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Not So Juris-prudent: The Misguided Movement to Abandon Chevron Deference Through the Lens of Mifepristone and the Attacks on FDA Autonomy

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Introduction

Since its establishment in 1906, the U.S. Food and Drug Administration (FDA) has continuously worked to safeguard public health.[1] While FDA and drug technology have come a long way since then, FDA's core mission of promoting the safety and efficacy of drugs has not wavered.[2] Years of medical innovation and testing culminated in FDA's 2000 approval of Mifiprex, the name-brand for mifepristone.[3] Originally known as RU-486, this drug was approved for use to terminate pregnancy by blocking the hormone progesterone, which is needed

[1] *When and why was FDA formed?*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/about-fda/fda-basics/when-and-why-was-fda-formed (last visited June 17, 2023).

[2] *What we do*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/about-fda/what-we-do (last visited June 17, 2023).

[3] *See Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last visited June 17, 2023) [hereinafter FDA Questions and Answers].

for pregnancy to continue.[4] Combined with misoprostol, which triggers contractions, the two-drug regimen effectively terminates pregnancy and expels it from the uterus.[5]

Eventually, FDA recommended approval of Mifeprex, and despite legal and manufacturing problems that delayed the process, it was officially approved on September 28, 2000.[6] As part of its approval, mifepristone was authorized under Subpart H protocol, which

[4] *Id.*; *The History of Mifepristone* REPRODUCTIVE HEALTH ACCESS PROJECT (Apr. 18, 2022), https://www.reproductiveaccess.org/2023/04/history-of-mifepristone/ [hereinafter History of Mifepristone].

[5] *The Facts on Mifepristone*, PLANNED PARENTHOOD (2019), https://www.plannedparenthood.org/uploads/filer_public/42/8a/428ab2ad-3798-4e3d-8a9f-213203f0af65/191011-the-facts-on-mifepristone-d01.pdf.

[6] History of Mifepristone, *supra* note 4.

allowed FDA to restrict distribution and add safety restrictions.[7] As of February 2022, medication abortion accounts for 54% of all abortions in the United States.[8]

The enabling force behind these decades of FDA development and autonomy is the previously protected *Chevron* doctrine.[9] Stemming from its namesake case, *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,[10] the *Chevron* doctrine expounds on the principle of agency deference, illuminating when and how such autonomy is invoked.[11] *Chevron* deference is broken down into a two-part test that asks, first, if Congress has either spoken on or addressed

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[7] *See Accelerated and Restricted Approvals Under Subpart H (drugs) and Subpart E (biologics)*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/accelerated-and-restricted-approvals-under-subpart-h-drugs-and-subpart-e-biologics (last visited June 17, 2023); 21 CFR § 314.520; U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 14 (2008) [hereinafter GAO Report].

[8] *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INSTITUTE (February 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

[9] *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 and Drug Law Journal, no. 3, at 359–60 [hereinafter *Open the Floodgates*] (noting how *Chevron* deference has protected FDA's rules from successful challenges).

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

[11] *See id.*

the issue directly.[12] If Congress is "silent or ambiguous," the inquiry then turns to the agency's interpretation and whether it is reasonable.[13] Most importantly, a proper application of *Chevron* precludes a court from applying its own interpretation in place of the agency's reasonable judgement.[14] This fundamental pillar of deference is exactly what the mifepristone cases, and numerous other judicial challenges to agencies, are poised to destroy.[15]

There are currently four primary cases, all in different geographical locations and judicial circuits, that have mifepristone access and FDA deference at the forefront.[16] The rulings of

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[12] Benjamin M. Barczewski, CONG. RSCH. SERV., R44954, *CHEVRON* DEFERENCE: A PRIMER 2 (2023) [hereinafter *Chevron* Primer].

[13] *Id*.

[14] *Id.* at 12; Young v. Cmty. Nutrition Inst., 476 U.S. 974, 981 (1986).

[15] *See id.* at 17; *Open the Floodgates*, *supra* note 9, at 369. *See generally* Christina Jewett and Pam Belluck, *Abortion Ruling Could Undermine the F.D.A.'s Drug-Approval Authority*, N.Y. TIMES (Apr. 10, 2023), https://www.nytimes.com/2023/04/10/health/abortion-pill-fda.html; *Beltway Bulletin: West Virginia v. EPA— Will Chevron Go the Way of the Dinosaurs?*, FEDERAL BAR ASSOCIATION (Oct. 26, 2022), https://www.fedbar.org/blog/beltway-bulletin-west-virginia-v-epa-will-chevron-go-the-way-of-the-dinosaurs/; Josh Gerstein and Alex Guillén, *Supreme Court move could spell doom for power of federal regulators*, POLITICO (May 1, 2023), https://www.politico.com/news/2023/05/01/supreme-court-chevron-doctrine-climate-change-00094670.

[16] CONG. RSCH. SERV., LSB10919, MEDICATION ABORTION: NEW LITIGATION MAY AFFECT ACCESS 2 (2023) [hereinafter CRS New Litigation].

Alliance for Hippocratic Medicine v. FDA and *Washington v. FDA* are fundamentally incompatible as they each direct diametrically opposing actions from FDA, which means that the Supreme Court is forced to step in and issue its own opinion.[17] The issue lies within *Alliance for Hippocratic Medicine*, where the recent appeals decision affirmed plaintiffs' ask to reinstate the pre-2016 REMS, contrary to FDA's own repeal of those measures and repeated safety assessments in coming to that decision.[18]

Comparable to the anti-*Chevron* approach in the mifepristone cases, there have been several similar efforts against other agencies with the same goal of undermining deference and autonomy. In 2022, the Court heard *West Virginia v. EPA*, which examined the major questions doctrine (MQD) and its use.[19] While the new formula for application and interpretation of MQD

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[17] On April 14, 2023, the Supreme Court responded to the Fifth Circuit's ruling by issuing an administrative stay. FDA v. All. for Hippocratic Med., 215 L.Ed.2d 646 (U.S. 2023). *See* Washington v. FDA, No. 1:23-CV-3026-TOR, 2023 WL 2825861, at *6 (E.D. Wash. Apr. 7, 2023). *But see* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026, at *32 (5th Cir. Aug. 16, 2023).

[18] The appeals decision upheld the lower court ruling on all claims except for the request to pull mifepristone from the market entirely because of its 2000 approval, since the claim is no longer timely. *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 5266026, at *32 (5th Cir. Aug. 16, 2023). *But see* GAO Report, *supra* note 7; FDA Questions and Answers, *supra* note 3.

[19] *West Virginia v. EPA*, 142 S. Ct. 2587, 2614 (2022); Natasha Brunstein & Donald L. R. Goodson, *Unheralded and Transformative: The Test for Major Questions after West Virginia*, 1 WM. & MARY ENV'T L. & POL'Y REV. 47, 73–74 (2022); *The major questions doctrine post-West*

was not clarified in the majority opinion, some of the key takeaways for the future of agency authority lie within Justice Gorsuch's concurrence: political significance, substantial economic impact, or domains of state law can trigger MQD.[20]

Overall, the cases and state regulations attacking executive agencies by disregarding *Chevron* deference are dangerous for scientific development, public health, and safety because losing formal prioritization of experts' voices allows a single judge to dictate agency direction.[21] This Comment analyzes the current threats to *Chevron* with a focus on attacks on FDA and presents several specific avenues for solutions to this encroachment on agency authority. First, FDA has a variety of options to both emphasize its own authority in the face of judicial and state challenges to mifepristone while also using these avenues to protect access to the medication in question.[22] Particularly in light of the constant wave of attacks to reproductive freedom, only FDA, as an objective, expert agency, must be responsible for keeping mifepristone on the market, or exploring alternative means to preserve medication abortion. Second, executive

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Virginia v. EPA, AMERICAN BAR ASSOCIATION (Jan. 3, 2023), https://www.americanbar.org/groups/environment_energy_resources/publications/trends/2022-2023/january-february-2023/the-major-questions-doctrine/ [hereinafter *post-West Virginia*].

[20] West Virginia v. EPA, 142 S. Ct. 2587, 2621 (2022); *post-West Virginia*, *supra* note 19.

[21] *See generally What Happens If the Supreme Court Ends "Chevron Deference"?*, NRDC (June 21, 2023), https://www.nrdc.org/stories/what-happens-if-supreme-court-ends-chevron-deference [hereinafter NRDC].

[22] Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984); 21 C.F.R. § 10.115(a); 21 C.F.R. § 310.200(b).

agencies must utilize all tools at their discretion to strength agency deference outside of *Chevron* and out of the scope of judicial review. As part of their discretion as agencies under *Chevron*, they are entitled to autonomy and authority free from judicial or political intermeddling. Therefore, the Executive branch must work to reinforce and protect the significance of its agencies from the polemics against the precedent agencies depend upon.

Part I of this Comment analyzes the numerous mifepristone cases and their implications for the role of FDA on drug approvals and access to medication abortion.[23] Part II further investigates current and impeding challenges to *Chevron* across agencies, as part of the growing movement to eradicate *Chevron* and trample agency autonomy.[24] Part III discusses the enormous, far-reaching impacts that losing agency deference would have on FDA as a whole, as well as on access to medication abortion.[25] Part IV explores recommendations for both securing medication abortion through alternative measures and for enforcing agency deference within the Executive branch's own authority.[26]

I. MIFEPRISTONE AND FDA: A MICROCOSM OF ATTACKS ON DEFERENCE

A. Mifepristone From Past to Present

Even prior to mifepristone's official approval by FDA in 2000, the United States drug market demonstrated great opposition to mainstream medication abortion.[27] Much of this

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[23] *See infra* Part I.

