

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

MARIANA OLIVIA SAVU, *

Plaintiff, *

v. * **Civ. No. DLB-22-1149**

PUROLITE COMPANY, et al., *

Defendants. *

MEMORANDUM OPINION

Mariana Olivia Savu alleges that she suffered permanent injuries after taking the drug cholestyramine. She claims the drug manufacturer, Purolite Corporation (“Purolite”), and the pharmacy that filled her prescription, Hopkinton Drug, Inc. (“Hopkinton”), failed to warn her of cholestyramine’s adverse side effects. Purolite and Hopkinton moved to dismiss the complaint.¹ ECF 7 & 11. Savu, who is proceeding without counsel, opposed both motions. ECF 14 & 17. Neither defendant filed a reply. Savu also moved to amend her complaint. ECF 15. Neither defendant opposed this motion. For the following reasons, the Court grants Savu’s motion to amend her complaint and grants Purolite’s and Hopkinton’s motions to dismiss the amended complaint with prejudice.²

¹ Purolite notes in its motion to dismiss that Savu’s complaint incorrectly refers to Purolite Corporation as “Purolite Company.” *See* ECF 7, at 1.

² The Court grants Savu’s motion to amend her complaint because she could have filed an amended complaint as a matter of right. *See* Fed. R. Civ. P. 15(a)(1)(B). The amended complaint, ECF 15-2, is the operative complaint. In keeping with its obligation to construe *pro se* pleadings liberally, the Court treats the 171-page Medical Notice (ECF 16 & 16-1 – 16-15), filed one day after the amended complaint, as an exhibit to the amended complaint. *See Bing v. Brivo Sys., LLC*, 959 F.3d 605, 618 (4th Cir. 2020); *Folkes v. Nelsen*, 24 F.4th 258, 272 (4th Cir. 2022) (“[P]ro se filings are ‘h[e]ld to less stringent standards than formal pleadings drafted by lawyers.’” (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972))). And the Court considers the Medical Notice in deciding the Rule 12(b) motions. *See* Fed. R. Civ. P. 12(b), 12(d); *see also* Fed. R. Civ. P. 10(c).

I. Savu's Allegations

From January until May 2019, Mariana Olivia Savu took the medication cholestyramine as prescribed by her doctor, Susan Black, M.D., to treat mycotoxin-induced illness following exposure to toxic mold. ECF 16, at 1, 2.

Hopkinton, a pharmacy located and incorporated in Massachusetts, filled Savu's prescription at the request of Dr. Black and mailed Savu the medication. ECF 15-2, at 5. Hopkinton's prescription label, which noted its address and phone number, stated that Savu could "check with your pharmacist or doctor about the safe use of any non-prescription drug based on your condition or other medications you take," and "[c]all your doctor for medical advice about side effects." ECF 16-5, at 1. Savu also received from Hopkinton a pamphlet stating that "Hopkinton Drug is your trusted source for pure Cholestyramine," instructing her to "call us for more information on these compounds," and providing Hopkinton's phone number, fax number, and website. *Id.* at 3. Purolite allegedly manufactured the cholestyramine powder that Savu received. *Id.* at 2.

Before taking her first dose of cholestyramine, Savu called Hopkinton and spoke with owner Dennis Katz, a pharmacist. ECF 15-2, at 5. Savu inquired about cholestyramine's side effects and other contraindications. *Id.* Katz informed Savu:

Cholestyramine is safe even for people with diabetes, thyroid or stomach ulcer/gastritis . . . In terms of side effects: no problems, maybe some GI/abdominal discomfort, even for patients with GI Ulcer/gastritis it is safe. We prescribe this drug all the time for thousands of [sic] thousands of patients. It is effective and safe.

Id.

On May 20, 2019, several months after she began taking cholestyramine, Savu began to experience severe stomach pain, vomiting, dizziness, rapid breathing, and confusion. *Id.* She was

unable to stand. *Id.* She feared she would die. *Id.* She was taken in an ambulance to the emergency room at a hospital in Rockville, Maryland. *Id.* There, she was referred to a GI specialist, who performed an endoscopy. *Id.* at 6. The doctor diagnosed her with acute GI inflammation/gastritis and advised her to stop taking cholestyramine. *Id.*

Savu later called Dr. Black and described the pain she experienced, the damage to her stomach, and the endoscopy results. *Id.* Dr. Black stated that Savu should continue to take cholestyramine because its benefits are greater than its side effects. *Id.* Savu did not resume taking cholestyramine and stopped seeing Dr. Black. *Id.*

Savu continued to experience severe stomach issues. *See id.* She visited the emergency room by ambulance twice in 2020 and was hospitalized several times. *Id.* at 6–8. By August 2022, her GI specialist determined that she “clearly has chronic atrophic and reactive gastritis. These conditions are forever. She had a terrible reaction to the Cholestyramine.” *Id.* at 8. Her primary care doctor, after reviewing and evaluating her records, likewise concluded that “[m]ore likely than not, to a reasonable degree of medical certainty, Ms. Savu was permanently injured by being treated with cholestyramine.” ECF 16, at 7.

In her amended complaint, Savu asserts failure-to-warn product liability claims under negligence, gross negligence, and strict liability theories; negligent and fraudulent misrepresentation claims; violations of the Federal Food, Drug, and Cosmetic Act; and intentional infliction of emotional distress claims.

