IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHELLER, P.C.	:	CIVIL ACTION
	:	
	:	
v.	:	
	:	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.	:	NO. 15-cv-440
	:	

ORDER

AND NOW, this 11th day of August 2015, upon consideration of Defendants United States Department of Health and Human Services ("HHS"), the United States Food and Drug Administration ("FDA"), Sylvia Matthews Burwell, and Margaret A. Hamburg's Motion to Dismiss First Amended Complaint (Doc. No. 14), Plaintiff Sheller, P.C.'s response in opposition thereto (Doc. No. 15), and Defendants' reply (Doc. No. 19), it is hereby ORDERED that the Motion to Dismiss is GRANTED.

I. Background

Plaintiff Sheller, P.C. ("Sheller") "is a law firm that represents hundreds of children who have suffered serious injury caused by their ingestion of Risperdal®, generic versions of risperidone, and Invega®."[1] (Am. Compl. ¶ 1.) The firm represents these clients on a contingency fee basis. (Am. Compl. ¶ 1.) Plaintiff filed a citizen petition with the Food and Drug Administration on July 27, 2012. (Am. Compl. ¶ 22.) In its petition, Plaintiff requested that the

[1] The Amended Complaint explains that "[r]isperidone and its active metabolite, paliperidone are second-generation atypical anti-psychotic drugs." (Am. Compl. ¶ 44). Plaintiff states that "the Risperdal Drugs cause serious adverse events including gynecomastia, an abnormal enlargement of glandular tissue in male breasts, and other adverse events related to an increase in the hormone prolactin." (Am. Compl. ¶ 49.) Other linked conditions include "galactorrhea (discharge from the breast), amennorhea (absence of menstruation), infertility in girls, gynecomastia and diminished libido in boys, and adverse impact on sexual maturation in children of both genders." (Am. Compl. ¶ 65.)

FDA "immediately revoke the pediatric indication for the Risperdal Drugs unless and until the long term safety of those drugs could be demonstrated, or [] in the alternative, immediately require that labeling for those drugs include a black box warning based on the lack of sufficient data to prove their safety." (Am. Compl. ¶ 22.) Plaintiff also requested that the FDA obtain certain confidential documents that Plaintiff received in the course of its litigation against Johnson & Johnson ("J&J") and subsidiary Janssen, manufacturers of Risperdal, from J&J and Janssen directly. (Am. Compl. ¶ 10). As an alternative, since Plaintiff had received these confidential documents in the course of its Risperdal Drugs litigation, Plaintiff requested that the FDA "instruct J&J and Janssen to release Sheller from the confidentiality orders [in the Risperdal matters] so that Sheller could submit the confidential documents to the FDA itself." (Am. Compl. ¶ 10.) Plaintiff states that these documents "describe the risks associated with the Risperdal Drugs and contradict, complicate and/or substantially call into question safety data provided by J&J and/or Janssen to the FDA." (Am. Compl. ¶ 26.)

The FDA denied Plaintiff's request for a hearing on its petition and instructed Plaintiff to submit the documents for which it sought the FDA's review. (Am. Compl. ¶¶ 32–33.) Plaintiff responded with a letter explaining that it could not submit the documents, pursuant to the confidentiality orders in the Risperdal Drugs litigation. (Am. Compl. ¶¶ 34–35.) On November 25, 2014, the FDA denied Plaintiff's petition. (Am. Compl. ¶ 39.) According to Plaintiff, "[t]he FDA denied Sheller's request to revoke the pediatric indication for the Risperdal Drugs or to require a black box warning," and "noted that it had issued the Information Request to Janssen, but otherwise denied Sheller's request to obtain additional information from J&J and Janssen." (Am. Compl. ¶ 39.) Plaintiff alleges that the FDA decision to deny its petition "has been used as the basis to assert federal preemption and other arguments against Sheller's clients in

Risperdal®-related litigation." (Am. Compl. ¶ 40.) According to Plaintiff, the FDA decision "increases the cost to Sheller of litigating its clients' Risperdal®-related personal injury claims and interferes with Sheller's representation of hundreds of consumers of the Risperdal Drugs and its ability to exercise its responsibilities as liaison counsel for Risperdal®-related litigation at the Philadelphia Court of Common Pleas." (Am. Compl. ¶ 42.)