[24] *See infra* Part II.

[25] *See infra* Part III.

[26] *See infra* Part IV.

[27] *See generally* History of Mifepristone, *supra* note 4.

hesitation was influenced by vocal social and political opposition, echoing the current movements behind the attempted backpedaling of mifepristone.[28] Despite being approved for use in France in 1988, and later in China, the United Kingdom, and Sweden, the United States stood in steadfast opposition to any consideration of or research on mifepristone.[29] Eventually, after President Clinton's inauguration in 1993, he directed the Department of Health and Human Services (HHS) to research mifepristone for medication abortion, ultimately spurring FDA's approval process.[30]

FDA's eventual approval of mifepristone was not the end of its tumultuous journey, as it was still strongly condemned in the public eye and was therefore politically suspect as well.[31]

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[28] *See* Thomas Fitton, *A Judicial Watch Special Report: The Clinton RU-486 Files*, JUDICIAL WATCH 1, 3 (Apr. 26, 2006), https://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf [hereinafter Judicial Watch Report] (alleging that President Clinton illicitly forced HHS and FDA into approving mifepristone); Lars Noah, *A Miscarriage in the Drug Approval Process: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 571-73, 603 (2001) (suggesting impropriety in mifepristone's approval process); *see generally* Alanna Durkin Richer and Lindsay Whitehurst, *Abortion pill order latest contentious ruling by Texas judge,* AP NEWS (Apr. 8, 2023), https://apnews.com/article/texas-judge-matthew-kacsmaryk-abortion-pill-fda-75964b777ef09593a1ad948c6cfc0237 (about politically-charged judge and appointment).

[29] *See* History of Mifepristone, *supra* note 4.

[30] *See id.*

[31] *See, e.g.,* Judicial Watch Report, *supra* note 28.

Despite having undergone an uncharacteristically rigorous approval process,[32] mifepristone was and has continually been over-scrutinized because of its use in abortive healthcare.[33] Specifically, the 2006 House Hearing encompasses the fiercely contested, partisan attitudes on mainstream medication, where ideological beliefs are touted in place of scientific study.[34] The partisan rhetoric from the Hearing transcript encapsulates just how starkly divided American society is over reproductive healthcare measures, which still persists to this day.[35] During the hearing, the Republican representatives, who identified themselves in the transcript as "pro-life," expressed views that mifepristone was "forced through the FDA" and was fatal to women's health.[36] These claims were refuted both by the hearing statement from Janet Woodcock, the

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[32] *RU-486: DEMONSTRATING A LOW STANDARD FOR WOMEN'S HEALTH?: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources of the H. Comm. on Government Reform*, 109th Cong. (2006) [hereinafter *Hearings*] (statement of Rep. Cummings, Member, H. Comm. on Government Reform) (describing mifepristone's approval process as "thorough and unusually lengthy.").

[33] *Id*.; Lars Noah, *A Miscarriage in the Drug Approval Process: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 603 (2001).

[34] *Hearings*, *supra* note 32.

[35] *See id.*

[36] *Id.* (statement of Rep. Souder, Chairman, H. Comm. on Government Reform) ("…FDA's imposition of Subpart H was unlawful, unnecessary, and undesirable. But that did not deter the FDA in its extraordinary political complicity with President Clinton's administration from forcing an abortion pill onto the market…").

Deputy Commissioner for Operations for FDA at the time, and by the subsequent Government Accountability Office (GAO) report on Mifeprex approval, both of which provided evidence that disproved conservatives' claims.[37]

The 2008 GAO inquiry into mifepristone similarly highlighted the tense dispute between partisan, ideological motivation and scientific neutrality. The inquiry was started because of intense backlash from mifepristone's approval under Subpart H.[38] The GAO report presented clear and objective findings that FDA was meeting its post market oversight responsibilities—also questioned in the House Hearing—and that mifepristone was approved with sufficient evidence proving its safety and efficacy.[39] However, despite the plethora of GAO's conclusive findings on mifepristone's approval and safety, these same allegations are being raised today in the current battle over medication abortion.[40]

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[37] *Id.* (Statement of Janet Woodcock, Deputy Comm'r for Operations, Food and Drug Admin. U.S, Dep't of Health and Human Serv.); GAO Report, *supra* note 7, at 5–7.

[38] *See* GAO Report, *supra* note 7, at 1–3.

[39] *Id.* at 11–14; *Hearings*, *supra* note 32.

[40] *See* GAO Report, *supra* note 7, at 13. *Contra* Brief of Family Research Council as Amici Curiae at 1–3, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) (lending supports to Plaintiffs' claims about the mifepristone's initial approval and the supposed influence of the Clinton Administration); *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 5266026, at *32 (5th Cir. Aug. 16, 2023) (despite overruling plaintiffs' claims about mifepristone's initial 2000 approval, affirming their push to reinstate pre-2016 REMS contrary to FDA findings on safe use without them).

B. FDA's Administrative Authority

While FDA works through a variety of enforcement and regulation mechanisms, its primary tool for drug regulation is the Food, Drug, and Cosmetic Act (FDCA). The FDCA, codified starting at 21 U.S.C. § 301, serves as the framework for FDA operations and for the parameters of its regulations.[41] Under the parameters of the FDCA, FDA can develop regulations as well as oversee the process for new drugs to enter the market.[42] The creation of the current FDCA process for new drug approval ensures that drugs being marketed are "safe, effective, and properly labeled."[43] Known as the effectiveness requirement, all new drugs are thoroughly evaluated under this standard with requirements for studies and other evidence prior to the approval and marketing of a drug.[44] Contrary to the claims of the staunch mifepristone critics, FDA cannot compel or be compelled to initiate research into a particular new drug; FDA

[41] *What is the difference between the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA regulations, and FDA guidance?*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/about-fda/fda-basics/what-difference-between-federal-food-drug-and-cosmetic-act-fdc-act-fda-regulations-and-fda-guidance (last visited July 3, 2023); 21 U.S.C. § 301.

[42] *Id.*; Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 832-33.

[43] Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 834.

[44] *Id.* at 863-64; 21 U.S.C. § 355.

has no power to instigate testing.[45] Instead, the responsibility for requesting and initiating testing is on the manufacturer seeking to have the drug approved; the manufacturer will then hire independent medical experts for the testing.[46]

Several amendments have also been made to the FDCA which reflect modern changes and have overall strengthened FDA's administrative authority over the drug approval process.[47] Specifically, by raising the threshold for proving safety and effectiveness to FDA standards, the 1962 Amendments gave FDA direct control over the process and scope of new drug approval and increased its overall authority.[48] From there, the FDA Modernization Act of 1997 further reformed the drug investigation and approval process.[49] Also referred to as FDAMA, it reinforced FDA's independent authority by publishing FDA's guidance protocols, which were then endorsed by Congress, and solidified its autonomous use of guidance documents.[50] Ten years later, the FDA Amendments Act of 2007 worked to strengthen FDA's administrative authority.[51] The 2007 Amendments specifically work alongside traditional deference principles

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[45] *See id.* at 865; *contra* Judicial Watch Report, *supra* note 28 (claiming "President Clinton ordered HHS and FDA to coordinate and promote the marketing of RU-486 as his first official act in office.").

[46] *See* Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 865.

[47] *Id.* at 834.

[48] *Id.* at 957.

[49] *Id.* at 834.

[50] *Id.* at 76.

[51] *Id.* at 834.

to empower and further expand FDA's regulatory control, including the development of the REMS program.[52]

It is the very foundation of this process, and the Act itself, that are now being questioned and set up for the slaughter by the legal challenges to mifepristone.[53] FDA's power to exert relative control over the drug market and approval process ensures that the public is safeguarded from unsafe products, as was the basis for the creation of the FDCA.[54]

As a federal agency, FDA is governed by the Administrative Procedure Act (APA) which mandates the process for agencies to develop and issue regulations.[55] Specifically, APA requires agencies to adhere to a specific rulemaking process, known as notice-and-comment, that entails

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[52] Susan Wood and Kristen Perosino, *Increasing transparency at the FDA: the impact of the FDA Amendments Act of 2007*, 123 NIH PUBLIC HEALTH REPORTS 527, 528 (2008); Jerry Avorn, et al., *The FDA Amendments Act of 2007 — Assessing Its Effects a Decade Later*, 379 N ENGL J MED 1097, 1099 (2018).

[53] *See* CRS New Litigation, *supra* note 16 (explaining the onslaught of upcoming and current cases targeting FDA and medication abortion).

[54] *See* Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 832–33.

[55] Administrative Procedure Act, 5 U.S.C. §§ 551–59; *Summary of the Administrative Procedure Act*, U.S. ENVIRONMENTAL PROTECTION AGENCY, https://www.epa.gov/laws-regulations/summary-administrative-procedure-act (last visited July 9, 2023).

publishing the proposed rule in the Federal Register and allowing for public feedback.[56] While FDA is bound by the APA and notice-and-comment rulemaking, one prominent exception to this is interpretive guidance.[57] An interpretive guidance, also known as an interpretive rule, is issued by an agency to "advise the public of the agency's construction of the statutes and rules which it administers."[58] As a non-legislative rule, interpretive guidances are not immediately nor uniformly subject to judicial review—so long as they do not effect substantive change.[59]

FDA has its own protocols for guidances, Good Guidance Practices (GGPs), which are "FDA's policies and procedures for developing, issuing, and using guidance documents."[60] FDA's GGPs establish levels for the types of guidances it may issue and set forth what type of

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[56] Administrative Procedure Act, 5 U.S.C. § 553(b); *Summary of the Administrative Procedure Act*, U.S. ENVIRONMENTAL PROTECTION AGENCY, https://www.epa.gov/laws-regulations/summary-administrative-procedure-act (last visited July 9, 2023).

