Nos. 25-2575 & 25-2662

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

COMMONWEALTH OF PENNSYLVANIA, and STATE OF NEW JERSEY,

Plaintiffs-Appellees,

v.

PRESIDENT UNITED STATES OF AMERICA, *et al*.,

Defendants-Appellants,

and

LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,

Intervenor-Defendant-Appellant.

BRIEF OF *AMICI CURIAE* DR. MARGARET HAMBURG, DR. STEPHEN OSTROFF, AND DR. PETER LURIE

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TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

INTERESTS OF *AMICI CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 6

I. The FDA approval process demonstrates and ensures that Covered Contraceptives are safe and effective. 6

A. FDA approval is a rigorous standard that ensures the safety and effectiveness of drugs and devices. 8

i. FDA rigorously vets new drugs 9

ii. FDA imposes similar requirements for medical devices 11

iii. FDA and industry continue to monitor products postmarket ...12

B. The Covered Contraceptives received approval through these rigorous processes and continue to be monitored.....13

II. HRSA chose to include contraceptives in its Guidelines because they are demonstrably safe and effective, based on FDA review. 16

III. The Final Rules do not contain a sufficient basis for Defendants to cast doubt on whether contraception is safe, effective, and beneficial. 18

A. The Final Rules do not identify any novel health concerns associated with Covered Contraceptives.....20

i. The Final Rules do not contain data supporting uncertainty as to the health effects of Covered Contraceptives.....20

ii. FDA warnings already contemplate and discuss side effects of contraception.....24

iii. Concerns about side effects of hormonal contraceptives provide no basis for diminishing coverage of other Covered Contraceptives 25

B. Defendants identify no "uncertainty" as to whether contraceptives are effective at preventing pregnancy 27

CONCLUSION.....31

TABLE OF AUTHORITIES

CASES

Am. Radio Relay League, Inc. v. FCC, 524 F.3d 227 (D.C. Cir. 2008) 19

Ctr. for Auto Safety v. Fed. Highway Admin., 956 F.2d 309 (D.C. Cir. 1992) 19

Encino Motorcars, LLC v. Navarro, 579 U.S. 211 (2016) 19

FCC v. Fox Television Stations, Inc., 556 U.S. 502 (2009) 19

Getty v. Fed. Savs. & Loan Ins. Corp., 805 F.2d 1050 (D.C. Cir. 1986) 24

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983)) 19

Schering Corp. v. FDA, 51 F.3d 390 (3d Cir. 1995) 6

STATUES & REGULATIONS

21 U.S.C. § 3.2 9

21 U.S.C. § 3.4 9

21 U.S.C. § 360c 11

21 U.S.C. § 360e 11

21 U.S.C. § 393 6

42 U.S.C. § 300gg-13(a)(4) 16

21 C.F.R. § 312.21 9

21 C.F.R. § 312.32 9

21 C.F.R. § 312.33 9

21 C.F.R. § 314.50 10

21 C.F.R. § 314.80 12

21 C.F.R. § 314.81 12

21 C.F.R. § 314.101 10

21 C.F.R. § 807.87 11

21 C.F.R. § 807.92 11

21 C.F.R. § 814.82 12

21 C.F.R. § 814.84 12

21 C.F.R. § 860.7 12

Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013) 2

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A.S. Kesselheim et al., *Physicians' Perspectives on FDA Approval Standards and Off-Label Drug Marketing*, 179 JAMA Internal Med. 707 (2019), https://doi.org/10.1001/jamainternmed.2018.8121 7

Ctrs. for Disease Control and Prevention, *Unintended Pregnancy* (2019), https://tinyurl.com/yk3vftch 29

Dalkon Shield Sale Halted by Company, N.Y. TIMES (June 29, 1974), https://tinyurl.com/2rhb6v3r 14

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Food & Drug Admin., *Development & Approval Process* (Aug. 8, 2022), https://tinyurl.com/bdekkwzw 10

Food & Drug Admin., *Plan B One-Step (1.5 mg levonorgestrel) Information* (Dec. 23, 2022), https://tinyurl.com/yu6ckhtu 14

Food & Drug Admin., *Premarket Notification 510(k)* (Aug. 22, 2014), https://tinyurl.com/msmpp7es 11

Food & Drug Admin, *Prescribing Information: Yaz* (May 2023), https://tinyurl.com/yuvymah7 ..... 11, 24

Food & Drug Admin., *Sentinel System Overview* (2017), https://tinyurl.com/3r8ubfpy 12

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Marlon Perera & Michael J. Morris, *From Concept to Regulatory Drug Approval: Lessons for Theranostics*, 63 J. Nucl. Med. 1793 (2022), https://doi.org/10.2967/jnumed.121.2633012 7

Nat'l Insts. of Health, *Reimbursement Knowledge Guide for Medical Devices*, § 2.1. Available at: https://tinyurl.com/bdf6p4an 7

Paragard, *Fact Sheet*, https://tinyurl.com/mpawhm6x 14

S. White Junod, *FDA Approval of First Oral Contraceptive* (July 1998), https://tinyurl.com/4t89aevc 14

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INTERESTS OF *AMICI CURIAE*

Amicus Dr. Margaret Hamburg is a physician and former Commissioner of the Food and Drug Administration ("FDA"). Dr. Hamburg held this position from May 2009 to April 2015.

