UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

REBECCA GOMPERTS, an individual and AID ACCESS, GmbH, Plaintiffs, v. ALEX AZAR, Secretary of Health and Human Services, *et al*., Defendants.	Case No. 1:19-cv-00345-DCN **MEMORANDUM DECISION AND ORDER**

I. INTRODUCTION

Pending before the Court is Defendants Alex M. Azar, Secretary of Health and Human Services; United States Food and Drug Administration ("FDA"); Norman Sharpless, M.D.; Janet Woodcock, M.D.; Thomas Christl; and Ilise Bernstein's (collectively "Defendants") Motion to Dismiss (Dkt. 4), as well as Plaintiffs Rebecca Gomperts and Aid Access's (collectively "Plaintiffs") Motion for Preliminary Injunction/Temporary Restraining Order (Dkt. 16). The Court held oral argument on May 28, 2020, and took the matters under advisement.

Upon review, and for the reasons set forth below, the Court GRANTS Defendants' Motion to Dismiss and DENIES as MOOT Plaintiffs' Motion for Preliminary Injunction.

II. BACKGROUND

A. Factual Background

On September 28, 2000, the FDA approved a new drug application ("NDA") for mifepristone under the brand name Mifeprex. The NDA authorized Mifeprex's use—in conjunction with another drug (misoprostol)—to terminate intrauterine pregnancy through 49 days' gestation. The FDA approved the NDA for Mifeprex with certain restrictions for safe use under 21 C.F.R. Part 314, Subpart H. 21 C.F.R. § 314.520. For example, these restrictions mandate that Mifeprex be dispensed only in certain healthcare settings by a certified healthcare provider who can accurately assess the duration of a pregnancy, diagnose an ectopic pregnancy (for which Mifeprex is *not* recommended), and provide—or otherwise assure access to—surgical intervention in cases of incomplete abortion or severe bleeding.

Plaintiff Rebecca Gomperts ("Dr. Gomperts") is a physician licensed to practice medicine in Austria. She is also the founder and director of Aid Access. Aid Access was incorporated in Austria in 2018, and as its website (aidaccess.org) indicates, was created "to serve women with unwanted first trimester pregnancies." Dkt. 1, at ¶¶ 18, 20–21. Because Dr. Gomperts resides in Europe, her patients in the United States receive a consultation with her over the internet. If Dr. Gomperts determines the patient is a suitable candidate for a medical abortion, Dr. Gomperts prescribes misoprostol and mifepristone and provides "instructions on how to get [the patient's] prescriptions . . . delivered to them in the U.S." Dkt. 12, ¶ 47.

The mifepristone that Dr. Gomperts prescribes is neither the FDA-approved Mifeprex, nor the FDA-approved generic version of Mifeprex. Instead, it is a product known as "a-Kare," which is a combination pack of mifepristone and misoprostol tablets. Dkt. 1, ¶¶ 40–57; Ex. B at 1. The "a-Kare" product is manufactured by Synokem Pharmaceuticals Ltd. and marketed by DKT India. *Id.* The product is shipped from Mumbai, India, to Dr. Gomperts' patients in the United States (and around the world).

On March 8, 2019, the FDA issued a letter ("Warning Letter") to Aid Access explaining that, "sourcing drugs from outside of the legitimate U.S. drug supply chain can pose serious risks to patients who may receive medications that are adulterated and are not shipped and/or stored properly." Dkt. 1, at 30. The Warning Letter noted that the "a-Kare" product was not dispensed in a clinic, medical office, or hospital as required by law. *Id.* Finally, the Warning Letter requested that aidaccess.org cease causing the introduction of violative drugs into United States commerce and warned that "[f]ailure to correct these violations may result in FDA regulatory action. . . ." *Id.*

The FDA has not taken any further action against Dr. Gomperts or Aid Access since it sent the Warning Letter in March 2019.

B. Procedural Background

On September 9, 2019, Dr. Gomperts and Aid Access filed their Complaint alleging violations of Substantive Due Process, Equal Protection, and the Administrative Procedures Act ("APA"). Dkt. 1.

Dr. Gomperts and Aid Access's Complaint outlines thirteen (13) requests for relief. These requests can be grouped into two interrelated categories. First, Plaintiffs ask that the

Court declare that certain actions allegedly taken by the FDA violate Plaintiffs' patients' constitutional rights. Second, Plaintiffs asks that the Court enjoin Defendants from taking further similar action in the future.

