NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15-3443

SHELLER, P.C.,
Appellant

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;
UNITED STATES FOOD AND DRUG ADMINISTRATION;
SECRETARY DEPARTMENT OF HEALTH AND HUMAN SERVICES;
COMMISSIONER OF FOOD AND DRUG ADMINISTRATION

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(E.D. Pa. No. 2-15-cv-00440)
District Judge: Honorable Legrome D. Davis

Submitted Under Third Circuit L.A.R. 34.1(a)
July 11, 2016

Before: FUENTES,[*] SHWARTZ, and RESTREPO, *Circuit Judges*

(Filed: October 6, 2016)

OPINION[**]

FUENTES, *Circuit Judge*.

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[*] Honorable Julio M. Fuentes assumed senior status on July 18, 2016

[**] This disposition is not an Opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

Plaintiff Sheller, P.C. ("Sheller" or "Appellant") appeals the District Court's Order granting the motion to dismiss filed by Defendants United States Department of Health and Human Services, *et al.* ("Appellees"). Because we agree with the District Court that Appellant lacks standing to bring its claims, we affirm.

I.[1]

Sheller is a law firm that represents hundreds of children who are alleged to have suffered serious injury caused by ingesting the anti-psychotic drugs Risperdal and Invega, and generic versions of risperidone (collectively, "Risperdal").[2] Specifically, Sheller has brought suit against Risperdal's manufacturer, Janssen Pharmaceuticals, Inc., and its parent company, Johnson & Johnson (collectively, "Janssen"), in California and Pennsylvania state courts (collectively, the "Risperdal Litigation"), arguing that Risperdal causes serious side effects in children such as gynecomastia (the abnormal enlargement of tissue in male breasts) and weight gain.[3] Sheller has argued, and continues to argue, in the Risperdal Litigation that the long-term safety of Risperdal for children has not been established and current labeling of these drugs fails to adequately warn of adverse health risks.[4]

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[1] Because this appeal arises out of the District Court's grant of a motion to dismiss, we assume the facts alleged in Plaintiff's Complaint are true. *See Gould Elec. Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000).

[2] App. at A20 ¶ 1; A30 ¶ 44.

[3] *Id.* at A30 ¶¶ 44, 49; A31 ¶ 50; A47 ¶ 130.

[4] *Id.* at A33 ¶ 60.

Independent from the Risperdal Litigation, the Sheller firm filed a citizen petition (the "Petition") with the United States Food and Drug Administration ("FDA").[5] Citizen petitions may be filed by any interested person and may ask the FDA to "issue, amend, or revoke a regulation or order[,] or take or refrain from taking any other form of administrative action."[6] The Petition urged the FDA to (a) immediately revoke the approval of Risperdal for children unless and until the long-term safety of those drugs could be demonstrated, or, in the alternative, (b) immediately require that the labeling for Risperdal include a black box warning based on the lack of sufficient data to prove the drugs' safety.[7] After several letters between Sheller and the FDA,[8] the FDA asked Janssen for "any data in [its] possession relevant to the use of risperidone or paliperidone

[5] *Id.* at A24 ¶ 22. Sheller later filed an amended petition that provided additional factual background and sought the same relief as the Petition. *Id.* at A25 ¶ 25.

[6] 21 C.F.R. §§ 10.25(a), 10.30. Although Sheller's dispute with the FDA arises under the Food, Drug, and Cosmetics Act, *see* App. at A24 ¶¶ 18-21, it is well settled that this statute creates no private right of action. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) (citing 21 U.S.C. § 337(a)).

[7] App. at A24-25 ¶ 22. Sheller also asked the FDA to direct Johnson & Johnson "to consent to release Sheller from the Confidentiality/Protective orders that govern dissemination of certain confidential documents that Sheller [] obtained in the course of its representation of its clients [] so that Sheller can present those documents to the FDA." App. at A25 ¶ 23. In the alternative, Sheller asked the FDA to request that Johnson & Johnson submit these confidential documents directly. *Id.* at A25 ¶ 24. Sheller mentions this aspect of the Petition in its Statement of Case, Appellant Br. at 6-7, but it fails to brief how the lack of these documents relate to its standing arguments. As such, we deem arguments related to the FDA's lack of confidential documents waived for this appeal. *See Nagle v. Alspach*, 8 F.3d 141, 143 (3d Cir. 1993) ("When an issue is either not set forth in the statement of issues presented or not pursued in the argument section of the brief, the appellant has abandoned and waived that issue on appeal.").

