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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

REBECCA GOMPERTS, an individual, and AID ACCESS, GmbH, Plaintiffs, vs. ALEX M. AZAR, II, Secretary of Health and Human Services, et al., Defendants.	Case No.: 1:19-cv-00345-DCN **PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT**

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COME NOW the Plaintiffs, Rebecca Gomperts and Aid Access, GmbH, by and through their counsel of record, Richard A. Hearn, HEARN LAW, PLC, and submit Plaintiffs' Response to Defendants' Motion to Dismiss Plaintiffs' Complaint.

INTRODUCTION

In Defendants' Motion to Dismiss Plaintiffs' Complaint ("*Defendants' Motion*"), the Federal Food and Drug Administration ("*FDA*") asks this Court to dismiss the constitutional claims of Dr. Rebecca Gomperts' ("*Dr. Gomperts*") patients based upon standing. Since founding Aid Access in the spring of 2018, more than seven thousand of Dr. Gomperts' patients in the U.S. have already safely terminated their unwanted pregnancies in the privacy of their homes.

The FDA is threatening legal action against Dr. Gomperts if she continues to treat patients seeking to terminate their unwanted pregnancies in the U.S. Dr. Gomperts has filed this constitutional challenge to the actions of the FDA, not on her own behalf, but, on behalf of her current and future patients wanting to terminate their unwanted pregnancies. It is their right under the U.S. Constitution to choose to terminate their unwanted pregnancies that is being burdened by the FDA's actions against Dr. Gomperts and Aid Access.

The FDA also seeks to dismiss the Complaint pursuant to *Federal Rule of Civil Procedure12(b)(6)*. But, nowhere in Defendants' Motion to Dismiss does the FDA attempt to justify its use of its statutory authority to regulate the manufacture and distribution of prescription drugs as authority to regulate the practice of medicine in any context, much less in the context of women seeking medical abortions.

Neither Dr. Gomperts nor Aid Access have ever manufactured or distributed any drugs in the U.S. Like other physicians, Dr. Gomperts provides prescriptions to her patients. When she determines that a medical abortion would be safe and appropriate, Dr. Gomperts provides her

patient with a prescription for medicine approved by the FDA. Dr. Gomperts' patients can then fill their prescriptions either at a retail pharmacy in Europe or online using an exporter of prescription medication into the U.S.

In March of 2019, the FDA sent a letter to Aid Access and Dr. Gomperts threatening to prosecute them for causing the introduction into interstate commerce of misbranded and unapproved new drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Packages of medicine sent to Dr. Gomperts' patients by the merchant exporter have been seized by federal authorities. A non-physician (Ursula Wing) was recently indicted in the Western District of Wisconsin for importing foreign sourced versions of mifepristone and misoprostol into the U.S.

Threatening Dr. Gomperts with prosecution, seizing medicine prescribed for Dr. Gomperts' patients and criminally charging women for importing the same medications prescribed by Dr. Gomperts pose significant burdens on women who seek Dr. Gomperts' help in exercising their constitutional right to terminate their pregnancies. Dr. Gomperts has brought this action seeking injunctive and declaratory relief against Defendants on behalf of her patients residing in the U.S.

FACTUAL ALLEGATIONS

A. Dr. Rebecca Gomperts is a licensed physician practicing medicine in Europe.

Plaintiff Rebecca Gomperts is a licensed physician who has been legally treating patients over the internet for the last 15 years. Dr. Gomperts' patients seek her help as a physician in safely terminating their unwanted pregnancies. After an online consultation with each patient to determine whether they would be a suitable candidate for a medical abortion, Dr. Gomperts prescribes two FDA approved drugs, misoprostol and mifepristone, for each patient that, in her medical judgment, can safely medically abort their unwanted pregnancies.

Since founding "Women on Web" in 2005, Dr. Gomperts has treated women seeking to terminate their unwanted pregnancies in many different countries where safe abortion was unavailable. Through Women on Web, Dr. Gomperts has provided both information and prescriptions from her offices in Europe to her patients who wanted to terminate their pregnancies from all over the world. But, Women on Web has never served women seeking to terminate their pregnancies in the U.S.[1]

B. Through Aid Access, Dr. Gomperts prescribes FDA approved medicine to women all over the world.

Dr. Gomperts founded Aid Access as an Austrian corporation ("*GmbH*") in early 2018 to serve women with unwanted first trimester pregnancies all over the world, *including women in the United States*. Dr. Gomperts and Aid Access operate the webpage "aidaccess.org."[2] Since March 30, 2018, Dr. Gomperts – through Aid Access – has consulted with women desiring to end their unwanted pregnancies in all 50 states and the District of Columbia.[3] Between March 30, 2018, and August 27, 2019, Dr. Gomperts prescribed misoprostol and mifepristone for seven thousand, one hundred and thirty-one (7,131) women in the U.S.[4] During that same length of time, Dr. Gomperts prescribed misoprostol and mifepristone to induce a medical abortion prior to viability for thirty-nine (39) women residing in Idaho.[5]

But, neither Dr. Gomperts nor Aid Access send any medication into the United States. If, after review of all the information available, Dr. Gomperts believes in her professional judgment that a woman can safely have a medical abortion, Dr. Gomperts will provide that woman with a

[1] *Verified Complaint*, ¶ 9-17.
[2] *Verified Complaint*, ¶ 18-21.
[3] *Verified Complaint*, ¶ 41.
[4] *Verified Complaint*, ¶ 43.
[5] *Verified Complaint*, ¶ 44.

prescription for the appropriate dose of mifepristone and misoprostol with instructions on how to safely take these medications to induce the desired medical abortion.[6] Dr. Gomperts also provides her patients with instructions on how to fill their prescriptions for misoprostol and mifepristone.[7]

Dr. Gomperts' prescriptions can be filled at any pharmacy that recognizes prescriptions for misoprostol and mifepristone from a European doctor. If they choose, Dr. Gomperts' patients may also send their prescriptions to a merchant exporter of prescription medications in India.[8]

C. The FDA is using its authority to regulate the manufacture and distribution of drugs to threaten a licensed physician legally practicing outside the U.S. for prescribing FDA approved drugs to her patients in the U.S.