Amicus Dr. Stephen J. Ostroff is a physician, researcher, and former Acting Commissioner of FDA. Dr. Ostroff held this position from April 2015 to February 2016 and again from January to May 2017.

Amicus Dr. Peter Lurie is a physician who currently serves as President and Executive Director of the Center for Science in the Public Interest, a 501(c)(3) nonprofit consumer advocacy organization whose work focuses on the promotion of evidence-based policy, transparency, and scientific integrity. Dr. Lurie previously worked in senior roles at FDA for eight years, including serving as an Associate Commissioner from 2014 through 2017.

Amici in this case are intimately familiar with the approval and monitoring processes used by FDA to ensure that the drugs and devices it approves are safe and effective.[1] They are interested in ensuring that accurate information regarding the safety and effectiveness of FDA-approved products is communicated to the

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[1] This brief is filed with the consent of all parties. Fed. R. App. P. 29(a)(2). No counsel for a party authored any part of this brief and no party, party's counsel, or person other than the *Amici* and their counsel made a monetary contribution to fund the brief's preparation or submission. Fed. R. App. P. 29(a)(4)(E).

public, and that the rigors of FDA's scientific evaluations are not improperly disregarded by policies that, without a rational basis or evidence, cast doubt upon or call into question whether products that FDA has approved are safe and effective.

SUMMARY OF ARGUMENT

This case concerns the expanded Religious and Moral Exemptions, *see* JA0410, JA0465 (the "Final Rules"), which concern employers' obligation to provide no-cost coverage for 17 methods of birth control for which FDA has approved products as safe and effective ("Covered Contraceptives"), and which the Health Resource and Services Administration ("HRSA") has included in its Women's Preventative Care Guidelines (the "Guidelines") since their first issuance in 2011.[2] Until the Final Rules were promulgated, it is undisputed that Defendants "considered contraceptive methods and counseling services to be safe, effective, and beneficial." JA0051 (citing 78 Fed. Reg. 39,870, 39,872-73, 38,887 (July 2, 2013)); *see also* JA0701-02 (recognizing the "overall benefits" of access to Covered Contraceptives, including prevention of unintended pregnancy and the

[2] Although FDA has approved 18 methods of birth control (*see* JA1741-60), because the coverage guidelines from HRSA focus on preventative care for women, vasectomies are excluded. Thus, only 17 of FDA's approved methods are at issue in this case. *See* JA0715-18.

"demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy").

In the Final Rules, however, responding to comments that purport to flag safety concerns surrounding certain Covered Contraceptives and questions about the effectiveness of contraception in reducing pregnancy rates, Defendants assert that "reexamination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues [of safety and effectiveness] than the Departments previously acknowledged" and that "[t]he uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions [to the Covered Contraceptives mandate] and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines." *See* JA0428.

For three critical reasons, however, the "uncertainty" and "ambiguity" that the Final Rules purportedly identify do not provide a sufficiently reasoned explanation, as required by the Administrative Procedure Act ("APA"), for the decision to depart from existing policy, which is comprehensive insurance coverage of these contraceptive methods. *First*, Defendants ignore that FDA has – in accordance with its expertise and rigorous approval processes – already made

determinations as to the safety and effectiveness[3] of Covered Contraceptives, with some products having been approved and safely used on the market for over 50 years.

As the Plaintiff States correctly asserted at the District Court, the Final Rules "ignore the FDA's undisputed determination that the [17] approved methods of contraception are 'proven safe and effective.'" Pls.' Sum. J. Br., Dist. Ct. Dkt. 341-1, at 30. By failing to acknowledge FDA's determination that the Covered Contraceptives are safe and effective based on FDA's rigorous approval process, as well as the ongoing safety monitoring of the products once they have entered the market, Defendants have ignored a key aspect of the coverage-determination scheme that the expanded exemptions now upend.

Second, HRSA chose to include FDA-approved contraceptives in the Guidelines precisely because of the robust evidence of their safety and effectiveness. Further, the Guidelines were informed by the importance of access to the full array of FDA-approved contraceptives, acknowledging that not every method of contraception will be appropriate for the needs of each individual. By

[3] In public health, a distinction is commonly made between "efficacy" (the effectiveness of a product in clinical trials) and "effectiveness" (the product's measured performance in clinical settings and the real world). FDA assesses efficacy, while as explained *infra* Sec. III., Defendants cite to data on effectiveness. Because throughout this litigation, these terms generally have been used interchangeably, this Brief uses the term effectiveness as its default.

failing to acknowledge the diversity in the covered products that range from daily pills to devices inserted into the body for years, and instead treating all Covered Contraceptives in the same way, Defendants have acted unreasonably, contrary to the mandates of the APA.

Third, the discussion in the Final Rules fails to supply an adequate basis for Defendants to depart from their prior position that FDA-approved contraceptives are safe and effective and that access thereto is beneficial. Instead, in the Final Rules, Defendants briefly reference a limited number of cherry-picked studies that do not support their assertions of "uncertainty," let alone provide a sufficient basis for casting doubt on the safety, effectiveness, and benefits of products that FDA has approved and HRSA has included in its Guidelines. And although the Final Rules purportedly "do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines," JA0429, by justifying limiting women's access to FDA-approved contraceptives based on "uncertainty" surrounding whether they are safe and effective products that benefit women, the Final Rules directly undermine the basis for including them in the Guidelines.