[57] Administrative Procedure Act, 5 U.S.C. § 553(b)(A), (d)(2); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 100 (2015); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like--Should Federal Agencies Use Them to Bind the Public*, 41 DUKE L.J. 1311,1313 (1992) [hereinafter Anthony].

[58] *Rulemaking Process*, FEDERAL COMMUNICATIONS COMMISSION, https://www.fcc.gov/about-fcc/rulemaking-process (last visited July 15, 2023); Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947).

[59] Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 77; CONG. RSCH. SERV., LSB10591, AGENCY USE OF GUIDANCE DOCUMENTS 2–3 (2021); Anthony, *supra* note 57, at 1313–14.

[60] 21 C.F.R. § 10.115(a); *see* Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 76.

protocol must accompany each guidance designation.[61] An FDA guidance of any level documents the agency's "current thinking on a topic," which in practice serves an interpretation of FDA policy on a regulatory issue.[62] In particular, FDA guidances often address specific products and enforcement policies.[63] Within FDA GGPs, Level One applies to guidances that, "set forth initial interpretations of statutory or regulatory requirements; set forth changes in interpretation or policy that are of more than a minor nature; include complex scientific issues; or cover highly controversial issues.[64] Level Two covers guidances that address existing practices or minor changes in interpretation and include all other documents not classified as Level 1.[65] While there is a difference between the types of materials classified at each level, there is also a difference between the protocols for each; Level One is to be published in the Federal Register

[61] 21 C.F.R. § 10.115(c); Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 76.

[62] *Guidances*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/industry/fda-basics-industry/guidances (last visited July 15, 2023); 21 C.F.R. § 10.115(b).

[63] *Guidances*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/industry/fda-basics-industry/guidances (last visited July 15, 2023).

[64] 21 C.F.R. § 10.115(c)(1); *see Fact Sheet: FDA Good Guidance Practices*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/about-fda/transparency-initiative/fact-sheet-fda-good-guidance-practices (last visited July 22, 2023) [hereinafter FDA Good Guidance Practices].

[65] 21 C.F.R. § 10.115(c)(2); *see* FDA Good Guidance Practices, *supra* note 64.

and is available for public comment and workshop, while Level Two will only take comments after publication.[66]

Another integral pillar of FDA oversight is the over-the-counter (OTC) approval process and modifying existing drug classifications. OTC medications, also known as nonprescription, are those approved by FDA as safe and effective for use without supervision by a doctor or other authorized medical professional.[67] An OTC designation can be reached through either an OTC monograph or through the New Drug Approval (NDA) process.[68] Specifically with the NDA process, this can be used for a previously-approved prescription drug to do a market designation switch to OTC.[69] Also referred to as a Prescription-to-Nonprescription (RX-to-OTC) switch, this process requires the drug manufacturer to submit an efficacy supplement to an approved NDA or a 505(b)(2) application for a full switch.[70] FDA then will review the supplement, which must show that the drug is safe for use in a nonprescription setting and can be used safely without medical supervision, to determine if the drug's previous prescription status is "not necessary for

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[66] 21 C.F.R. § 10.115(g)(3), (4); Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 76; FDA Good Guidance Practices, *supra* note 64.

[67] *What criteria must drugs meet to be sold over the counter?*, AMERICAN ACADEMY OF PEDIATRICS (AAP) NEWS, 1 [hereinafter OTC criteria].

[68] *Id.*

[69] *Prescription-to-Nonprescription (Rx-to-OTC) Switches*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches (last visited July 16, 2023).

[70] *Id.*

the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and . . . the drug is safe and effective for use in self-medication as directed in proposed labeling."[71] Additionally, FDA can halt a drug from the prescription use requirement if this measure is found to be unnecessary for the protection of public health; this can be done through a regulation, issued by FDA on its own or by petition from an interested party.[72]

The RX-to-OTC switch is a relatively common phenomenon as "[n]inety-five percent of nonprescription drug products marketed under an approved NDA or ANDA previously were marketed for the same indication by prescription."[73] Additionally, there is also a proposed rule that would allow for a wider range of drugs to be incorporated as OTC, through the use of an Additional Condition for Nonprescription Use (ACNU).[74] This proposed rule would apply to drugs where labeling alone does not sufficiently account for consumer nonprescription self-use

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[71] 21 C.F.R. § 310.200(b); *Prescription-to-Nonprescription (Rx-to-OTC) Switches*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches (last visited July 16, 2023).

[72] 21 C.F.R. § 310.200(b); 21 U.S.C. § 353(b)(3); Agata Bodie, CONG. RSCH. SERV., R46985, FDA REGULATION OF OVER-THE-COUNTER (OTC) DRUGS: OVERVIEW AND ISSUES FOR CONGRESS 5 (2021).

[73] OTC criteria, *supra* note 67.

[74] *See Drug Application Process for Nonprescription Drugs*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/types-applications/drug-application-process-nonprescription-drugs (last visited July 15, 2023).

and the ANCU would represent a condition that must be met by the consumer to successfully obtain the drug.[75] Adopting the ANCU rule would increase access to many drugs that are presently only available as prescription by expanding them into types of nonprescription drugs, as well as further ensuring safety and efficacy of nonprescription drug use.[76]

Regardless of the avenue of authority exercised by FDA, the *Chevron* doctrine is what permits these types of actions and helps ensure their longevity.[77] Although there is some dispute over the exact amount of deference given to interpretive guidances, the central principle of agencies being able to act where Congress has not explicitly spoken remains the same.[78]

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[75] *See id.*

[76] *See The FDA Announces Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/fda-announces-proposed-rule-nonprescription-drug-product-additional-condition-nonprescription-use (last visited July 16, 2023).

[77] *See Open the Floodgates*, *supra* note 9; *see generally* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

[78] *See* CONG. RSCH. SERV., LSB10591, AGENCY USE OF GUIDANCE DOCUMENTS 3 (2021) (differentiating how issue statements, unlike legislative rules, are not legally binding); Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 80.

C. Judicial Battleground for Reproductive Autonomy

Directly at the intersection between FDA approval of mifepristone and its authority to do so under *Chevron* lies the legal challenges to both: the mifepristone cases (the "Mife Cases").[79] This collection of lawsuits and legal challenges encompasses at least three cases, all with one central theme: mifepristone and FDA's ability to modify its use and conditions.[80] Two of these are state cases from North Carolina and West Virginia and they seek to attack medication abortion restrictions in their states through federal preemption.[81] These two lawsuits are against their respective states, asserting federal preemption through the FDCA in response to the states' restrictive legislation on reproductive healthcare.[82] Specifically, the plaintiffs in both cases cite FDA protocol on mifepristone as directly in conflict with, and superior to, the states' anti-abortion measures that either heavily restrict it or prohibit it entirely.[83] While a ruling has not

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[79] *See Open the Floodgates*, *supra* note 9 (explaining FDA's authority for rulemaking rooted in the FDCA and how *Chevron* deference has protected the resulting FDA expertise); *Does the Mifepristone Case Tee Up a Chevron Challenge?*, DAVIS WRIGHT TREMAINE LLP (Apr. 24, 2023), https://www.dwt.com/blogs/energy--environmental-law-blog/2023/04/mifepristone-chevron-deference-environmental-law (discussing how Judge Kacsmaryk disregarded FDA's "medical and scientific judgment" and "afforded no deference to FDA's expertise.").

[80] CRS New Litigation, *supra* note 16.

[81] *Id.*

[82] *Id.* at 4.

[83] *Id.;* GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 3211847 (S.D.W.V. May 2, 2023); *Bryant v. Stein*, No. 23-cv-00077 (M.D.N.C. Jan. 25, 2023). *See* W. Va. Code Ann. § 16-

been issued for either case, the outcomes will have tremendous effects FDA autonomy and preemption, particularly as it relates to such a partisan and politicized issue.[84]

The primary legal threat to FDA authority and *Chevron* deference lies within *Alliance for Hippocratic Medicine v. FDA*, as recently clarified in the appeals ruling.[85] This case directly challenges FDA's authority and both the district court and appeals court opinions rely on disproven claims, which questions scientific findings based on personal and political opinion.[86] This represents a divergence into exactly what Congresswoman Holmes Norton warned of in the

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2R-1 (banning all acts or attempted acts of abortion, including by medicine, in West Virginia). *But see* 21 U.S.C. § 355-1 (FDA safety protocols and REMS program).

[84] *See* CRS New Litigation, *supra* note 16, at 4 (explaining how the Mife Cases have the potential to permanently alter legal precedent and the accessibility of medication abortion).

[85] All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026 (5th Cir. Aug. 16, 2023).

[86] *See id.* at 23–25 and 33–35 (challenging FDA's research into the 2016 Amendments and 2021 Non-Enforcement Decision on mifepristone). *Compare* All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-CV-223-Z, 2023 WL 2825871, at *55–57 (N.D. Tex. Apr. 7, 2023) (discussing the Plaintiffs' arguments against FDA and its alleged overstep of authority in approving mifepristone) *with* NARAL Pro-Choice American Research Team, *Memo: Federal Ruling Against Medication Abortion Advances Anti-Choice Extremism*, NARAL PRO-CHOICE AMERICA 1, 1 (2023), https://www.prochoiceamerica.org/wp-content/uploads/2023/04/Memo_-Federal-Ruling-Against-Medication-Abortion-Advances-Anti-Choice-Extremism-.pdf [hereinafter NARAL Anti-Choice Extremism] (explaining the discredited claims, disinformation, and ideological rhetoric that fill Judge Kacsmaryk's district court opinion).

