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IN THE 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.	No. 1:19-cv-00345-DCN **DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT**

Rebecca Gomperts, a physician who is not licensed to practice medicine in the United States, and Aid Access, an Austrian corporation (collectively "Plaintiffs"), seek relief against the United States Food and Drug Administration ("FDA") so that Plaintiffs can continue to prescribe over the Internet and distribute from overseas an unapproved version of the prescription drug mifepristone to consumers in the United States. Unapproved drugs do not have the same assurance of safety and effectiveness as those subject to FDA oversight and may be contaminated or counterfeit, or may contain different ingredients. Plaintiffs' suit seeks to circumvent the long-standing prohibition on introducing drugs that are either misbranded or not approved by FDA into United States commerce. Plaintiffs' suit also disregards Supreme Court precedent establishing that district courts lack jurisdiction to enjoin enforcement proceedings that have yet to take place under the Federal Food, Drug, and Cosmetic Act ("FDCA").

Despite engaging in conduct that runs counter to the regulatory scheme Congress enacted to ensure the safety of the nation's drug supply and protect the public health, Plaintiffs nonetheless claim they have suffered a laundry list of harms, including the alleged seizure by one or more federal agencies of an unspecified number of packages containing the unapproved drug product, the alleged interruption of patients' ability to pay Plaintiffs for this unapproved drug product, and speculative fears of criminal prosecution for introducing this unapproved drug product into interstate commerce. *See* Compl. ¶¶ 93-96, 98-101. However, none of Plaintiffs' purported harms constitute an injury-in-fact caused by Defendants. And none are redressable by the relief Plaintiffs request. Plaintiffs cannot even show that FDA has taken any final agency action subject to judicial review. Thus, Plaintiffs cannot establish Article III standing and Plaintiffs' Complaint should therefore be dismissed for lack of jurisdiction.

Plaintiffs have also failed to state a claim for which relief can be granted. Plaintiffs assert

violations of substantive due process, equal protection, and the Administrative Procedure Act ("APA"). Plaintiffs, however, cannot demonstrate a fundamental right to distribute an unapproved drug product from overseas to United States patients, have not identified a manner in which they are being treated differently from a similarly-situated class, and have failed to articulate any plausible violation of the APA. For all of these reasons, Plaintiffs' Complaint should be dismissed under Rules 12(b)(1) and 12(b)(6).

BACKGROUND

A. Statutory and Regulatory Background

The FDCA's overriding purpose is protecting the public health. *See United States v. Dotterweich*, 320 U.S. 277, 280-81 (1943). Consistent with that purpose, a manufacturer must apply for and secure FDA approval to market a "new drug" in interstate commerce. 21 U.S.C. § 355(a); *see* 21 U.S.C. § 321(p) (defining "new drug"). Articles are drugs within the meaning of 21 U.S.C. § 321(g) if they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or because they are intended to affect the structure or function of the body. Drugs are also "new" drugs as defined by 21 U.S.C. § 321(p) if they are not generally recognized as safe and effective for their labeled use. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA. 21 U.S.C. § 355(a).

FDA approves two general categories of applications: a new drug application ("NDA") for what are commonly referred to as "brand-name drugs," and an abbreviated new drug application ("ANDA") for what are commonly referred to as "generic" versions of brand-name drugs. *See* 21 U.S.C. § 355(a), (b), and (j). An NDA must include, among other things, the drug product's proposed indications for use; full reports of the clinical investigations of the drug product's safety and effectiveness for the proposed indications; and the drug product's proposed

labeling. *See* 21 C.F.R. § 314.50(a)(1); 21 U.S.C. § 355(b)(1)(A), (F).

FDA will approve an NDA only if it determines that the drug product is safe and effective for use in accordance with its proposed labeling. 21 U.S.C. § 355(d); s*ee FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000); *United States v. Bel-Mar Labs., Inc.*, 284 F. Supp. 875, 880-81 (E.D.N.Y. 1968). A drug is misbranded under section 352(f)(1) "unless its labeling bears adequate directions for use" and the drug does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1); *see* 21 C.F.R. § 201.5; *United States v. Premo Pharm. Labs., Inc.*, 511 F. Supp. 958, 977 n.23 (D.N.J. 1981).