Defendants sent a letter addressed to "aidaccess.org" dated March 8, 2019, in which Defendants stated that it had "recently reviewed your website, http://aidaccess.org, and determined that [Aid Access] caused the introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [*21 U.S.C. §§ 331(a), 331(d), and 355(a)*]."[9] Dr. Gomperts was cc'd on this letter.[10]

In the final section of the FDA letter, Defendants stated that "[t]his letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the sale of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act."[11] Defendants' letter concluded with the following threat: "**Failure to correct these violations may result in FDA regulatory action,**

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[6] *Verified Complaint*, ¶¶ 46-47.
[7] *Verified Complaint*, ¶ 48.
[8] *Verified Complaint*, ¶ 49-56.
[9] *Verified Complaint*, ¶ 62.
[10] *Verified Complaint*, ¶ 66.
[11] *Verified Complaint*, ¶ 63.

including seizure or injunction, without further notice."[12] Based upon package tracking information and confidential communications with her patients, Dr. Gomperts reasonably believes that, since receipt of the March 8th letter, the FDA has not only caused the seizure of between three and ten packages containing misoprostol and mifepristone, but, has also blocked money transfers between Dr. Gomperts' patients in the U.S. and Dr. Gomperts and/or Aid Access in Europe.[13]

As a result of the threats contained in the FDA letter dated March 8, 2019, Dr. Gomperts and Aid Access temporarily discontinued providing medical abortions to women in the U.S. for nearly two months.[14] During this period, Dr. Gomperts and Aid Access were forced to deny help to literally hundreds of women in the U.S. who were seeking to terminate their pregnancies.[15] Despite the legal risk to both Dr. Gomperts and her patients in the U.S., Dr. Gomperts restarted providing medical abortions to women in the U.S. seeking to terminate their pregnancies on May 10, 2019, and, despite that risk, has continued to do so.

Approximately six weeks after Dr. Gomperts restarted providing her patients in the U.S. with prescriptions for misoprostol and mifepristone, Ursula Wing ("*Wing*") was indicted in the Western District of Wisconsin for importing foreign sourced versions of mifepristone and misoprostol into the U.S. for resale in the U.S.[16] Wing was allegedly causing the introduction of foreign sourced versions of misoprostol and mifepristone, *i.e.*, misbranded and unapproved new drugs, into interstate commerce in violation of 21 U.S.C. § 331(a).[17] This is the identical statute cited in the FDA letter threatening Dr. Gomperts and Aid Access.[18]

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[12] *Verified Complaint*, ¶ 64 (*emphasis added*).
[13] *Verified Complaint*, ¶¶ 70-73.
[14] *Verified Complaint*, ¶ 67.
[15] *Verified Complaint*, ¶ 68.
[16] *Verified Complaint*, ¶ 78.
[17] *Verified Complaint*, ¶ 79.
[18] *Verified Complaint*, ¶ 80.

If convicted of violating *21 U.S.C. § 331(a)* "with the intent to defraud or mislead," Dr. Gomperts, like Wing, could "be imprisoned for not more than three years or fined not more than $10,000 or both" pursuant to *21 U.S.C. 333(a)(2)*.[19]

Dr. Gomperts' patients also face a real threat of criminal prosecution under *21 U.S.C. 331(a)*. Dr. Gomperts' patients in the U.S. seeking medical abortions may be criminally prosecuted, like Wing is currently being prosecuted, for conspiracy to violate *21 U.S.C. 331(a)*.

STANDARD OF REVIEW

A. Motion to Dismiss for Lack of Standing pursuant to Rule 12(b)(1).

When any defendant challenges a plaintiff's standing, the plaintiff bears the burden of persuasion. As discussed below, a defendant may either challenge the plaintiff's standing by referring to the face of the complaint or by presenting extrinsic evidence.

> When subject matter jurisdiction is challenged pursuant to *Federal Rule of Civil Procedure 12(b)(1)*, the plaintiff bears the burden of persuasion. *Indus. Tectonics, Inc. v. Aero Alloy*, 912 F.2d 1090, 1092 (9th Cir. 1990) (*citations omitted*). A party who brings a *Rule 12(b)(1)* challenge may do so by referring to the face of the pleadings or by presenting extrinsic evidence. *See White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000) ("*Rule 12(b)(1)* jurisdictional attacks can be either facial or factual."). In the former, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction. *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). "By contrast, in a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." *Id.* In resolving a factual attack on jurisdiction, the court need not presume the truthfulness of the plaintiff's allegations and may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment. *Id.*[20]

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[19] *Verified Complaint*, ¶ 90.

[20] *Thornton v. Kenneth J.*, 2019 U.S. Dist. LEXIS 53388 *; 2019 WL 1386372 (D. Idaho March 27, 2019).