On November 15, 2019, Defendants filed a Motion to Dismiss. Dkt. 4. The Court scheduled a hearing on the same. Dkt. 13. Shortly thereafter, the worldwide COVID-19 pandemic took center stage. The Court reset the hearing on Defendants' Motion to Dismiss for a later date. Plaintiffs then filed a Motion for Preliminary Injunction/Temporary Restraining Order seeking to preliminarily enjoin Defendants from taking certain actions.[1] Dkt. 16. Because of the interrelated nature of the motions, the Court asked the parties to also argue the preliminary injunction motion at the newly reset hearing for the motion to dismiss. The parties obliged and the Court took both matters under advisement after the hearing.

III. DISCUSSION

At the outset, the Court must discuss what this case is actually about. As Plaintiffs themselves noted at oral argument, the outcome of the pending motions hinges on whether or not this case is about abortion. Plaintiffs explained that if, as Defendants argue, abortion is *not* at issue, Defendants should prevail. Plaintiffs went on to state, however, that if abortion is at issue—as they suggest—then the FDA has placed "an undue burden or substantial obstacle" on women in the United States' constitutional right to obtain an

[1] Substantively, the requested relief in the preliminary injunction is almost identical to the overall relief requested in this case. Nonetheless, Plaintiffs assert that a preliminary injunction is necessary at this time to protect their interest during the pendency of this litigation and as a result of the uncertainties caused by the COVID-19 pandemic.

abortion and Plaintiffs should prevail. *See Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 878 (1992)

As will be explained throughout this decision, the Court finds that this case *is not* about abortion; it is about FDA drug regulations. While the drugs at issue are used to induce abortions, the "rights" at issue are not (as Dr. Gomperts continually asserts) truly abortion rights. It is fairly well settled law in this country that Dr. Gomperts' patients have a constitutional (i.e., fundamental) right to abortion. This aside, Dr. Gomperts' patients do not have a constitutional or fundamental right to unapproved drugs—even if they use those drugs to further a constitutional, or fundamental, right. The fact that the drugs Dr. Gomperts prescribes *leads* to an abortion does not mean the drugs themselves can be subsumed in a woman's right to an abortion. While clearly related, the topic of "access to abortion" is secondary in this case to the topic of FDA drug regulation.[2]

The Court does not take issue with Plaintiffs' representation that under Supreme Court precedent, an impermissible undue burden exists on women seeking abortions if a statute's "purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability."[3] *Casey*, 505 U.S. at 878; *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2299 (2016), *as revised* (June 27, 2016). Critically, however, there is no statute at issue in this case per se—i.e. Plaintiffs are not facially

[2] The Court is not trying to split this hair too finely, nor is this simply a matter of semantics. There is a real distinction between the rights Plaintiffs are asserting and those that are actually at issue. The language Dr. Gomperts uses throughout her briefing contextualizes the case as one about "the constitutional rights of Dr. Gomperts' patients seeking medical abortions." Dkt. 10, at 23; see also Dkt. 10, at 11, 15, 16. As the Court will explain, however, this does not accurately describe the controversy before the Court.

[3] Defendants do not dispute this either.

challenging the legality of any statute or other provision of law. To be sure, Plaintiffs are challenging the *application* of a regulation. *But*, the regulation Plaintiffs challenge—namely the underlying legal authority of the FDA's Warning Letter—is based on a set of statutes that are all related to *unapproved drugs*, not abortion. For these reasons, as well as others that will be explained throughout this decision, the Court finds that this case is not about abortion rights.

While Defendants filed a single motion to dismiss, they base their motion on two separate, but related, legal theories. For organizational purposes, the Court will address each topic in turn, followed by a discussion regarding Plaintiffs' Motion for Preliminary Injunction.

A. Motion to Dismiss for Lack of Jurisdiction (F.R.C.P. 12(b)(1))

1. Legal Standard

A motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) is premised on the fundamental concept that federal courts are courts of limited jurisdiction. *See Vacek v. United States Postal Serv.*, 447 F.3d 1248, 1250 (9th Cir. 2006). "It is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Id.* (quoting *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994)).

At the pleading stage, although the courts "presume that general allegations embrace those specific facts that are necessary to support the claim," the plaintiff, at a minimum, must allege "general factual allegations of injury resulting from the defendant's conduct" that justify federal jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)

(internal quotations omitted). In deciding a 12(b)(1) motion, a court need not limit itself to the allegations of the complaint, and it may consider such materials outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction over the case. *See id*. at 14; *Herbert v. Nat'l Acad. Of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992).

2. Analysis

One of the first—if not *the* first—questions a federal court should concern itself with in any case is jurisdiction. Accordingly, the Court begins its analysis here with Defendants' Rule 12(b)(1) arguments in support of dismissal. Upon review, the Court finds that despite Dr. Gomperts' arguments to the contrary, it lacks jurisdiction and must dismiss this case.

