No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellants,

and

DANCO LABORATORIES, LLC,
Intervenor-Appellant,

On Appeal from the United States District Court
for the Northern District of Texas
No. 2:22-cv-00223-Z (Hon. Matthew J. Kacsmaryk)

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 29.2, the undersigned counsel of record for *amicus curiae* GenBioPro, Inc. certifies that the following listed persons and entities, in addition to those listed in Appellants' and Intervenor-Appellant's Certificates of Interested Persons, have an interest in this brief. These representations are made in order that judges of this Court may evaluate possible disqualification or recusal.

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Pursuant to Federal Rule of Appellate Procedure 29, GenBioPro, Inc. respectfully submits this brief as *amicus curiae* in support of appellants. All parties have consented to this filing.[1]

INTERESTS OF *AMICUS CURIAE*

GenBioPro, Inc. ("GenBioPro") holds a U.S. Food and Drug Administration ("FDA")-approved Abbreviated New Drug Application ("ANDA") to market generic mifepristone. GenBioPro is the sole supplier of generic mifepristone in the United States.

Plaintiffs in this case challenge FDA's approval of GenBioPro's ANDA, which implicates GenBioPro's interests. GenBioPro agrees in full with appellants that the District Court's sweeping order purporting to "stay" the approval of both GenBioPro's ANDA and appellant Danco Laboratories, LLC's ("Danco") New Drug Application ("NDA"), along with a series of subsequent FDA actions related to mifepristone, should be reversed for numerous independent reasons.

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[1] No party's counsel authored this brief in whole or in part. Nor did any party or party's counsel, or any other person other than *amicus curiae*, its members, or its counsel, contribute money that was intended to fund preparing or submitting this brief.

Because GenBioPro provides all generic mifepristone used for medication abortion in the United States, a stay of its ANDA approval would put access to reproductive health care at risk for the hundreds of thousands of patients GenBioPro serves. It would also threaten GenBioPro's commercial viability given that more than 95 percent of GenBioPro's product revenue derives from the sale of generic mifepristone. GenBioPro submits this brief to highlight issues unique to GenBioPro and its ANDA.

SUMMARY OF ARGUMENT

This Court should reverse the District Court's preliminary injunction order in full. As appellants' briefs amply demonstrate, Plaintiffs lack standing; their key claims are time-barred; they are unlikely to succeed on the merits because the administrative and scientific record proves decisively that FDA's challenged actions were lawful; and the equities overwhelmingly favor appellants.

In particular, if this Court reverses the District Court's stay of Danco's NDA approval, as it clearly should, it must also reverse the stay of GenBioPro's ANDA approval. The motions panel of this Court, which on April 12, 2023 partially stayed the District Court's order (the "April

12 Order"), incorrectly drew a distinction between the two approvals, treating GenBioPro's generic approval as stayed while the original branded approval remained in effect. ROA.4379. This was wrong for several reasons.

First, consistent with the mandatory chemical and therapeutic equivalence of brand-name and generic mifepristone, *see* 21 U.S.C. § 355(j)(2)(A)(iv), FDA has always treated GenBioPro's approval identically to Danco's, including by regulating their distribution and use under a single program, *see* ROA.768-769.

Second, neither the Plaintiffs' complaint nor the District Court's order contemplated any distinction between the two drugs other than their approval dates, and no party has suggested one before this Court. Instead, Plaintiffs have challenged GenBioPro's ANDA approval solely on the ground that it relied on the underlying approval of Danco's product Mifeprex.® R.4499.

Third, any distinction that enables sale of Mifeprex while prohibiting sale of GenBioPro's product would violate the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Hatch-Waxman Amendments that established the modern generic drug-approval regime. These

amendments to the FDCA were framed to ensure that the products are the "same drug" and subject to identical requirements. Yet there is one distinction: By virtue of that program's requirements, FDA's approval of GenBioPro's ANDA actually rests on an even more robust overall scientific database than the support that existed at the time of the original Mifeprex approval in 2000.

Finally, there is no rational basis for treating GenBioPro's approval differently from Danco's. A contrary approach, like the one taken in the April 12 Order, would raise constitutional equal protection concerns, upend protected reliance interests of both GenBioPro and FDA, and create grave practical consequences for access to reproductive health care nationwide.