2006 Congressional hearing on mifepristone.[87] Specifically, in the district court opinion, Judge Kacsmaryk said FDA relied on "unsound reasoning" and "overstepped its authority" and in his concurrence in the appeals ruling, Judge Ho expressly advocated against FDA scientists being the primary authority on matters in their disciplines.[88] This is in addition to a Judge using propagandized rhetoric in place of scientifically accurate language; Judge Kacsmaryk continuously refers to mifepristone as "chemical abortion,"[89] and refers to the byproduct as an "aborted child."[90] This reflects a larger trend within the anti-abortion movement and

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[87] *Hearings*, *supra* note 32 ("What we don't want is to investigate scientists, for example, who give us answers contrary to our personal or moral or religious beliefs. We want to leave them free and unfettered to tell us what the scientific method reveals to them.").

[88] CRS New Litigation, *supra* note 16, at 3; *All. for Hippocratic Med.*, 2023 WL 2825871, at *35–60 (N.D. Tex. Apr. 7, 2023); *All. for Hippocratic Med.*, 2023 WL 5266026, at *45.

[89] *See ACOG Guide to Language and Abortion*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS 1, 1 (2022), https://www.acog.org/contact/media-center/abortion-language-guide [hereinafter *ACOG Guide*] (explaining the term chemical abortion is a "biased term designed to make medication
abortion sound scarier than the safe, effective medical intervention it is."). *But see All. for Hippocratic Med.,* 2023 WL 2825871 (repeatedly using the biased term, "chemical abortion" throughout the opinion).

[90] *See ACOG Guide*, *supra* note 89, at 2 (emphasizing that language centered on the future state of a pregnancy, such as baby or unborn child, is medically inaccurate). *But see All. for Hippocratic Med.,* 2023 WL 2825871, at *16, 41, footnote 1.

disinformation movements to intentionally confuse and mislabel abortive healthcare terminology.[91] Furthermore, Judge Ho's rhetoric in his concurrence sees him comparing the byproduct of abortion to aesthetic injury, such as what one experiences when visiting wildlife, and pesticides.[92] Using language contrary to what is sanctioned by reproductive health experts,[93] which Judge Ho is not, his inflammatory concurrence transforms a germane appeals opinion into messianic propaganda for anti-abortion judges, politicians, and other public servants.[94]

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[91] *See Medication Abortion Disinformation Trends Surrounding* Alliance for Hippocratic Medicine v. FDA, NARAL PRO-CHOICE AMERICA (June 15, 2023), https://www.prochoiceamerica.org/report/medication-abortion-disinformation-trends-surrounding-alliance-for-hippocratic-medicine-v-fda/ [hereinafter NARAL Disinformation Trends] (discussing the prevalence of disinformation within the anti-abortion moving, noting how it increased 502.9% in 2023 as compared to in 2022).

[92] *All. for Hippocratic Med*., 2023 WL 5266026, at *34–35.

[93] *Id.* ("*Unborn babies* are a source of profound joy for those who view them…Doctors delight in working with their *unborn patients*—and experience an aesthetic injury when they are aborted…Dr. Francis testified to working with an *unborn child* who was subsequently *killed* by mifepristone") (emphasis added). *Contra ACOG Guide*, *supra* note 89, at 2.

[94] *See generally* Lydia Wheeler, *Ho Cites Doctor 'Aesthetic' Injuries in Abortion Pill Case*, BLOOMBERG LAW (Aug. 17, 2023), https://news.bloomberglaw.com/us-law-week/judge-ho-cites-doctor-aesthetic-injuries-in-abortion-pill-case; Pamela King, *Why the latest abortion pill ruling has enviros rolling their eyes*, POLITICO (Aug. 19, 2023), https://www.politico.com/news/2023/08/19/abortion-pill-ruling-environment-00111843.

In addition to the problematic rhetoric of both opinions, the concern for *Chevron* deference lies in the central ask of the case, wherein Judge Kacsmaryk approves, and the appeals court confirmed, plaintiffs' request to rescind FDA's 2016 Amendments and 2021 Non-Enforcement Decision regarding removing some of mifepristone's safety measures.[95] While Judge Kacsmaryk also granted the plaintiffs' motion to pull mifepristone from the market entirely—based on the circumstances of its approval in 2000—[96] the appeals ruling, apart from Judge Ho's concurrence in part,[97] denied this motion on the grounds of timeliness.[98] This judicial mandate is in direct opposition of FDA approval of mifepristone in 2000 and is contrary to all findings of safety, efficacy, and post market surveillance, as found by the GAO report and House hearing.[99] The Fifth Circuit opinion calls into question the Court's stance on agency deference, as it will be forced to decide whether the best practice is to follow twenty-three years of FDA approval precedent or the ruling of a single judge.[100] In the face of these challenges to

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[95] *All. for Hippocratic Med.*, 2023 WL 2825871, at *96; *All. for Hippocratic Med*., 2023 WL 5266026, at *32.

[96] *All. for Hippocratic Med.,* 2023 WL 2825871, at *8–9.

[97] *All. for Hippocratic Med*., 2023 WL 5266026, at *38–39.

[98] *Id.* at *1.

[99] *See generally* GAO Report, *supra* note 7; *Hearings*, *supra* note 32; FDA Questions and Answers, *supra* note 3.

[100] *But cf. Hearings*, *supra* note 32 ("What we don't want is to investigate scientists, for example, who give us answers contrary to our personal or moral or religious beliefs. We want to leave them free and unfettered to tell us what the scientific method reveals to them.").

its autonomy under *Chevron,* FDA must begin to explore alternative options that are both exercises of its authority and that protect access to the products it works to oversee.[101]

II. BEYOND FDA: *CHEVRON* ATTACKS ACROSS AGENCIES

A. Creating and Commanding Chevron *Deference*

The onslaught of the Mife Cases are not the only challenges to *Chevron* circling the docket. At present, there are several cases that signal the Court's path toward ending *Chevron* entirely, in particular, *West Virginia v. EPA* from the 2022–2023 term.[102] Additionally, there is an upcoming case that is almost certainly poised to overturn *Chevron*: *Loper Bright Enterprises. v. Raimondo*.[103] The impact of losing *Chevron* would gut all agencies, beyond just EPA and FDA

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[101] *See Infra* Part IV.A; *infra* part IV.B; *infra* part IV.C.

[102] *See* 142 S. Ct. at 2635; Halina Bereday, West Virginia v. EPA*: Majorly Questioning Administrative Agency Action & Authority*, 82 MD. L. REV. 820, 854–56 (2023); Jonathan H. Adler, *West Virginia v. EPA: Some Answers about Major Questions*, 2021 CATO SUP. CT. REV. 37, 54–56 (2021–2022).

[103] Loper Bright Enterprises v. Raimondo, No. 22-451, 2023 WL 3158352 (U.S. May 1, 2023). *See generally Supreme Court to Hear Challenge to Chevron Doctrine Seeking to Limit Courts' Deference to FCC and Other Agencies*, NELLSON MULLINS (May 12, 2023), https://www.nelsonmullins.com/idea_exchange/alerts/fcc-download/all/supreme-court-to-hear-challenge-to-chevron-doctrine-seeking-to-limit-courts-deference-to-fcc-and-other-agencies; *What Justices' Loper Bright Ruling Will Mean For Chevron*, LAW 360 (May 16, 2023), https://www.law360.com/articles/1607619/what-justices-loper-bright-ruling-will-mean-for-chevron.

and have catastrophic consequences for each of their respective fields as expert voices would be replaced with judicial interpretations.[104]

The *Chevron* framework is the backbone of agency discretion, allowing experts to set practical objectives for the public from their respective fields.[105] Specifically, the two-prong test for *Chevron* asks if Congress has previously addressed the topic in question and if Congress has not or is ambiguous, the inquiry proceeds to the second step.[106] At this step, the agencies' reasonable interpretation of the statute is controlling.[107] Overall, the two-steps of *Chevron* combine to diligently assesses Congressional intent to infer delegation and appropriate agency interpretation within their respective disciplines.[108]

There is an additional—and unofficial—aspect of *Chevron* interpretation that seeks to determine if *Chevron* applies at all: "Step-Zero."[109] Closely intertwined with the Major Questions Doctrine (MQD), this precursor step is favored by the anti-Chevron contingent as a way to bar its application from the get-go.[110] In a practical sense, a Step-Zero inquiry asks

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[104] *See* NRDC, *supra* note 21.

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

[106] *Chevron* Primer, *supra* note 11.

[107] *Id.*

[108] CONG. RSCH. SERV., LSB10976 *CHEVRON* DEFERENCE IN THE COURT OF APPEALS 2 (2023).

[109] *Chevron* Primer, *supra* note 11, at 5.

[110] *See* Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 192–93 (2006) [hereinafter Sunstein, *Step Zero*]; *Did Step Zero Help Doom Chevron?*, THE REGULATORY REVIEW (June 13,

whether Congress authorized the agency to speak with the "force of law."[111] While the Court has largely rejected a clearcut definition of Step-Zero and what exactly agencies are authorized to speak on, they have acknowledged a general set of preconditions for *Chevron* to apply.[112]

The once-solid foundation of *Chevron* is now beginning to crumble, as this long-revered doctrine is becoming a test subject for the neo-conservative and polarized judicial appointments' agenda.[113] As Supreme Court precedent, *Chevron* is currently safe, but can just as easily be undone if the Court says otherwise which is especially likely considering the current majority's stated willingness to discard precedent.[114] This fate has slowly become foreseeable for *Chevron*

2022), https://www.theregreview.org/2022/06/13/coglianese-did-step-zero-help-doom-chevron/ [hereinafter *Doom Chevron*].