II. Personal Jurisdiction over Hopkinton

Hopkinton moves to dismiss for lack of personal jurisdiction under Rule 12(b)(2). On a Rule 12(b)(2) motion, the plaintiff generally bears the burden to prove grounds for jurisdiction by a preponderance of the evidence. *Mylan Labs., Inc. v. Akzo, N.V.*, 2 F.3d 56, 60 (4th Cir. 1993).

But when, as here, the Court considers a personal jurisdiction argument before any evidentiary hearing has taken place, the plaintiff “need only prove a *prima facie* case of personal jurisdiction.” *Id.* In deciding whether the plaintiff has proved a *prima facie* case, the Court “must take all disputed facts and reasonable inferences in favor of the plaintiff.” *Carefirst of Md., Inc. v. Carefirst Pregnancy Ctrs., Inc.*, 334 F.3d 390, 396 (4th Cir. 2003) (citing *Mylan Labs*, 2 F.3d at 60).

To exercise personal jurisdiction over a nonresident defendant, “two conditions must be satisfied: (1) the exercise of jurisdiction must be authorized under the state’s long-arm statute; and (2) the exercise of jurisdiction must comport with the due process requirements of the Fourteenth Amendment.” *Id.* (citing *Christian Sci. Bd. of Dirs. of the First Church of Christ v. Nolan*, 259 F.3d 209, 215 (4th Cir. 2001)). Maryland’s long-arm statute is coextensive with the limits of personal jurisdiction under the Constitution’s due process clause. *Id.* (citing *Mohamed v. Michael*, 370 A.2d 551, 553 (Md. 1977)).³ While courts often state that the “statutory inquiry merges with [the] constitutional inquiry,” *id.* at 396–97 (citation omitted), that does not mean it is “permissible to simply dispense with analysis under the long-arm statute.” *Mackey v. Compass Mktg., Inc.*, 892 A.2d 479, 493 n.6 (Md. 2006). Instead, “Maryland law requires that courts ‘interpret the long-arm statute to the limits permitted by the Due Process Clause when we can do so consistently with the canons of statutory construction.’” *A Love of Food I, LLC v. Maoz Vegetarian USA, Inc.*, 795 F. Supp. 2d 365, 369 (D. Md. 2011) (quoting *Mackey*, 892 A.2d at 493 n.6); *Bond v. Messerman*, 895 A.2d 990, 999 (Md. 2006) (reiterating that “determining whether a Maryland court may exercise personal jurisdiction over a foreign defendant requires a two-step analysis”); *Dring v. Sullivan*,

³ For cases decided when the Supreme Court of Maryland and the Appellate Court of Maryland had different names, the Court will utilize the earlier citation format.

423 F. Supp. 2d 540, 545 (D. Md. 2006) (noting that “a more correct understanding of the first” step of the jurisdictional analysis “is that to the extent that a defendant’s activities are covered by the statutory language, the reach of the statute extends to the outermost boundaries of the due process clause” (quoting *Joseph M. Coleman & Assocs., Ltd. v. Colonial Metals*, 887 F. Supp. 116, 118 n.2 (D. Md. 1995))).

A. Long-Arm Statute

Maryland’s long-arm statute limits specific jurisdiction to cases where the cause of action “aris[es] from any act enumerated in the statute itself.” Md. Code Ann., Cts. & Jud. Proc. § 6-103(a). The statute authorizes jurisdiction over a party who directly or by an agent:

- (1) Transacts any business or performs any character of work or service in the State;
- (2) Contracts to supply goods, food, services, or manufactured products in the State;
- (3) Causes tortious injury in the State by an act or omission in the State;
- (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if he regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from goods, food, services, or manufactured products used or consumed in the State;
- (5) Has an interest in, uses, or possesses real property in the State; or
- (6) Contracts to insure or act as surety for, or on, any person, property, risk, contract, obligation, or agreement located, executed, or to be performed within the State at the time the contract is made, unless the parties otherwise provide in writing.

Id. § 6-103(b). Savu does not specify in the complaint which provision of Maryland’s long-arm statute she believes authorizes jurisdiction over Hopkinton. But the Court readily can discern that (b)(1) is the only possible applicable provision based on the allegations in the complaint.

Section 6-103(b)(1) of Maryland’s long-arm statute authorizes personal jurisdiction over a person who “transacts any business or performs any character of work or service” in Maryland. A defendant need not have been physically present in Maryland for its contacts with the state to satisfy this subsection. *Aphena Pharma Sols.-Md. LLC v. BioZone Labs., Inc.*, 912 F. Supp. 2d 309, 315 (D. Md. 2012) (citation omitted); *Bond v. Messerman*, 873 A.2d 417, 428 (Md. Ct. Spec.

App. 2005) (noting the “Court of Appeals has held that one who sends communications into Maryland can be found to have transacted business in the State, without ever entering the State, under § 6-103(b)(1)” (citing John A. Lynch, Jr. & Richard W. Bourne, *Modern Maryland Civil Procedure* § 3.3(c)(3)(a) at 3-40 to 3-43)), *aff’d*, 895 A.2d 990 (Md. 2006). The plaintiff must, however, show the defendant engaged in “some purposeful act in Maryland in relation to one or more of the elements of [the] cause of action.” *Aphena*, 912 F. Supp. 2d at 315.