BACKGROUND

A. As Federal Law Requires, FDA Has Always Treated GenBioPro's Generic Mifepristone as Scientifically and Medically Equivalent to Danco's Mifeprex

In 1984, Congress amended the FDCA to expand access to affordable generic drugs by reducing barriers to generic market entry. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Those Hatch-Waxman Amendments created the modern generic drug industry. *See PLIVA, Inc. v. Mensing*,

564 U.S. 604, 626 (2011). While a branded company seeking to market a novel drug product must submit an NDA based on a multi-phase clinical trial program, Hatch-Waxman permits a company like GenBioPro that seeks to market a generic version of a previously approved "reference" drug to file only an ANDA that demonstrates its product is the same drug and therapeutically equivalent. *See id.* at 612-13. It was under this framework that GenBioPro brought its generic version of mifepristone to market in 2019, after spending nearly a decade developing its therapeutically equivalent medication. *See* ROA.768-769.

Like every other ANDA, GenBioPro's ANDA approval is justified, as a matter of both science and law, by all of the data supporting the original NDA. *See* 21 U.S.C. § 355(j). In approving GenBioPro's application, FDA explicitly determined its generic mifepristone "to be bioequivalent and, therefore therapeutically equivalent to the reference listed drug (RLD), Mifeprex Tablets, 200 mg, of Danco Laboratories, LLC." ROA.768. As the FDCA further requires, GenBioPro's generic mifepristone and Danco's Mifeprex have labels that are identical in every meaningful respect, again in recognition of the fact that they are "bioequivalent" and have "the same therapeutic effect," with exactly the

same benefits and risks reflected in approved labeling. 21 U.S.C. § 355(j)(2)(A)(iv)-(v), (j)(4)(F)-(G).

As set forth in FDA's 2019 ANDA approval letter, and as required by federal law, FDA subjected GenBioPro's generic mifepristone to the same distribution and administration conditions, known as a "Risk Evaluation and Mitigation Strategy" or "REMS," including Elements to Assure Safe Use ("ETASU"), as Danco's product. Those conditions were all contained in a single, unified document and shared system: the "Mifepristone REMS Program." ROA.768-769 (approving GenBioPro's ANDA application based on 21 U.S.C. § 355(j) and 21 U.S.C. § 355-1, which authorizes FDA to require a REMS for drug approvals). At all times since 2019, FDA has continued to treat GenBioPro's generic mifepristone as chemically and therapeutically identical to Danco's Mifeprex, applying each new REMS iteration with equal force to GenBioPro's product. *See generally Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN. (Mar. 23, 2023), http://bit.ly/41usBjY.[2]

[2] Any changes to the REMS for Mifeprex would thus apply equally to GenBioPro's generic mifepristone.

In short, the scientific basis for the approval of the Danco NDA and the GenBioPro ANDA is identical; they are rated by FDA as completely substitutable at the pharmacy level; and both their labeling and the FDA restrictions on how they can be distributed, prescribed, and used are all precisely the same.

B. The Parties and District Court Have Treated GenBioPro's Generic Mifepristone Identically to Danco's Mifeprex

The parties and the District Court treated the branded and generic mifepristone products as the same drug and subject to precisely the same set of FDA requirements and restrictions. That is clear from the record below. The only basis Plaintiffs offered to set aside GenBioPro's 2019 ANDA at the District Court—summed up well by Plaintiffs' counsel at the preliminary injunction hearing—was that "the underlying approval upon which [the ANDA approval] relied" was unlawful. ROA.4499. That position was entirely consistent with Plaintiffs' Complaint, in which they relied on the fact that FDA approves an ANDA only after finding the generic drug product is chemically identical to the approved reference drug. *See* ROA.98. Plaintiffs never offered any other grounds for invalidating GenBioPro's ANDA.

The record below further establishes that the parties and the District Court agreed that GenBioPro's generic mifepristone is bioequivalent and therapeutically equivalent to Danco's Mifeprex and that the two should be treated identically. In fact, Plaintiffs' claim for relief in their Complaint and other submissions relied on that equivalent treatment. *See* ROA.137 ("FDA determined GenBioPro's Mifepristone . . . 'to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Mifeprex'"); ROA.1044; *see also* ROA.1060-1061 ("FDA approved GenBioPro, Inc.'s abbreviated new drug application for a generic version of mifepristone, relying on Mifeprex's safety data. . . . GenBioPro's generic version of mifepristone has the same labeling and post-marketing restrictions as does Danco's Mifeprex.").

