defendants. Upon consideration of the pleadings, relevant law, and the entire record herein, the Court will GRANT the motions and DISMISS the amended complaint.

BACKGROUND

Plaintiffs Terry Aston, John Fratti, Linda Martin, David Melvin, and Jennifer Wilcox are five individuals who allege that they were injured by taking Levaquin, a brand-name drug manufactured and sold by Johnson & Johnson. Am. Compl. ¶¶ 30–31, 78. Plaintiffs state that as result of their taking Levaquin, they suffered from "a constellation of medical issues" including "mitochondrial toxicity, neuropsychiatric adverse events, and multi-system disability," and have sustained damage "to the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular, plus[] endocrine, nutritional, metabolic and immunity; blood and blood forming organs; circulatory system; respiratory system; digestive system; genitourinary system; and connective tissue." Am. Compl. ¶ 78. Plaintiffs also say they have experienced

> widespread bodily pain, fatigue, muscle weakness, muscle twitching, muscle wasting, gait disturbances, severe balance issues, stiffness, spasms, joint pain, tendon issues, seizures, tremors, numbness, burning, tingling, fasciculation, spasticity, nerve damage, autonomic issues, voice issues, exercise intolerance, difficulty swallowing, slow digestive motility, abdominal pain, acid reflux, gastritis, nausea, constipation, diarrhea, colitis, cognitive impairment, memory impairment, cardiac issues, urinary issues, kidney damage, liver damage, pancreatic damage, thyroid abnormalities, hair loss, glucose issues, respiratory issues, emotional issues, depression, psychosis, depersonalization, dissociation, anxiety, insomnia, abnormal dreams, suicidal thoughts, thought alterations, agitation, fatigue, dizziness, inability to concentrate, panic attacks, difficulty communicating, forgetfulness, bruising, vision issues, hearing issues, tinnitus, dental issues, gum issues, skin issues, rashes, multiple chemical sensitivity, sexual dysfunction, reproductive issues, and DNA damage.

Am. Compl. ¶ 79. The amended complaint does not associate any of these symptoms with any individual plaintiff; nor does it allege when or why any individual plaintiff was prescribed Levaquin, or when they began taking it. It does, however, assert that all five plaintiffs were left "unable to secure, maintain, and or perform the duties of employment" as a "direct result" of "the purchase and ingestion of Levaquin." Am. Compl. ¶ 80. Four of the five plaintiffs state that they have been unable to work since 2008 or earlier. Am. Compl. ¶¶ 82–85. The fifth plaintiff, David Melvin, states that he has been unable to work since 2012. Am. Compl. ¶ 81.

Plaintiffs further allege that Levaquin is dangerous and that its label failed to adequately warn of these dangers when they took the drug. Levaquin contains the antibiotic levofloxacin. Am. Compl. ¶ 31. Levofloxacin is a fluoroquinolone, a class of broad-spectrum antibiotic drugs. Am. Compl. ¶¶ 31–32. Levaquin was approved by the FDA in 1996, Am. Compl. ¶ 31, went generic in 2011, Decl. of Lauren A. Moskowitz, Ex. C (FDA News Release) [Dkt. #24-4], and has nine approved indications and uses: pneumonia; acute bacterial sinusitis; acute bacterial exacerbation of chronic bronchitis; skin and skin structure infections; chronic bacterial prostatitis; urinary tract infections; acute pyelonephritis; inhalational anthrax, post-exposure; and plague, Decl. of Jonah M. Knobler ("Knobler Decl."), Ex. 1 (2014 Levaquin Label) [Dkt. #22-3].[1] The label for Levaquin warns of numerous potential side effects. These warnings—which were

[1] I may take judicial notice of drug labels and other documents "publicly available on the FDA's website." *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 588 F. App'x 171, 174 n.14 (3d Cir. 2014); *see also Demissie v. Starbucks Corporate Office & Headquarters*, 19 F. Supp. 3d 321, 324 (D.D.C. 2014) ("In ruling on a motion to dismiss, the Court may consider . . . documents attached to a motion to dismiss for which no party contests authenticity.").