The first inquiry is whether Hopkinton “transact[ed] any business” in Maryland. Maryland courts “construe[] the phrase ‘transacting business’ narrowly, requiring, for example, significant negotiations or intentional advertising and selling in the forum state.” *Id.* (citations omitted). Savu alleges that Hopkinton filled one prescription for her, which was ordered for her by her doctor. Savu does not allege that she directly contacted Hopkinton to fill the prescription in response to an invitation, advertisement, or solicitation by Hopkinton. These circumstances do not meet Maryland’s narrow definition of “transacting business.”

The next inquiry, then, is whether Hopkinton “performed any character of work or service” that culminated in purposeful activity within Maryland. Savu alleges that Hopkinton mailed her a prescription and accompanying materials that included the pharmacy’s contact information and encouraged her to call with questions. *See* ECF 16-5, at 1, 3. When she called, Hopkinton’s owner and pharmacist Dennis Katz counseled Savu over the phone that the cholestyramine was safe and effective even for patients with stomach ulcers or gastritis, that there should be “no problems,” and that Hopkinton prescribes the drug for thousands of patients. ECF 15-2, at 5. He then provided further instructions about dosage and timing. *Id.*

There is limited authority on whether “the providing of advice or counsel, legal or otherwise” satisfies subsection (b)(1). *Bond*, 873 A.2d at 427 (citing *Giannaris v. Cheng*, 219 F.

Supp. 2d 687 (D. Md. 2002) (holding there was *in personam* jurisdiction over out-of-state attorneys sued for legal malpractice where cause of action arose from litigation in Maryland)). In *Bond*, an Ohio attorney was sued in Maryland for legal malpractice by his former client for failing to timely expunge his client’s juvenile record. The court considered whether Maryland had personal jurisdiction over the attorney who, while living and practicing law in Ohio, provided his former client with advice about juvenile record expungement over the phone and in letters after the former client had moved to Maryland and then reached out about expungement. The defendant argued that Maryland’s long-arm statute did not confer jurisdiction over him because he was never in Maryland when he provided legal advice. The court rejected the out-of-state attorney’s argument, reasoning that he “failed to address the significance of his communications with his client in Maryland.” *Id.* After noting that the definition of practicing law under Maryland’s Code included giving legal advice, the court concluded that the Ohio attorney’s actions in that case constituted the practice of law in Maryland. *Id.* at 428 (citing *Lawson v. Balt. Paint & Chem. Corp.*, 298 F. Supp. 373 (D. Md. 1969) (finding personal jurisdiction over out-of-state attorneys where “[a]lthough the legal services may have been rendered in New York, they were used in Maryland”)). The court then stated that “it would appear that [defendant’s] conduct brought him within the purview of 6-103(b)(1),” though it ultimately declined to reach the issue and ruled instead on due process grounds. *Id.*; *see also id.* at 427 (noting that the court’s analysis as to whether defendant’s actions constituted the practice of law in Maryland “is to be distinguished from the question of whether there were minimum contacts under a Due Process analysis, although both focus on his actions”)).

Here, Katz’s advice to Savu over the phone appears to qualify under Maryland law as pharmaceutical care, which is defined as “the provision of a patient’s drug regimen . . . which may

include patient counseling.” Md. Code Ann., Health Occ. § 12-101(r) (2022) (emphasis added). And Katz appears to be a pharmacist under Maryland law, which is a person who practices pharmacy “regardless of the location where the activities of practice are performed.”⁴ *Id.* § 12-101(s). Hopkinton’s argument that it was never physically present in Maryland, like the out-of-state attorney’s argument in *Bond*, “fail[s] to address the significance of [its] communications with” its patient in Maryland. *See Bond*, 873 A.2d at 427. And much like the attorney’s legal advice in *Bond* gave rise to the plaintiff’s legal malpractice claims, Katz’s pharmaceutical advice to Savu gave rise to her failure to warn claims against Hopkinton. Thus, Savu has made a *prima facie* showing that Hopkinton engaged in “some purposeful act in Maryland in relation to one or more of the elements of [the] cause of action,” satisfying subsection (b)(1) of the long-arm statute. *Aphena*, 912 F. Supp. 2d at 315.

B. Constitutional Minimum Contacts

Savu also must make a *prima facie* showing that exercising jurisdiction over Hopkinton satisfies due process. This Court’s exercise of jurisdiction over a nonresident defendant comports with due process if the defendant has such “minimum contacts” with Maryland so as “to make the exercise of jurisdiction over [the defendant] consistent with ‘traditional notions of fair play and substantial justice.’” *Foster v. Arletty 3 Sarl*, 278 F.3d 409, 414 (4th Cir. 2002) (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Courts recognize two types of personal jurisdiction: general and specific. *A Love of Food I, LLC v. Maoz Vegetarian USA, Inc.*, 795 F. Supp. 2d 365, 371 (D. Md. 2011). General jurisdiction is proper when a defendant’s contacts with the forum are “continuous and systematic.” *Carefirst*, 334 F.3d at 397. Savu does not allege in her amended