Dr. Gomperts premises her case on vague and speculative past actions purportedly taking by the FDA and requests relief from this court in anticipation of future FDA action that may or may not actually occur. While future FDA action may occur here (as Dr. Gomperts believes it will), the Court is divested of jurisdiction until such a time as there is actually a case in controversy and something for the Court to review. Under the *Ewing* Doctrine and the APA, the Court cannot, as a matter of law, grant the relief Dr. Gomperts and Aid Access request at this time.

a. Ewing Doctrine

In *Ewing v. Mytinger & Casselberry, Inc.*, the Supreme Court held the FDA's determination of whether there was probable cause to seize mislabeled but physically harmless drugs was not reviewable. 339 U.S. 594 (1950). Since that time, Courts have uniformly held that they "do not have jurisdiction to enjoin enforcement proceedings under

the Federal Food, Drug, and Cosmetic Act." *Forsythe v. United States*, 502 F. App'x 689, 691 (9th Cir. 2012); *see also, United States v. Alcon Labs.*, 636 F.2d 876, 882 (1st Cir. 1981) ("The Supreme Court's decision in *Ewing* precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context."); *Holistic Candlers & Consumer Ass'n v. U.S. Food & Drug Admin.*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011), *aff'd sub nom. Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940 (D.C. Cir. 2012) ("Unless and until the FDA has completed such an inquiry (into the individual Plaintiff's 'unique products and labeling') and taken legal action, *this Court does not have jurisdiction over plaintiffs' claims and may not review requests for injunctive or declaratory relief preventing the FDA from bringing enforcement actions against plaintiffs*.") (emphasis added).

In short, the Court lacks jurisdiction at this time to review Defendants' preliminary actions in relation to Plaintiffs' prescribing unapproved drugs from outside of the legitimate United States' drug supply chain to United States' residents, let alone to preemptively enjoin Defendants from taking *future* enforcement actions against Plaintiffs.

Unlike many of the cases cited above where official agency action had already begun, the only thing that has happened in this case is the FDA sent a Warning Letter to Plaintiffs. To the Court's knowledge, *nothing* has transpired since that time.

To be sure, if the FDA takes future action (which is its prerogative) and Dr. Gomperts feels that those administrative proceedings warrant judicial review,[4] she is then

[4] The Court notes that during the agency proceedings, Dr. Gomperts and Aid Access will have an opportunity to litigate and defend themselves as they see fit. *See Ewing*, 339 U.S. at 598–99.

free to file suit; however, until that occurs, the Court is barred from reviewing her requests.

b. Administrative Procedures Act

Second, and similarly, under the APA, the Court must dismiss Counts III, IV, and V of Plaintiffs' Complaint[5] because it does not yet have jurisdiction to review the FDA's actions.

Under the APA, judicial review is limited to "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The reason the APA limits judicial review to "final agency action" is to permit the agency "'an opportunity to correct its own mistakes and to apply its expertise' and prevents 'piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary.'" *Pub. Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 30 (D.C. Cir. 1984) (citations omitted).

Fundamentally, a warning letter *is not* final: it is a warning. *Holistic,* 664 F.3d at 944 (while FDA Warning Letters "may lead to enforcement action" if the cited violations are not corrected, they "do[] not commit FDA to taking enforcement action"); *see also, Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) (holding FDA regulatory letter was not final agency action where it did not commit FDA to bring enforcement action).

[5] Plaintiffs' Compliant outlines five (5) causes of action: Count 1 – Substantive Due Process – Patients' right to Privacy; Count II – Equal Protection; Count III – Administrative Procedures Act – Contrary to Constitutional Right; Count IV – Administrative Procedures Act – In Excess of Statutory Authority; Count V – Administrative Procedures Act – Arbitrary, Capricious and Abuse of Discretion.

This generalized understanding aside, a warning letter *could* be final for purposes of the APA if the following two criteria are met: (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 (1997).

Defendants contend that because the Warning Letter sent to aidaccess.org does not constitute the "consummation of the agency's decisionmaking process," is "merely tentative or interlocutory," and does not determine any "rights or obligations" or have "legal consequences," it is not final agency action and is non-reviewable. *See Bennett*, 520 U.S. at 177–78.

Intriguingly, Dr. Gomperts argues the exact opposite: that the FDA letter is final, that "there is nothing tentative or interlocutory" about the letter, and that claiming the letter is not final is a farce by the FDA to avoid judicial review. Dkt. 10, at 20–21. The Court disagrees.