In its preliminary injunction order, the District Court also relied on the fact that the NDA and ANDA products had been deemed the "same" drug by FDA. Indeed, the District Court found that Plaintiffs were likely to succeed on their challenge to the 2019 ANDA precisely *because* the two FDA approvals must stand or fall together. *See* ROA.4366 ("If FDA withdraws the listed drug on which the ANDA-approved generic drug is

based, the agency is generally required to withdraw the generic drug as well." (citing 21 U.S.C. § 355(j)(6); 21 C.F.R. § 314.151)).[3]

As the Plaintiffs' legal theory and the District Court's decision reflect, no evidence of any kind has been offered that the GenBioPro ANDA has any less scientific validity than the Danco NDA. To the contrary, as the motions panel of this Court recognized in the April 12 Order, "[t]o approve a generic version of a previously approved drug, FDA reviews whether an [ANDA] contains information showing that the proposed generic drug is materially the 'same' as the approved drug." ROA.4380.

ARGUMENT

I. Drawing Non-Scientific Distinctions Between Generic and Brand-Name Drugs Would Violate the FDCA as Amended by Hatch-Waxman

As the Supreme Court recognized in *Mensing* and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), and as this Court has confirmed, *see Eckhardt v. Qualtest Pharms.*, 751 F.3d 674, 676, 678 (5th Cir. 2014), the right to manufacture and distribute generic drugs

[3] GenBioPro has filed a separate suit against FDA to protect its constitutional and statutory rights in FDA's approval of its ANDA. *See GenBioPro, Inc. v. FDA*, No. 8:23-cv-01057-TDC (D. Md.).

rests on the complete identity of the original NDA- and ANDA-approved products. Any distinctions between brand-name and generic drugs must be rejected as contrary to Congress' mandate in the Hatch-Waxman Amendments that bioequivalent drugs be treated alike for purposes of FDA regulation. As Justice Thomas wrote for the Supreme Court in *Mensing*, "[u]nder this law, 'generic' drugs can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA. . . . This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." 564 U.S. 604, 612 (2011) (citing 21 U.S.C. § 355(j)(2)(A)); *accord Bartlett*, 570 U.S. at 477; *see FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).

Indeed, the very purpose of the Hatch-Waxman Amendments was to "speed the introduction of low-cost generic drugs to market," by allowing "a generic competitor to file an [ANDA] piggy-backing on the brand's NDA." *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012); *see also Eckhardt*, 761 F.3d at 676 ("In essence, these amendments allow a generic drug manufacturer to piggy-back on

the FDA approval of a brand name drug—greatly accelerating the process for receiving approval . . . .").

Against the FDCA's well-settled statutory backdrop, this litigation illustrates the manifest danger of allowing federal drug approvals—especially generic approvals—to be enjoined or "stayed" nationwide in decisions rendered by individual district courts based on the claims of particular private litigants.[4] Instead of a predictable, science-based

[4] The District Court erroneously invoked Section 705 of the Administrative Procedure Act to invalidate the longstanding drug approvals in this case. Section 705 does not authorize a court to stay years-old agency action, but instead permits the "reviewing court [to] issue 'all necessary and appropriate process to *postpone the effective date* of an agency action or to preserve status or rights pending conclusion of the review proceedings.'" *Fort Worth Nat'l Corp. v. Fed. Sav. & Loan Ins. Corp.*, 469 F.2d 47, 53 (5th Cir. 1972) (quoting 5 U.S.C § 705) (emphasis added). Consistent with that standard, this Court has utilized Section 705 to stay only agency action that is pending or contemporaneous with the challenge. *See, e.g.*, *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1143 (5th Cir. 2021) (issuing a stay of FDA's contemporaneous issuance of marketing denial order pursuant to Section 705); *Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (staying *pending* agency action pursuant to Section 705). The District Court's extension of Section 705 to reach backwards more than two decades to "stay" long-past agency action would implicate serious separation of powers concerns and run counter to the intended function of the rule. *See Sampson v. Murray*, 415 U.S. 61, 68 n.15 (1974) (Section 705 was not intended "to fashion new rules of intervention for District Courts" (citing S. REP. NO. 79-752, at 27, 44 (1945)); *see also* Brief for Appellants at 62-63, No. 23-10362 (5th Cir. Apr. 26, 2023), Doc. No. 222.

system that, by congressional mandate, treats chemically and therapeutically identical products alike and therefore allows the many participants in a nationwide market to plan rationally, such an *ad hoc* approach yields a haphazard process under which the lawfulness of drug products that are considered the same drug can change in the space of a few days based on courtroom science and sources like unpublished law review articles. *See, e.g.*, ROA.4335 n.21 (citing forthcoming law review article). That is no way to regulate the approval and marketing of drugs in a nationwide market.