As demonstrated herein, Defendants have failed to provide a sufficiently reasoned explanation for asserting purported "uncertainty" as to the safety, effectiveness and benefits of Covered Contraceptives, or for changing their

position on this issue; rather, as FDA has made clear by granting and maintaining approval for these products, they are safe and effective methods for pregnancy prevention when used as labeled. Further, Defendants rely on studies concerning certain forms of contraception (primarily hormonal contraception) to make sweeping conclusions about all 17 Covered Contraceptives (which include five different drugs, five different devices, and six combination products, in addition to a surgical method), disregarding the diversity of mechanisms of action, health effects, and track record of safety.

ARGUMENT

I. The FDA approval process demonstrates and ensures that Covered Contraceptives are safe and effective.

By mandate of Congress, determinations as to the safety and effectiveness of drugs and devices – including contraceptives – are to be made by FDA – the agency with the requisite competence and authorization to make such determinations. 21 U.S.C. § 393(b)(2) (charging FDA with "ensuring that … drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use."); *see also Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (explaining that "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise").

To execute its congressional mandate, FDA requires both rigorous premarket evaluation and continuing postmarket monitoring, creating a comprehensive review system for drugs and devices that is widely considered to be among the world's most stringent.[4] As a result, FDA approval is considered by most providers to ensure that a given drug or device is safe, effective, and beneficial for patients when prescribed for its approved use.[5]

Insurers, including the U.S. government through Medicare and Medicaid, and private insurers, typically rely on these determinations in setting reimbursement policies.[6] The Guidelines themselves seemingly recognize FDA's expertise and unique competency to assure that contraceptives are safe and effective, covering not only an existing slate of products, but also "any additional contraceptives approved, granted, or cleared by the FDA." JA0715-18.

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[4] G. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, 1 J. Am. Coll. Cardiol.: Basic Transl. Sci. 170 (2016), https://doi.org/10.1016/j.jacbts.2016.03.00 (discussing stringency of FDA approval standard); Marlon Perera & Michael J. Morris, *From Concept to Regulatory Drug Approval: Lessons for Theranostics*, 63 J. Nucl. Med. 1793 (2022), https://doi.org/10.2967/jnumed.121.2633012 (same).

[5] A.S. Kesselheim et al., *Physicians' Perspectives on FDA Approval Standards and Off-Label Drug Marketing*, 179 JAMA Internal Med. 707 (2019), https://doi.org/10.1001/jamainternmed.2018.8121.

[6] *See, e.g.,* Nat'l Insts. of Health, *Reimbursement Knowledge Guide for Medical Devices*, § 2.1, https://tinyurl.com/bdf6p4an.

Despite FDA's oversight of Covered Contraceptives, Defendants, in enacting the Final Rules, have reversed policy course on the Covered Contraceptives without a reasonable basis. In prior versions of the religious exemption, Defendants accepted that FDA-approved contraceptives are safe, effective, and beneficial. *See* JA0640. But in the Final Rules, they claim "reexamination of the record … has reinforced the Departments' conclusion that … uncertainty and ambiguity exists on … issues" including contraception's safety and effectiveness, and "uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation." JA0429; *see also* JA0051 (discussing Defendants' change in position). The purported "ambiguity" and "uncertainty" surrounding contraception's safety and effectiveness is belied, however, by the rigorous scientific standards that led FDA to approve the Covered Contraceptives.

A. FDA approval is a rigorous standard that ensures the safety and effectiveness of drugs and devices.

Before a drug or device may be marketed, it must meet FDA's approval standards. While approval and monitoring requirements differ somewhat for drugs (such as oral contraceptives) and medical devices (such as barrier contraceptives),

both classes of products undergo strict scientific scrutiny by separate centers within FDA both before and after being made available to the public.[7]

i. FDA rigorously vets new drugs.

Before a drug is brought to market, the drug's sponsor (typically a manufacturer) must make an initial showing of safety and effectiveness through three rounds of clinical trials. 21 C.F.R. § 312.21. These trials are designed to first ensure basic safety, then to demonstrate clinical effectiveness and assess potential side effects in groups of hundreds to thousands of test subjects. *Id*. § 312.21(a). Clinical testing is rigorous, often lasting years and requiring significant documentation of findings for later submission to FDA. Throughout the clinical trial process, the sponsor has an obligation to review "all information relevant to the safety of the drug," including information from clinical investigations, animal studies, scientific literature, and unpublished reports, and to notify FDA of the clinical trials' progress and evidence of any potential safety risks. *Id*. §§ 312.32(b), 312.32(c), 312.33.

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[7] Some products – including contraceptive methods like intrauterine devices ("IUDs") – are "combination products," containing both drug and device elements. 21 U.S.C. § 3.2(e). In such cases, FDA determines the "primary mode of action" of the product in order to determine which FDA Center should be tasked with premarket review. *Id*. § 3.4.