B. Factual Background

1. On September 28, 2000, FDA approved an NDA for mifepristone, under the brand name Mifeprex, authorizing the drug product's use in a 600-mg dose, in a regimen with another drug (misoprostol), to terminate intrauterine pregnancy through 49 days' gestation. FDA approved the NDA with certain restrictions for safe use under 21 C.F.R. part 314, subpart H, including 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 contraindicated), and provide—or otherwise assure access to—surgical intervention in cases of incomplete abortion or severe bleeding. Because of that initial approval with restrictions, Mifeprex was "deemed to have in effect an approved risk evaluation and mitigation strategy" (*i.e.*, a "REMS") in 2007 pursuant to Section 909(b)(1) of the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85.

In 2016, FDA approved a supplement to the Mifeprex NDA that included changes to the dose of Mifeprex and the dosing regimen for taking Mifeprex and misoprostol, the gestational age up to which Mifeprex may be used, and the process for follow-up after administration of the

drug product. FDA also approved certain changes to the Mifeprex REMS. *See* https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information. On April 11, 2019, FDA approved an ANDA for a generic version of Mifeprex, sponsored by GenBioPro, Inc. *See* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.[1]

2. Dr. Gomperts is a physician licensed to practice medicine in Austria, and is the founder and director of Aid Access. Compl. ¶¶ 9, 12, 19. Aid Access was incorporated in Austria in 2018, and its website "aidaccess.org" was created "to serve women with unwanted first trimester pregnancies." Compl. ¶¶ 18, 20-21. Dr. Gomperts provides "medical abortions to women in the United States" by prescribing misoprostol and mifepristone to induce an abortion in those patients that Dr. Gomperts determines can safely have a medical abortion. Compl. ¶¶ 22, 45-46. Plaintiffs state that Idaho contains some physicians certified to prescribe Mifeprex. Compl. ¶ 37. Instead of receiving an in-person examination and diagnosis, Dr. Gomperts' patients in the United States receive a consultation over the Internet, Compl. ¶¶ 40-42, and "are provided instructions on how to get their prescriptions for misoprostol and mifepristone delivered to them in the U.S." Compl. ¶ 47.

The mifepristone that Dr. Gomperts prescribes is neither FDA-approved Mifeprex nor the FDA-approved generic version. *See* Compl. ¶¶ 40-57; Ex. B at 1 (noting aidaccess.org facilitates the sale of the product "a-Kare," a combination pack of mifepristone and misoprostol tablets manufactured by Synokem Pharmaceuticals Ltd and marketed by DKT India). Nor is it dispensed in a clinic, medical office, or hospital, as FDA-approved Mifeprex must be. Instead, the unapproved product is exported from India by N N Agencies and shipped to patients. *See id*.

[1] Danco, the sponsor of Mifeprex, and GenBioPro participate in a single, shared system REMS.

On March 8, 2019, FDA issued a 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." Compl. Ex. B at 3. The letter further explained that FDA's regulation of the drug approval process "protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness," and manufacturing at FDA-registered and FDA-inspected facilities. *Id*.[2] The letter requested that aidaccess.org cease causing the introduction of such violative drugs into U.S. commerce and warned that "[f]ailure to correct these violations *may* result in FDA regulatory action. . . ." *Id.* at 3 (emphasis added).

STANDARD OF REVIEW

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

[2] The letter advised Aid Access that the a-Kare product it distributed was an unapproved drug and misbranded in various ways, including because its labeling lacked "adequate directions for its intended use," and "adequate warnings against use . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration . . . ." *Id.* at 2-3.

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).

A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of the claims in the complaint. *See Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001); *Int'l Union of Operating Eng'rs Local 370 v. Wasden*, 217 F. Supp. 3d 1209, 1212 (D. Idaho 2016). "All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party," *Cahill v. Liberty Mut. Ins. Co.,* 80 F.3d 336, 337-38 (9th Cir. 1996), but "[t]he court does not necessarily assume the truth of legal conclusions merely because they are cast in the form of factual allegations in plaintiff's complaint." *Zoellner v. St. Luke's Reg'l Med. Ctr.*, 937 F. Supp. 2d 1261, 1265 (D. Idaho 2013). A court will not consider material outside the complaint when ruling on a Rule 12(b)(6) motion. *Branch v. Tunnell*, 14 F.3d 449, 453-54 (9th Cir. 1994).