B. Motion to Dismiss under Rule 12(b)(6).

A Rule 12(b)(6) motion challenging the legal sufficiency of a complaint should be denied if, assuming the facts alleged in the complaint are true, the claims in the complaint appear plausible and the complaint raises a cognizable legal theory.

> A motion to dismiss for failure to state a claim challenges the legal sufficiency of the claims stated in the complaint. *Conservation Force v. Salazar*, 646 F.3d 1240, 1242 (9th Cir. 2011). To sufficiently state a claim to relief and survive a *12(b)(6)* motion, the pleading "does not need detailed factual allegations," however, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). Mere "labels and conclusions" or a "formulaic recitation of the elements of a cause of action will not do." *Id.* Rather, there must be "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* at 556. The plausibility standard is not akin to a "probability requirement," but does require more than a sheer possibility that a defendant acted unlawfully. *Id.*
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> . . .
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> In light of *Twombly* and *Iqbal*, the Ninth Circuit has summarized the governing standard as follows: "**In sum, for a complaint to survive a motion to dismiss, the nonconclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief.**" *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009). Apart from factual insufficiency, a complaint is also subject to dismissal under *Rule 12(b)(6)* where it lacks a cognizable legal theory, *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990), or where the allegations on their face show that relief is barred for a legal reason. *Jones v. Bock*, 549 U.S. 199, 215, 127 S. Ct. 910, 166 L. Ed. 2d 798 (2007).
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> **A dismissal without leave to amend is improper unless it is beyond doubt that the complaint "could not be saved by any amendment."** *Harris v. Amgen, Inc.*, 573 F.3d 728, 737 (9th Cir. 2009).[21]

C. Women have a constitutionally protected right to an abortion in the United States prior to viability.

> We begin with the standard, as described in *Casey*. We recognize that the "State has a legitimate interest in seeing to it that abortion, like any other medical

[21] *Thornton*, 2019 U.S. Dist. LEXIS 53388 at **14-16 (*emphasis added*).

> procedure, is performed under circumstances that insure maximum safety for the patient." *Roe v. Wade*, 410 U.S. 113, 150, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973). But, we added, "**a statute which, while furthering [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.**" *Casey*, 505 U.S., at 877, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (*plurality opinion*). Moreover, **"[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.**" *Id.*, at 878, 112 S. Ct. 2791, 120 L. Ed. 2d 674.[22]

ARGUMENT

A. This Court has already held that the U.S. Constitution prohibits the prosecution of women who terminate their pregnancies using medicine obtained over the internet.

This case brought by Dr. Gomperts is similar to another case which involved a woman who induced her own abortion at home using medication she obtained over the internet.[23] In *McCormack v. Hiedeman*, Chief Judge Winmill enjoined the Bannock County prosecutor from criminally prosecuting Jenny McCormack for having a medical abortion using medicines (mifepristone and/or misoprostol) she obtained over the internet.

> Women have a Fourteenth Amendment right to terminate a pre-viability pregnancy. *Planned Parenthood v. Casey*, 505 U.S. 833, 895, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992). Although the Constitution guarantees women the liberty to make the "ultimate decision" to undergo an abortion, *Casey*, 505 U.S. at 879, the state may safeguard its interest in potential life by regulating the means by which abortion may be secured, so long as its regulations do not pose an "undue burden" on the woman's ability to obtain an abortion, *id.* at 874. "**An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.**" *Id.* at 878.[24]

The preliminary injunction enjoining the State from prosecuting McCormack was then affirmed by the 9th Circuit.

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[22] *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309; 195 L. Ed. 2d 665, 685 (2016) (*emphasis added*).
[23] *McCormack v. Hiedeman*, 2011 U.S. Dist. LEXIS 107823 (D. Idaho September 23, 2011).
[24] *McCormack*, 2011 U.S. Dist. LEXIS 107823 at **17-18 (*emphasis added*).

> **While the Supreme Court has permitted many restrictions that make obtaining an abortion more difficult, particularly for low-income women**, *see Casey*, 505 U.S. at 886-87, **it has not authorized the criminal prosecution of women seeking abortion care. Imposing criminal liability upon women for their providers' purported failure to comply with state abortion regulations places a substantial obstacle in the path of women seeking an abortion.** Accordingly, McCormack is likely to succeed on her claim that Chapter 6 constitutes an undue burden on a woman's constitutional right to terminate her pregnancy before viability.[25]

Like Jenny McCormack, Dr. Gomperts' patients are being threatened with criminal prosecution "for [Dr. Gomperts'] purported failure to comply with [FDA] regulations." Defendants' threatened legal action against Dr. Gomperts and Aid Access "places a substantial obstacle in the path of women seeking an abortion" in the U.S.

B. Dr. Gomperts has Article III standing to assert the constitutional rights of her patients seeking medical abortions prior to viability in the U.S.

1. A "credible threat of prosecution" is all that is necessary for a plaintiff to have Article III standing to challenge a criminal statute arguably effected with a constitutional interest.

First, Defendants argue that "the harms asserted flow from [Dr. Gomperts' and her patients'] own independent decisions." Second, Defendants argue that Dr. Gomperts and her patients "alleged harms cannot be considered 'certainly impending' as they must be to constitute injury-in-fact."[26] Finally, Defendants argue that Dr. Gomperts' and her patients "fear of imminent prosecution – based upon an FDA Warning Letter and the unrelated prosecution of a different individual is equally insufficient to support standing."[27]

To support their arguments, Defendants have not cited a single case involving an abortion provider and/or her patients. Instead, Defendants have elected to simply ignore the well-settled

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[25] *McCormack v. Hiedeman*, 694 F.3d 1004, 1018 (9th Cir. 2012) (*emphasis added*).
[26] *Defendants' Motion to Dismiss*, 11.
[27] *Defendants' Motion to Dismiss*, 12.

law related to standing which allows abortion providers to bring pre-enforcement constitutional challenges to abortion laws and regulations *on behalf of their patients*.