Plaintiff filed this suit against the FDA, HHS, Sylvia Mathews Burwell as Secretary of HHS, and Margaret A. Hamburg as Commissioner of the FDA, challenging the denial of its citizen petition. (See Compl., Doc. No. 1.) After Defendants filed a motion to dismiss for lack of standing, Plaintiff filed an Amended Complaint. Defendants have again moved to dismiss the case for lack of standing. Plaintiff responded (Doc. No. 15), Defendants filed a reply (Doc. No. 19), and the Motion is now ripe for our review.[2]

II. Legal Standard

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." Simon v. E. Kentucky Welfare Rights Org., 426 U.S. 26, 37 (1976). "The 'core component' of the requirement that a litigant have standing to invoke the authority of a federal court 'is an essential and unchanging part of the case-or-controversy requirement of Article III.'" DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 342 (2006) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). "At bottom, 'the gist of the question of standing' is 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.'" Massachusetts v. E.P.A., 549 U.S. 497, 517 (2007) (quoting Baker v.

[2] Plaintiff also filed a request for oral argument on its Motion. (See Doc. No. 20.) As is within our discretion, we dispose of this Motion without oral argument, see Local Rule 7.1(f).

Carr, 369 U.S. 186, 204 (1962)). In Lujan v. Defenders of Wildlife, the Supreme Court explained that

> the irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be 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. Third, it must be likely, as opposed to merely speculative that the injury will be redressed by a favorable decision.

504 U.S. at 560–61 (citations omitted). Each of the three elements of constitutional standing "blends into the others." 13A Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure § 3531.4 (3d ed.). "[P]laintiffs bear the burden of demonstrating that they have standing in the action that they have brought." Blunt v. Lower Merion Sch. Dist., 767 F.3d 247, 278 (3d Cir. 2014).

III. Analysis

Plaintiff advances two primary bases upon which it asserts standing to challenge the FDA's action: that the FDA's denial of Plaintiff's petition harmed it by increasing the cost of litigating its clients' claims, and that the denial of the petition impeded Plaintiff's ability to fulfill its ethical duty to advocate for its clients and to provide information to the public. (See Pl.'s Resp. 9–15.) We address each of these arguments in turn.

1. The Cost of Litigating "Incorrect" Arguments

Plaintiff's first asserted basis for standing is that the FDA denial of Plaintiff's citizen petition increased Plaintiff's costs in litigating its clients' Risperdal cases. Plaintiff alleges that Janssen, the defendant in those cases, "has argued that the FDA's denial of the Petition proves, as a matter of law, that the Risperdal label is adequate" and "that the FDA's denial of the Petition established that gynecomastia is not a 'serious adverse event.'" (Pl.'s Resp. 10, citing Am.

Compl.) Plaintiff argues that it "must continue to expend resources in defending against that argument, and it faces the risk that a Court will accept it, lowering Sheller's contingent fee recovery." (Id.) Plaintiff argues that the possible diminution of its contingent fee recovery constitutes an economic injury and is an injury in fact for the purpose of standing. (Pl.'s Resp. 10 (citing Toll Bros. v. Twp. of Readington, 555 F.3d 131 (3d Cir. 2009)).)

The parties discuss whether litigation expenses may constitute injury-in-fact as a general matter, but we are not persuaded by the precedent relied upon by either side. Defendants cite the Third Circuit's broad statement that "litigation expenses alone do not constitute damage sufficient to support standing." (See Defs.' Mot. 14–16; Defs.' Reply 3–5.) See Fair Housing Council of Suburban Philadelphia v. Montgomery Newspapers, 141 F.3d 71, 79 (3d Cir. 1998). Defendants' reliance on Fair Housing Council is misplaced. The rationale underlying that case—that a party cannot create standing simply by initiating litigation (and thus incurring litigation expenses)—is inapt where, as here, the litigation in which standing is at issue is separate from the litigation expenses that the party claims as an injury. Indeed, Spann v. Colonial Village, Inc., the case upon which the Third Circuit relied in Fair Housing Council, turns on the rationale that "any litigant could create injury in fact by bringing a case" if litigation expenses constituted injury creating standing for the purpose of that same litigation. 899 F.2d 24, 27 (D.C. Cir. 1999). While Defendants note that "the Third Circuit … did not limit its reasoning to litigation expenses in the pending federal case" (Defs.' Reply 3), they fail to explain how the specific bootstrapping rationale underlying the Third Circuit's admittedly broad statement would apply outside of the context it addresses. We cannot conclude that the extension that Defendants would have us make is justified, regardless of the sweeping language employed in the case that Defendants cite.