ARGUMENT

A. Plaintiffs' Requests for Injunctive Relief Are Foreclosed by the *Ewing* Doctrine

At the outset, the relief that Plaintiffs seek in this case is foreclosed by *Ewing v. Mytinger & Casselberry, Inc.,* 339 U.S. 594, 601-02 (1950). Plaintiffs ask this Court to preemptively enjoin FDA from taking enforcement action against them or otherwise impeding delivery of unapproved, foreign-manufactured drug products to patients in the United States (Compl. at 20-22). But *Ewing* and its progeny stand for the notion that courts "do not have jurisdiction to enjoin enforcement proceedings under the [FDCA]." *Forsythe v. United States*, 502 Fed. Appx. 689, 691 (9th Cir. 2012); *see also Basic Research, LLC v. FTC*, 807 F. Supp. 2d 1078, 1093 (D. Utah 2011) ("the *Ewing* line of cases preclude a court from enjoining enforcement actions"). Instead, a party has ample opportunity to litigate any constitutional, statutory, or factual defenses in the enforcement action itself. *Ewing*, 339 U.S. at 598-99; s*ee Holistic Candlers & Consumer Ass'n v. United States FDA*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011) ("The determination of

FDCA violations is, of course, a factual one that the FDA must conduct on a plaintiff-by-plaintiff basis, at a relevant time and in light of each plaintiff's unique products and labeling. Unless and until the FDA has completed such an inquiry 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.").

The Supreme Court reaffirmed the *Ewing* rule in *Abbott Labs. v. Gardner*, calling it "clearly correct." 387 U.S. 136, 147 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977). Since then, the rule has been "consistently and strictly observed" to apply to any enforcement action under the FDCA. *See, e.g.*, *United States v. Alcon Labs.*, 636 F.2d 876, 882 (1st Cir. 1981) ("*Ewing* precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context"). Because this Court lacks jurisdiction to enjoin seizures or prosecutions brought pursuant to the FDCA, or to declare such actions unconstitutional—especially where no enforcement action even exists—Plaintiffs are not entitled to the preemptive relief they seek. This alone requires dismissal of their claims.

B. There is No Final Agency Action Subject to Review Under the APA

Counts III, IV, and V are subject to dismissal for lack of jurisdiction because they challenge non-final agency 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 a court." 5 U.S.C. § 704. "The requirement of finality permits '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). Finality is a jurisdictional requirement for obtaining judicial review of agency action. *Navajo Nation v.*

U.S. Dep't of Interior, 819 F.3d 1084, 1090 (9th Cir. 2016).[3]

Contrary to Plaintiffs' allegations, Compl. ¶¶ 103, 106, 109, FDA Warning Letters do not constitute final agency action under the APA. *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943-44 (D.C. Cir. 2012); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) (holding FDA regulatory letter not final agency action where it did not commit FDA to bring enforcement action). 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." *Holistic,* 664 F.3d at 944. Because the Warning Letter received by 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. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).[4] Accordingly, Counts III, IV, and V of Plaintiffs' Complaint should be dismissed.

C. Plaintiffs Lack Standing to Bring These Claims

To establish the "irreducible constitutional minimum" for Article III standing, a plaintiff must both plead and prove three familiar and essential elements: *First*, "[t]he plaintiff must have suffered an injury-in-fact—an invasion of a legally protected interest which is (a) concrete and

[3] The Ninth Circuit has held that Section 704 of the APA is jurisdictional because it limits the scope of the APA's waiver of sovereign immunity. *See Tucson Airport Auth. v. Gen. Dynamics Corp.*, 136 F.3d 641, 645 (9th Cir. 1998); *Gallo Cattle Co. v. USDA*, 159 F.3d 1194, 1198-99 (9th Cir. 1998). *But see Gros Ventre Tribe v. United States*, 469 F.3d 801, 809 (9th Cir. 2006) (noting tension as to whether Section 704 poses a jurisdictional barrier to constitutional claims). But even if finality were not jurisdictional, Counts III, IV and V would still be subject to dismissal under Fed. R. Civ. P. 12(b)(6) for failure to state a claim under the APA.