Upon completion of clinical trials, a sponsor seeking drug approval must submit a new drug application ("NDA") to FDA, comprised of, typically, hundreds of pages of scientific data and analysis. *Id*. § 314.50(d). The NDA must also include a summary that is "written at approximately the level of detail required for publication in, and [that] meet[s] the editorial standards generally applied by, refereed scientific and medical journals." 21 C.F.R. § 314.50(c)(1). Once an application is accepted as complete, *see id.* § 314.101(d), FDA reviews this information to assess evidence of safety, effectiveness, and the relationship between those risks and benefits as revealed by the clinical data.[8] Only after many months of review and approval can a new drug proceed to the market.[9] In addition, approval is subject to conditions from FDA, including the issuance of a product-specific label which "accurately and objectively describes the basis for approval and how to best use the drug," including detailed information about potential side effects, warnings, and contraindications.[10] A typical label will contain many pages

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[8] Food & Drug Admin., *Development & Approval Process* (Aug. 8, 2022), https://tinyurl.com/bdekkwzw.

[9] Food & Drug Admin, *Step 4: FDA Drug Review* (Jan. 4, 2018), https://tinyurl.com/zewtdjyx.

[10] *Id*.

of material aimed at informing patients and providers about proper use as well as all known contraindications, risks, and side effects.[11]

ii. FDA imposes similar requirements for medical devices.

Medical devices undergo a different, but similarly rigorous, review process. Each medical device falls into a "class" – either I, II, or III – depending on the level of danger it poses to human health. 21 U.S.C. § 360c(a)(1). While devices in the first two (lower-risk) classes can receive faster approval through a procedure known as the "510(k) process" based on a showing of "substantial equivalence" to a "predicate product" that is already on the market,[12] the devices with the greatest potential risk – class III devices – must undergo premarket review akin to that of a new drug. 21 U.S.C. § 360e.

FDA assesses scientific evidence in the premarket approval application, including clinical data, and determines whether or not to approve the device as safe and effective based on the following factors: (1) the persons for whose use the

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[11] *See, e.g.,* Food & Drug Admin, *Prescribing Information: Yaz* (May 2023), https://tinyurl.com/yuvymah7.

[12] *See* Food & Drug Admin., *Premarket Notification 510(k)* (Aug. 22, 2014), https://tinyurl.com/msmpp7es. Device manufacturers seeking to introduce a product via the 510(k) process must submit a 510(k) application, which includes, *inter alia*, a description of the product; proposed labels and advertising; photographs and engineering designs (where applicable); a description of the approved predicate product to which the device seeking approval is equivalent; and data to support an equivalence determination. 21 C.F.R. §§ 807.87, 807.92.

device is intended; (2) the conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use; (3) the probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and (4) the reliability of the device. 21 C.F.R. § 860.7.

iii. FDA and industry continue to monitor products postmarket.

For both drugs and devices, FDA involvement does not stop once a product reaches market. Instead, FDA – along with drug sponsors and device manufacturers – engages in ongoing product monitoring to ensure that products continue to meet rigorous safety and effectiveness standards in practice. In addition, both drug sponsors and device manufacturers have a legal obligation to review scientific literature for any safety concerns and to report any adverse events to FDA. *See* 21 C.F.R. §§ 314.80(b); 314.80(c); 314.81(b)(2); 814.82; 814.84. FDA also employs its own monitoring programs to ensure that adverse health effects from drugs and devices are tracked and handled.[13] Should it deem it necessary, FDA can order further clinical testing, additional black box warnings, or can withdraw a product's approval. *Id*. § 314.150.

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[13] *See, e.g.,* Food & Drug Admin., *Sentinel System Overview* (2017), https://tinyurl.com/3r8ubfpy.

In all, before drugs or devices – including the Covered Contraceptives at issue in this case – can make it to market, years of clinical study, months of scientific review, and tailored approval to ensure that they are safe and effective for members of the public have occurred. The rigors of the review process ensure that drugs and devices that are brought to market are effective, generally safe, and contain appropriate warnings and contraindications for patients and providers to make informed decisions.

B. The Covered Contraceptives received approval through these rigorous processes and continue to be monitored.

The 17 different types of contraceptive products at issue in this case, the Covered Contraceptives, include both drugs and devices. While the list of Covered Contraceptives spans a variety of different methods of use, including long-term implantable methods, oral contraceptives, single-use barrier methods (such as diaphragms or condoms), and even menstrual tracking software, each method of Covered Contraceptives contains products that have met the demanding standard to be granted – and maintain – FDA approval.[14] Under the HRSA Guidelines,

[14] Importantly, FDA approves *products*, not methods. *See* JA1761-64. The approval of one oral contraceptive, for example, does not excuse future oral contraceptives from undergoing clinical trials to prove their safety and effectiveness.

employer-sponsored plans must make available at least one product in *each* of the 17 covered categories at no cost to the plan participant. JA0715-18.

In many cases, products in these categories have been approved for marketing in the U.S. for many decades: the first oral contraceptive was approved in 1960; the first copper IUD was approved in 1984; and emergency contraceptives were first approved in 1999.[15] As a result of their longstanding approval (and ongoing product-specific monitoring), decades of scientific literature have accumulated, demonstrating that these contraceptive methods are both safe and effective at preventing pregnancy. JA0834-41.