[111] Sunstein, *Step Zero*, *supra* note 110, at 193.

[112] *Chevron* Primer, *supra* note 11, at 8.

[113] *Doom Chevron*, *supra* note 110; *The Supreme Court curtails but retains agency rule deference – How much will it matter?*, BROOKINGS (Sept. 24, 2019), https://www.brookings.edu/articles/the-supreme-court-curtails-but-retains-agency-rule-deference-how-much-will-it-matter/; Cass R. Sunstein, *Chevron as Law*, 107 Geo. L.J. 1613, 1665 (2019); Ian Millhiser, *How the Supreme Court put itself in charge of the executive branch*, VOX (July 17, 2023), https://www.vox.com/scotus/23791610/supreme-court-major-questions-doctrine-nebraska-biden-student-loans-gorsuch-barrett [hereinafter Millhiser].

[114] *Compare* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2320 (2022) (Breyer, J., dissenting) ("[The] Court reverses course today for one reason and one reason only: because the composition of this Court has changed. Stare decisis, this Court has often said, 'contributes to the

based on the trend from recent cases, particularly *West Virginia v. EPA* and soon *Loper Bright Enterprises. v. Raimondo*.[115]

B. The Larger Framework of Concerted Efforts Against Chevron

West Virginia v. EPA redefined the MQD and sent shockwaves as an omen of what is to come for agency deference and *Chevron*.[116] Prior to this case, the MQD was best defined by *King v. Burwell*, which made *Chevron* inapplicable for "question[s] of deep 'economic and political significance.'"[117] This interpretation of the doctrine made it so that *Chevron* does not always apply—similar to a Step-Zero qualifier—where certain major questions are in play, assuming they were not intended for delegation by Congress.[118] While there is no set definition

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actual and perceived integrity of the judicial process' by ensuring that decisions are 'founded in the law rather than in the proclivities of individuals'…Today, the proclivities of individuals rule. The Court departs from its obligation to faithfully and impartially apply the law.") *with* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2320 (2022) (Alito, J., majority) ("We have long recognized, however, that stare decisis is 'not an inexorable command,'… [t]herefore, in appropriate circumstances we must be willing to reconsider and, if necessary, overrule constitutional decisions.").

[115] West Virginia v. EPA, 142 S. Ct. 2587 (2022); *Loper Bright Enterprises,* No. 22-451, 2023 WL 3158352 (U.S. May 1, 2023).

[116] *See* 142 S. Ct. at 2610, 2614.

[117] King v. Burwell, 135 S. Ct. 2480, 2489 (2015).

[118] *See* Christopher J. Walker, *Attacking Auer and Chevron Deference: A Literature Review*, 16 GEO. J.L. & PUB. POL'Y 103, 117 (2018).

for what counts as "major," the clear theme throughout the cases where the Court has invoked the doctrine is taking expertise away from the agency experts.[119] The undefined boundaries of this legal fiction have the practical effect of enabling the Court to continue its trend of acting in place of agency knowledge in cases where the subject matter is politically-aligned.[120]

After *West Virginia v. EPA*, the Court made clear that MQD is here to stay and demonstrated its use as a mechanism for shrinking agency autonomy to only cases where there is "clear congressional authorization"—one step closer to fulfilling Roberts' dissenting wishes from *Arlington.*[121] In the first opinion where the legal fiction was referenced by name, this identification in *West Virginia v. EPA* represents a shift in Court treatment of agency deference, as

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[119] *See* Kate R. Bowers, CONG. RSCH. SERV., IF12077, THE MAJOR QUESTIONS DOCTRINE 1, 1–2 (2022) (listing all the recent cases where the Court has used MQD to reject agencies asserting regulatory authority).

[120] *See id.*; West Virginia v. EPA, 142 S. Ct. 2587, 2641 (2022) (Kagan, J., dissenting) ("When that method [textualism] would frustrate broader goals, special canons like the 'major questions doctrine' magically appear as get-out-of-text-free cards. Today, one of those broader goals makes itself clear: Prevent agencies from doing important work, even though that is what Congress directed. That anti-administrative-state stance shows up in the majority opinion…"). *See also* Millhiser, *supra* note 113.

[121] *See* West Virginia v. EPA, 142 S. Ct. 2587, 2609 (2022); City of Arlington v. FCC, 569 U.S. 290, 317 (Roberts, J., dissenting) (writing that "step zero" should be the norm and the Courts should first decide if an agency is entitled to deference).

the lack of clarity on when and how it is to be invoked gives expansive discretion as to what constitutes a "major question."[122]

The scope of this decision's impact on administrative law has yet to be fully realized but it will surely be detrimental, as the Court's formal recognition of MQD empowers a shift to this framework in advance or in place of a *Chevron* inquiry.[123] This formalized use of MQD shrinks agency authority because it permits courts to avoid a *Chevron* analysis entirely, mirroring a Step-Zero effect of disqualifying *Chevron*.[124] By recognizing an exception to agency deference in cases of "vast economic or political significance" without a clear framework for doing so, the Court in *West Virginia v. EPA* altered the process for judicial review of and deference to agency

[122] 142 S. Ct. at 2609; Kate R. Bowers, CONG. RSCH. SERV., LSB10791, SUPREME COURT ADDRESSES MAJOR QUESTIONS DOCTRINE AND EPA'S REGULATION OF GREENHOUSE GAS EMISSIONS 1, 5 (2022) [hereinafter Bowers, MQD and EPA]; Millhiser, *supra* note 113.

[123] *See* Bowers, MQD and EPA, *supra* note 122 (predicting how *West Virginia v. EPA* may permanently shift the judicial review process for agency actions, as agencies must now be able to identify "clear congressional authorization").

[124] *Compare id.* (highlighting how MQD often prevents *Chevron* from being invoked) *with* Sunstein, *Step Zero*, *supra* note 110, at 193 (analyzing cases raising the Step Zero question, that indicates deference may be reduced or rendered nonexistent if a fundamental issue is involved).

actions.[125] However, in terms of biggest threats to *Chevron*, *West Virginia v. EPA* is a drop in the bucket as compared to *Loper*, which will be heard in the upcoming 2023–2024 term.[126]

The Court has agreed to hear *Loper Bright Enterprises. v. Raimondo*, which is widely regarded as the case set to overturn *Chevron*—if not already overturned by the mifepristone cases before it is heard.[127] The outcome of this case is not just limited to the Department of Commerce (DOC) and National Marine Fisheries Service (NMFS); overruling *Chevron* will directly undermine the authority and decades of work of every single agency.[128] The Court has granted certiorari to determine "Whether the Court should overrule *Chevron* or at least clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency."[129] This represents an unprecedented ask of the Court, directly propositioning the Court to do away with

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[125] West Virginia v. EPA, 142 S. Ct. 2587 (2022). *See* Bowers, MQD and EPA, *supra* note 122 (discussing the changes to the process for judicial review of agency action and potential impact on how agencies will choose to regulate).

[126] West Virginia v. EPA, 142 S. Ct. 2587 (2022); *Loper Bright Enterprises,* No. 22-451, 2023 WL 3158352 (U.S. May 1, 2023).

[127] NRDC, *supra* note 21.

[128] *Id.*; *Threatening Chevron Deference Threatens Government as a Whole*, THE REGULATORY REVIEW (Jan. 19, 2023), https://www.theregreview.org/2022/01/19/penava-threatening-chevron-deference-threatens-government/ [hereinafter *Threatening Chevron*].

[129] *Loper* Petition for Writ of Certiorari (Nov. 10, 2022) at pp. i-ii.

historic precedent and permanently alter the way in which agencies operate.[130] Considering the ideological composition of the Court, and recent trends away from adhering to precedent and agency deference, it is more than likely that *Loper* will be the end of *Chevron*.[131] This Court does not give the impression of shying away from the potential to overturn yet another revered precedent in favor of simply modifying it.[132]

III. IMPACTS

The Clean Air Act; the Clean Water Act; the Clean Power Plan; every medication, food product, cosmetic, or tobacco restriction authorized under the FDCA, even the newest developments such as an OTC oral contraceptive and the development Alzheimer's drug. All of

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[130] *See* NRDC, *supra* note 21 (hypothesizing how the end of *Chevron* could cause legal and administrative chaos).

[131] *See Threatening Chevron*, *supra* note 128 (remarking on the conservative position shift on *Chevron* that led to current movements to overrule it). *Cf.* CONG. RSCH. SERV., LSB10976 *CHEVRON* DEFERENCE IN THE COURT OF APPEALS 2 (2023) (explaining how *Chevron* has increasingly fallen out of favor with the new composition of the Court).

[132] *See e.g.,* Dobbs v. Jackson Women's Health Org., 213 L. Ed. 2d 545, 142 S. Ct. 2228, 2320 (2022) (Breyer, S., dissenting) ("[The] Court reverses course today for one reason and one reason only: because the composition of this Court has changed. Stare decisis, this Court has often said, "contributes to the actual and perceived integrity of the judicial process" by ensuring that decisions are 'founded in the law rather than in the proclivities of individuals'…Today, the proclivities of individuals rule. The Court departs from its obligation to faithfully and impartially apply the law.").

these major innovations and protections for the public health and wellbeing are derived from deference to agencies and their expertise.[133] These same innovations could soon come to an end with any of the recent cases that poised to destroy *Chevron* and all it has helped accomplish.[134] It is a Herculean task to describe all of the potential impacts and fallout that would come from eradicating *Chevron* within the span of this Comment, but examining this catastrophe through the lens of FDA is a microcosm of what is to come.[135]

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[133] *See* Natasha Brunstein and Richard L. Revesz, *Mangling the Major Questions Doctrine*, 74 ADMIN L. REV. 217, 225, 230 (2022) (discussing the extensive public health and safety measures enacted by FDA and EPA through agency deference); *US Supreme Court Will Hear Case Affecting Agency Power*, AVALERE (May 8, 2023), https://avalere.com/insights/us-supreme-court-will-hear-case-affecting-agency-power (delineating the numerous health law cases that have been based in *Chevron* deference and the impacts that losing *Chevron* will have on the field).