[4] To the extent these Counts also purport to challenge other, unidentified "agency action and inaction" as described elsewhere in the complaint, those challenges also fail for want of final agency action. Plaintiffs' claimed fear of prosecution and allegations of blocked payments by non-governmental third parties fail to identify any final agency action by FDA. Likewise, the unspecified product seizures described in the complaint are not final agency action; on the contrary, the detention of an imported product merely initiates an action in which any aggrieved party would have an opportunity to challenge the detention.

particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560; *see also Novak v. United States*, 795 F.3d 1012, 1017-18 (9th Cir. 2015). A "concrete" injury is one that is "distinct and palpable," *Warth v. Seldin*, 422 U.S. 490, 501 (1975), not merely "[a]bstract," *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974). To be "particularized," the alleged injury must be "personal, individual, distinct, and differentiated—not generalized or undifferentiated." *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1292 (D.C. Cir. 2007); *see also Parr v. L & L Drive-Inn Restaurant*, 96 F. Supp. 2d 1065, 1077 (D. Haw. 2000). An injury is "actual or imminent" only if it has already occurred or is "certainly impending and immediate—not remote, speculative, conjectural, or hypothetical." *Id.* at 1078; *see also Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990).

Second, 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." *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976); *Allen v. Wright*, 468 U.S. 737, 757 (1984). When a plaintiff alleges that government action has caused injury by affecting the conduct of third parties, courts have held that particular facts are necessary to show standing. *See Mendia v. Garcia*, 768 F.3d 1009, 1013 (9th Cir. 2014).

Third, a plaintiff must demonstrate that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561. The burden is on the plaintiff to show that "there would be a 'change in a legal status,' and that a 'practical consequence of that change would amount to a significant increase in the likelihood that the plaintiff would obtain relief that directly redresses the injury suffered.'" *Renee v. Duncan*, 686 F.3d 1002, 1013 (9th Cir. 2012) (quoting *Utah v. Evans*, 536 U.S. 452 (2002)). Where a plaintiff "is not the object of an alleged government action or inaction," it is "ordinarily

'substantially more difficult' to establish" standing because redressability, like causation, frequently turns on actions of "independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Lujan,* 504 U.S. at 562 (quotation marks omitted). As a result, a plaintiff bears the burden "of adduc[ing] facts showing that those [third-party] choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id*.

As the parties invoking this Court's jurisdiction, Plaintiffs bear the burden "clearly to allege facts demonstrating" each of the three elements required for Article III standing. *See Warth*, 422 U.S. at 518; *see also Schmier v. United States Court of Appeals*, 279 F.3d 817, 821 (9th Cir. 2002). The necessary facts "must affirmatively appear in the record" and "cannot be inferred argumentatively from averments in the pleadings." *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990). Moreover, "[s]ince they are not mere pleading requirements but rather an indispensable part of the [Plaintiffs'] case, each [standing] element must be supported in the same way as any other matter on which the [P]laintiff[s] bear the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *See Lujan*, 504 U.S. at 561; *see also Townley v. Miller*, 722 F.3d 1128, 1133 (9th Cir. 2013).

1. The Plaintiffs Lack Individual Standing

Plaintiffs' claims center on the difficulties their patients have allegedly encountered in obtaining unapproved drug products from Plaintiffs' foreign supplier. Plaintiffs speculate that FDA is behind these impediments but their Complaint is devoid of facts to support Plaintiffs' allegations that they face any actual or impending injury fairly traceable to FDA action. Plaintiffs rest their claims on three separate sources of alleged injury: (1) the alleged seizure by one or more federal agencies of a small number of packages containing unapproved drug

products prescribed by Dr. Gomperts; (2) the asserted blockage of fund transfers by independent third-parties, and (3) Plaintiffs' speculative fear of criminal prosecution. Compl. ¶¶ 92-101. None of these purported injuries, however, rises to the level of concrete and particularized injury-in-fact, much less injury attributable to FDA or redressable by the relief sought.