II. The Scientific Data Supporting the Safety and Effectiveness of Mifepristone Was Even More Robust In 2019 Than In 2000

FDA first approved Mifeprex in 2000 based on an extensive body of scientific data substantiating its safety and effectiveness. As the body of available data grew exponentially over the next two decades, FDA, under leadership appointed by five separate presidents, repeatedly reaffirmed those safety and effectiveness determinations for Mifeprex. As a result, by the time GenBioPro's ANDA was approved in 2019, the scientific and medical data in favor of mifepristone *was far more compelling* than the already unassailable foundation for Mifeprex's initial approval in 2000.

In addition to general advances in research, the data supporting mifepristone has become stronger over time because FDA is required by law to continue monitoring a drug's safety and efficacy after approval. Once FDA approves an NDA, the FDCA and FDA's implementing regulations impose post-marketing monitoring and reporting requirements on drug manufacturers. *See* 21 U.S.C. § 355(k) (imposing record-keeping and reporting requirement on NDA- and ANDA-holders); *id.* § 355(o) (explaining FDA's authority to require post-marketing studies and clinical trials); 21 C.F.R. § 314.80 (explaining requirements for "post-marketing reporting of adverse drug experiences"); *see also Wyeth v. Levine*, 555 U.S. 555, 569 (2009) (noting "that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments"). Those obligations are even greater for drugs, like mifepristone, approved subject to a REMS. *See* 21 U.S.C. § 355-1(f)(5) (requiring FDA to periodically reassess REMS requirements and performance to ensure that the benefit-risk balance of distribution and use restrictions is maintained).[5]

[5] No party has alleged in this case that either Danco or GenBioPro ever failed to comply with any of these post-marketing data collection requirements.

Here, the facts demonstrate that FDA has received and scrutinized additional data supporting the safety and effectiveness of mifepristone. FDA's initial approval of mifepristone in 2000 was based on three clinical studies involving about 2,500 patients. *See* ROA.591. That was a typical amount of supporting clinical study data for drugs approved at that time (as well as today).[6] But, by 2019, when FDA approved GenBioPro's ANDA, the supporting clinical data had grown *exponentially*. According to an official audit and report of the U.S. Government Accountability Office ("GAO"), an independent investigatory body within Congress, by March 2018, FDA's continuing approval of mifepristone (including the specific requirements for its safe use promulgated by FDA in a 2016 update to the Mifepristone REMS) was supported by nearly 100 studies involving more than 50,000 women safely treated with the drug. U.S. GOVERNMENT ACCOUNTABILITY OFFICE, INFORMATION ON MIFEPREX

[6] *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective (Phase 3 studies typically involve "several hundred to about 3,000 people").

LABELING CHANGES AND ONGOING MONITORING EFFORTS, GAO-18-292, 12-16 (2018), https://bit.ly/3HaESCO.

The 2018 GAO audit and report, which had been commissioned by Members of Congress opposed to abortion, focused on many of the same specific issues now raised by Plaintiffs. In each instance, GAO found that the most recent changes in the REMS were supported by voluminous data, most of which did not exist in 2000 when the drug was initially approved. GAO reported that FDA had properly reviewed 19 studies that supported the extension of the period for the safe use from seven to ten weeks gestation. *Id*. at 12-13. GAO likewise found that FDA's reduction of the appropriate number of office visits (from 3 to 1), and the agency's expansion of the types of health care providers who could dispense the drug, were amply supported by scores of studies involving more than 45,000 patients. *Id.* at 13-15. Virtually all of those studies were conducted and published *after* the initial NDA approval in 2000. *Id*. at 12-15, nn.32-42.

Even beyond the published clinical studies, by the time of the 2019 ANDA approval, there was also extensive real-world data from the use of mifepristone in normal medical practice in the United States, which had

accumulated from the time of the initial NDA approval in 2000 (and continues to accumulate today). There was, of course, no such use in an American population before mifepristone was initially approved in 2000. But, as GAO reported to Congress, by 2016 there were some 15 years of such data which "demonstrated acceptable safety for the [2016] changes to the Mifeprex regimen." *Id.* at 18-19.