⁴ “Pharmacy” is defined as “an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.” Md. Code Ann., Health Occ. § 12-101(t).

complaint or suggest in her filings that Hopkinton engaged in “continuous and systematic” activities within Maryland that would warrant a finding of general jurisdiction. *See id.* The question then is whether the Court has specific jurisdiction over Hopkinton. Specific jurisdiction is proper when a defendant’s contacts with the forum provide the basis for the suit. *Id.*

To determine whether Hopkinton, a nonresident defendant, had the minimum contacts necessary to confer specific jurisdiction, the Court focuses “on the relationship among the defendant, the forum, and the litigation.” *Walden v. Fiore*, 571 U.S. 277, 284 (2014) (citing *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 775 (1984)). The Court considers “(1) the extent to which the defendant has purposefully availed itself of the privilege of conducting activities in the state; (2) whether the plaintiff[’s] claims arise out of those activities directed at the state; and (3) whether the exercise of personal jurisdiction would be constitutionally ‘reasonable.’” *Carefirst*, 334 F.3d at 397 (citing *ALS Scan, Inc. v. Digital Serv. Consultants, Inc.*, 293 F.3d 707, 711–12 (4th Cir. 2002)). The Court focuses on “the quality and nature of [Hopkinton’s Maryland] contacts.” *Id.* (quoting *Nichols v. G.D. Searle & Co.*, 783 F. Supp. 233, 238 (D. Md. 1992), *aff’d*, 991 F.2d 1195 (4th Cir. 1993)). Even a single contact may suffice to confer jurisdiction if the cause of action arises out of that contact, so long as principles of “fair play and substantial justice” are not violated. *Id.*

As to whether Hopkinton purposefully availed itself of the privilege of conducting activities in Maryland, Savu alleges that the pharmacy, a Massachusetts corporation physically located in that state, mailed a drug to her in Maryland. A “physical entry into the State—either by the defendant in person or through an agent, *goods, mail*, or some other means—is certainly a relevant contact.” *Walden*, 571 U.S. at 285 (emphasis added). Hopkinton’s mailing a prescription

to Maryland is a physical entry into the state that constitutes a relevant (if not necessarily sufficient) contact between the defendant and the forum state.

More broadly, Savu alleges Hopkinton had additional contacts with Maryland, beyond the act of mailing a prescription, that demonstrate it purposefully availed itself of the privilege of conducting business here. Before ingesting the drug, Savu called Katz, Hopkinton’s owner and pharmacist, to ask questions about it. Hopkinton, citing the Supreme Court’s decision in *Walden*, contends that the mere fact that Savu “unilaterally” called from Maryland, where she resides, does not give rise to a relevant contact between Hopkinton and Maryland. *See* ECF 11-1, at 6; *Walden*, 571 U.S. at 286; *see also Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985) (noting “[t]he unilateral activity of those who claim some relationship with a nonresident defendant cannot satisfy the requirement of contact with the forum state” (quotation omitted)). In *Walden*, a police officer seized cash from a couple in an Atlanta airport who were on their way home to Nevada. 571 U.S. at 280. He then drafted an allegedly false affidavit regarding the cash seizure, which he forwarded to the United States Attorney’s Office in Georgia for prosecution of the couple whom the officer knew lived in Nevada. *Id.* at 280–81. The Supreme Court reversed the Court of Appeals’ finding of personal jurisdiction over the officer in the District of Nevada, reasoning that the officer never “conducted activities within, contacted anyone in, or sent anything or anyone to Nevada” and thus had no jurisdictionally relevant contacts there. *Id.* at 289. The couples’ own residence in Nevada could not suffice to establish personal jurisdiction, as that would impermissibly “allow a plaintiff’s contacts with the defendant and forum to drive the jurisdictional analysis,” and “improperly attribute[] a plaintiff’s forum connections to the defendant and make[] those connections ‘decisive’ in the jurisdictional analysis.” *Id.* at 290 (citation omitted); *see ESAB Grp., Inc. v. Centricut, Inc.*, 126 F.3d 617, 626 (4th Cir. 1997) (noting that “[a]lthough the place

that the plaintiff feels the alleged injury is plainly relevant to the inquiry, it must ultimately be accompanied by the defendant’s own contacts with the state . . .”).

Hopkinton is correct that, like the officer in *Walden*, none of its alleged misconduct technically occurred in the forum state. And it is true that Savu called Hopkinton from Maryland; Hopkinton did not call her. But Hopkinton ignores the broader “relationship among the defendant, the forum, and the litigation.” *Id.* at 283 (internal quotations omitted). Hopkinton not only mailed a prescription to Maryland, but it invited Savu to call for pharmaceutical advice in pamphlets and labels accompanying the prescription, and it then provided advice when she accepted Hopkinton’s invitation. Unlike the defendant in *Walden*, Hopkinton conducted activities in Maryland by mailing a prescription to Savu here and inviting her to engage in a pharmacist–patient relationship. Hopkinton’s own actions, not Savu’s, drive the jurisdictional analysis.