When safety concerns *do* surface regarding an approved product, FDA has historically acted to ensure that such products are discontinued or relabeled. For example, during the first wave of development of modern contraceptive technology, FDA halted sale of the Dalkon Shield, an early progenitor of the copper IUD,[16] and Oracon, an early oral contraceptive that was found to have unacceptable rates of adverse health effects.[17]

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[15] S. White Junod, *FDA Approval of First Oral Contraceptive* (July 1998), https://tinyurl.com/4t89aevc; Paragard, *Fact Sheet*, https://tinyurl.com/mpawhm6x; Food & Drug Admin., *Plan B One-Step (1.5 mg levonorgestrel) Information* (Dec. 23, 2022), https://tinyurl.com/yu6ckhtu.

[16] *Dalkon Shield Sale Halted by Company,* N.Y. TIMES (June 29, 1974), https://tinyurl.com/2rhb6v3r.

[17] *Sequential Pills Being Withdrawn,* N.Y. TIMES (Feb. 6, 1976), https://tinyurl.com/4ae3vv5p.

Put simply, FDA's approval and monitoring processes are designed to ensure that contraceptive drugs and devices are able to safely perform their intended purpose of reducing unwanted pregnancy. Approvals are based on years-long clinical studies and thorough evaluations of voluminous, data-packed applications that allow FDA to utilize its expertise to determine whether a product is fit to enter the market.

Importantly, approval as safe and effective does not mean FDA has not considered that there could be side effects associated with a product. As FDA notes, different contraceptive methods may differ in their overall effectiveness and may produce differing side effects; accordingly, FDA encourages patients to "[t]alk with [their] healthcare provider about the best birth control option for" them, given that "[n]o one product is best for everyone."[18] Yet, here, Defendants have attempted to use known side effects as the rationale to change their position and cast doubt on the safety and effectiveness of an entire *category* of FDA-approved products, all without conducting *any* of the same rigorous, scientific evaluation that led to their approval and ongoing marketing.

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[18] *Id*.

II. HRSA chose to include contraceptives in its Guidelines because they are demonstrably safe and effective, based on FDA review.

While under the Federal Food, Drug, and Cosmetic Act, FDA is congressionally tasked with assessing the safety and effectiveness of drugs and devices, under the 2010 Affordable Care Act, HRSA is tasked with creating "comprehensive guidelines" for women's preventative care that details what care must be provided by health plans without cost-sharing. 42 U.S.C. § 300gg-13(a)(4). To effectuate this goal, Defendant United States Department of Health and Human Services ("HHS") contracted with the National Academy of Sciences to produce a report and set of recommendations from the Institute of Medicine[19] ("IOM Report" or "Report") as to what care ought to be covered. *See* JA0834-41. Among those recommendations was the contraceptive coverage mandate.

As the 2011 IOM Report's recommendations – later adopted by HRSA – make clear, there is no genuine scientific controversy as to the benefits of FDA-approved contraceptives. The Report notes the "wide array of safe and highly effective FDA-approved methods of contraception" on the market. Rather than assume their safety, however, IOM independently analyzed the relevant data and confirmed what was already made clear from FDA's approval: FDA-approved

[19] The Institute of Medicine is now referred to as the National Academy of Medicine.

contraception is safe to use and efficacious at preventing pregnancy. JA0836-37. Citing four recent studies that analyzed pregnancy prevention across populations, the Report found that "[t]he failure rates of all FDA-approved methods in both U.S. and international populations have been well documented and are negligible with proper use," and that, although some methods may be less effective due to imperfect use in practice, use of any FDA-approved method of contraception is significantly less likely to result in pregnancy than non-use of protection. JA0837-40.

Importantly, the Report also discussed that contraceptive methods may have risks and side effects. *See* JA0837-39. However, the Report found that the risk of serious adverse events from those forms of contraception most associated with side effects – including death – was low when compared to the risks of childbirth. *Id*. Moreover, rather than falsely extrapolating the dangers of certain *forms* of contraception to contraceptives as a *category*, the Report acknowledged the value of the "wide array of … FDA-approved methods of contraception" and noted that while "some contraceptive methods may be contraindicated" for certain patients, such patient's needs "can be clinically assessed so that an appropriate method can be selected for the individual." JA0836-40.

All in all, the Report stands for the uncontroversial notion that FDA-approved contraceptives are safe to use as prescribed and that they prevent

pregnancy. In adopting the Report's recommendation to cover only FDA-approved contraceptives for its Guidelines in 2011, HRSA ensured that women would have access to the "wide array" of FDA-approved contraceptives, some of which will necessarily be more suitable to the health needs and preferences of particular individuals than others. Moreover, the Guidelines recognizing that FDA may continue to approve new safe and effective methods of birth control, ensured coverage for "any additional contraceptives approved, granted, or cleared by the FDA," a further endorsement of the FDA approval process. JA0715-18. Taken together, FDA's approval of contraceptives, the IOM's recommendation of coverage, and HRSA's inclusion of contraceptives in the Guidelines reflect a strong consensus that contraceptives approved by the FDA are safe, effective, and beneficial – a consensus that, until the Final Rules, Defendants endorsed.