The FDA sent the Warning Letter to Aid Access and Dr. Gomperts on March 8, 2019. The FDA would likely *not* have allowed Plaintiffs an opportunity to respond to the Warning Letter—which they did—were this their final position on the topic.

Furthermore, while Dr. Gomperts and Aid Access apparently stopped prescribing medications to their United States' patients immediately following receipt of the Warning Letter, they resumed issuing prescriptions two months later. To the best of the Court's

knowledge, the FDA has done nothing since that time. Clearly, had the FDA wanted to initiate formal action against Aid Access and Dr. Gomperts, it could have done so by now.[6]

Dr. Gomperts and Aid Access's continual prescription of a-Kare shows, in part, that the FDA Warning Letter had little practical effect on Plaintiffs' behavior. The drugs Dr. Gomperts prescribes were unapproved prior to the Warning Letter, remain unapproved to this day, and yet Dr. Gomperts still writes prescriptions for patients and faces little to no interference. These factors undercut Plaintiffs' argument that the FDA Warning Letter was final—as opposed to an interlocutory step taken in conjunction with a larger investigation.

Ultimately, the Court must dismiss the APA claims (Claims III, IV, and V) as there has been no final agency action warranting review.

c. Standing

Another threshold issue in any case—and, again, one that concerns the Court here—is that of standing. Dr. Gomperts and Aid Access explain that they are not bringing this case on their own behalf, but on behalf of their clients located in the United States.

Standing is the determination of whether a specific person is the proper party to bring a particular matter to the court for adjudication. Typically, for a court to have the authority to hear a case, a plaintiff must allege: (1) he or she has suffered or will suffer an injury, (2) the injury is fairly traceable to the defendant's conduct, and (3) a favorable court decision is likely to redress the injury. *See Biodiversity Legal Found. v. Badgley*, 309 F.3d

[6] Is it particularly interesting that the FDA has not taking formal action against Plaintiffs despite Plaintiffs' continuing refusal to abide by the Warning Letter. The Court does not wish to read into this decision unnecessarily, but it again lends credence to the argument that the FDA is still deciding how to address this situation.

1166, 1171 (9th Cir. 2002). Furthermore, the prudential standing requirements prohibit third-party standing and the filing of generalized grievances. The idea behind preventing third-party standing is that individuals must assert his/her own rights; not the rights of others. There are, however, certain exceptions to this general rule.

For example, in *Singleton v. Wulff*, the Supreme Court found that physicians had standing to sue on behalf of their clients in a case regarding the constitutionality of a Missouri statute prohibiting Medicaid funding of abortions that were not "medically indicated." 428 U.S. 106, 118 (1976). The Court there ultimately found that a plaintiff may bring a suit when the right is inextricably bound with the activity the litigant wishes to pursue and it is unlikely that the party can or will sue on his or her behalf. *Id.* at 114–15. *See also Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004).

Here, the question is whether Plaintiffs have the appropriate standing to bring suit on behalf of women in the United States who seek to induce a medical abortion via the use of unapproved FDA drugs. Dr. Gomperts is closely bound to the activity the potential litigant might wish to pursue: she is the doctor acting on behalf of these women, and she has a financial stake in the litigation. It could also be argued that it is unlikely that the women in question would bring suit on their own (due to their desire for confidentiality or the "imminent mootness at least in the technical sense, of any individual woman's claim," *Singleton*, 428 U.S. at 117). And as already noted, however, this case is not really about abortion, thus Plaintiffs' reliance on *Wulff* and its progeny is somewhat misplaced. To be sure, the Court is not disputing the general principle that an abortion provider can bring suit on behalf of his or her clients. That said, caselaw does not support the proposition that

an abortion provider can bring suit on his or her client's behalf for claims only *indirectly* related to abortion.[7]

Additionally, the Court is troubled by the fact that of Dr. Gomperts' alleged harms, none show an injury-in-fact and likewise appear to lack redressability. Dr. Gomperts argues she and/or her patients were injured by (1) the seizure by one or more federal agencies of an unknown number of packages containing unapproved products prescribed by her, and (2) a fear of prosecution. As explained above, these vague and/or potential future "harms" are not reviewable by the Court at this time. Furthermore, as will be discussed in greater detail below, Plaintiff's alleged harms are also lacking in substance. A "concrete" injury is one that is "distinct and palpable," *Warth*, 422 U.S. at 501, not merely "[a]bstract," *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974). Any alleged injury must be fairly traceable to the Defendants' conduct. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) (a plaintiff must show that any such injury "fairly can be traced to the challenged action of [a defendant], and [is] not injury that results from the independent action of some third party not before the court"). The initial complaint in this case speaks to Dr. Gomperts' "belief" concerning these allegations; however, she cannot fairly trace any of those beliefs directly to the Defendants' conduct.