For its part, Plaintiff cites various cases in which courts have found injury-in-fact for the purpose of standing where agency decisions caused advocacy organizations to expend program resources differently than the organizations otherwise would have. (See Pl.'s Resp. 12–13 (citing Pac. Legal Found. v. Goyan, 664 F.2d 1221, 1224 (4th Cir. 1981) (concluding that a nonprofit advocacy group had standing to challenge an FDA public participation reimbursement program that would result in "increased time and expense necessary" for the organization to "maintain its institutional presence" in FDA proceedings); Younger v. Turnage, 677 F. Supp. 16, 20–22 (D.D.C. 1988) (concluding that the plaintiff organizations had an injury-in-fact because their effort expended due to the Veterans Administration's failure to provide sufficient outreach to homeless veterans "puts a concrete and demonstrable strain on these organizations that they would otherwise devote their limited resources to other assistance efforts on behalf of homeless people"); Ragin v. Harry Macklowe Real Estate Co., 6 F.3d 898, 905 (2d Cir. 1993) (finding an injury-in-fact due to a housing nonprofit's time and effort "investigating and attempting to remedy" the defendant's discriminatory advertisements)). But as Defendants point out, Plaintiff is not the kind of public interest or advocacy entity that could claim organizational injury based on the diversion of its resources to the Risperdal litigation. (See Defs.' Reply 1–4.) See Havens Realty Corp. v. Coleman, 455 U.S. 363, 378–79 (1982) (describing how a "concrete and demonstrable injury to [a housing organization's] activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests" and may constitute an injury for the purpose of standing).) Plaintiff's expenditure of resources in its Risperdal Drugs litigation does not trade off with other organizational purposes; indeed, Plaintiff's institutional raison d'etre is presumably the business of law itself. Plaintiff's alleged diminution of contingency fee therefore represents only a

possible decrease in the firm's profits from the Risperdal Drugs litigation, not the kind of mission-based tradeoff at issue in the cases upon which Plaintiff relies. As Plaintiff is a law firm, not a public advocacy organization, these cases are inapposite.

Having thus isolated Plaintiff's first asserted basis for standing to the purely economic injury it alleges, we next consider whether this economic injury—namely, the possible lost profits from increased costs in a contingency fee matter constitute the kind of injury that Article III would allow a federal court to address. Of course, "[m]onetary harm is a classic form of injury-in-fact." Danvers Motor Co. v. Ford Motor Co., 432 F.3d 286, 293 (3d Cir. 2005). Although Plaintiff's diminished contingency fee recovery relies on several assumptions and intermediate steps, it is sufficient at this stage that it alleges some actual economic injury. See Danvers Motor Co., 432 F.3d at 292 (noting that "[t]o state an injury-in-fact sufficient to survive a motion to dismiss, [a plaintiff] must simply plead that they suffered some concrete form of harm"); In re Global Indus. Techns., Inc., 645 F.3d 201, 210 (3d Cir. 2011) (noting that "the contours of the injury-in-fact requirement, while not precisely defined, are very generous. The standard is met as long as the party alleges a specific, identifiable trifle of injury, or a personal stake in the outcome of the litigation." (citations omitted)). At this stage, Plaintiff's alleged economic injury is enough to implicate Plaintiff's interest in this litigation—the touchstone for the injury-in-fact inquiry.

However, even accepting Plaintiff's allegedly diminished contingency fee as an injury-in-fact sufficient to survive a motion to dismiss, Plaintiff has failed to demonstrate that Defendants caused its injury. Plaintiff asserts that it has satisfied the causation requirement because "by wrongfully denying the Petition based on a biased and incomplete factual record, the FDA created an incorrect legal argument that Sheller is required to defend against in other litigation."

(Pl.'s Resp. 15.) But as Defendants highlight (see Defs.' Reply 5–6), even Plaintiff's own formulation of this "causal chain" belies its position that the FDA and not an outside party caused its injury. Moreover, the FDA did not "create" Janssen's argument; although Janssen's argument may rely on the FDA's actions, Plaintiff does not allege that the FDA directly influenced Janssen's litigation strategy. Janssen's independent litigation decisions therefore constitute an intervening cause of Plaintiff's purported injury. Plaintiff offers no indication that its litigation landscape would be substantially different absent the FDA decision that Plaintiff seeks to challenge; presumably, Plaintiff's adversaries would vigorously litigate the Risperdal matters with other arguments, even if not with the particular strategy based on the FDA decision that Plaintiff labels "incorrect" and "without legal merit." (Pl.'s Resp. 13, 10.) Plaintiff's "causal chain" is too attenuated to show that Defendants caused Plaintiff's contingent fee injury.