In this sense, Hopkinton’s relevant contacts with Maryland also differ from those in *Bond*, in which the Appellate Court of Maryland found that an out-of-state lawyer’s provision of legal services to his former client in Maryland appeared to satisfy the long-arm statute, but did not satisfy due process. 873 A.2d at 431. There, “[o]f the seven relevant contacts [the lawyer] had with [the client], five were contacts made by [the client]—either by letter or phone—to [the lawyer] in Ohio.” *Id.* The sixth contact from the lawyer to the client was made in response to the client’s “missive,” and not as a result of the lawyer encouraging the client to reach out. *Id.* The sole contact that the lawyer appears to have initiated himself was a letter asking the client to remind him in two years to file an expungement, but when the client told him he should file without a reminder, the lawyer agreed. *Id.* The court held that requiring the lawyer to defend suit in Maryland would “offend traditional notions of fair play and substantial justice” because his “contacts with Maryland exist only by virtue of the unilateral conduct of his client.” *Id.* On appeal,

the Supreme Court of Maryland affirmed, stressing that the attorney-client relationship had been created in Ohio; the content of the interactions concerned Ohio law; the lawyer derived no revenue from his interactions with the former client; and the lawyer did not solicit business or advertise his services in Maryland. *Bond*, 895 A.2d at 731. Here, by contrast, Hopkinton mailed goods to Savu (a new patient) in Maryland, received payment, encouraged and enabled her to reach out for advice, and provided advice when she called. Even though Savu initiated the call to Hopkinton, she did so in response to Hopkinton's invitation. By inviting Savu to call for pharmaceutical advice about the prescription it sent her and by advising her about the drug when she did call, Hopkinton purposefully availed itself of the privilege of providing pharmaceutical care in Maryland.

Hopkinton's mailing of the prescription and provision of pharmaceutical advice over the phone then gave rise to Savu's failure to warn claims. When Savu called, Katz informed her that the drug "is safe even for people with diabetes, thyroid or stomach ulcer/gastritis" and gave instructions about dosage and timing. ECF 15-2, at 5. Regarding side effects, he stated: "No problems, maybe some GI/abdominal discomfort, even for patients with GI ulcer/gastritis it is safe. We prescribe this drug all the time for thousands of [sic] thousands of patients. It is effective and safe." *Id.* After mailing a drug, inviting a patient to reach out in materials accompanying that drug, and then providing pharmaceutical services when that patient did reach out, Hopkinton now faces suit over a cause of action arising from those pharmaceutical services.

Finally, the Court considers whether exercising jurisdiction over Hopkinton would be constitutionally reasonable. Exercising jurisdiction is constitutionally reasonable where "the defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980). There are surprisingly few cases assessing whether exercising personal

jurisdiction is constitutionally reasonable in analogous circumstances, but two are worth discussing. In a case out of the Western District of Pennsylvania, the court found that specific jurisdiction over a nonresident doctor who monitored a patient's health by phone after the patient moved to Pennsylvania, including changing the patient's prescription, satisfied due process. *Walsh v. Chez*, 418 F. Supp. 2d 781, 787 (W.D. Pa. 2006). In *Acero v. Pollner*, No. AW-08-2683, 2009 WL 10685438, at *4–6 (D. Md. June 16, 2009), this Court found no specific jurisdiction over a Virginia-based doctor who remotely monitored the plaintiff's health condition during homecare in Maryland, primarily through reviewing faxed blood test results from a Walgreens in Maryland. *Id.* at *5. The patient continually returned to the doctor's office in Virginia for appointments. This Court distinguished the facts before it from those in *Chez*, because there, “all of the subsequent contact between doctor and patient occurred over the phone while the patient was in Pennsylvania . . . demonstrat[ing] that the doctor purposefully availed himself of the privileges of treating the patient in Pennsylvania.” *Acero*, 2009 WL 10685438, at *5. And, “in *Chez* the doctor changed his patient's dosage over the phone. This contact bore a very close relationship to the harm for which the plaintiffs sued.” *Id.* Under these circumstances, the doctor in *Chez* (as opposed to the doctor in *Acero*) “should have reasonably expected that they could be ‘haled into court’ in [the forum state].” *Chez*, 418 F. Supp. 2d at 789. While neither case is directly on point nor controlling, this case bears a closer resemblance to *Chez* than *Acero*.

Here, Hopkinton's conduct and statements show an intent to establish a remote pharmacist–patient relationship with Savu in Maryland, akin to the remote physician–patient relationship in *Chez*. Savu sufficiently demonstrates, at least for a *prima facie* showing, that by filling a mail-order prescription to a patient in Maryland and by inviting, and then providing, telephonic pharmaceutical consultation services to the patient while she was in Maryland, Hopkinton

purposefully availed itself of the privileges of conducting activities in Maryland. And as discussed, the harm for which Savu sues—*injury allegedly resulting from Hopkinton’s failure to warn her about cholestyramine’s adverse side effects*—stems directly from the prescription drug that Hopkinton mailed her and the pharmaceutical advice it encouraged her to seek. Under these facts, Hopkinton “could have foreseen being haled before a Maryland court as a result of” its mailing a prescription into the state and its invitation to engage in remote pharmaceutical consultation services. *See Acero*, 2009 WL 10685438, at *6; *Universal Leather, LLC v. Koro AR, S.A.*, 773 F.3d 553, 559–60 (4th Cir. 2014) (citing *World-Wide Volkswagen*, 444 U.S. at 297). These circumstances do not violate principles of “fair play and substantial justice.” It is constitutionally reasonable for this Court to exercise jurisdiction over Hopkinton.