III. The Final Rules do not contain a sufficient basis for Defendants to cast doubt on whether contraception is safe, effective, and beneficial.

The Final Rules mark a departure from Defendants' previous recognition of contraceptives as safe, effective, and beneficial, to a new position of doubt. Dist. Ct. Op., JA0052 ("Defendants do not dispute that the pre-Final Rules Accommodation framework engendered serious reliance interests, nor that the Agencies changed their position as to contraceptive's efficacy and safety."). Defendants' reversal of course is particularly puzzling in light of the clear positions on these issues of FDA and HRSA, both of which are agencies within HHS. It is

even more puzzling, however, when one looks at the scant evidence upon which Defendants base their newfound position.

In determining whether agency action is "arbitrary" or "capricious," a reviewing court must "insist that an agency 'examine the relevant data and articulate a satisfactory explanation for its action.'" *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). However, when an agency announces a "change in position," particularly one that affects "significant reliance interests," a court must look even closer to assess whether the agency has provided a "reasoned explanation for its decision to depart from … existing … policy." *Encino Motorcars, LLC v. Navarro,* 579 U.S. 211, 222 (2016).

In articulating its rationale, an agency is not permitted to cherry-pick its evidence. *See Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008) (citations omitted) (indicating that "there is no APA precedent allowing an agency to cherry-pick a study on which it has chosen to rely"). Finally, "[a]n agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence." *Ctr. for Auto Safety v. Fed. Highway Admin.,* 956 F.2d 309, 314 (D.C. Cir. 1992) (Thomas, J.).

As the District Court correctly decided, Defendants fail to clear these APA requirements.

A. The Final Rules do not identify any novel health concerns associated with Covered Contraceptives.

Defendants first assert that there is "uncertainty" on "empirical issues" surrounding the health effects of contraception. JA0429. This finding is unreasonable on its face for three reasons:

i. The Final Rules do not contain data supporting uncertainty as to the health effects of Covered Contraceptives.

With respect to asserted health effects of FDA-approved contraceptives, the Final Rules cite – but provide no meaningful analysis of – a small number of studies cited by commenters in favor of the expanded exemptions, which Defendants assert create "uncertainty" surrounding this issue. *See* J0426-29. Actual analysis of those studies, however, demonstrates that they lend no support to Defendants' change in position.

First, several of the studies that purport to establish uncertainty as to the health effects of contraception do not support that any uncertainty about their effects exists. Regarding the alleged concerns of commenters that "certain contraceptives cause or are associated with … venous thromboembolic disease," the Final Rules' first citation is to a review of hormonal contraception by the

Practice Committee of the American Society for Reproductive Medicine.[20] That review, however, concludes that the risk of venous thromboembolism is "low," and concludes explicitly that "[h]ormonal contraception is a safe and effective form of reversible contraception."[21]

Likewise, regarding alleged concerns about pulmonary embolism, the Final Rules cite only to a single commentary describing the findings of a previous study, which itself describes the identified risk of embolism as "very small, and much less than that associated with pregnancy."[22] These studies do not support a reversal of position on the Covered Contraceptives. If Defendants claim that they do, at the least, they should have explained why they were reversing their position when the contents of these publications include determinations that undermine their newfound concerns about health effects. The Final Rules, however, contain no such explanation.

Second, the scientific evidence cited concerning alleged health effects of contraception exhibits several recurring problems as to its validity and

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[20] *See* JA0427 at n. 29 (citing Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception: Recent Advances and Controversies," 82 Fertility and Sterility S20, S26 (2004)).

[21] *Id*.

[22] *Id*. at n. 30 (citing N.R. Poulter, "Risk of Fatal Pulmonary Embolism with Oral Contraceptives," 355 Lancet 2088 (2000)).

generalizability.[23] The majority of the data cited is observational, rather than controlled, randomized studies, which are the standard for FDA approval and the ideal way to assess a drug's safety.[24] Moreover, each study looks only at a small subset of contraceptive products (typically, hormonal contraceptives), and some of those studies identify concerns only with a subset of the methods being analyzed.[25] Not a single study cited examines the risks associated with many Covered Contraceptives, including, *e.g.*, copper IUDs, barrier contraceptives, and spermicides. In other words, the Final Rules point to health concerns surrounding contraceptive products based on imperfect observational data, covering only a small subset of the products at issue in this case, and, in some cases, finding that certain contraceptive methods are perfectly safe.

Third, the Final Rules also make statements about asserted health effects of contraception that are simply unsupported by the provided citations. For example,

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[23] JA0426-27, n. 28-34.

[24] The value of controlled trials is well-established, as such trials are able to eliminate confounding variables that might provide alternative explanations for a study's findings. For example, the lone study cited in the Final Rules to support concerns about contraceptives and depression is an observational study that found that women who were prescribed an oral contraceptive were more likely to subsequently be prescribed an antidepressant. *See* JA0426 at n. 28. However, this observation does not establish that contraceptives are the *reason* these women subsequently sought antidepressants; rather, there are potential confounding variables, including that patients who proactively seek out a prescription to address one health concern may be more likely to do so for another.