[7] Plaintiffs recently provided the Court with supplemental authority from the United States Supreme Court in support of its standing argument. Dkt. 23. In the Supreme Court's recent decision in *June Medical Services L.L.C., et al v. Stephen Russo, Interim Secretary, Louisiana Department of Health and Hospitals*, it reiterated that abortion providers have standing to bring suit on behalf of their clients. Again, however, the Supreme Court's finding in *June Medical Services* specifically concerned abortion providers who were challenging *abortion* regulations on behalf of their clients. 591 U.S. ___ at 15 (2020). The Court has thoroughly reviewed *June Medical Services* and finds no indication that "provider standing" can be extending to challenges to FDA drug regulations *that are not directly related to abortions.*

Ultimately, Plaintiffs have not met their burden of establishing they have standing to bring claims related to non-FDA approved drugs on behalf of their clients. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (finding that the party "invoking federal jurisdiction bears the burden of establishing [standing]").

Even if the Court had jurisdiction to hear Plaintiffs' claims (which it finds it does not), and were to determine Plaintiffs have standing (which it does not), it would nonetheless have to dismiss Plaintiffs' claims for failure to state a claim under Rule 12(b)(6). While the jurisdictional barriers to this case under Rule 12(b)(1) are paramount today, the Court briefly addresses the substantive claims as that subject matter also relates to the pending Motion for Preliminary Injunction.

B. Motion to Dismiss for Failure to State a Claim (F.R.C.P. 12(b)(6))

1. Legal standard

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss a claim if the plaintiff has "fail[ed] to state a claim upon which relief can be granted." Fed. R. Civ. P 12(b)(6). "A Rule 12(b)(6) dismissal may be based on either a 'lack of a cognizable legal theory' or 'the absence of sufficient facts alleged under a cognizable legal theory.'" *Johnson v. Riverside Healthcare Sys., LP*, 534 F.3d 1116, 1121 (9th Cir. 2008) (citation omitted). Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007). "This is not an onerous burden." *Johnson*, 534 F.3d at 1121.

A complaint "does not need detailed factual allegations," but it must set forth "more than labels and conclusions, and a formulaic recitation of the elements." *Twombly*, 550 U.S. at 555. If the facts pleaded are "merely consistent with a defendant's liability," or if there is an "obvious alternative explanation" that would not result in liability, the complaint has not stated a claim for relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662 678, 682 (2009).

In deciding whether to grant a motion to dismiss, the court must accept as true all well-pleaded factual allegations made in the pleading under attack. *Id.*, at 663. A court is not, however, "required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors,* 266 F.3d 979, 988 (9th Cir. 2001).

In cases decided after *Iqbal* and *Twombly*, the Ninth Circuit has continued to adhere to the rule that a dismissal of a complaint without leave to amend is inappropriate unless it is beyond doubt that the complaint could not be saved by an amendment. *See Harris v. Amgen, Inc*., 573 F.3d 728, 737 (9th Cir. 2009).

2. Analysis

It is well settled that conclusory statements are insufficient to support a claim for relief. *See Iqbal*, 556 U.S. at 678. As explained above, Dr. Gomperts' request that the Court preliminarily enjoin Defendants from taking future action is premature. Additionally, the purported reasons for the requested relief are speculative at best.

In their Complaint, Plaintiffs outline that Dr. Gomperts "*believes* that FDA has seized between three and ten individual doses of misoprostol and mifepristone prescribed

for between three and ten of her patients residing in the U.S.,"[8] and "believes" the FDA "or other agencies in the U.S. government" caused business entities to cease transferring funds between Plaintiffs and individuals in the United States. Dkt. 1, ¶¶ 68–71. Dr. Gomperts also points to the prosecution of an unrelated third-party—Ursula Wing—as evidence that she may face criminal prosecution in the near future. This, too, is pure speculation.[9]

While these factors undermine Plaintiffs' standing—as they are speculative and fail to point to any concrete or particularized injury—they also undermine Plaintiffs' claims themselves. None of these purported "facts" lend credence to Plaintiffs' constitutional arguments that the FDA violated their Due Process and/or Equal Protection rights.