approved by the FDA, and which remain publically available on the FDA's website in current and historic form—were amended in 1998, 2000, 2004, 2007, 2008, 2011, 2013, and 2014. *Id.*, Exs. 1–8 [Dkts. #22-3, #22-4, #22-5, #22-6, #22-7, #22-8, #22-9, #22-10]. Because the amended complaint does not allege when any individual plaintiff took Levaquin, or what the label said at that time, it is impossible to tell precisely which warnings were in place at any relevant period. Nevertheless, the amended complaint alleges that plaintiffs were not adequately warned and that the label should have included additional warnings. Am. Compl. ¶¶ 34–38.[2]

Up to this point, the allegations in the amended complaint sound similar to those brought in a spate of products liability cases involving Levaquin about a decade ago, which the Judicial Panel on Multi District Litigation centralized in the U.S. District Court for the District of Minnesota. *See In re Levaquin Prods. Liab. Litig.*, 560 F. Supp. 2d 1384 (J.P.M.L. 2008).[3] From there, however, the amended complaint turns melodramatic. According to plaintiffs, the reason the labels on Levaquin were inadequate when they took the drug is because the defendants, "each and every one of them," were engaged in a "racketeering enterprise and conspiracy to fraudulently cover up and/or fail to disclose the

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[2] As the J&J defendants point out and the labels show, Levaquin has included extensive warnings since at least 1998. Mem. of Law in Supp. of J&J Defs.' Mot. to Dismiss the Am. Compl. 2-4 ("J&J Mem.") [Dkt #22-1]; Decl. of Jonah M. Knobler ("Knobler Decl."), Ex. 2 (1998 Levaquin Label) [Dkt. #22-3]. Potentially relevant to some of the symptoms plaintiffs allege, the label has warned of peripheral neuropathy since 2004, and has included "black box" warnings—the "strongest" warnings FDA can provide, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 610 (2011)—for tendinitis and tendon rupture since 2008, and for muscle weakness since 2011. Knobler Decl., Exs. 4 (2004 Levaquin Label), 6 (2008 Levaquin Label), 7 (2011 Levaquin Label).

[3] Indeed, it appears that one of the plaintiffs in this case, John Fratti, voluntarily withdrew from the multi-district litigation. *See* Stip. of Voluntary Dismissal Without Prejudice, *Fratti v. Johnson & Johnson*, No. 0:09-cv-00812-JRT (D. Minn.), ECF No. 17.

true extent of the devastating, life-threatening, and deadly side effects of Levaquin." Am. Compl. ¶ 33. The amended complaint accuses a full cast of characters of participating in this scheme. The principle role goes to defendant Dr. Margaret Hamburg, Commissioner of the FDA from 2009 to 2015. Am. Compl. ¶ 26. She is supported by her husband, defendant Peter Brown, who, along with defendant Robert Mercer, is Co-Chief Executive Officer of defendant Renaissance Technologies, LLC, a hedge fund that owned stock in defendant Johnson & Johnson, manufacturer of Levaquin. Am. Compl. ¶¶ 25–26, 30, 42, 52. Defendant James Simons, another Renaissance executive, was also allegedly involved. Am. Compl. ¶ 49. According to the amended complaint, Dr. Hamburg, "upon knowledge and agreement of all Defendants," "willfully covered up" and "suppressed" information about Levaquin. Am. Compl. ¶¶ 34, 96, 164. The key document Dr. Hamburg is said to have covered up is an April 2013 report from FDA scientists identifying a potential link between fluoroquinolones (such as levofloxacin) and peripheral neuropathy caused by mitochondrial toxicity. Am. Compl. ¶¶ 34, 164. The alleged purpose of the cover up was to inflate the price of Johnson & Johnson stock and to obtain unspecified "gratuities and bribes" from the J&J defendants. Am. Compl. ¶¶ 96, 125. Amazingly, former presidents Barack Obama and Bill Clinton also make cameo appearances in plaintiffs' alleged scheme, together with former Secretary of State Hillary Clinton, and the Clinton Foundation; these actors are alleged to have solicited, or received, "gratuities" from defendants in exchange for securing Dr. Hamburg's appointment as FDA Commissioner. Am. Compl. ¶ 43–47.