[8] App. at A26-28 ¶¶ 27-39.

in children and adolescents" that had not already been provided to the FDA.[9] In all other respects, the FDA denied the Petition.[10]

Sheller now claims that it is aggrieved by the FDA's denial of the Petition because that decision has been used by Janssen as support for various arguments in the Risperdal Litigation, thus forcing Sheller to spend money defending against these arguments and concomitantly reducing its profits.[11]

II.[12]

The issue in this appeal is whether the Sheller firm has standing to challenge the FDA's denial of the Petition in federal court. In essence, standing focuses on "whether petitioners have such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination."[13] To establish Article III standing, a plaintiff must demonstrate "(1) an injury-in-fact, (2) a sufficient causal connection

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[9] *Id.* at A26 ¶ 28.

[10] *Id.* at A28 ¶ 39.

[11] *Id.* at A28-29 ¶ 40.

[12] Sheller brought this suit pursuant to 28 U.S.C. § 1331. We have appellate jurisdiction under 28 U.S.C. § 1291. Notwithstanding the presence of statutory appellate jurisdiction, however, our conclusion that Sheller lacks Article III standing means that we do not have subject matter jurisdiction to reach the merits of its claims. *Finkelman v. Nat'l Football League*, 810 F.3d 187, 192 n.31 (3d Cir. 2016). "We exercise plenary review over the grant of a motion to dismiss." *Brown v. Card Serv. Ctr.*, 464 F.3d 450, 452 (3d Cir. 2006).

[13] *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007) (internal quotation marks omitted) (quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962)).

between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision."[14]

To sufficiently allege an injury-in-fact, a plaintiff must claim "the invasion of a concrete and particularized legally protected interest resulting in harm that is actual or imminent, not conjectural or hypothetical."[15] To be "concrete, an injury must be real or distinct and palpable, as opposed to merely abstract."[16] To be "particularized," an injury must "affect the plaintiff in a personal and individual way."[17] So although a plaintiff's alleged injury may be widely shared, it "must nonetheless be concrete enough to distinguish the interest of the plaintiff from the generalized and undifferentiated interest every citizen has in good government."[18]

To sufficiently demonstrate the second element—causation—a plaintiff must allege that the injury is "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court."[19] For standing purposes, an "indirect causal relationship will suffice, provided that there is a

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[14] *Finkelman*, 810 F.3d at 193 (quoting *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 358-59 (3d Cir. 2015)).

[15] *Id.* (internal quotation marks omitted) (quoting *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 278 (3d Cir. 2014)).

[16] *Id.* (internal quotation marks omitted) (quoting *N.J. Physicians, Inc. v. President of the U.S.*, 653 F.3d 234, 238 (3d Cir. 2011)).

[17] *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 n.1 (1992).

[18] *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 (3d Cir. 2009) (citing *FEC v. Akins*, 524 U.S. 11, 24 (1998), and *Defenders of Wildlife*, 504 U.S. at 573-74).

[19] *Defenders of Wildlife*, 504 U.S. at 560.

fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant."[20] On the other hand, plaintiffs do not adequately allege causation when they rely on a "chain of contingencies [] which amounts to mere speculation".[21]

Finally, the plaintiff must establish redressability. This requires the plaintiff to show that it is "likely, as opposed to merely speculative," that the alleged injury will be redressed by a favorable decision.[22]

The burden to establish each element of standing rests with the plaintiff.[23] Accordingly, to survive a motion to dismiss for lack of standing, a plaintiff "must allege facts that affirmatively and plausibly suggest that it has standing to sue."[24] Speculative or conjectural assertions are not sufficient.[25]

III.

Sheller primarily argues that it has standing to challenge the FDA's denial of the Petition because this denial forces Sheller to expend extra resources in the parallel Risperdal Litigation. This constitutes a cognizable injury that is traceable to the FDA, the argument goes, because the defendants in the Risperdal Litigation have used the FDA's

[20] *Finkelman*, 810 F.3d at 193-94 (quoting *Toll Bros.*, 555 F.3d at 142).

[21] *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1148 (2013).

[22] *Defenders of Wildlife*, 504 U.S. at 561 (internal quotation marks omitted).

[23] *Finkelman*, 810 F.3d at 194 (quoting *Berg v. Obama*, 586 F.3d 234, 238 (3d Cir. 2009)).

[24] *Id.* (quoting *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011)).

[25] *Id.* (citing *Schering Plough*, 678 F.3d at 248).

denial to support various arguments in both summary judgment motions and motions *in limine*, thus requiring Sheller to spend time and money rebutting those arguments and, due to Sheller's contingency fee arrangement, concomitantly reducing its profit from the Risperdal Litigation. If this chain of events seems tortuous, we agree. We need not, however, decide whether Sheller has pleaded facts that demonstrate an injury-in-fact, as we hold that Sheller lacks standing because it cannot adequately demonstrate causation and redressability.