GAO specifically found that, from the time of initial approval in 2000 through mid-2017, FDA's adverse event reporting system showed a total of 20 deaths among the 3.2 million patients who by then had used the drug—a rate GAO calculated to be 0.0006 percent. *Id.* at 21.[7] GAO then contextualized this data, explaining that "a study of mortality among women who did not have an abortion and proceeded to a live birth estimated a mortality rate of 0.009 percent"—that is, 15 times greater. *Id.*

[7] Even those 20 deaths were not found to be "caused" by mifepristone; the report explained that "unrelated health condition[s] observed near the time that a woman took Mifeprex may be included in FDA's adverse event summary data." *Id.* at 21 n.52; *see id.* at 3 n.9 (noting "adverse events associated with Mifeprex in [FDA's] summary reports do not necessarily reflect a conclusion by the company or FDA that the drug caused or contributed to an adverse event").

Given the central political importance of the abortion debate in the United States, mifepristone is one of the most scrutinized drugs in history. Yet, in study after study and report after report, politically neutral experts have declared mifepristone to be safe and effective for its intended use. And the decades of additional study data bolstering the scientific basis for the initial 2000 approval gave FDA's 2019 ANDA decision even more support—though, again, under the FDCA and Supreme Court precedent, the approval of the branded drug is all that is necessary to establish the lawfulness of the 2019 ANDA.

III. There Is No Rational Basis to Treat GenBioPro's ANDA Differently from Danco's NDA in This Litigation

As a matter of the FDCA, as well as scientific and medical fact, GenBioPro's ANDA approval is equivalent to Danco's NDA approval. The April 12 Order's distinction between the two, preliminarily concluding that a challenge to Danco's approval was barred by statute-of-limitations grounds while GenBioPro's approval was not, *see* ROA.4400, was irrational and contrary to multiple legal and practical principles. This Court should not continue that approach.[8]

[8] In fact, there are circumstances where a generic approval may remain in effect even when the reference drug NDA approval is withdrawn or

First, in light of the legal framework for the approval of generic drugs, once the statute of limitations has run on any challenge to the underlying NDA approval, the same should be true for the ANDA. Given that a generic drug must be the same drug and therapeutically equivalent to the brand-name drug, a distinction between the two based solely on the date of approval is "at odds with the basic policies of all limitations provisions: repose, elimination of stale claims, and certainty about a plaintiff's opportunity for recovery and a defendant's potential liabilities." *Rotella v. Wood*, 528 U.S. 549, 555 (2000).

When manufacturers are weighing whether to invest in a generic version of a branded drug that has been on the market for 19 years, they should be entitled to rely on FDA's continued approval of the reference NDA. *See* 28 U.S.C. § 355(j). That reliance interest is even stronger where, as here, FDA has received and rejected a citizen petition, ROA.635-667, and the six-year statutory period for challenging the denial of that petition has run, 28 U.S.C. § 2401.

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suspended. That is true when the underlying NDA withdrawal or suspension was not based on safety and effectiveness, in which case the ANDA is unaffected. 21 U.S.C. § 355(j)(6).

FDA, too, must be able to develop its drug approval programs in reliance on reasonable assumptions about potential judicial challenges. Once the statute of limitations has run for challenges to the approval of a brand-name drug, FDA's interests in certainty and legal repose should apply equally to its approval and consideration of any ANDA application. *See FDIC v. RBS Sec. Inc.*, 798 F.3d 244, 263 (5th Cir. 2015) (recognizing FDIC's enhanced interest in "certainty" regarding the time period in which it could bring suit so the agency could plan and execute its critical statutory duties). In the case of mifepristone, FDA's approval has become cemented in the agency's regulatory framework, and the American practice of medicine, over almost a quarter-century.