Even leaving aside the litigation strategy of Plaintiff's adversaries in the Risperdal Drugs litigation, the circumstances giving rise to Plaintiff's alleged economic injury are outside of Defendants' control. If Plaintiff was litigating the Risperdal Drugs matters on an hourly fee basis rather than on a contingency fee arrangement, it would presumably benefit from, not be injured by, the additional effort it has apparently spent litigating arguments that it finds frivolous. Under such an arrangement, Plaintiff's clients would compensate it for the time it spent, at the rate that Plaintiff and its clients would have mutually determined Plaintiff's services to be worth. That Plaintiff has been retained pursuant to a certain fee arrangement sets the stage for economic injury whenever it expends additional resources in litigation, regardless of the causes for the expenditure. This arrangement is fully separate from any action by the FDA on which Plaintiff bases its claims, again indicating the disconnect between the actions giving rise to this suit and the injury that Plaintiff claims.

Relatedly, the intervening causes of Plaintiff's contingency fee injury demonstrate that Plaintiff's purported injury is not redressable in this suit, as is required for Plaintiff to have standing under Article III. The limitations of Article III require that "a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court." Simon v. E. Kentucky Welfare Rights Org., 426 U.S. 26, 41–42 (1976). See Lujan, 504 U.S. at 561–62 (explaining that when "a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else* . . . causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction"). Although Plaintiff's litigation of the Risperdal Drugs cases is ongoing, it is far from clear that the relief Plaintiff seeks would rectify the injury it claims. According to Plaintiff, its adversaries are asserting an "incorrect" argument in the Risperdal Drugs cases, an argument that is "meritless." (See, e.g., Pl.'s Resp. 13, 15, 16.) While Plaintiff insists that its opponents' litigation position is already unsound, Plaintiff offers no indication that Janssen and J&J will change their strategy, even if the argument becomes still more incorrect. This demonstrates the fundamental flaw in Plaintiff's argument: that a third party—Plaintiff's adversaries in the Risperdal Drug cases—has ostensibly caused and would need to rectify Plaintiff's injury undermines Plaintiff's position as to both causation and redressibility in its suit against the FDA. See Lujan , 504 U.S. at 571 (finding no basis for standing where it was "entirely conjectural whether the nonagency activity that affects respondents will be altered or affected by the agency activity they seek to achieve"). Without these elements, Plaintiff fails to establish its standing to bring this case based on its alleged contingency fee injury.

Plaintiff argues that procedural violations during the FDA's consideration of its citizen petition provide a separate basis for standing and "lower the bar for Sheller to show redressability and immediacy" regarding its related concrete injuries. (Pl.'s Resp. 16–18.) Of course, it is well-settled that procedural violations in agency proceedings do not themselves inflict injury for which a party would have Article III standing to bring suit, absent concrete injury. See Lujan, 504 U.S. at 572–73. While Plaintiff is correct that "[t]he person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy," see id. at 572 n.7, the nature of Plaintiff's asserted contingency fee injury does not justify the lower bar for which Plaintiff advocates. Plaintiff does not assert an injury based on any concrete right that the FDA's procedures are intended to protect. Instead, the cognizable injury that Plaintiff alleges is several steps attenuated from the decision on the petition itself, much less the procedures governing the agency consideration of the petition. This distinguishes Plaintiff's injury from the kind of injury described by the Supreme Court in Lujan as triggering a lower standard for redressability and causation. Even if Plaintiff is correct on the merits regarding the procedural violations it alleges, which we need not decide, Plaintiff still must show a sufficient connection between the interests protected by the procedure allegedly violated and its injury, and it has failed to do so here.

