliance for Hippocratic Medicine*, the courts hint that the FDA cannot ignore a large part of the problem by failing to account for important data to base decisions on.[196] If the FDA recognizes that courts will be more critical of its decision-making, the FDA may be forced to become more transparent and thorough about its reasoning in taking certain actions, such as explaining the scientific justification and benefit of keeping opioids on the market, despite growing evidence that the drug was deceptively marketed. It also may force the FDA to take more accountability in its stamp of approval by compelling the FDA to pay closer attention to drug companies' actions post-approval. This of course assumes that the FDA will obtain more resources to sift through thousands of opioid advertisements to control the narrative behind the drug.[197] The goal of FDA transparency will have to be accompanied by an increase in appropriation of funding—in past years, Congress has increased the FDA's regulatory responsibilities but has failed to increase necessary appropriation.[198]

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195. This point assumes courts would follow the logic in *Alliance for Hippocratic Medicine*. *See All. for Hippocratic Med.*, 78 F.4th 210 (2023).

196. *All. for Hippocratic Med.*, 78 F.4th at 247.

197. The FDA only had thirty-nine staff to review Purdue Pharma's thirty-four thousand promotional packages and failed to review a video advertisement, which was only reviewed by the FDA after the General Accounting Office ("GAO") indicated its importance in Purdue Pharma's false advertisements. Ronald Chow, *Purdue Pharma and OxyContin – A Commercial Success but a Public Health Disaster*, 25 HARV. PUB. HEALTH REV. 1, 3 (2019).

198. David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? - A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 998–99 (2008).

4. Courts Will Continue to Scrutinize Through Statutory Interpretation

Even before the Justices decided *Loper Bright*, the Supreme Court indicated its desire to limit *Chevron* by enforcing a more stringent Step 1 of the test. *Chevron* only applies if the statute is ambiguous, meaning that the Court finds that Congress has not directly spoken on the issue at hand. The Court has been hesitant to move past Step 1, if at all, by applying more strict tools of statutory interpretation at Step 1 to find that the "statute is not ambiguous."[199] This was the approach used by both the district court and the Fifth Circuit in *Alliance for Hippocratic Medicine*; by using the "arbitrary and capricious" form of judicial review, the Court was able to sidestep deference and instead focus on examining an agency's decision-making and data.[200] With the advent of the "major questions doctrine," in *West Virginia v. EPA*, the Court also can simply ignore deference using the doctrine because in cases of high economic and political significance, the Court will assume that Congress did not mean to delegate interpretation powers to the agency absent clear Congressional authority.[201] The effect of the absence of *Chevron* thus may simply add to the list of legal doctrines that allow courts to perform judicial review of agency decisions without deference.

CONCLUSION

The prescription drug litigation landscape, more specifically the opioid litigation landscape, is about to undergo a major change because of the overruling of *Chevron*. Although the amount of litigation against drug manufacturers may remain stagnant because of the hard-to-meet standard of federal preemption under the FDCA and plaintiffs' successes in crafting arguments that avoid the Court's invocation of preemption, the FDA will most likely experience a floodgate of litigation against itself. This is because courts will no longer have to defer to the FDA's position on a drug's safety and effectiveness, giving plaintiffs an avenue to challenge drug approval. One illustration of this effect is the potential lawsuits against the FDA for its approval of prescription opioids, which has caused hundreds of thousands of deaths in America. The fall of *Chevron* will most likely have four long-term effects on FDA decision-making and the opioid crisis: circuit splits on whether the drug is safe and effective; the FDA will be unable to respond to the crisis in light of new scientific progression; the FDA will be forced to pay closer attention to the crisis and become more transparent about its drug

199. *See* Chad Landmon, Alexander Alfano & Michelle Divelbiss, *Open the Floodgates: The Potential Impact on Litigation Against FDA If the Supreme Court Reverses or Curtails* Chevron *Deference*, 74 FOOD & DRUG L.J. 358, 363 (2019) (citing Barnhart v. Sigmon Coal Co., 534 U.S. 438 (2002)).

200. *See supra* Section IV.B.1.

201. *West Virginia*, slip op. at 18–20.

approval process; and lastly, a clearer pathway will be developed for courts to scrutinize FDA decisions on drugs, like opioids. Are we ready for it?