To establish causation and redressability, Sheller's litigation costs and lost profits in the Risperdal Litigation must be "fairly traceable to the challenged action of the defendant," and it must be "likely, as opposed to merely speculative," that its injury will be redressed by a favorable decision.[26] When, as here, "the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily substantially more difficult to establish."[27] Indeed, in such circumstances, we have recognized two instances in which standing may lie:

> First, a federal court may find that a party has standing to challenge government action that permits or authorizes third-party conduct that would otherwise be illegal in the absence of the Government's action. Second, standing has been found where the record presents substantial evidence of a causal relationship between the government policy and the third-party

[26] *Defenders of Wildlife*, 504 U.S. at 560-61 (internal quotation marks omitted).

[27] *Id.* at 562 (internal quotation marks omitted).

> conduct, leaving little doubt as to causation and likelihood of redress.[28]

Sheller's case falls into neither of these categories.

Sheller contends that the FDA's denial of the Petition created

> the factual predicate for a particular legal argument that has been and continues to be advanced by Janssen – specifically, that the FDA's denial of the Citizen Petition establishes, as a matter of law, that the labeling on the Risperdal Drugs is adequate and that gynecomastia is not a "serious adverse event."[29]

According to Sheller, then, Janssen is using the FDA's Petition denial as support for its legal arguments. But Janssen's litigation strategy would not be illegal in the absence of the Petition's denial; Janssen is entitled to defend itself against Sheller's lawsuits regardless of whether the FDA grants or denies the Petition. Thus, the government action (denial of the Petition) does not authorize third-party conduct (Janssen's arguments in the Risperdal Litigation) that would otherwise be illegal in the absence of such action, and Sheller cannot maintain standing on these grounds.

Likewise, there is no "substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and likelihood of redress."[30] Janssen would likely make the same arguments in the Risperdal Litigation even absent the "factual predicate" created by denial of the Petition. Indeed, in

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[28] *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 366 (3d Cir. 2014) (quoting *Bloomberg L.P. v. CFTC*, 949 F. Supp. 2d 91, 116 (D.D.C. 2013)).

[29] Appellant Br. at 18 (citing App. at A45 ¶ 123).

[30] *Constitution Party of Pa.*, 757 F.3d at 366 (quoting *Bloomberg L.P.*, 949 F. Supp. 2d at 116).

the Risperdal Litigation, Sheller has brought claims against Janssen on the grounds that "Risperdal is defective because its warnings were inadequate and failed to warn of the risk of gynecomastia."[31] Janssen could not defend such claims *without* arguing that Risperdal's labeling is adequate, and its use of the FDA's Petition denial as *support* for its argument does not transform Janssen's argument into a harm *caused* by the FDA.

With respect to redressability, a favorable decision in this case is not likely to redress Sheller's injury. Janssen will probably continue arguing that the Risperdal labeling is adequate and that gynecomastia is not a serious adverse event, even without the "factual predicate" of the Petition denial. In fact, that is the very gravamen of Janssen's defense in the Risperdal Litigation. And even if Sheller were to obtain the relief it seeks—a District Court order enjoining the FDA to grant the Petition[32]—Sheller may seek to use the granting of the Petition to *its* advantage in the Risperdal Litigation in the same ways Janssen has done so. That strategy, in turn, would also increase Sheller's litigation costs and cut into its profits. Put simply, Sheller's injury—increased Risperdal Litigation costs—depends heavily on the actions of both Janssen and Sheller, not the FDA, and granting the Petition produces only a "chain of contingencies [] which amounts to mere speculation"[33] about how Janssen and Sheller will conduct the Risperdal Litigation and accrue associated litigation costs. There is simply no basis to say that a favorable decision in this case is "likely" to redress Sheller's injury.

[31] App. at A45 ¶ 122.

[32] App. at A49.

[33] *Clapper*, 133 S. Ct. at 1148.

We therefore reject Sheller's statement that it has suffered injury due to "specific arguments and motions advanced by Janssen that Janssen could not make absent the FDA's wrongful denial of the Citizen Petition."[34] Sheller's increased litigation costs are not "fairly traceable" to the FDA's Petition denial and a favorable decision in this case is unlikely to redress Sheller's injury.

IV.

For the foregoing reasons, we conclude that the District Court did not err in granting Appellees' motion to dismiss. We therefore affirm.

[34] Appellant Br. at 18.