Savu has made a *prima facie* showing that exercising jurisdiction over Hopkinton satisfies due process. Hopkinton’s motion to dismiss for lack of personal jurisdiction is denied.

III. Failure to State a Claim

A. Standard of Review

Under Rule 12(b)(6), a party may seek dismissal for failure “to state a claim upon which relief can be granted.” *Robertson v. Anderson Mill Elementary Sch.*, 989 F.3d 282, 290 (4th Cir. 2021) (quoting Fed. R. Civ. P. 12(b)(6)). To survive the challenge, the opposing party must have pleaded facts demonstrating it has a plausible right to relief from the Court. *Lokhova v. Halper*, 995 F.3d 134, 141 (4th Cir. 2021) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A plausible claim is more than merely conceivable or speculative. *See Holloway v. Maryland*, 32 F.4th 293, 299 (4th Cir. 2022). The allegations must show there is “more than a sheer possibility that the defendant has acted unlawfully.” *Int’l Refugee Assistance Project v. Trump*, 961 F.3d 635, 648 (4th Cir. 2020) (quoting *Iqbal*, 556 U.S. at 678)). But the claim does not need to be probable, and

the pleader need not show “that alternative explanations are less likely” than their theory. *Jesus Christ is the Answer Ministries, Inc. v. Balt. Cnty., Md.*, 915 F.3d 256, 263 (4th Cir. 2019) (quoting *Houck v. Substitute Tr. Servs., Inc.*, 791 F.3d 473, 484 (4th Cir. 2015)).

When ruling on a Rule 12(b)(6) motion, the Court must accept the allegations as true and draw all reasonable inferences in favor of the pleader. *Williams v. Kincaid*, 45 F.4th 759, 765, 777 (4th Cir. 2022). But the Court does not accept “legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments.” *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 189 (4th Cir. 2022) (quoting *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013)). Merely reciting a claim’s elements “and supporting them by conclusory statements does not meet the required standard.” *Sheppard v. Visitors of Va. State Univ.*, 993 F.3d 230, 234 (4th Cir. 2021) (quoting *ACA Fin. Guar. Corp. v. City of Buena Vista, Va.*, 917 F.3d 206, 212 (4th Cir. 2019)). On a Rule 12(b)(6) motion, the Court “does not resolve contests surrounding facts, the merits of a claim, or the applicability of defenses.” *Ray v. Roane*, 948 F.3d 222, 226 (4th Cir. 2020) (quoting *Tobey v. Jones*, 706 F.3d 379, 387 (4th Cir. 2013))

“Pro se filings are ‘h[e]ld to less stringent standards than formal pleadings drafted by lawyers.’” *Folkes v. Nelsen*, 24 F.4th 258, 272 (4th Cir. 2022) (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972)). Accordingly, the Court must construe pro se pleadings liberally. *Bing v. Brivo Sys., LLC*, 959 F.3d 605, 618 (4th Cir. 2020). But “liberal construction does not require [the Court] to attempt to ‘discern the unexpressed intent of the plaintiff[;]’” the Court need only “determine the actual meaning of the words used in the complaint.” *Williams v. Ozmint*, 716 F.3d 801, 805 (4th Cir. 2013) (quoting *Laber v. Harvey*, 438 F.3d 404, 413 n.3 (4th Cir. 2006) (en banc)). Thus, a pro se complaint “still ‘must contain enough facts to state a claim for relief that is plausible on its face.’” *Thomas v. The Salvation Army S. Territory*, 841 F.3d 632, at 637 (4th Cir.

2016) (quoting *King v. Rubenstein*, 825 F.3d 206, 212, 214 (4th Cir. 2016) (quoting *Twombly*, 550 U.S. at 570)).

B. Discussion

1. Failure to warn claims

a. Purolite

Purolite moves to dismiss Savu’s negligence and gross negligence claims for failure to warn her of the risks of cholestyramine. To state a claim for negligence, Savu must allege that Purolite “(1) was under a duty to protect the plaintiff from injury, (2) that the defendant breached that duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant’s breach of the duty.” *Gourdine v. Crews*, 955 A.2d 769, 779 (Md. 2008) (quotation omitted). To state a claim for gross negligence, Savu must allege “an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another.” *Cooper v. Rodriguez*, 443 Md. 680, 686 (Md. 2015). In Maryland, “[p]roducts liability law imposes on a manufacturer a duty to warn if the item produced has an inherent and hidden danger that the producer knows or should know could be a substantial factor in causing an injury.” *Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 103–104 (D. Md. 2020) (citation omitted). Negligence and strict liability concepts (which Savu alleges in her amended complaint) have “morphed together in failure to warn cases” because “traditional concepts of duty, breach, causation, and damage are required for both causes of action.” *Id.* at 104 (citing *Gourdine*, 955 A.2d at 782).