[25] *See* JA0426-27 at n. 28-34 (citing various observational studies).

the Final Rules state that commenters "contended that studies show certain contraceptives cause or are associated with … breast, cervical, and liver cancers," but none of the referenced sources – several of which are simply webpages, without underlying studies – make any mention of liver cancer.[26] Moreover, for the other forms of cancer mentioned, those risks are encompassed in FDA-required warning labels. *See infra* Sec. III.a.ii. Lastly, certain of the flagged health effects, such as increased risk of HIV transmission, are not effects that have been well-established in the scientific literature.[27]

In other words, it appears that Defendants, rather than actually "examin[ing] the relevant data," as required by the APA, *see State Farm*, 463 U.S. at 43, simply noted that there were comments, themselves representing only selected articles from the literature on these topics, taking conflicting positions and, without further analysis, credited comments that lacked adequate scientific or factual support to reach a determination that "uncertainty" exists on these issues. JA0429. Such conclusory analysis of the underlying science cannot constitute reasoned decision-

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[26] *See* JA0427 at n. 34.

[27] *See, e.g.,* World Health Org., *WHO revises recommendations on hormonal contraceptive use for women at high HIV risk* (Aug. 29, 2019), https://tinyurl.com/5habpkxp (discussing that "new high-quality" data shows no clinical association between hormonal contraceptives and HIV transmission risk, "supersed[ing]the low to low-moderate quality evidence from observational studies").

making. *See Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986) (holding that an agency must provide more than "conclusory statements" to prove it "consider[ed] [the relevant] priorities").

ii. FDA warnings already contemplate and discuss side effects of contraception.

To the extent that the Final Rules *do* identify legitimate potential side effects of contraception, those risks are identified and known to patients and providers. As described herein, *supra* Sec. I, FDA provides detailed labels for its approved products that both describe potential side effects and contraindicate products for groups of patients who may be at higher risk. This labeling allows patients to understand and weigh the risks and benefits of certain methods of contraception and choose options that may be right for them – one of the benefits that the IOM Report identified of providing access to the "wide array" of FDA-approved contraception. JA0836-37.

Here, the health effects purportedly identified as concerns in the Final Rule are already contemplated by FDA's label and contraindication warnings. For example, common oral contraceptives are expressly contraindicated for women with breast cancer or with "high risk of arterial or venous thrombotic diseases."[28]

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[28] *See, e.g.,* Food & Drug Admin., *Prescribing Information: Yaz* (May 2023), https://tinyurl.com/yuvymah7.

The label further warns of, *inter alia*, risk of "thrombotic event" and high blood pressure; cautions that "[w]omen with a history of depression should be carefully observed" while using the medication; and provides information about the data on hormonal contraception's link to breast and cervical cancers.[29] Women who should not take hormonal contraceptives because of a contraindication, or who are concerned about any of the listed side effects, are, by design, free to choose an alternative form of birth control that suits their unique needs and preferences. This is a feature of the current system – not a concern that justifies denying access.

iii. Concerns about side effects of hormonal contraceptives provide no basis for diminishing coverage of other Covered Contraceptives.

As both Plaintiffs and the District Court correctly identified, the Final Rules selectively cite studies that deal with the side effects of *particular* contraceptives – not contraceptives *as a whole*. JA0053. For example, Defendants point to studies that show hormonal methods of contraception may have significant side effects for certain women. JA0427. Yet, these studies have no bearing on whether the nine forms of FDA-approved contraception that do not rely on hormonal manipulation – such as barrier contraceptives, spermicides, or copper IUDs – have similar health

[29] *Id*.

risks, nor do Defendants even purport to address this issue despite enacting a policy that impacts access to such products.

Beyond the conflation of different contraceptive methods, however, there is another problem with Defendants' generalized assertions of doubt as to the benefits of contraception. Defendants assert that "uncertainty surrounding these weighty and important issues [concerning safety and effectiveness] makes it appropriate to maintain the expanded exemptions and accommodation *if and for as long as HRSA continues to include contraceptives in the Guidelines*." JA0429 (emphasis added). But the Guidelines include *all* FDA-approved contraception and FDA approval occurs on an ongoing, product-by-product basis. FDA is empowered to approve particular new contraceptives it deems safe and effective and to withdraw approval from contraceptives for which evidence exists that they do not meet FDA's stringent standards. Yet, without knowing what contraceptive products are in the pipeline, Defendants ask this Court to believe that "uncertainty" and "ambiguity" will exist for them as well.

HRSA's Guidelines reflect FDA's role in the process and the fact that new products may be identified that are safe and effective, but that are not yet known. Defendants, however, in essence contend that there exists a generalizable, apparently permanent "uncertainty" surrounding the risks and benefits of contraceptives as a category of products, even as new, rigorously vetted products

continue to be introduced. Such a determination does not reflect the scientific evidence or data before Defendants, but rather a generalized desire to disparage contraceptives as a category of care – even when demonstrated to be safe and effective.

B. Defendants identify no "uncertainty" as to whether contraceptives are effective at preventing pregnancy.

In the Final Rules, Defendants attempt to assert an "empirical question" as to whether contraception is the driver of reductions in teen pregnancy. JA0428-29. But in support, Defendants cite only studies indicating that the factors affecting teen and unwanted pregnancies are multi-faceted. JA0053-54.