As noted, while Plaintiffs try to couch these claims more broadly as "interference with their ability to obtain an abortion," they are really challenging FDA's interference with their ability to obtain certain drugs. Because Dr. Gomperts' patients could obtain an abortion using FDA approved channels, the inability to secure *this type of abortion from this provider* does not infringe on their abortion rights generally.[10]

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[8] It is important to note that the FDA itself does not "seize" packages at the border, but rather assists Customs and Border Patrol in conducting warrantless searches of incoming package. *See, e.g.*, *U.S. v. Alfonso*, 759 F.2d 728, 735 (9th Cir. 1985). If the FDA determines that a package contains products that appear to violate the Federal Food, Drug, and Cosmetic Act ("FDCA"), it may detain the shipment and send a "Notice of Detention and Hearing" to the importer, owner, or consignee. *See* 21 C.F.R. § 1.94(a). It is unclear whether the FDA was involved in any seizures in this case (as opposed to another governmental agency), and/or whether the FDA sent any such notices to Plaintiffs.

[9] Wing was importing wholesale quantities of drugs, repackaging them, and then dispensing them (in clandestine packages) to customers without a prescription. A federal grand jury ultimately indicted Wing for importing foreign sourced versions of mifepristone and misoprostol into the United States. While the drugs at issue are the same, none of the other factors are present in this case and there is nothing to suggest Dr. Gomperts or her patients face imminent legal action.

[10] Additionally, Dr. Gomperts' patients have access to other forms of legal abortion in Idaho.

Furthermore, the fact that an internet prescription abortion might be the "only option" available for some women, if true,[11] misses the point because Dr. Gomperts' patients still do not have a fundamental right to non-FDA approved drugs—whether used for an abortion or otherwise. *See United States v. Rutherford,* 442 U.S. 544 (1979) (finding there is no right to acquire unapproved drugs—even for terminally ill patients); *accord Carnohan v. United States,* 616 F.2d 1120, 1122 (9th Cir. 1980) (The constitutional rights to privacy and personal liberty "do not give individuals the right to obtain [unapproved drugs] free of the lawful exercise of government police power."); *see also Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695, 711 (D.C. Cir. 2007) (finding no evidence "of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions. To the contrary, our Nation's history evidences increasing regulation of drugs as both the ability of government to address these risks has increased and the risks associated with drugs have become apparent").

Plaintiffs agree that there is no fundamental right to unapproved drugs, but assert that there is a "well-established constitutional right to an abortion." Dkt. 10, at 23. The Court does not dispute this. But again, that is not what this case is about. While Dr. Gomperts cites caselaw outlining a women's right to an abortion—as well as a women's right to be free from "substantial obstacles" when seeking an abortion—this case only limits a woman's right to an abortion in the same context in which the case arises: the use

[11] Plaintiffs have not submitted anything beyond their argument for this far-reaching proposition. It isn't difficult to imagine that an internet prescription might be the *most convenient* option for many women, but there is nothing in the record to suggest it is the *only* option for those same women.

of unapproved drugs. In other words, yes: the FDA's future actions would limit a woman's right to an abortion via those *unapproved drugs*, but that is not a right a woman has in the first instance.[12]

The FDA did not sent the Warning Letter to Plaintiffs because the drugs at issue induce abortions, but because the drugs at issue are unapproved and, ultimately, illegal. The statutes at issue in the Warning Letter are not related to abortion in any way—they do not mention the word "abortion" by plain text or implication—but are, rather, directed at the safe and effective use of drugs.

That abortion rights are tangentially implicated in this case is a secondary effect. The real issue Plaintiffs are challenging in the instant action concerns FDA drug regulations—namely whether the FDA can sanction or monitor the use in commerce of an unapproved drug.[13]

Finally, it is helpful to view the Court's analysis in the negative. If the Court were to accept Plaintiffs' position and preliminarily enjoin Defendants from taking future action against Plaintiffs, the Court would, in effect, be sanctioning the sale and interstate use of

[12] Taking the situation out of the abortion context demonstrates the universality of this holding. For example: a person has the right to do "A." Additionally, there are laws that prohibit "B." Even if a person wishes to engage in "A"—a legal activity—he or she cannot do so with the help of "B" because "B" is illegal. Furthermore, one cannot successfully argue that "B" should be legal simply because "A" is legal and/or that a person is only using "B" to further "A" because "B" is, nonetheless, still illegal.

[13] Again, the abortion element in this case may make the Court's analysis appear more significant than it actually is. The Court is not being asked to determine the parameters of a women's right to an abortion; only the parameters of a women's right to unapproved drugs. Thus, in determining that a woman does not have a fundamental right to an unapproved drug (for whatever purpose), the Court *is not* taking any position on a woman's right to abortion.

unapproved drugs in commerce.[14] This is something the Court is unwilling to do. The FDA and Dr. Gomperts can argue whether "a-Kare" should be approved or not in administrative proceedings, but the subject matter at issue in this case concerns whether the FDA can control the use and sale of unapproved drugs and whether the Court can review those determinations before they have actually happened.