To have Article III standing to contest the constitutionality of a criminal statute, a plaintiff is not required to first expose herself to actual arrest or prosecution under the statute that she claims deters the exercise of her constitutional right.[28]

> Rather, if the plaintiff alleges an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder, she "should not be required to await and undergo a criminal prosecution as the sole means of seeking relief." *Doe v. Bolton*, 410 U.S. 179, 188, 93 S. Ct. 739, 35 L. Ed. 2d 201 (1973).[29]

To determine whether a plaintiff has Article III standing to pursue a pre-enforcement constitutional challenge to a law, courts must decide whether that plaintiff faces a credible or genuine "threat of prosecution" under the law in question.

> [The Ninth Circuit] has recognized that "neither the mere existence of a proscriptive statute nor a generalized threat of prosecution satisfies the 'case or controversy' requirement." *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) (*en banc*). Rather, a plaintiff must face a "genuine threat of prosecution." *Id.* **In evaluating the genuineness of a claimed threat of prosecution, courts examine three factors: (1) "whether the plaintiffs have articulated a 'concrete plan' to violate the law in question," (2) "whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings," and (3) "the history of past prosecution or enforcement under the challenged statute."** *Id.*; *see also Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298, 99 S. Ct. 2301, 60 L. Ed. 2d 895 (1979) (holding that, "[w]hen contesting the constitutionality of a criminal statute, it is not necessary that the plaintiff first expose himself to actual arrest or prosecution to be entitled to challenge the statute that he claims deters the exercise of his constitutional rights.") (*citation and alterations omitted*).[30]

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[28] *McCormack*, 2011 U.S. Dist. LEXIS 107823 at ** 8-10 (*quoting Steffel v. Thompson*, 415 U.S. 452, 459, 94 S. Ct. 1209, 39 L. Ed. 2d 505 (1974)).
[29] *McCormack*, 2011 U.S. Dist. LEXIS 107823 at ** 8-10.
[30] *McCormack v. Hiedeman*, 694 F.3d 1004, 1021 (9th Cir. 2012) (*emphasis added*).

The warning letter sent by the FDA to Aid Access and Dr. Gomperts **"**communicated a specific warning or threat to initiate proceedings" and the recent prosecution of Ursula Wing is clear evidence that there is a "history of past prosecution [of women like Dr. Gomperts' patients] or enforcement for importing [misoprostol and mifepristone] under the challenged statute."[31]

This principle allowing for pre-enforcement challenges to statutes is widely accepted in the context of constitutional challenges to statutes arguably affecting a woman's right to choose.

> In *Griswold v. Connecticut*, 381 U.S. 479, 481, 85 S. Ct. 1678, 14 L. Ed. 2d 510 (1965), the Supreme Court concluded that a medical director who had been convicted for giving information, instruction, and medical advice regarding contraception had standing to challenge the constitutionality of the Connecticut law. Then in *Carey v. Population Servs., Int'l*, 431 U.S. 678, 682-84, 97 S. Ct. 2010, 52 L. Ed. 2d 675 (1977), the Court held that a corporation that had been advised by New York authorities that they were violating the New York statute prohibiting sale of contraception to minors under 16, and had at least been threatened with prosecution on at least one occasion, had standing to challenge the statute. **Finally, in *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 916-18 (9th Cir. 2004), an abortion provider, Dr. Glenn Weyhrich, stated his clear intention to continue to perform abortions for his patients, including some minors, despite a statute prohibiting him from performing abortions on minors. *Id.* at 916. We concluded that Dr. Weyhrich's clear intention resulted in a "sufficiently concrete and imminent injury-possible prosecution and imprisonment-to challenge the provisions that ban abortion providers from performing abortions on minors." *Id.*** (*citing Diamond v. Charles*, 476 U.S. 54, 65, 106 S. Ct. 1697, 90 L. Ed. 2d 48 (1986) ("A physician has standing to challenge an abortion law that poses for him a threat of criminal prosecution.")). **Therefore, we held that Dr. Weyhrich had standing based upon a threat of prosecution by the county prosecuting attorney. *Id.* at 917**.[32]

There should be no dispute that this pre-enforcement challenge to the FDA's threats to prosecute Dr. Gomperts, and possibly even her patients in the U.S., arises in the abortion context.

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[31] *McCormack v. Hiedeman*, 694 F.3d at 1021.
[32] *McCormack v. Hiedeman*, 694 F.3d at 1021 FN10 (*emphasis added*).

2. Physicians who state a clear intention to perform abortions in violation of a statute prohibiting physicians from performing such abortions have a "sufficiently concrete and imminent injury" to allow those physicians to bring a pre-enforcement challenge to that abortion statute.

Physicians who state a clear intent to perform abortion on their patients in violation of a statute have a sufficiently concrete and imminent injury to have Article III standing to challenge that statute prior to its enforcement.