First and foremost, the harms asserted flow from Plaintiffs' own independent decisions; rather than working with certified health care providers to widen access to FDA-approved Mifeprex for patients in the United States, Plaintiffs imply that they had no recourse but to distribute unapproved drugs to United States patients. However, a self-inflicted harm does not amount to an injury cognizable under Article III, and "would not be fairly traceable to defendant's challenged conduct" in any event. *Nat'l Family Planning & Reproductive Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006) (concluding that the plaintiff lacked standing because its "asserted injury appears to be largely of its own making"); *see also Boating Indus. Assoc. v. Marshall*, 601 F.2d 1376, 1380-81 (9th Cir. 1979). Here the Plaintiffs "[have] within [their] grasp an easy means for alleviating" the alleged injuries of which they complain. *Gonzales*, 468 F.3d at 831. But rather than prescribe and dispense FDA-approved Mifeprex, or attempt to increase patients' access to certified providers, Plaintiffs chose to conduct an overseas Internet pharmacy operation and direct their patients to unapproved, foreign-sourced drugs.

Nor can Plaintiffs' alleged harms be considered "certainly impending" as they must be to constitute injury-in-fact. *See Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). Dr. Gomperts states that she has prescribed misoprostol and mifepristone for 7,131 women in the U.S. between March 30, 2018, and August 27, 2019, Compl. ¶ 43, but alleges that, at most, ten of the packages containing those drug products were seized. *Id.* ¶ 68. Thus, based on Plaintiffs' own allegations, a mere 0.14% of Dr. Gomperts' patients' packages have been seized, while over 99% of those

patients received the (non-FDA-approved) medications they were prescribed since March 2018. Plaintiffs' allegations bely any claim that patients' drug shipments are "likely" to be seized—and fall far short of actual or certainly impending injury necessary to support Article III standing.

Plaintiffs' asserted fear of imminent prosecution—based upon an FDA Warning Letter and the unrelated prosecution of a different individual—is equally insufficient to support standing. *See* Compl. Exs. B, D. Warning Letters "do not mark the consummation of FDA's decisionmaking," *Holistic*, 664 F.3d at 944, but are merely "informal and advisory." *Id*. They "communicate the agency's position on a matter," and give "firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action." *Id.* 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." *Id.*

Nor does the prosecution of Ursula Wing have any bearing on this case or make Plaintiffs' asserted fear of prosecution any more credible. As the indictment in that case makes clear, Ms. Wing was importing wholesale quantities of drugs, repackaging them, and then dispensing them to customers without a prescription. *See* Compl. Ex. D. Ms. Wing also attempted to conceal her conduct by, for example, shipping unapproved prescription drugs in a hidden panel inside envelopes that contained "cover" pieces of jewelry. *Id.* None of those factors are present here. *See* Compl. ¶¶ 46, 53, 56, 57. Moreover, there is no suggestion that the recipients of Ms. Wing's products faced criminal prosecution, whereas Plaintiffs' asserted fear of criminal prosecution encompasses patients of Dr. Gomperts who received unapproved drugs.

Plaintiffs have also failed to demonstrate the second element of standing: that their claimed injuries are fairly attributable to FDA. According to the Complaint, "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." Compl. ¶ 68 (emphasis added). The Complaint further alleges that Dr. Gomperts' "belief" as to the number of packages "likely seized by the FDA" is based upon tracking information and communications from patients. *Id.* At the same time, however, the Complaint further speculates that the packages were seized by "the U.S. Department of Homeland Security, Customs, and Border Protection and/or the U.S. Postal Inspection Service" at the asserted direction of FDA. Compl. ¶¶ 85-87. Thus, it is not clear even from Plaintiffs' own allegations whether FDA or one or more other government agencies are responsible for the asserted seizure of drug products described in the Complaint.[5] Indeed, apart from Plaintiffs' unadorned conjecture and belief, the Complaint pleads no facts to show that FDA played a role in these seizures.