Plaintiffs filed the instant action in January 2016. Their amended complaint alleges twenty-two counts. Counts One through Four allege that all defendants violated the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"). Am. Compl. ¶¶ 139–71. Count Five alleges that all defendants violated Arizona's version of the RICO statute. Am. Compl. ¶¶ 172–78. Counts Six through Fourteen allege that the J&J defendants are liable under various common law theories sounding in tort and contract, and that the J&J defendants and the Renaissance defendants unjustly enriched themselves through the sale of Levaquin. Am. Compl. ¶¶ 179–263. Count Fifteen alleges that the J&J defendants violated the Lanham Act. Am. Compl. ¶¶ 264–70. Counts Sixteen through Twenty-Two allege that the J&J defendants violated the consumer fraud statutes of the District of Columbia, New York, Maryland, Pennsylvania, Illinois, Arizona, and California. Am. Compl. ¶¶ 271–318.

On May 6, 2016, defendants each moved to dismiss the amended complaint. *See* J&J Defs.' Mot. to Dismiss the Am. Compl. [Dkt. #22]; Def. Dr. Margaret A. Hamburg's Mot. to Dismiss the Am. Compl. [Dkt. #23]; Mot. by the Renaissance Defs.' for Dismissal of the Am. Compl. [Dkt. #24]. I held a motions hearing on July 28, 2016, after the motions were fully briefed. On August 2, 2016, plaintiffs filed a notice clarifying and expanding some of their oral arguments. *See* Pls.' Supp. to Oral Arg. [Dkt. #45]. In addition, on July 13, 2016, plaintiffs' moved for leave to file a surreply, Pls.' Mot. for Leave to File Surreply [Dkt. #39], which I denied.

STANDARD OF REVIEW

Defendants move to dismiss the amended complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The Court assumes a plaintiff's factual assertions to be true and draws all reasonable inferences his favor. *See RSM Prod. Corp. v. Freshfields Bruckhaus Deringer U.S. LLP*, 682 F.3d 1043, 1046 (D.C. Cir. 2012). The court need not, however, "accept inferences drawn by plaintiff if those inferences are not supported by the facts set out in the complaint." *Hettinga v. United States*, 677 F.3d 471, 476 (D.C. Cir. 2012) (per curiam) (citing *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994)). Nor must the court "accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678.

Several counts in the amended complaint allege claims for fraud or misrepresentation. Federal Rule of Civil Procedure 9(b) requires claims for fraud or misrepresentation to be pled "with particularity." To survive a motion to dismiss under this heightened standard, "the pleader [must] state the time, place and content of the false misrepresentations, the fact misrepresented and what was retained or given up as a consequence of the fraud." *U.S. ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004) (quoting *Kowal*, 16 F.3d at 1278). The pleader must also

"identify individuals allegedly involved in the fraud." *Id.* (citing *U.S. ex rel. Joseph v. Cannon*, 642 F.2d 1373, 1385–86 (D.C. Cir. 1981)). These requirements "discourage the initiation of suits brought solely for their nuisance value and safeguard[] potential defendants from frivolous accusations of moral turpitude." *Id.* In addition, "because 'fraud' encompasses a wide variety of activities, the requirements of Rule 9(b) guarantee all defendants sufficient information to allow for preparation of a response." *Id.*

ANALYSIS

1. Federal RICO Claims

The centerpiece of the amended complaint is its four counts alleging that all defendants violated the federal Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961–1968, and seeking treble damages under the statute. Am. Compl. ¶¶ 139–71. RICO "created four new criminal offenses involving the activities of organized criminal groups in relation to an enterprise." *RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2096 (2016) (citing 18 U.S.C. §§ 1962(a)-(d)). "RICO also created a new civil cause of action for '[a]ny person injured in his business or property by reason of a violation' of those prohibitions." *Id.* (quoting 18 U.S.C. § 1964(c)). RICO's civil cause of action has been read as conferring "standing," *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985), and as such, states "a jurisdictional requirement" that must be established by adequate pleading, *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 255 (1994).