[134] *See* Millhiser, *supra* note 113 (connecting the changing attitudes towards *Chevron* deference and agency initiatives to current conservative disdain for the Biden administration and its platforms).

[135] While this Comment covers only impacts to FDA in detail, it is important to note the grave impacts that would span across other agencies, particularly the EPA. *See generally* NRDC, *supra* note 21; Natasha Brunstein and Richard L. Revesz, *Mangling the Major Questions Doctrine*, 74 ADMIN L. REV. 217, 230–32 (2022); *What Does the Supreme Court's Decision in West Virginia v. EPA Mean for U.S. Action on Climate?*, COUNCIL ON FOREIGN RELATIONS (July 19, 2022), https://www.cfr.org/blog/what-does-supreme-courts-decision-west-virginia-v-epa-mean-us-action-climate; *Do We Still Need the EPA?*, NEW YORK TIMES (Jan. 28, 2019),

Specifically, FDA's entire rulemaking authority will come under fire by nature of its subjection to judicial review and, by extension, to the whims of courts. Any decision on a medication or product that can be considered controversial or politically charged will be left in the hands of judges, whose legal expertise does not logically extend to the intricacies of abortifacient research or other highly-specialized fields.[136] In the context of reproductive healthcare specifically, it is well documented that banning abortions only stops safe abortions, but does not actually prevent them from occurring.[137] Medication abortion was a glimmer of hope for abortion access post-*Dobbs* but now in states where that too is being eradicated, abortion-related fatalities are on the rise—the direct result of these near-total bans on all forms of

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https://upfront.scholastic.com/issues/2018-19/012819/do-we-still-need-the-epa.html?language=english#1210L.

[136] *See* Anne Zimmerman, *Politicizing Deference to the FDA Considering the Alliance for Hippocratic Medicine Cases*, YALE JOURNAL ON REG. (April 17, 2023), https://www.yalejreg.com/nc/politicizing-deference-to-the-fda-considering-the-alliance-for-hippocratic-medicine-cases-by-anne-zimmerman/ (explaining the fallout from the mifepristone cases politicizing deference to FDA and that "the worst result may be deferring to agency decisions when the judges or justices politically agree with them and using judicial review to privilege interpretations from outside the agency when they do not.").

[137] *Abortion restrictions don't lower rates, report says*, CNN (Mar. 21, 2018), https://www.cnn.com/2018/03/21/health/abortion-restriction-laws/index.html [hereinafter *abortion restrictions*].

abortion.[138] Particularly in the context of Black maternal mortality, restrictions on abortion increase Black maternal deaths by thirty-nine percent.[139] Black maternal mortality is an ongoing, raging epidemic that will only be exacerbated by restrictions on abortion care, particularly with medication abortion being the only accessible solution to many women in rural areas or those in states with complete bans.[140] Additionally, this health crisis is worsened in those states that

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[138] *See* Lauren Saxe, *No Longer Viable: The Push for the FDA's Removal of Mifepristone from the Rems Program under Dobbs*, 8 Admin. L. Rev. Accord 101, 117–18 (2022) (discussing the use of medication abortion to remediate abortion access post-*Dobbs*); *Nearly two years after Texas' six-week abortion ban, more infants are dying*, CNN (July 20, 2023), https://www.cnn.com/2023/07/20/health/texas-abortion-ban-infant-mortality-invs (connecting Texas' strict abortion regulations to a spike in infant mortalities for those forced to carry nonviable fetuses to term).

[139] *Overturning Roe Will Exacerbate the Black Maternal Mortality Crisis. It's Time for Our Leaders To Act*, MS. MAGAZINE (Aug. 23, 2022), https://msmagazine.com/2022/08/23/overturn-roe-black-women-maternal-mortality/ ("[t]otal abortion bans can increase the number of Black maternal deaths by 39 percent, and overall maternal deaths by 24 percent."); Cecilia Lenzen, *Facing higher teen pregnancy and maternal mortality rates, Black women will largely bear the brunt of abortion limits*, THE TEXAS TRIBUNE (June 30, 2022), https://www.texastribune.org/2022/06/30/texas-abortion-black-women/.

[140] *See Overturning Roe Will Exacerbate the Black Maternal Mortality Crisis. It's Time for Our Leaders To Act*, MS. MAGAZINE (Aug. 23, 2022), https://msmagazine.com/2022/08/23/overturn-roe-black-women-maternal-mortality/; *Nearly two years after Texas' six-week abortion ban,*

criminalize abortion, as people who undertake self-managed abortion and face complications may be unable to seek proper medical care for fear of criminal repercussions.[141] The loss of *Chevron* and protected agency deference will cause a health crisis that will severely inhibit FDA, an agency focused on protecting the health and wellbeing of the public, from fulfilling its role.

The consequences of administrative law without *Chevron* will be extremely expansive. Despite the authority FDA has carefully created for itself through formal amendments and rulemaking, any legal contention over actions enacted through these measures will be subject to judicial scrutiny with little to no deference.[142] This is mirrored by *Alliance for Hippocratic Medicine*, where FDA's prior decisions about a drug through its safety evaluation process is now being questioned by judicial scrutiny.[143] With the downfall of *Chevron*, this would represent the fate of countless other medications, either in the approval process or previously approved and

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more infants are dying, CNN (July 20, 2023), https://www.cnn.com/2023/07/20/health/texas-abortion-ban-infant-mortality-invs.

[141] *See As states ban abortions, more people may turn to self-managed abortion care – with more legal challenges to come*, PBS (Oct. 13, 2022), https://www.pbs.org/newshour/politics/as-states-ban-abortions-more-people-turn-to-self-managed-abortion-care-with-more-legal-challenges-to-come.

[142] 5 U.S.C. § 553(b).

[143] *See* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026, at *32 (5th Cir. Aug. 16, 2023). (affirming Plaintiffs' demands for a reversion back to pre-2016 REMS).

now scrutinized.[144] Since formalized deference to agencies can often be the only thing that stands between scientific voices prevailing over judicial ideology, losing this protection means that there is nothing stopping FDA approvals from being rejected or revoked.[145] Similar to the current situation with mifepristone, the current political climate and agenda can influence how a drug is perceived or treated by those with the power to legally challenge it.[146] Any politically-charged medication or anything with an ideological division could be lost without judicial deference to the FDA scientists recommending those medications in the interest of public health.

IV. RECOMMENDATIONS

A. FDA Should Issue an Interpretive Guidance on Mifepristone

The most direct option for FDA to take would be to issue an interpretive guidance on mifepristone. This could effectively force federal preemption and supersede state regulations,

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[144] *See Open the Floodgates*, *supra* note 9, at 370 (explaining that with *Chevron* either narrowed or overruled entirely, "it will open up the floodgates to lawsuits and unleash a new wave of litigation against FDA on a host of issues.").

[145] *Id.* at 359–60; *Chevron* Primer, *supra* note 12, at 1 and 4.

[146] *See* Anne Zimmerman, *Politicizing Deference to the FDA Considering the Alliance for Hippocratic Medicine Cases*, YALE JOURNAL ON REG. (April 17, 2023), https://www.yalejreg.com/nc/politicizing-deference-to-the-fda-considering-the-alliance-for-hippocratic-medicine-cases-by-anne-zimmerman/. *See generally RU-486: DEMONSTRATING A LOW STANDARD FOR WOMEN'S HEALTH?: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources of the H. Comm. on Government Reform*, 109th Cong. (2006).

particularly in the state mifepristone cases.[147] Most importantly, an interpretive guidance would largely be exempt from traditional notice-and-comment rulemaking and judicial review, allowing FDA to use its enforcement discretion relatively unchallenged.[148] This aspect of an interpretive guidance would help effectuate FDA protection of mifepristone against cases such as *Alliance for Hippocratic Medicine*, where the judges acted contrary to deference principles.[149]

FDA's own good guidance practices (GGPs) distinguish levels for each type of guidance it issues, with different types of protocol at each level.[150] The implications of these Level distinctions is that Level One guidances are published in the Federal Register and are available for public comment, while Level Two only receives comments after publication.[151] Under FDA GGPs, an interpretive guidance concerning medication abortion in any form would likely be

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[147] GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 3211847 (S.D.W.V. May 2, 2023); Bryant v. Stein, No. 23-cv-00077 (M.D.N.C. Jan. 25, 2023); Patricia Zettler and Ameet Sarpatwari, *State Restrictions on Mifepristone Access-The Case for Federal Preemption*, 386 N ENGL. J MED. 705, 706 (2022).

[148] Lewis Grossman, *Enforcement Discretion Under Attack: Implications for FDA*, ADMINISTRATIVE & REGULATORY LAW NEWS Vol. 41 Iss. 4 (2016) at 26.

[149] All. for Hippocratic Med. v. FDA, No. 2:22-CV-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023); All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026 (5th Cir. Aug. 16, 2023). *See generally* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

[150] 21 C.F.R. § 10.115(c); Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 76.