2. Ability to Advocate and Fulfill Ethical Obligations

Plaintiff also argues that the FDA's denial of Plaintiff's citizen petition impairs its ability to advocate for its clients. This argument is primarily directed at the FDA's denial of Plaintiff's request that the FDA direct Janssen to release Plaintiff from any confidentiality agreement regarding information that Plaintiff received from J&J and Janssen. (See Pl.'s Resp. 14–15.) According to Plaintiff, the denial of this request impedes Plaintiff's representation of its clients

because Plaintiff continues to be bound by an unspecified protective order or confidentiality agreement that precludes its use of this information. (Id.) We understand Plaintiff's argument to incorporate two related possible injuries: its diminished ability to fulfill its responsibilities in representing its clients, and its inability to act on its social concern for affected individuals whom it does not represent.

We turn first to Plaintiff's argument about its obligations to its current clients. Plaintiff cites no precedent for the proposition that an imposition on its ethical obligation to clients is an injury-in-fact for the purpose of standing. But, even assuming that such an imposition could represent an injury that is sufficiently concrete, there is no such injury here because the FDA's denial of Plaintiff's citizen petition did not change any circumstances affecting Plaintiff's obligations to its clients. Plaintiff was bound by the confidentiality agreement to which it refers prior to the citizen petition; presumably, the limitation that Plaintiff would call an injury occurred at that time. That the FDA did not remove this apparent burden—an action which it does not obviously have the authority to take—did not injure Plaintiff, as it did not change the status quo. See Reilly v. Ceridian Corp., 664 F.3d 38, 45 (3d Cir. 2011). To the extent that the confidentiality agreement impairs Plaintiff's interests, the injury is the agreement itself, not the decision declining to direct private entities J&J and Janssen to release Plaintiff from the agreement. The Defendants in this case have nothing to do with it.

Plaintiff's argument as to the general population of potential victims is similarly attenuated. Plaintiff is not in any position to assert standing on behalf of the general public. See, e.g., Massachusetts v. E.P.A., 549 U.S. at 518–20 (explaining the doctrine of parens patriae as a basis upon which a state may bring suit to protect public interests). Plaintiff lacks any kind of contractual or ethical duty to the general public beyond that applicable to any law firm. At best,

Plaintiff's assertion of a duty to any individual who may be injured by Risperdal sounds in the kind of "vocational nexus" standing that the Supreme Court rejected in Lujan. 504 U.S. at 566–67. There, the Supreme Court concluded that the risk to parties with a generalized professional interest in studying certain endangered animals was too probabilistic to be sufficient as an injury for the basis of standing because the professionals did not face "perceptible harm" from the risk that the animals would be affected by development projects. Id. Plaintiff's assertion that it suffers an injury based on its inability to publicly disclose information is similarly speculative. In essence, Plaintiff's argument relies on individuals suffering harm because they lack certain information apparently in Plaintiff's possession. Plaintiff does not show that such individuals exist, and more importantly, Plaintiff offers no indication that an injury to these individuals works an injury on Plaintiff itself. At best, Plaintiff is affected by the potential injury to individuals on the same kind of hypothetical basis that the scientists in Lujan asserted, which the Supreme Court rejected—that the subjects of their professional interest may be harmed. But unlike endangered crocodiles, the population in which Plaintiff has a professional interest is defined by the very injury that Plaintiff is purportedly seeking to help prevent. If Plaintiff is correct that some potential victims would be saved by the disclosure of the information Plaintiff wishes to disseminate, Plaintiff's professional interest in those individuals evaporates, as the would-be victims would lack a claim on which Plaintiff might represent them. Thus, Plaintiff's asserted injury based on the general population of potential victims is self-defeating.

We again note that, even if Plaintiff asserts a valid injury based on its ethical obligations, Plaintiff cannot demonstrate the causation and redressability elements of Article III standing. It is Plaintiff's apparent confidentiality agreement with J&J and Janssen that prevent it from disseminating the information at issue. The FDA's denial of Plaintiff's citizen petition did not

cause this obstacle, and it is not clear that the FDA would have the authority to remove it. These problems separately undercut Plaintiff's assertion of standing on the basis that its ethical obligations are impeded by the protective order or confidentiality agreement that the FDA decision left in place. Since the FDA did not cause the injury that Plaintiff alleges, and since the Court cannot obviously resolve it, Plaintiff does not have standing to bring this suit against the FDA on the basis of this injury.

Conclusion

For the foregoing reasons, we conclude that Plaintiff lacks standing to bring this suit. Defendants' Motion to Dismiss (Doc. No. 14) is GRANTED. Plaintiff may file an amended complaint by August 27, 2015.

BY THE COURT:

/s/ Legrome D. Davis

Legrome D. Davis, J.