The motions panel's illogical distinction[9] between the NDA and ANDA for statute of limitations purposes is underscored by its diametrically opposed approach to the issue of exhaustion. On that matter of reviewability, the motions panel was content to treat the NDA

[9] Prior to the motions panel, no one—not the parties, not even the District Court—had ever suggested that generic mifepristone should be treated differently from its brand-name counterpart. Instead, as explained above, Plaintiffs' sole basis for challenging—and the District Court's sole basis for "stay[ing]"—the ANDA approval was the recognition that generic and branded drugs must be treated identically. ROA.4366, 4373.

and ANDA *as exactly the same*, concluding that Plaintiffs' failure to exhaust any challenge to GenBioPro's 2019 ANDA approval at the agency could be excused based on futility given that FDA had previously denied a challenge to the 2000 Approval back in 2016. The motions panel declared that futility applied "with equal force to plaintiffs' challenge to the 2019 Generic Approval *because it's entirely dependent on the 2000 Approval*." ROA.4409 (emphasis added). If the two approvals are interchangeable for exhaustion purposes, however, there is no logical basis to treat them differently for statute-of-limitations purposes.[10]

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[10] More fundamentally, Plaintiffs' challenge to the ANDA approval *should* have been dismissed on exhaustion grounds. *See* ROA.2111-112. Plaintiffs never filed a citizen petition contesting GenBioPro's ANDA approval at the FDA, ignoring express statutory requirements for challenging generic approvals. 21 U.S.C. § 355(q). That omission is fatal to their claim given that FDA regulations expressly require that step prior to judicial review. 21 C.F.R. § 10.45(b); s*ee Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 180-81 (D.C. Cir. 2009); *see also* 21 C.F.R. § 10.35(b) (establishing procedure for requesting a stay of FDA action). Both the District Court and the motions panel were wrong to excuse exhaustion based on "futility," especially since some Plaintiffs had a citizen petition related to mifepristone pending at the FDA from 2019 through 2021, yet they never used that vehicle to raise any of their concerns about the ANDA approval. Their failure should not be overlooked under the guise of futility. *See Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (futility exception is "quite restricted" and only applies in "the most exceptional circumstances") (citation omitted); *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 176 (5th Cir. 2012) ("exceptions [to administrative exhaustion] apply ... only

Second, this Court should avoid an interpretation of the FDCA and Hatch-Waxman that would implicate serious constitutional concerns. *See Cargill v. Garland*, 57 F.4th 447, 471-72 (5th Cir. 2023). It is an elementary principle of constitutional and administrative law that similarly situated parties must be treated equally. *See, e.g.*, *Hines v. Quillivan*, 982 F.3d 266, 277 (5th Cir. 2020) (Elrod, J., concurring) ("The Equal Protection clause forbids the Government from giving differential treatment to people who are similarly situated, unless the Government has a rational basis for doing so."); *St. Joseph Abbey v. Castille*, 712 F.3d 215, 217 (5th Cir. 2013) (sustaining Equal Protection challenge to law granting funeral homes exclusive rights to sell caskets); *Univ. of Texas M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 479 (5th Cir. 2021) ("An agency must provide an adequate explanation to justify treating similarly situated parties differently.") (quoting *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005)). Because GenBioPro's generic drug is the biological and medical equivalent of Danco's NDA, any distinction between the two drugs based

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in extraordinary circumstances") (alterations in original) (citation omitted).

on Plaintiffs' delay in filing suit is inherently arbitrary and should thus be rejected.

Finally, reviving the statute of limitations for a generic drug approval, while precluding challenges to the brand-name drug, creates potentially devastating practical consequences. Because generic approvals typically occur many years after the initial NDA approval, such an application of the statute of limitations would set a concerning precedent and put generics at far greater risk of belated "second-guessing" by challengers and courts. That would be no small problem for the generic competition Congress has mandated. Generic drug products were used to fill 91 percent of all prescriptions in 2021, enabling savings of more than $370 billion. ASSOCIATIONS OF ACCESSIBLE MEDICINES, THE U.S. GENERIC AND BIOSIMILAR MEDICINES SAVINGS REPORT 3 (Sept. 2022), https://accessiblemeds.org/resources/reports/2022-savings-report. Serious threats to the stability of the generic drug-approval program accordingly risk destabilizing access to prescription drugs nationwide.

CONCLUSION

For the foregoing reasons, the Court should reverse the District Court's preliminary injunction order and reject any erroneous dichotomy between the NDA and ANDA approvals for mifepristone.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on May 1, 2023, I electronically filed the foregoing brief with the Clerk of the Court by using the appellate CM/ECF system. I further certify that the participants in this case are CM/ECF users and that service will be accomplished by using the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief contains 4,439 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook font) using Microsoft Word.

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