[151] 21 C.F.R. § 10.115(g)(3), (4); Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 76; FDA Good Guidance Practices, *supra* note 64.

classified as Level One.[152] Due to the controversial nature of abortive healthcare and controversial subject matter, a guidance on mifepristone would likely be classified as Level One.[153] Even so, this classification of guidance is still exempt from judicial review, the central issue eroding FDA autonomy at present.[154] By avoiding mandatory language and making clear a nonbinding disclaimer in accordance with its GGPs, FDA can effectively exempt its interpretive guidance from notice-and-comment requirements and therefore from judicial review.[155]

An FDA interpretive guidance on mifepristone use and access should address its long-standing, proven safety for use in medication abortion, the extensive research conducted for its approval, and a reiteration of FDA's authority to have approved it as it did in 2000.[156] Serving as a revamped and updated version of the GAO research findings from 2008, an interpretive guidance on the continued safe use of mifepristone to terminate pregnancy would specifically counter the claims raised by abortion opponents—like those encapsulated by Judges Kacsmaryk and Ho in *Alliance for Hippocratic Medicine* and its appeals decision.[157]

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[152] *See generally* FDA Good Guidance Practices, *supra* note 64.

[153] 21 C.F.R. § 10.115(c)(1).

[154] Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 77; NARAL Anti-Choice Extremism, *supra* note 86.

[155] Lewis Grossman, *Enforcement Discretion Under Attack: Implications for FDA*, ADMINISTRATIVE & REGULATORY LAW NEWS Vol. 41 Iss. 4 (2016) at 26.

[156] GAO Report, *supra* note 7, at 5–7.

[157] *See id.* at 2–5; *compare* All. for Hippocratic Med. v. FDA, No. 2:22-CV-223-Z, 2023 WL 2825871, at *16, 41, footnote 1 (N.D. Tex. Apr. 7, 2023) *and* All. for Hippocratic Med. v. FDA,

Issuing an interpretive guidance would benefit both FDA and consumers as it would reinforce the agency's authority with undisputable clarity about its approvals as well as protect access to a vital medication for those who need it.[158] Additionally, such a guidance would also create federal preemption over the state restrictions that purport to do more than FDA has called for, paralleling the premise of the West Virginia and North Carolina cases against the respective state restrictions.[159] Furthermore, in the middle of a legal battleground over medication abortion, addressing misconceptions through an interpretive guidance would also quell disinformation, a tool weaponized by anti-abortion zealots to distort the public perception of mifepristone and FDA.[160] This objective is also in furtherance of President Biden's goals in Executive Order 14076, directing Department of Health and Human Services (HHS) to "consider options to address deceptive or fraudulent practices related to reproductive healthcare services, including online, and to protect access to accurate information."[161] An interpretive guidance would

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No. 23-10362, 2023 WL 5266026, at *34–35 (5th Cir. Aug. 16, 2023) *with* NARAL Anti-Choice Extremism, *supra* note 86.

[158] *See generally* FDA Good Guidance Practices, *supra* note 64.

[159] GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 3211847 (S.D.W.V. May 2, 2023); Bryant v. Stein, No. 23-cv-00077 (M.D.N.C. Jan. 25, 2023); Patricia J. Zettler and Ameet Sarpatwari, *State Restrictions on Mifepristone Access — The Case for Federal Preemption*, 386 ENGL J MED 705, 706–07 (2022).

[160] NARAL Disinformation Trends, *supra* note 91.

[161] Exec. Order No. 14076, 87 Fed. Reg. 42,053, 41,581–42,057 (July. 13, 2022).

accomplish this Executive Branch priority because it would serve as an irrefutable tool of scientifically sound knowledge and expertise, especially considering the rigor of FDA GGPs.[162]

B. FDA Should Approve an RX-to-OTC Switch Application for Mifepristone

Perhaps a more radical—but certainly not unprecedented—solution would be for FDA to approve an RX-to-OTC switch for mifepristone. Alongside misoprostol, the two-drug regimen successfully and safely terminates a pregnancy, and along with evidence of effective self-management, it qualifies for the switch to OTC.[163] Furthermore, there is already strong consumer support for it to be made OTC, as well as evidence of its ability to be used safely, with no risk of overdose or addiction, and prior history of being properly used and self-manage without medical supervision.[164] By approving an OTC switch, FDA would be exercising its administrative authority over the drug approval process under the FDCA to protect access to

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[162] *See generally* FDA Good Guidance Practices, *supra* note 64.

[163] *The Facts on Mifepristone*, PLANNED PARENTHOOD (2019), https://www.plannedparenthood.org/uploads/filer_public/42/8a/428ab2ad-3798-4e3d-8a9f-213203f0af65/191011-the-facts-on-mifepristone-d01.pdf.; OTC criteria, *supra* note 67; *Over-the-Counter Medication Abortion*, UCSF-ANSIRH, https://www.ansirh.org/research/ongoing/over-counter-medication-abortion.

[164] *Over-the-Counter Medication Abortion*, UCSF-ANSIRH, https://www.ansirh.org/research/ongoing/over-counter-medication-abortion; M. Antonia Biggs, et al., *A cross-sectional survey of U.S. abortion patients' interest in obtaining medication abortion over the counter*, 109 CONTRACEPTION 25, 25–26 (2022).

medication abortion, further supporting a medication it already approved as safe.[165] This would be a way for FDA to utilize its existing authority to improve access to medication abortion while it is under attack, and coupled with the regulatory analysis protections advocated for in Recommendation D, an OTC switch would persevere beyond immediate judicial opposition.[166]

Much of this research comes from the lead up to the 2023 REMS change that officially removed mifepristone's in-person dispensing requirement.[167] While this modification to mifepristone's REMS was certainly a step in the right direction, the current onslaught of attacks on access to mifepristone calls for a more radical, accessible solution.[168] Even with the updated 2023 REMS that discarded the in-person dispensing requirement, medication abortion still requires medical professionals or designated pharmacies to obtain arduous certifications and the user must get a prescription, which represents its own challenging barriers.[169] Furthermore,

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[165] 21 C.F.R. § 310.200(b).

[166] *See infra* Part IV.D.

[167] *See* FDA Questions and Answers, *supra* note 3; *see generally* ARA Aiken, et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, 128 BJOG 1464, 1465 (2021).

[168] *See generally* GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 3211847 (S.D.W.V. May 2, 2023); Bryant v. Stein, No. 23-cv-00077 (M.D.N.C. Jan. 25, 2023); All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026 (5th Cir. Aug. 16, 2023).

[169] *A cross-sectional survey of U.S. abortion patients' interest in obtaining medication abortion over the counter*, 109 CONTRACEPTION 25, 25 (2022); Lewis Grossman, *Pushing Back with Pills*

because of partisan roadblocks there are numerous states that prohibit telemedicine abortion, or telemedicine generally, and those that need medication abortion the most by mail are unable to obtain it.[170] An RX-to-OTC switch would combat all of these shortcomings of the 2023 REMS update, as well as quelling any potential for Comstock Act-based challenges.[171]

Additionally, the possibility of FDA's pending ACNU rule would be something well applied to bolster OTC approval for mifepristone.[172] While this Comment does not advocate for additional obstacles to medication abortion, there would likely be a vocal contingent opposed to

— *Enhancing Access to Reproductive Health Drugs after Dobbs*, 387 N ENGL J MED 1056, 1057 (2022).

[170] *Id.*; *State Restrictions on Telehealth Abortion*, KAISER FAMILY FOUNDATION (Dec. 2, 2021), https://www.kff.org/womens-health-policy/slide/state-restrictions-on-telehealth-abortion/.

[171] While this Comment will not assess the validity of the Comstock Act contentions, it is important to acknowledge that allowing the consumer to obtain medication abortion directly at a pharmacy would render these challenges mute and protect FDA from further judicial threats. All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026, at *33 (5th Cir. Aug. 16, 2023). Matthew Perone, *What does the Comstock Act, a law from the 1870s, have to do with abortion pills?*, PBS (Apr. 8, 2023), https://www.politico.com/news/2023/05/01/supreme-court-chevron-doctrine-climate-change-00094670; NARAL Anti-Choice Extremism, *supra* note 86.

[172] *See supra,* Part I. B. (discussing the background and use of the proposed rule for additional conditions on over-the-counter approvals).

OTC medication abortion as with anything abortion related.[173] This could be successfully combatted with the use of proposed rule, ACNU, alongside OTC approval.[174] It also further supports the practicality of this recommendation, as an additional safeguard for such a drastic shift in medication abortion access would likely be more supported with additional measures to ensure safe access, as this rule purports to accomplish.[175]

Medication abortion can and should be switched to an OTC, nonprescription medication to eliminate the burdens on its access and greatly expand avenues for people to obtain abortions, especially in light of the recent onslaught of attacks on abortion and on FDA as an agency.[176]

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[173] *See, e.g.,* Kristan Hawkins, *Abortion-by-vending-machine is much worse than it sounds,* FOX NEWS (July. 12, 2023), https://www.foxnews.com/opinion/abortion-vending-machine-much-worse-sounds (representative of the sentiment anti-abortion advocates have towards easily-accessible reproductive healthcare).

[174] *The FDA Announces Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/fda-announces-proposed-rule-nonprescription-drug-product-additional-condition-nonprescription-use (last visited July 16, 2023).

[175] *Id.*; *cf.* Lewis Grossman, *Pushing Back with Pills — Enhancing Access to Reproductive Health Drugs after Dobbs*, 387 N ENGL J MED 1056, 1058 (2022).

[176] *See generally* GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 3211847 (S.D.W.V. May 2, 2023); Bryant v. Stein, No. 23-cv-00077 (M.D.N.C. Jan. 25, 2023); All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026 (5th Cir. Aug. 16, 2023).