> The Ninth Circuit has held that physicians who state a clear intention to perform abortions for their patients allege "a sufficiently concrete and imminent injury — possible prosecution and imprisonment" to challenge statutes that regulate abortion providers: "**Whether [a physician] continues to perform abortions subject to the statute, desists from performing them to avoid the statute's penalties, or violates the statute so as to practice his profession in accord with his medical judgment, his liberty will be concretely affected."** *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004). This is true, according to the Ninth Circuit, even if the physician does not express a specific intent to violate the statute. *Id*.[33]

Arguments that providers wanting to perform abortions in violation of a statute must first comply with that statute

> [f]undamentally misapprehends the applicable inquiry and generally settled Supreme Court precedent on standing, particularly in abortion cases. First, a plaintiff contesting the constitutionality of a criminal statute is not required to "first expose himself to actual arrest or prosecution to be entitled to challenge [the] statute that he claims deters the exercise of his constitutional rights." *Steffel v. Thompson*, 415 U.S. 452, 459, 94 S. Ct. 1209, 39 L. Ed. 2d 505 (1974). Second, in limited circumstances, litigants are entitled to predicate injury on the existence of a statute that results in more than a "subjective chill" on the exercise of constitutionally protected rights, even when arrest and prosecution do not occur. *See Meese v. Keene*, 481 U.S. 465, 472-73, 107 S. Ct. 1862, 95 L. Ed. 2d 415 (1987).
> Both sorts of injury are, of course, related because both hinge on the existence of a credible threat that the challenged law will be enforced against the plaintiff. . ..
> The Supreme Court has emphasized, however, that "[o]ne does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough." *Babbitt*, 442 U.S. at 298. **Also, in the abortion context, the Ninth Circuit's decisions teach that the existence of an abortion regulation aimed at physicians that would prevent or chill a pregnant**

[33] *McCormack v. Hiedeman*, 900 F.Supp.2d 1128, 1141 (D. Idaho 2013) (*emphasis added*).

> **woman from seeking an abortion she would otherwise seek is sufficient to satisfy the injury requirement.** *Wasden*, 376 F.3d at 917.[34]

Defendants' attempt to enforce a statute or regulation aimed at physicians like Dr. Gomperts "that would prevent or chill a pregnant woman from seeking an abortion she would otherwise seek is sufficient to satisfy the injury requirement."[35] The FDA's attempt to enforce the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)] against a doctor licensed in Europe simply for prescribing medication approved by the FDA to her patients in the U.S. and possibly even enforce the FD&C Act against that doctor's patients clearly could prevent or chill a pregnant woman from seeking a medical abortion from Dr. Gomperts.

3. Physicians who perform abortions are routinely recognized as having Article III standing to assert the constitutional rights of their patients who seek abortions.

Although abortion providers do not have a constitutional right to perform abortions, those providers who face a credible threat of prosecution because they either perform abortions or state a clear intent to perform abortions have standing to bring constitutional challenges to those statutes on behalf of their patients who do seek abortions. Because Dr. Gomperts faces a credible threat of prosecution because she prescribes medical abortions, Dr. Gomperts has standing to bring a constitutional challenge to FDA action burdening that right on behalf of her patients in the U.S.

> [Defendant] concedes that we have held that a physician possesses standing on his own behalf and on that of his patients to challenge the validity of another Idaho abortion statute. *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004). ("[P]hysicians and clinics performing abortions are routinely recognized as having standing to bring broad facial challenges to abortion statutes."). The Supreme Court has also repeatedly held that a physician may "assert the rights of women patients as against governmental interference" in the abortion context. *Singleton*, 428 U.S. at 118 (recognizing that "there seems little loss in terms of effective advocacy from allowing [an assertion of a woman's right to an abortion] by a physician"); *see also Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 845, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992) (allowing abortion providers to

[34] *McCormack*, 900 F.Supp.2d at 1141-1142 (*emphasis added*).
[35] *McCormack*, 900 F.Supp.2d at 1142.

> challenge a state statute on behalf of third-party women who seek abortion services); *Griswold v. Connecticut*, 381 U.S. 479, 481, 85 S. Ct. 1678, 14 L. Ed. 2d 510 (1965) (holding that physicians have standing to assert the constitutional rights of patients to whom they prescribed contraceptive devices).[36]

When determining whether a physician can effectively represent the constitutional rights of her patients to terminate their pregnancies before viability, any inquiry by the court into the "medical appropriateness" of a physician's medical practice would be unwarranted.

> Dr. Hearn's intent to provide FDA-approved medication to women to terminate their pregnancies prior to fetal viability does not need to be supported by a demonstration of the "medical appropriateness" of his ability to provide medical abortions. Whether Dr. Hearn can provide medical abortions in "an appropriate clinical setting" is irrelevant to whether he, as an Idaho licensed physician, can effectively represent the constitutional right to terminate a pregnancy before viability. **The Supreme Court has looked to the professional relationship between a physician and a patient, *Griswold*, 381 U.S. at 481, the economic harm on abortion providers, *Singleton*, 428 U.S. at 112-13, and a physician's "direct stake" in the abortion process, *Diamond v. Charles*, 476 U.S. 54, 67, 106 S. Ct. 1697, 90 L. Ed. 2d 48 (1986), when determining standing. But an inquiry into the "medical appropriateness" of an abortion provider's practice is not only unprecedented, but is also too ambiguous, and thus unwarranted.**[37]

As this Court held in the case of Dr. Hearn, any inquiry into the "medical appropriateness" of Dr. Gomperts' medical practice would be "not only unprecedented, but is also too ambiguous, and thus unwarranted."[38]

C. Dr. Gomperts' and her patients' claims for prospective relief are not foreclosed by the so called "Ewing Doctrine."

Rather than present arguments based upon authority specifically developed in the abortion context, Defendants cite *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601-02 (1950) as support for their contention that courts lack jurisdiction to enjoin enforcement proceedings brought