Plaintiffs also "believe" that FDA "or other agencies in the U.S. government" caused business entities to cease transferring funds between Plaintiffs and individuals in the United States. Compl. ¶¶ 69-71. However, both the Supreme Court and the Ninth Circuit have refused "to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 398 (2013); *Physicians for Integrity in Med. Research, Inc. (PIMR) v. Hamburg*, 556 F. App'x 621, 622 (9th Cir. 2014). The companies named in paragraphs 69 and 70 of the complaint make independent decisions regarding doing business with Plaintiffs; none are part of FDA. Unlike a complaint that "relies

[5] FDA does not "seize" packages at the border, but FDA can assist Customs and Border Patrol ("CPB") in conducting warrantless searches of incoming packages in coordination with CBP. *See, e.g.*, *U.S. v Alfonso*, 759 F.2d 728, 735 (9th Cir. 1985). If FDA determines that a package contains products that appear to violate the 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). The FDA Notice of Detention and Hearing lists the apparent FDCA violations; if the importer, owner, or consignee does not respond, or fails to offer FDA sufficient evidence to overcome the appearance of violation, FDA will issue a "Notice of Refusal of Admission" providing for the exportation or destruction of the shipment, under CBP supervision.

on words directly from the mouths of the relevant third parties explaining why they took the actions that caused [plaintiff's] injury," *see Mendia*, 768 F.3d at 1014, Plaintiffs simply assert that because the companies did not explain why they ceased transferring funds to Aid Access, Plaintiffs "believe" they must have been directed to do so by FDA. Compl. ¶¶ 69, 71. This unsupported, conclusory statement couched as a factual allegation is pure speculation. As the Ninth Circuit has explained,

> To plausibly allege that the injury was not the result of the independent action of some third party, the plaintiff must offer facts showing that the government's unlawful conduct is at least a substantial factor motivating the third parties' actions. So long as the plaintiff can make that showing without relying on speculation or guesswork about the third parties' motivations, she has adequately alleged Article III causation.

Mendia, 768 F.3d at 1013 (internal quotations and citations omitted). Here, by contrast, Plaintiffs rely entirely on speculation and guesswork to attempt to show a causal link between FDA and Plaintiffs' purported harm regarding the blocking of fund transfers.

Not only does this claimed harm fail to satisfy the traceability prong of the standing inquiry, it also fails to satisfy the redressability prong. As the Ninth Circuit has explained, "[t]here is no standing if, following a favorable decision, whether the injury would be redressed would still depend on the 'unfettered choices made by independent actors not before the courts.'" *Novak v. United States*, 795 F.3d 1012, 1020 (9th Cir. 2015) (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989)). Here, even if this Court were to grant Plaintiffs' requested relief and declare that "the blocking of transfers of funds" violated Plaintiffs' constitutional rights, *see* Compl. at 20-22, Plaintiffs have not alleged that any companies would resume doing business with them after issuance of such a declaration. Plaintiffs' purported harm stemming from the blocking of fund transfers is thus not redressable.

2. Plaintiffs Lack Organizational and Third-Party Standing

To establish standing to sue on behalf of its members, an organization must show: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Assoc. Gen. Contractors of Am., San Diego Chapter, Inc. v. California Dep't of Transp.*, 713 F.3d 1187, 1194 (9th Cir. 2013). To meet the first requirement, an organization must assert "specific allegations establishing that at least one *identified* member had suffered or would suffer harm." *Id.* (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) (emphasis in original)).

Aid Access's claim to standing fails at the threshold. It is not clear that Aid Access has any members other than Dr. Gomperts, and thus Aid Access has failed to specifically identify a member who would have standing to sue in his or her own right. *See Assoc. Gen. Contractors*, 713 F.3d at 1194-95. This is not a case, moreover, "'[w]here it is relatively clear, rather than merely speculative, that one or more members have been or will be adversely affected" by the challenged actions, and "where the defendant need not know the identity of a particular member to understand and respond to an organization's claim of injury." *Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015).

Similarly, Dr. Gomperts' failure to establish her own standing necessarily means she lacks standing to bring suit on behalf of her patients. *See McCormack v. Herzog*, 788 F.3d 1017, 1027-28 (9th Cir. 2015) (whether physician has third-party standing to assert rights of patients in the abortion context depends on "(1) whether the physician alleges 'injury in fact' to . . . herself; and (2) whether the physician is a proper proponent of the legal rights on which he or she bases the suit."). Here, Dr. Gomperts satisfies neither requirement. Indeed, this situation is easily

distinguished from *McCormack*, where a physician who had "continuously been registered with the . . . Idaho State Board of Pharmacy" and was able to "legally prescribe FDA-approved abortion medication" could demonstrate "an 'actual and imminent' injury—the risk of criminal prosecution for prescribing abortion pills prior to viability." *Id.* Dr. Gomperts, however, is not licensed to practice medicine in Idaho, is not prescribing FDA-approved medication, and is not at risk of prosecution for violating a state abortion statute.