Defendants contend that this alleged finding justifies calling into question the effectiveness of contraceptive access as a whole, arguing that "studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments' conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general." JA0428. But this misses the mark. The fact that issues like unintended pregnancy are multi-faceted is precisely the reason why clinical trial data is considered the gold standard on which FDA relies in assessing effectiveness.

Indeed, the entire purpose of the randomized, controlled trials upon which FDA relies for drug and most Class III device approval is to disentangle product

effectiveness from other factors that might affect pregnancy rates. By randomizing patients to different products (and/or placebos), investigators are assured that it is the effectiveness of only the product, not the other factors, that they are testing. These other factors could obscure the actual effectiveness of a product.

The studies cited to support Defendants' purported "uncertainty" only highlight these issues. The Final Rules contain *no* citations to studies with controlled, individual-level data that tracks the personal impact of contraceptive access on unintended pregnancy. Instead, the Final Rules cite a host of papers that range in focus, including: a law review article making no empirical claims; a prospective mathematical model replete with multiple assumptions; and studies seeking to ascertain whether other, unrelated factors, such as representation of African American teachers, may also impact birth rates.[30]

Curiously, one of the only studies cited that sought to identify the policy drivers of overall teen or unintended pregnancy found, based on state-level data from 1991-2010, that "the only targeted policies that have had a statistically discernible impact on aggregate teen birth rates are declining welfare benefits and *expanded access to family planning services through Medicaid*," which accounted for 12.6 percent of the overall reduction in teen pregnancy over that period.[31]

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[30] *See* JA0428-29 at n. 41-45.

[31] JA0428 at n. 44.

While this, using Defendants' approach, would seemingly provide an indication that expanded access to contraception *does* reduce teen pregnancy (even if it is only one contributor), Defendants instead cite the study for the inaccurate proposition that "studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments' conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general." JA0428. Conspicuously, to the extent that Defendants were interested in the population-level effects on unintended pregnancy that corresponded with the contraceptive coverage mandate, they failed to cite data published by HHS's own sub-agency showing that the rate of unintended pregnancy declined (particularly amongst teens) in the years following the enactment of the ACA and the issuance of the Guidelines.[32]

While Defendants may point to evidence suggesting that unintended pregnancy is a complex, multi-faceted issue, they highlight *no* evidence that undermines the well-documented scientific literature showing that contraceptives empirically *do* prevent pregnancy when used as prescribed. *See supra* Sec. II. The mere acknowledgement that teen pregnancy and unintended pregnancy are driven

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[32] Ctrs. for Disease Control and Prevention, *Unintended Pregnancy* (2019), https://tinyurl.com/yk3vftch.

by a multitude of factors cannot be considered a reasoned explanation to enact a policy that reduces access to contraceptive products that have been clinically proven to prevent pregnancy.

To the contrary, typically, coverage determinations for clinically effective methods of care are not made based on whether the condition being treated is increasing, given the multi-faceted nature of medical outcomes. For example, although pancreatic cancer rates are rising,[33] CMS (an HHS sub-agency) still provides Medicare coverage for pancreatic cancer screening and medication.[34] CMS, thus, provides patients with access to clinically effective care that can prevent or treat conditions of concern, even if environmental and social factors are causing that condition to become more prevalent. Yet Defendants abandon that logic when it comes to contraceptives, arguing that broad, population-level data (even with reliability issues) justifies stripping access to such care.

All in all, the Final Rules lack a sufficiently reasoned explanation for Defendants' new departure from existing policy.

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[33] *See* Alessandro Mannucci & Ajay Goel, *Advances in Pancreatic Cancer Early Diagnosis, Prevention, and Treatment: The Past, the Present, and the Future*, 75 CA: A Cancer J. for Clinicians caac.70035 (Sept. 19, 2025), https://doi.org/10.3322/caac.70035.

[34] Donna Frederick, *Medicare Covers Pancreatic Cancer Screening & Treatment* (Nov. 29, 2021), https://tinyurl.com/2mxr2xdr.

CONCLUSION

Defendants' change in position contradicts the expertise of the scientific community and of other agencies, including FDA and HRSA, and lacks the reasoned basis necessary to satisfy the requirements of the APA, especially considering the reliance interests. The Order of the District Court granting summary judgment to the Plaintiffs and denying summary judgment to the Defendants should be affirmed.

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COMBINED CERTIFICATIONS

1. I hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

2. This *amicus* brief complies with the type-volume limitations imposed by Federal Rule of Appellate Procedure 29(a)(5) as it contains 6,410 words, excluding the portions exempted by Federal Rule of Appellate Procedure 32(f).

3. This brief complies with the typeface and typestyle requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because it was prepared in 14-point Times New Roman, a proportionally spaced font.

4. This brief complies with the electronic filing requirements of Local Rule 31.1(c). The text of this electronic brief is identical to the text of the paper copies, and SentinelOne virus protection software has been run on the file containing the electronic version of this brief and no virus has been detected.

5. On March 2, 2026, this *amicus* brief was electronically filed with the Clerk of Court using the CM/ECF System, which will send notice of such filing to all registered users.

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