Under the learned intermediary doctrine, a drug manufacturer has no duty to warn a consumer about a drug’s side effects or risks so long as the doctor who prescribed the drug received adequate notice of its risks. *Gourdine*, 955 A.2d at 775 n.8 (noting that “under the doctrine, a

manufacturer which has adequately warned the physician, in almost every circumstance, has no duty to warn a patient" (citation omitted)); *Ames v. Apothecon, Inc.*, 461 F. Supp. 2d 566, 572 (D. Md. 2006) (granting drug manufacturer's motion for summary judgment where doctor received adequate warning of drug's risks). Savu does not allege that Purolite failed to adequately warn her prescribing physician, Dr. Black, about the risks associated with cholestyramine. This pleading defect could not be cured because Savu claims that Dr. Black was aware of the drug's side effects that she experienced. Savu states that she "told [Dr. Black] that I stopped Cholestyramine . . . because it caused me this terrible pain, injuries/damages on my stomach. She said 'Any chemical drugs have side effects, and you should continue to take it, because the benefits are greatest [sic] than side effects.'" See ECF 15-2, at 6. Whether Dr. Black learned of cholestyramine's side effects from Purolite or another source does not matter for purposes of the learned intermediary doctrine; what matters is that she knew of them. See *Ames*, 461 F. Supp. 2d at 572 ("Even if a label's warnings are inadequate, the doctrine protects a manufacturer from liability provided the doctor has been sufficiently warned from other sources."). Purolite had no legal duty to warn Savu about the drug's side effects and risks.

Purolite's motion to dismiss Savu's claims based on its alleged failure to warn is granted, and the claims are dismissed.

b. Hopkinton

Hopkinton, like Purolite, owed no duty to warn Savu of cholestyramine's side effects. The Maryland Supreme Court has endorsed application of the learned intermediary doctrine to pharmacies, reasoning that to require a pharmacist to issue warnings directly to a patient would "create an intolerable confusion and foster obviously dangerous practices in the consumption of prescription drugs" by inviting second-guessing of a physician's medical advice. *Hofherr v. Dart*

Indus., Inc., 853 F.2d 259, 263–64 (4th Cir. 1988) (applying learned intermediary doctrine to affirm directed verdict in pharmacist’s favor on duty to warn claim where “only danger would result” from requiring “that the physician by second-guessed by the pharmacist”); *People’s Serv. Drug Stores, Inc. v. Somerville*, 158 A. 12, 14 (Md. 1932) (applying learned intermediary doctrine to pharmacist–patient relationship).⁵ Hopkinton’s motion to dismiss Savu’s negligence and gross negligence claims for failure to warn (and, by extension, Savu’s strict liability claim) is thus granted, and the claims are dismissed.

2. Federal Food, Drug, and Cosmetic Act and false representation claims

Savu alleges that Purolite and Hopkinton made false representations in violation of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (“FDCA”). 21 U.S.C. § 321(g); *see generally id.* Ch. 9. Savu asserts that by providing her with cholestyramine, a defective product, and by failing to provide her with adequate “caution, warnings, or instructions concerning the proper use of the drug to me, they promised, affirmed, and described the drug as being safe and free from any defective conditions.” ECF 15-2, at 11–12. These representations, she alleges, “were false when made.” *Id.* She alleges that the defendants “failed to disclose to Plaintiff their knowledge of defective conditions” and that they intended for plaintiff to rely on their representations. *Id.* She

⁵ Though the learned intermediary doctrine applies to failure to warn claims involving “the ordinary pharmacist-patient relationship wherein the pharmacist merely fills the prescription as ordered by the physician,” it does not bar breach of express warranty claims when pharmacists provide further instructions. *Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 579 (Md. 2006) (affirming breach of express warranty verdict against pharmacy and declining to extend learned intermediary doctrine to cases in which pharmacies “disseminat[e] information concerning the properties and efficacy of a prescription drug”). Savu does not label her allegations against Hopkinton—in particular, Katz’s assurances that cholestyramine is safe for patients with gastritis—as a breach of express warranty. Even if her allegations could be construed as an assertion of a breach of express warranty claim, the claim would not pass muster under Rule 12(b)(6) unless, among other things, Savu provided notice of breach to Hopkinton. U.C.C. § 2-607(3).

further alleges that “the misrepresentation was made for the purpose of defrauding the Plaintiff,” because the defendants “wanted to sell at issue for economic gain . . . without ever disclosing” risks or warning about the drug. *Id.* at 23. The Court construes these allegations as claims under the FDCA and state law claims for fraudulent misrepresentation or fraudulent concealment.

Any FDCA claims must be dismissed because there is no private right of action to enforce the Act’s requirements. *Burrell v. Bayer Corp.*, 918 F.3d 372, 377 (4th Cir. 2019).

As for the fraudulent misrepresentation claim, Savu must allege “(a) a false representation; (b) made with the knowledge of its falsity, or in reckless indifference to the truth; (c) with the intent of defrauding the person claiming to be injured; (d) justifiable reliance by that person; and (e) damages caused as a result of the fraudulent statement.” *Heritage Oldsmobile-Imports v. Volkswagen of Am., Inc.*, 264 F. Supp. 2d 282, 291 (2003) (citing *Miller v. Fairchild Indus.*, 629 A.2d 1293, 1302 (Md. Ct. Spec. App. 1993)). Savu has not adequately alleged that Purolite made a false representation. Indeed, she does not identify any statement that Purolite made to her. By contrast, Savu does describe with particularity the statements that Hopkinton made to her both in the materials it sent with her prescription and in her subsequent conversation with Katz. But she does not sufficiently allege that those statements were made with knowledge of their falsity or in reckless indifference to the truth. Katz stated that cholestyramine is “safe even for people with . . . stomach ulcer/gastritis,” that “in terms of side effects: no problems, maybe some GI/abdominal discomfort,” and that Hopkinton prescribes it for “thousands of [sic] thousands of patients. It is effective and safe.” ECF 15-2, at 5. These broad statements about the drug’s general safety and efficacy proved to be false in Savu’s individual case, as she had a terrible reaction to the drug. But it does not follow that Katz knew he was making false statements or that he made them in reckless indifference to the truth. Savu’s own allegations belie such an inference. After she informed her