Similarly, Plaintiffs concede that patients have been able to procure Mifeprex in Idaho. Compl. ¶ 37. Dr. Gomperts can hardly claim that she is a proper proponent of vindicating, on behalf of her patients, a nonexistent right to unapproved foreign-sourced drugs, especially in light of her decision not to seek certification or work with certified providers to distribute FDA-approved Mifeprex. "Simply put, [Plaintiff] has failed to allege any action [] that has immediately and personally subjected [her] to sanctions or has adversely affected one or more of [Plaintiff's] clients." *Schmier*, 279 F.3d at 822. Because Plaintiffs have failed to allege an impending concrete injury, caused by FDA, and redressable by the relief sought, Plaintiffs lack standing and their Complaint should be dismissed pursuant to Rule 12(b)(1).

D. Plaintiffs Have Failed to State a Claim Upon Which Relief Can be Granted

Plaintiffs' Complaint is also subject to dismissal under Rule 12(b)(6) for failure to state a claim. "Dismissal under Rule 12(b)(6) is proper when the complaint either (1) lacks a cognizable legal theory or (2) fails to allege sufficient facts to support a cognizable legal theory." *Somers v. Apple, Inc*., 729 F.3d 953, 959 (9th Cir. 2013); *see also Balderas v. UPS*, 385 F. Supp. 3d 1090, 1095 (D. Idaho 2019). The factual allegations contained in the complaint "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also id.* at 570 (plaintiff must allege "enough facts to

state a claim to relief that is plausible on its face."). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Epstein v. Washington Energy Co.*, 83 F.3d 1136, 1140 (9th Cir. 1996) ("[C]onclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim.").

Plaintiffs' constitutional claims fail to satisfy this threshold pleading standard. As an initial matter, "[i]t is well established that certain constitutional protections available to persons inside the United States are unavailable to aliens outside of our geographic borders." *Zadvydas v. Davis*, 533 U.S. 678, 693 (2001); *United States v. Verdugo-Urquidez*, 494 U.S. 259, 269 (1990) (Fifth Amendment's protections do not extend to aliens outside the territorial boundaries). Dr. Gomperts currently resides in Wien, Austria, and Amsterdam, the Netherlands. Compl. at 3. Therefore, to the extent Dr. Gomperts is not a United States citizen and claims a violation of her own constitutional rights as opposed to those of her patients, *e.g.*, Compl. Counts I-IV, those claims should be summarily dismissed.

Even if Dr. Gomperts had standing to assert the constitutional rights of her patients (which she does not), those claims fail as a matter of law. Analysis of substantive due process and equal protection claims proceed similarly in that strict scrutiny is applied only if the right alleged to have been violated is a fundamental right, or the distinction alleged to have been drawn was based on a suspect classification. Fundamental rights are "those personal activities and decisions that this Court has identified as so deeply rooted in our history and traditions, or so fundamental to our concept of constitutionally ordered liberty, that they are protected by the Fourteenth Amendment." *Washington v. Glucksberg*, 521 U.S. 702, 727 (1997). Courts have held that these include "the right to marry, to have children, to direct the education and

upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, to abortion, and to refuse unwanted lifesaving medical treatment." *United States v. Juvenile Male*, 670 F.3d 999, 1012 (9th Cir. 2012). Suspect classifications include those based on race, nationality, or affecting fundamental rights. *See, e.g.*, *Clark v. Jeter*, 486 U.S. 456, 461 (1988).

Plaintiffs attempt to make this case about the right to abortion, but "[t]he Supreme Court require[s] in substantive-due-process cases a careful description of the asserted fundamental liberty interest." *Stormans, Inc. v. Wiesman*, 794 F.3d 1064, 1085 (9th Cir. 2015) (internal quotation and citation omitted). Plaintiffs allege interference with Dr. Gomperts' patients' ability to obtain unapproved mifepristone and misoprostol, not interference with those patients' ability to obtain an abortion. A more accurate description of the right Plaintiffs claim has been violated is the right to obtain unapproved drug products to terminate a pregnancy.