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[36] *McCormack v. Herzog*, 788 F.3d 1017, 1027 (9th Cir. 2015).
[37] *McCormack*, 788 F.3d at 1027-1028 (Dr. Hearn in the McCormack case refers to Richard Hearn who currently represents Dr. Gomperts and Aid Access in this action) (*emphasis added*).
[38] *McCormack*, 788 F.3d at 1028.

under the FDCA.[39] But, even if the "Ewing Doctrine" could foreclose many claims for prospective relief against the FDA brought by drug manufacturers under the APA, there is no reason to believe that the "Ewing Doctrine" could ever be used to dismiss constitutional challenges to FDA actions brought by abortion providers on behalf of their patients seeking to terminate their unwanted pregnancies. For purposes of Defendants' motion to dismiss, standing for Dr. Gomperts and her patients is established as set forth in Section B above.

Seventeen years after *Ewing*, the U.S. Supreme Court held in *Abbott Labs v. Gardner* that, in enacting the FDCA, Congress did not intend to forbid pre-enforcement review by the courts of regulations which had already been promulgated by the Commissioner.[40]

In a case not dissimilar to the one at bar, the District Court for the District of Columbia rejected out of hand the FDA's "*curious argument* that even if it ha[d] promulgated a policy which violate[d] the *First Amendment* rights of manufacturers and doctors, this court lack[ed] the power to declare such a policy unconstitutional or to enjoin defendants from enforcing it."[41]

> FDA contends that WLF's suit "in essence" requests this court to enjoin future FDA enforcement actions, something the courts do not have jurisdiction to do. Again, the FDA is mistaken. WLF's complaint alleges that the FDA has adopted a final agency policy, and that this policy interferes with the constitutional rights of its members. **The Supreme Court's decision in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140-41, 148, 18 L. Ed. 2d 681, 87 S. Ct. 1507 (1967) clearly establishes that the courts have jurisdiction to review final agency policy and to order suitable relief in the event such policy is determined to be unlawful**. FDA's argument that the court is without jurisdiction to order the relief sought by WLF is therefore rejected as well.

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[39] *Defendants' Motion to Dismiss*, 6-7 ("*Ewing* and its progeny stand for the notion that courts "'do not have jurisdiction to enjoin enforcement proceedings under the [FDCA]'" (*citation omitted*)).
[40] *Abbott Labs v. Gardner*, 387 U.S. 136 (1967), *abrogated on other grounds by Califano v Sanders*, 430 U.S. 99, 105 (1977).
[41] *Washington Legal Found. v. Kessler*, 880 F. Supp. 26, 37 (D.D.C. 1995) (*emphasis added*).

Defendants' argument here is just as curious. Even if the FDA's policy prohibiting Dr. Gomperts from prescribing misoprostol and mifepristone to her patients in the U.S. violates the constitutional rights of her patients in the U.S. to terminate their pregnancies prior to viability, the FDA argues that this Court would be without jurisdiction to review that policy and order suitable relief. The FDA was mistaken in Washington Legal Found. and is still mistaken today in the case of Dr. Gomperts.[42]

In *Abbott Labs*, the Court rejected the application of *Ewing* to dismiss a case where drug manufacturers were challenging the promulgation of a rule by the FDA that allegedly must be followed by an entire industry.

> The Administrative Procedure Act provides specifically not only for review "agency action made reviewable by statute" but also for review of final agency action for which there is no other adequate remedy in a court," *5 U.S.C. § 704*. The legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions, and this Court has echoed that theme by noting that the Administrative Procedure Act's "generous review provisions" must be given a "hospitable" interpretation.[43]

In Counts III, IV and V of the Complaint, Plaintiffs explicitly allege violations of *5 U.S.C. § 704*.

In *Ewing*, the FDA Administrator found that there was probable cause that a drug was "adulterated" because it was misbranded in such a way as to be "fraudulent" or "misleading to the injury or damage of the purchaser or consumer." Based upon the finding of probable cause by the FDA Administrator, multiple seizures of the drug were ordered. Rather than challenging the constitutionality of the seizures in the subsequent libel cases pending at the time, the manufacturer brought an action challenging the FDA Administrator's finding of probable cause. The Court held

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[42] Interestingly, *Ewing v. Mytinger & Casselberry, Inc.* is never mentioned in *Washington Legal Found. v. Kessler.*

[43] *Abbott Labs v. Gardner*, 387 U.S. 136, 140-141 (1967), *abrogated on other grounds by Califano v Sanders*, 430 U.S. 99, 105 (1977)

that the owner could raise his constitutional, statutory, and factual claims in the libel actions themselves, but that the mere finding of probable cause by the Administrator could not be challenged separately.[44]

Because Plaintiffs are not challenging any enforcement proceeding brought under the FDCA , "nothing in [*Ewing*'s] reasoning and holding has any bearing on this declaratory judgment action challenging a promulgated regulation."[45] Plaintiffs, like those in *Abbott Labs*, are challenging the constitutionality of regulations which were already promulgated under the FDCA and set out in the FDA letter.[46] Furthermore, unlike plaintiffs in *Ewing*, Plaintiffs have no other venue in which to raise their constitutional challenges to the actions threatened in the FDA letter.