Thus, because Plaintiffs' claims relate to FDA drug protocols, they do not implicate a fundamental right. As a result, the appropriate level of review for their Due Process claims is rational basis review. *See Washington v. Glucksberg*, 521 U.S. 702, 728 (1997) (law that does not implicate a fundamental right must be "rationally related to legitimate government interests"). In this context, Defendants' actions pass muster.

The FDA's long-held, overriding purpose is to protect the public health. *See United States v. Dotterweich*, 320 U.S. 277, 280–81 (1943). The seizure of unapproved drug products and the prosecution of individuals for violating the FDCA plainly serve the government's legitimate interest in protecting the public health. *See POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102, 115 (2014). These goals meet the rational basis test. *See id.*

Turning to Plaintiff's Equal Protection claims, the Court finds the same analysis applies. Plaintiffs contend that Dr. Gomperts' patients have been treated "differently from

[14] To be sure, Plaintiffs emphatically stated at oral argument that they *are not* asking the Court to sanction the use of unapproved drugs but simply asking the Court to enjoin the FDA from burdening women's rights. But again, this rests on the flawed premise that the FDA took actions in an effort to burden women seeking abortions in the first place. As explained, that is only a secondary effect of the FDA's goal of regulating the use and sale of drugs. Allowing an exception for drugs that are related to abortion, however, would negate the FDA's fundamental goals of regulating drugs and protecting the health and safety of the American public.

other similarly situated parties without a sufficient state interest." Dkt. 1, ¶¶ 98–101. Yet this is difficult to accept when, by all accounts, it appears the FDA would take similar actions (as it did here) against any person, business, or organization flouting regulations concerning unapproved drugs, i.e., sending a warning letter, investigating, etc.—regardless of whether the drugs are used for abortions or not.

Furthermore, even if there were minor discrepancies[15] in the manner in which the FDA investigated this case vis-à-vis *other unapproved drug cases*,[16] any FDA action that seeks to hinder or deter the unlawful distribution of an unapproved drug serves the FDA's purpose of protecting the public health. Accordingly, the Court must dismiss Plaintiffs' Due Process and Equal Protection claims as neither support a viable cause of action.

Upon review, and based upon the deficiencies identified above, the Court finds dismissal under Rule 12(b)(1) and Rule 12(b)(6) is appropriate in this case. Defendants' Motion to Dismiss (Dkt. 4) is GRANTED.

C. Motion for Preliminary Injunction

1. Legal Standard

"Plaintiffs seeking a preliminary injunction must establish that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of

[15] The Court is not implying there are discrepancies, however, Plaintiffs continue to suggest that the FDA singled them out because the drugs they are prescribing are unapproved drug used for abortion and that if it were an unapproved drug for any other purpose, the FDA would not have cracked down on them the way they did. This is pure speculation. Defendants have represented that they police the sale and use of unapproved drugs equally; regardless of the drug's purpose. The Court has no reason to doubt this.

[16] Again, Defendants' actions should not be viewed against the backdrop of other abortion drug cases as Plaintiffs' suggest, but in relation to other FDA unapproved drug cases.

preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest." *Short v. Brown*, 893 F.3d 671, 675 (9th Cir. 2018) (internal citations omitted).

The basic function of a preliminary injunction is to "preserve the status quo ante litem pending a determination of the action on the merits." *Los Angeles Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1200 (9th Cir. 1980). "A preliminary injunction should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Towery v. Brewer*, 672 F.3d 650, 657 (9th Cir. 2012) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)).

2. *Analysis*

Because the Court finds it lacks jurisdiction to hear Plaintiffs' claims (and that each claim fails as a matter of law), Plaintiffs' Motion for Preliminary Injunction is MOOT.

That said, because the Motion for Preliminary Injunction essentially asks for the same relief as the Complaint itself—just on a faster timeframe—the Court will briefly address some of the substantive timing and procedural issues raised in this motion.

Here, Plaintiffs ask for a nationwide injunction enjoining Defendants from taking any action that would (1) impede or delay the delivery of Dr. Gomperts' prescriptions in the United States or (2) cause criminal charges to be brought against Dr. Gomperts, Aid Access, and/or their patients.