It is well established, however, that there is no fundamental right to unapproved drugs. *See 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."). Indeed, the Ninth Circuit has held on multiple occasions that the Constitution does not confer on individuals an unfettered fundamental right to obtain unapproved drugs. *See, e.g.*, *Raich v. Gonzales*, 500 F.3d 850, 866 (9th Cir. 2007) ("federal law does not recognize a fundamental right to use medical marijuana prescribed by a licensed physician . . . ."); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain [the unapproved drug] laetrile . . . .").

Because Plaintiffs' claims do not implicate a fundamental right, the appropriate level of review is rational basis. *See Washington v. Glucksberg*, 521 U.S. at 728 (law that does not implicate a fundamental right must be "rationally related to legitimate government interests"). Government action that "neither utilizes a suspect classification nor draws distinctions among individuals that implicate fundamental rights" violates substantive due process rights only if the action is not rationally related to a legitimate governmental purpose. *Richardson v. City & Cty of Honolulu*, 124 F.3d 1150, 1162 (9th Cir. 1997). FDA's alleged actions easily pass muster under this test. The seizure of unapproved drug products and the prosecution of individuals for violating the FDCA plainly serve the legitimate governmental interest of protecting the public health. *See POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102, 115 (2014); *Dotterweich*, 320 U.S. at 280. Similarly, even if issuing a Warning Letter to Plaintiffs were to influence a business entity's decision to cease facilitating fund transfers to Plaintiffs, the issuance serves the legitimate governmental interest of protecting the public health. *See id.* Even accepting Plaintiffs' allegations at face value, their Complaint fails to state a substantive due process claim or an APA claim based on substantive due process.

Plaintiffs' equal protection claim fares no better. Plaintiffs contend that Dr. Gomperts' patients have been treated "differently from other similarly situated parties without a sufficient state interest," Compl. ¶¶ 98-101, but do not explain *how* the patients were treated differently or as compared to whom. Indeed, aside from that bald conclusory allegation, Plaintiffs have pleaded no facts to suggest that either Dr. Gomperts or her patients have been subject to any differential treatment. Presumably Plaintiffs mean to allege that FDA has taken, or will continue to take, the identified enforcement actions (seizure, blocking fund transfers, threatening prosecution) to the unfair disadvantage of Dr. Gomperts and her patients. *See* Compl. ¶¶ 98-101.

But Plaintiffs' argument is both factually inaccurate and lacks merit. Based on Plaintiffs' own allegations, less than 1% of the patients for whom Dr. Gomperts has prescribed mifepristone in combination with misoprostol in the past eighteen months are purported to have had packages seized. *See id.* ¶¶ 43, 68. With over 99% of Dr. Gomperts' patients receiving the (non-FDA-approved) medications prescribed, Plaintiffs' own numbers fail to show that Dr. Gomperts' patients are being treated differently than any other U.S. consumers who receive unapproved new drugs in the mail (or that any alleged difference in treatment lacks justification).

Similarly, Plaintiffs have not shown *any* likelihood that Dr. Gomperts or her patients face a credible threat of prosecution, much less that Dr. Gomperts or her patients will be prosecuted while other individuals will not be prosecuted for the same conduct, and without justification for the difference. More importantly, as noted above, *see supra* at 18-19, any FDA action that seeks to hinder or deter the unlawful distribution of an unapproved new drug serves the FDCA's goal of protecting the public health. At bottom, Plaintiffs' equal protection claim consists of no more than a "[t]hreadbare recital[s] of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 556 U.S. at 678. As such it fails to satisfy even the basic requirement of notice pleading, *see Porter v. Jones*, 319 F.3d 483, 494 (9th Cir. 2003) (minimal notice pleading . . . requires only that the complaint include "a short and plain statement of the claim showing that the pleader is entitled to relief"), let alone the *Twombly* standard of stating a claim to relief that is plausible on its face. *Twombly*, 550 U.S. at 570. Plaintiffs' equal protection claim, as well as any APA claim based on the same, should therefore be dismissed.

CONCLUSION

For the reasons discussed above, the Court should dismiss Plaintiffs' complaint pursuant to Rule 12(b)(1) and/or Rule 12(b)(6).

Respectfully submitted,

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Dated: November 15, 2019

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served on all counsel of record by operation of the court's electronic filing system and can be accessed through that system.

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