> The drug manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the Act. **That the Court refused to permit such an action is hardly authority for cutting off the well-established jurisdiction of the federal courts to hear, in appropriate cases, suits under the Declaratory Judgement Act and the Administrative Procedure Act challenging final agency action of the kind present here.**[47]

The Ewing Doctrine "is hardly authority for cutting off the well-established jurisdiction of the federal courts to hear" Plaintiffs' challenge to "final" agency action.[48]

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[44] *Abbott Labs*, 387 U.S. at 146-147.
[45] *Abbott Labs*, 387 U.S. at 147.
[46] FDA Letter attached as Exhibit B to the Complaint, p. 1. (The FDA has determined that Plaintiffs "cause[d] introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)]."
[47] *Abbott Labs*, 387 U.S. at 148.
[48] *Abbott Labs*, 387 U.S. at 148.

D. The FDA may not avoid judicial review of final agency action under the APA simply by referencing it in a "FDA Warning Letter."

Contrary to Defendants' claims, Dr. Gomperts and her patients are challenging "final agency action."[49] By labeling the letter to Plaintiffs as being a "FDA Waring Letter," Defendants seek to avoid any analysis of whether, in fact, the agency has completed its decision-making process and whether the results of that process will directly affect either Dr. Gomperts or her patients.

> For an agency action like this letter to be considered final for purposes of the APA, it must satisfy the following two criteria: (1) "the action must mark the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature;" and (2) "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997) (internal citations and quotation marks omitted). "The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." *Oregon Natural Desert Association v. United States Forest Service*, 465 F.3d 977, 982 (9th Cir. 2006) (*citation and quotation omitted*).[50]

The first of the two *Bennett* criteria is satisfied. There is nothing tentative or interlocutory about the fact that -- in its letter to Dr. Gomperts and Aid Access -- the FDA applies its longstanding misbranding rules to the misoprostol and mifepristone prescribed by Dr. Gomperts.

> The second *Bennett* criteria is also satisfied.
> In determining whether an agency action satisfies this second *Bennett* criteria, the court may properly consider whether the action "has a direct and immediate effect on the day-to-day business of the subject party," whether it "has the status of law or comparable legal force, and whether immediate compliance with its terms is expected." *Oregon Natural Desert Association*, 465 F.3d at 987.[51]

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[49] *Defendants' Motion to Dismiss*, 7 ("Counts III, IV and V are subject to dismissal for lack of jurisdiction because they challenge non-final action (i.e., an FDA Warning Letter). The APA limits judicial review to 'final agency action for which there is no other adequate remedy in court." *5 U.S.C. § 704*")

[50] *Mont. Shooting Sports Ass'n v. Holder*, 2010 U.S. Dist. LEXIS 104301 **19-20; 2010 WL 3926029 (D. Mont. August 31, 2010).

[51] *Mont. Shooting Sports Ass'n*, 2010 U.S. Dist. LEXIS 104301 at *21.

The letter sent to Dr. Gomperts and Aid Access had a "direct and immediate effect" on Dr. Gomperts and her patients: Dr. Gomperts stopped prescribing medicine for women in the U.S. and many of these women were unable to exercise their constitutional right to terminate their unwanted pregnancies.

In a decision addressing judicial review of agency decisions under *5 U.S.C. § 704*, the U.S. Supreme Court held that the EPA's "compliance order" asserting its authority to regulate the plaintiffs' property under the Clean Water Act constituted "final agency action" for purposes of judicial review under the APA. Like the FDA argues with regard to FDA Warning Letters, the EPA argued in *Sackett* that EPA compliance orders were not reviewable under *5 U.S.C. § 704* because they were not final agency action.[52] Relying on *Bennett v. Spear*, the Court disagreed.

> [The EPA's compliance order] has all of the hallmarks of APA finality that our opinions establish. Through the order, the EPA "'determined'" "'rights or obligations.'" *Bennett v. Spear*, 520 U.S. 154, 178, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997) (*quoting Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71, 91 S. Ct. 203, 27 L. Ed. 2d 203 (1970)). . . . Also, "'legal consequences . . . flow'" from issuance of the order. *Bennett, supra*, at 178, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (*quoting Marine Terminal, supra*, at 71, 91 S. Ct. 203, 27 L. Ed. 2d 203) . . .
>
> The issuance of the compliance order also marks the "'consummation'" of the Agency's decisionmaking process. *Bennett*, supra, at 178, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (*quoting Chicago & Southern Air Lines, Inc. v. Waterman S. S. Corp*., 333 U.S. 103, 113, 68 S. Ct. 431, 92 L. Ed. 568 (1948)).[53]

The FDA's "warning" letter has all the hallmarks of finality as required by *Bennett v. Spear.* First, the FDA's letter claims to have determined that Dr. Gomperts and Aid Access have caused the introduction of misbranded and approved drugs in violation of federal criminal statutes.[54] Second, the FDA's letter explicitly threatens legal consequences if the alleged legal

[52] *Sackett v. EPA*, 566 U.S. 120; 132 S. Ct. 1367; 182 L. Ed. 2d 367 (2012).
[53] *Sackett*, 566 U.S. at 126; 132 S. Ct. at 1371; 182 L. Ed. 2d at 374.
[54] *Verified Complaint*, ¶¶ 62-63.

violations are not corrected.[55] And finally, the FDA's letter purports to be the consummation of the FDA's review of Aid Access's web page.[56]

Furthermore, even assuming the FDA Warning Letter were to be found not to constitute "final agency action," Plaintiffs' constitutional challenge against the FDA may still proceed based upon Defendants' threats to prosecute Dr. Gomperts and Aid Access contained in that letter.