The current requirements for medication abortion are unnecessary and burdensome. For example, the American College of Obstetricians and Gynecologists found that, "a clinical examination or ultrasound examination is not necessary before medication abortion."[177] Additionally, there are existing frameworks for helping medication-abortion seekers accurately self-assess their gestational stage in order to take mifepristone within the established ten-week time frame.[178] All of the background research that led FDA to remove the in-person dispensing requirement support the greater step of approving medication abortion for an RX-to-OTC switch. This can be accomplished by FDA approval of the manufacturer's efficacy supplement to an approved NDA or a 505(b)(2) application for a full switch.[179]

C. Promote a Misoprostol-Only Regimen in the Absence of Mifepristone

Similar to the need for an FDA Emergency Use Authorization, an FDA interpretive guidance for a misoprostol-only regimen for medication abortion should be issued in the event of

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[177] *Medication Abortion Up to 70 Days of Gestation*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (October 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[178] Lauren J. Ralph, et al., *Accuracy of self-assessment of gestational duration among people seeking abortion,* 226 AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY 710.e1, 710.e12 (2022); *Over-the-Counter Medication Abortion*, UCSF-ANSIRH, https://www.ansirh.org/research/ongoing/over-counter-medication-abortion.

[179] *Prescription-to-Nonprescription (Rx-to-OTC) Switches*, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches (last visited July 16, 2023).

mifepristone being removed from the market. While this is uncertain, and hopefully unlikely, FDA needs to prepare materials for consumers on how to safely manage a medication abortion with misoprostol only. An interpretive guidance would be the most effective and direct tool to do so, and most importantly is exempt from judicial review.[180] This permits FDA to properly guide consumers in the interest of their health and safety, as banning abortions does not stop abortions, it just makes the abortion-seeker more at risk.[181]

While a misoprostol-only regimen is proven to be safe and effective,[182] it has a slightly higher risk of hospitalization and side effects than the two-drug medication abortion protocol and

[180] Peter Barton Hutt, et al., FOOD AND DRUG LAW (2022) at 77.

[181] *Medication abortion is still possible with just one drug. Here's how it works*, NPR (Apr. 10, 2023), https://www.npr.org/sections/health-shots/2023/04/10/1168857095/misoprostol-only-medical-abortion; *abortion restrictions*, *supra* note 137.

[182] *Medication Abortion Up to 70 Days of Gestation*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (October 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation; *Clinical practice handbook for safe abortion*, WORLD HEALTH ORGANIZATION 1, 22 (2014), https://apps.who.int/iris/bitstream/handle/10665/97415/9789241548717_eng.pdf.

needs to be more carefully managed.[183] While the other FDA recommendations in this Comment would be best to avoid resorting to a misoprostol-only usage, all avenues must be explored.[184]

D. Protect Agency Deference Through Regulatory Analysis Protocols

While many options for safeguarding *Chevron* are through legislative means, there is still a vital option for protecting agency deference and autonomy as a whole. The Office of Management and Budget (OMB) and the Office of Information and Regulatory Affairs (OIRA), a division of OMB, are collectively responsible for agenda-setting the priorities of agencies in conjunction with that of the Executive.[185] Additionally, they are responsible for reviewing and assessing agencies' proposed rules prior to the Federal Register.[186] The force of this supervisory power over executive agencies is that OIRA has a final say over significant rules, monitoring the content and formulation in a watchdog role.[187] As such, under Executive Order 14094 and related Memorandum, OIRA can issue an internal directive to give the utmost deference and "receptivity" to agency in rule review would have the effect of a complete deference rate under

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[183] *Medication abortion is still possible with just one drug. Here's how it works*, NPR (Apr. 10, 2023), https://www.npr.org/sections/health-shots/2023/04/10/1168857095/misoprostol-only-medical-abortion.

[184] *See supra,* Part IV.A; *supra,* Part IV.B.

[185] CONG. RSCH. SERV., RL32397, FEDERAL RULEMAKING: THE ROLE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS 1 (2011).

[186] *Id.*

[187] *Id.*

Chevron.[188] This authority under Executive Order 14094 directs OMB to ensure that the regulatory review process "promotes policies that reflect new developments in scientific and economic understanding."[189] That Order thereby charges OMB and OIRA with ensuring that the process for "significant regulatory action" include the perspectives of those most well-versed and connected to the agency actions.[190] This communication would go through OIRA communication with the desk officer and the rulemaking agency, acting under authority from OMB and the Executive.[191]

Specifically, OMB and OIRA should recommend agency rules for approval that concern issues of significant public importance, and that would otherwise be left unprotected by Congress or the courts. This is exactly what OIRA would be doing by advancing agencies' rules on important policy issues, which include any regulatory action that addresses legal or policy issues that are related to the President's objectives.[192] As connected to the priorities of the current Administration, Executive Order 14076 specifically calls for advancement and protection of reproductive healthcare services.[193] This clear agenda authorizes agencies to work to protect

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[188] *Id.* at 15; Exec. Order No. 14094 88 Fed. Reg. 21,879, 21,458–21,881 (Apr. 11, 2023).

[189] Exec. Order No. 14094, 88 Fed. Reg. at 21,458–21,881; Memorandum: Modernizing Regulatory Review, 86 Fed. Reg. 7,223, 7,059–7,224 (Jan. 26, 2021).

[190] Exec. Order No. 14094, 88 Fed. Reg. 21,879, 21,458–21,881 (Apr. 11, 2023).

[191] CONG. RSCH. SERV., RL32397, FEDERAL RULEMAKING: THE ROLE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS 1, 14 (2011).

[192] *Id.*

[193] Exec. Order No. 14076, 87 Fed. Reg. 42,053, 41,581–42,057 (July 13, 2022).

reproductive freedoms, so OIRA's directive to review regulatory actions that address the President's objectives show clear authorization for them to act in a protective, deferential manner towards FDA actions.[194] It is these same regulatory actions and rules of significance that are most targeted by attacks to strip agencies of their deference under *Chevron*, but would not be subject to judicial review in the same way through this regulatory mechanism.[195] Furthermore, this secondary layer of review and agenda setting insulates against later accusations against agencies, as they are being thoroughly analyzed by the OIRA.[196] The authorization given to OMB and OIRA through this Order empowers these Executive watchdogs to protect those rules by deferring to the agencies' reasonable interpretations as they are written.[197]

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[194] *Id.*; Exec. Order No. 14094, 88 Fed. Reg. at 21,458–21,881.

[195] *But cf. Statutory Clarity and Judicial Review of Regulatory Impact Analysis*, THE REGULATORY REVIEW (Apr. 13, 2019), https://www.theregreview.org/2019/04/15/bull-ellig-regulatory-impact-analysis/ (explaining that while there have been proposals to do so, there is not currently protocol for judicial review of regulatory impact analyses, which accompany OIRA review of significant actions).

[196] *See* CONG. RSCH. SERV., RL32397, FEDERAL RULEMAKING: THE ROLE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS 16–17 (2011). *But see* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026, at *32 (5th Cir. Aug. 16, 2023) (questioning FDA's 2016 Amendments and the 2021 Non-Enforcement Decision).

[197] *See generally* Exec. Order No. 14094 88 Fed. Reg. 21,879, 21,458–21,881 (Apr. 11, 2023); Memorandum: Modernizing Regulatory Review, 86 Fed. Reg. 7,223, 7,059–7,224 (Jan. 26, 2021).

Conclusion

The future of mifepristone, FDA, *Chevron* deference, and executive agency structure are uncertain and disconcerting, but this future is not unavoidable. Agency deference is an invaluable tool that has created much of what safeguards public health and wellbeing today, and the overthrowing of *Chevron* as precedent does not do away with deference as a principle. In the face of an onslaught of cases that threaten *Chevron* in their own ways, FDA and the Executive must act to safeguard the scientific and expert advancements that they have worked on for years.[198] Access to medication abortion must be protected and to do so, FDA must be proactive in exercising its regulatory channels in order to cement abortive healthcare as a priority for public health and this Administration's agenda.

In the face of unprecedented political polarization and ideological influence in mainstream politics, *Chevron* deference is fundamental for preventing deference to FDA from becoming politicized.[199] Medication abortion represents just one of numerous medications that have ideological ties and can be thrown to the wayside in the face of judicial review, particularly

[198] *See generally* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 5266026 (5th Cir. Aug. 16, 2023); Loper Bright Enterprises v. Raimondo, No. 22-451, 2023 WL 3158352 (U.S. May 1, 2023).

[199] Anne Zimmerman, *Politicizing Deference to the FDA Considering the Alliance for Hippocratic Medicine Cases*, YALE JOURNAL ON REG. (April 17, 2023), https://www.yalejreg.com/nc/politicizing-deference-to-the-fda-considering-the-alliance-for-hippocratic-medicine-cases-by-anne-zimmerman/.

with the partisan appointments from the Trump administration.[200] Similar to the ideological barriers COVID-19 vaccines faced, the loss of formalized agency deference will leave public health and wellbeing at the whims of judge's ideologies.[201] Giving disinformation and anti-choice propaganda a mainstream platform through judicial opinions contrary to agency expertise will plunge the country into a public healthcare crisis and prevent thousands of people from accessing reproductive healthcare, solely by virtue of where they live within a federal circuit.[202]

[200] *See generally* Natasha Brunstein and Richard L. Revesz, *Mangling the Major Questions Doctrine*, 74 ADMIN L. REV. 217 (2022); Millhiser, *supra* note 113.

[201] *See, e.g.,* Millhiser, *supra* note 113 (explaining the use of MQD to quell the Biden's administration's COVID-19 efforts).

[202] *Compare All. for Hippocratic Med.*, 2023 WL 5266026 *with* NARAL Anti-Choice Extremism, *supra* note 86.