In accordance with the Court's analysis above, Plaintiffs' likelihood of success on the merits of their case is slim to none. Jurisdictional bars—including standing, APA review, and the *Ewing* Doctrine—foreclose the relief they request. Simply put, the Court

is not in a position to preliminarily enjoin FDA action that may or may not occur. Plaintiffs fail to meet the first prong of the Preliminary Injunction test.

Second, there is little to no indication that Plaintiffs (or their clients) will suffer irreparable harm in the absence of a preliminary injunction. Since sending the Warning Letter in March of 2019, neither the FDA nor any other Defendant has taken action against Plaintiffs or Plaintiffs' clients. Plaintiffs continue to make much ado about the purported seizure of an extremely limited number of packages that contained Dr. Gomperts' patients' prescriptions, but there is no indication the FDA has actually been involved in such efforts.[17] Additionally, there is no indication the FDA intends to begin prosecuting Plaintiffs or Plaintiffs' clients at this time. These two factors cut against a finding that there will be irreparable harm absent a preliminary injunction.

Finally, the balance of equities does not tip in Plaintiffs' favor and an injunction is not within the public interest. The purpose of a preliminary injunction is to preserve the status quo pending adjudication on the merits. Prior to filing this lawsuit, Dr. Gomperts had not been prosecuted, her patients had not been prosecuted, and her mail and financial transactions were not interrupted on a wide-scale basis. Since the filing of the lawsuit, the status quo has remained the same: nobody related to this case has been prosecuted and there have not been any widescale attempts to curb Dr. Gomperts' shipments or financial

[17] Plaintiffs also note that Dr. Gomperts' prescriptions are filled and shipped by an exporter in Mumbai India and that because of the COVID-19 pandemic, the Indira Gandhi International Airport in Mumbai was closed for a time, thus disrupting delivery of Dr. Gomperts' prescriptions. It should go without saying that the Court has limited options in regard to this situation. The Court cannot compel the government of India to reopen its airport or force it to send shipments of drugs to the United States. Ultimately, this particular issue is moot as Dr. Gomperts states in her reply brief that she was able to find another supplier (outside of India) willing to ship "a-Kare" to the United States.

transactions. Simply put, nothing has changed that would warrant a preliminary injunction in this matter. Plaintiffs are in the exact same position today as they were in March 2019 (when they received the FDAs Warning Letter) and in September 2019 (when they filed suit).

Finally, hearkening to the Court's prior discussions regarding what is really at issue in this case—abortion rights or FDA drug regulations—the Court analyzes one last argument Plaintiffs' raise in support of a Preliminary Injunction. Plaintiffs spend a great deal of time discussing recent rulings from other courts wherein medical providers of abortion services challenged stay-at-home orders entered by states in response to the COVID-19 pandemic. Apparently, many courts granted temporary restraining orders or preliminary injunctions on the enforcement of these stay-at-home orders—specifically aspects of the orders that involved access to abortions. While interesting, stay-at-home orders are not at issue in this case and the findings of those Courts are only marginally relevant to the Court today. Again, the issue here is not whether a preliminary injunction should be entered to stop Defendants from inhibiting Plaintiffs' patients' rights to an abortion, but whether a preliminary injunction should be entered inhibiting Plaintiffs' patients' rights to unapproved drugs.

Weighing all the factors, even if the Court were not dismissing this case for jurisdictional reasons, it finds that a preliminary injunction is not appropriate as Plaintiffs have not shown they are likely to succeed on the merits or that they would suffer harm absent an injunction.

For all of these reasons, Plaintiffs' Motion for Preliminary Injunction is DISMISSED as MOOT.

IV. ORDER

1. Defendants' Motion to Dismiss (Dkt. 4) is GRANTED. This case is DISMISSED WITHOUT PREJUDICE and CLOSED.[18]
2. Plaintiffs' Motion for Preliminary Injunction/Temporary Restraining Order (Dkt. 16) is DISMISSED as MOOT.

DATED: July 13, 2020

David C. Nye
Chief U.S. District Court Judge

[18] The Ninth Circuit has continually held that dismissal of a complaint without leave to amend is inappropriate unless it is beyond doubt that the complaint could not be saved by an amendment. *See Harris v. Amgen, Inc.*, 573 F.3d 728, 737 (9th Cir. 2009). The Court today has dismissed Plaintiffs' complaint for very specific procedural and jurisdictional reasons and doubts any amendments could save Plaintiffs' Complaint. That said, it will not foreclose such an opportunity and dismisses the case without prejudice. Plaintiffs may wish to amend, appeal forthwith, or drop the matter entirely. It is up to them; however, should they wish to amend their Complaint and continue *in this forum*, they must do so within 30 days of the date of this order.