doctor of her side effects, the doctor nevertheless counseled her to continue taking cholestyramine, as (in her opinion) the benefits outweighed the side effects. ECF 15-2, at 6. And according to a “Drug Education Monograph” that Savu submitted to the Court, “[m]any people using this medication do not have serious side effects,” the drug’s “rare” side effects include “severe stomach/abdominal pain,” and “[a] very serious reaction to this drug is rare.” ECF 16-2, at 1. Given Savu’s own allegations and the documents in support of her amended complaint, it is not plausible to infer that Katz’s statements about cholestyramine’s general safety and efficacy were made with knowledge of their falsity or in reckless indifference to the truth. Savu has not sufficiently pled fraudulent misrepresentation as to either defendant.

To state a claim for fraudulent concealment, Savu must allege

that the defendant owed a duty to the plaintiff to disclose a material fact, the defendant failed to disclose that fact, the defendant intended to defraud or deceive the plaintiff, the plaintiff took action in justifiable reliance on the concealment, and the plaintiff suffered damages as a result of the defendant’s concealment.

Morris v. Biomet, 491 F. Supp. 3d 87, 106 (D. Md. 2020). Savu’s fraudulent concealment claims against both defendants fail because, as discussed, neither Purolite nor Hopkinton owed Savu a duty to warn or disclose any facts about cholestyramine’s safety.

Savu’s fraudulent misrepresentation and fraudulent concealment claims are dismissed.

3. Intentional infliction of emotional distress claim

Savu finally alleges intentional infliction of emotional distress.⁶ To state a claim for this tort, a plaintiff must allege four elements: (1) the conduct was intentional or reckless; (2) the conduct was extreme and outrageous; (3) there is a causal connection between the wrongful

⁶ Savu’s additional claim for “negligent . . . infliction of emotional distress” is not an independent tort under Maryland law. *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 839 (D. Md. 2000) (citing *Bagwell v. Peninsula Reg’l Med. Ctr.*, 665 A.2d 297 (Md. Ct. Spec. App. 1995)).

conduct and the emotional distress; and (4) the emotional distress is severe. *Figueiredo-Torres v. Nickel*, 584 A.2d 69, 74 (Md. 1991) (citing *Harris v. Jones*, 380 A.2d 611, 614 (Md. 1977)). Each element must be pled with specificity. *Id.* (citing *Foor v. Juvenile Serv. Admin.*, 552 A.2d 947, 959 (Md. Ct. Spec. App. 1989)). This Court has emphasized that in Maryland, “the tort of intentional infliction of emotional distress is rarely viable.” *Arbabi v. Fred Meyers, Inc.*, 205 F. Supp. 2d 462, 466 (D. Md. 2002) (citation omitted). Liability for this tort “should be imposed sparingly.” *Id.* (quoting *Figueiredo-Torres*, 584 A.2d. at 75).

Savu certainly has alleged severe emotional distress from the permanent, serious injuries caused by cholestyramine. *See* ECF 16, at 7 (“Medical Opinion” by Dr. Alan R. Vinitsky, M.D. concluding that “[m]ore likely than not, based on a reasonable degree of medical certainty, Ms. Savu was permanently injured by being treated with cholestyramine”); ECF 15-2, at 3–4 (“These heart wrenching episodes caused me . . . extreme emotional distress and mental anguish. I thought I was going to die on many occasions! I have present and future concerns regarding the serious injuries to my health . . .”). But she has not alleged that Purolite or Hopkinton intended to harm her, that they were reckless in manufacturing or prescribing the drug, or that manufacturing the drug and filling a prescription for it were outrageous or extreme conduct. On the contrary, Savu alleges that her doctor prescribed the drug and was aware of its potential side effects. And as discussed, according to the “Drug Education Monograph” she submitted, the drug’s rare side effects included “severe stomach/abdominal pain” and, also on rare occasions, “serious allergic reaction.” ECF 16-2, at 1. It appears that Savu was one of the rare people who suffered a severe reaction to the drug, but her reaction does not give rise to an intentional infliction of emotional distress claim against the drug manufacturer and the pharmacy that filled the prescription.

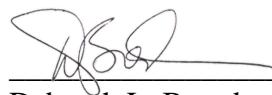
Savu’s claim of intentional infliction of emotional distress is dismissed.

IV. Conclusion

For the foregoing reasons, the Court grants Savu's motion to amend her complaint and grants Purolite's and Hopkinton's motions to dismiss the amended complaint with prejudice. A separate order follows.

2/21/2023

Date



Deborah L. Boardman
United States District Judge