> **[I]n *Robinson v. Salazar*, 885 F. Supp. 2d 1002, 1027-28 (E.D. Cal. 2012), the court found that constitutional challenges to agency action fell within *§ 702's* waiver of sovereign immunity and did not require "final agency action."**
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> **Similarly, the court in *Valentini v. Shinseki*, 860 F. Supp. 2d 1079, 1101 (C.D. Cal. 2012), held where the claims alleged arise not under the APA, but instead concern agency actions that violate another law, a "final agency action" is not required.** The court looked first at the text of the statute, and found that *§ 702* does not limit the waiver of sovereign immunity to only "final agency action." *Id.* at 1100. Rather, the plain language of the text "waives sovereign immunity for any action alleging injury as a result of agency action (or inaction), so long as the suit does not seek any money damages." *Id.* The court in *Valentini* then went on to reconcile *Presbyterian Church* and *Gallo Cattle*. **It found that "[w]here the allegation is that the agency action violates another—be it statutory, constitutional, or common law—the waiver of sovereign immunity is not so limited" by the "final agency action" requirements under *§ 704***, "but rather it is the broad, unqualified waiver described in *Presbyterian Church* and suggested in the plain language of the statute." *Id.* at 1101.
>
> The court here finds the reasoning in *Robinson* and *Valentini* persuasive, because the plain language of the statute does not limit *§ 702's* waiver of sovereign immunity in the way United States argues. **The court concludes that where a party raises constitutional challenges to agency action the action at issue does not need to be "final agency action."**[57]

At a minimum, *Duarte Nursery* stands for the proposition that Defendants' decision to entitle its letter "FDA Warning Letter," without more, is an insufficient reason to dismiss Dr. Gomperts' patients' constitutional challenge to Defendants' threatened actions against Plaintiffs.

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[55] *Verified Complaint*, ¶ 64.
[56] *Verified Complaint*, ¶ 62.
[57] *Duarte Nursery, Inc. v. United States Army Corps of Eng'rs*, 2016 U.S. Dist. LEXIS 76037 **33-35 (E.D. Cal. June 10, 2016) (*emphasis added*).

E. Defendants' Rule 12(b)(6) motion fails to adequately address the constitutional rights of Dr. Gomperts' patients seeking medical abortions in the U.S.

Defendants argue that the constitutional claims of Dr. Gomperts' patients seeking medical abortions in the U.S. "fail as a matter of law."[58] According to Defendants, this case is not about the right to abortion, but instead, it's about "the right to obtain unapproved drug products to terminate a pregnancy."[59] Not only is this argument whereby the Defendants simply substitute the words "terminate a pregnancy" for "abortion" nonsensical, the facts as alleged in the Complaint directly contradict Defendants' argument.

First, the drugs prescribed by Dr. Gomperts for her patients, misoprostol and mifepristone, are currently FDA approved and have been FDA approved for the last 20 years.[60] But, despite being FDA approved, access to these drugs in the U.S. is severely restricted by the FDA.[61] Second, the FDA here is not threatening to take action against a manufacturer or distributor of an allegedly unapproved drug. Instead, the FDA has decided to threaten to prosecute a doctor, Dr. Gomperts, for prescribing these FDA approved drugs to her patients who seek to terminate their pregnancies in the U.S. As discussed above, such threats to prosecute a doctor for providing abortions will chill the exercise of the constitutional right of that doctor's patients to elect to have an abortion prior to viability. This is the reason why federal courts have universally permitted abortion providers to challenge the constitutionality of such statutes or regulations on behalf of their patients.

Lastly, the Defendants argue that "there is no fundamental right to unapproved drugs."[62] Plaintiffs agree. But there is a well-established constitutional right to an abortion prior to viability.

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[58] *Defendants' Motion to Dismiss*, 18.
[59] *Defendants' Motion to Dismiss*, 19.
[60] *Verified Complaint*, ¶ 29.
[61] *Verified Complaint*, ¶¶ 30-34.
[62] *Defendants' Motion to Dismiss*, 19.

> We begin with the standard, as described in *Casey*. We recognize that the "State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that insure maximum safety for the patient." *Roe v. Wade*, 410 U.S. 113, 150, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973). But, we added, "a statute which, while furthering [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." *Casey*, 505 U.S., at 877, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (*plurality opinion*). Moreover, "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right." *Id.*, at 878, 112 S. Ct. 2791, 120 L. Ed. 2d 674.[63]

Here, Dr. Gomperts has alleged on behalf of her patients that threatening to prosecute her for prescribing misoprostol and mifepristone to her patients in the U.S. who seek to terminate their pregnancies under the FD&C Act "impose[s] an undue burden on the right."[64]

CONCLUSION

For all the reasons stated above, Plaintiffs respectfully requests that this Court deny Defendants' motion to dismiss pursuant to *Fed. R. Civil Proc. 12(b)(1) and 12(b)(6)*. If the Court were to grant Defendants' *12(b)(6) Motion*, Plaintiffs respectfully asks this Court to allow Plaintiffs' leave to amend the Complaint.

DATED this 20th day of December, 2019.

/s/ Richard A. Hearn
RICHARD A. HEARN
Counsel for Plaintiffs

[63] *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309; 195 L. Ed. 2d 665, 685 (2016) (*emphasis added*).
[64] *Id.*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 20th day of December, 2019, I filed the foregoing electronically through the CM/ECF system, which caused the following parties to be served by electronic means, as more fully reflected on the Notice of Electronic Filing:

Roger Gural
roger.gural@usdoj.gov

/s/ Richard A. Hearn
RICHARD A. HEARN
Counsel for Plaintiffs