Defendants argue that plaintiffs' federal RICO claims are not cognizable because they are premised on harms flowing from injuries to plaintiffs' personal health. "The overwhelming weight of authority discussing the RICO standing issue holds that the

'business or property' language of Section 1964(c) does not encompass personal injuries," *Burnett v. Al Baraka Inv. & Dev. Corp.*, 274 F. Supp. 2d 86, 101 (D.D.C. 2003) (collecting cases from the Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, and Eleventh Circuits), and the Supreme Court, in construing identical statutory language in the Clayton Act—the statute "RICO's private right of action was modeled after," *RJR Nabisco*, 136 S. Ct. at 2109—has explained that "[t]he phrase 'business or property' . . . exclude[s] personal injuries suffered," *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979). Plaintiffs contend that their claims are not fairly characterized as seeking to redress personal injuries because their amended complaint alleges that their injuries resulted in "loss of earnings." Pls.' Mem. of Law in Support of Their Opp'n to the Renaissance Defs.' Mot. to Dismiss 23 (quoting Am. Compl. ¶ 156) ("Opp'n to Renaissance") [Dkt. #34]; *see also* Am. Compl. ¶¶ 81–85. But, as plaintiffs' counsel is well aware, courts in this District and elsewhere have consistently rejected the argument that pecuniary losses derivative of personal injuries are injuries to "business or property" cognizable under RICO. *See, e.g.*, *Klayman v. Obama*, 125 F. Supp. 3d 67, 88 (D.D.C. 2015) (holding harm to Mr. Klayman's law practice did not confer RICO standing); *Burnett*, 274 F. Supp. 2d at 102 (agreeing that "even pecuniary losses that are derivative of personal injuries are not 'business or property' injuries under RICO"); *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565–66 (6th Cir. 2013) (explaining "lost wages, rehabilitation services, and medical expenses" are "personal injuries [that] fail to confer relief under § 1964(c)"); *Pilkington v. United Airlines*, 112 F.3d 1532, 1536 (11th Cir. 1997) (finding "not cognizable under RICO" claim for "pecuniary losses resulting from personal injury"); *Bast v. Cohen, Dunn & Sinclair,*

PC, 59 F.3d 492, 495 (4th Cir. 1995) ("[P]ersonal injury and pecuniary losses occurring therefrom are not sufficient to meet the statutory requirement of injury to 'business or property.'"). I find these decisions persuasive, and hold, consistent with the weight of authority, that plaintiffs have failed to plead injuries cognizable under RICO.[4]

Before moving on, I will address plaintiffs' argument that they have RICO standing under our Circuit's tobacco litigation precedents. Opp'n to Renaissance 1–2, 19–23. Specifically, plaintiffs contend that I must allow their case to go forward because the personal health injuries they allege are similar to the personal health injuries alleged in *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part, vacated in part,* 566 F.3d 1095 (D.C. Cir. 2009). Whatever similarities may exist between this case and that one, plaintiffs ignore a critical distinction. *Philip Morris* was brought by the U.S. Department of Justice under a separate statutory provision, 18 U.S.C. § 1964(b), which, unlike the private right of action created by 18 U.S.C. § 1964(c), does not require a showing of injury to business or property. *Compare Philip Morris*, 566 F.3d at 1145 (explaining "Section 1964(b) authorizes the Attorney General to institute proceedings . . . for equitable remedies" (internal quotations and citation omitted)) *with Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1076 (D.C. Cir. 2001) (acknowledging, in dictum, that "individual smokers" could "perhaps" bring civil

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[4] Plaintiffs urge me to reject the majority position in favor of the more expansive view of "business or property" taken by the Ninth Circuit in *Diaz v. Gates*, 420 F.3d 897 (9th Cir. 2005) (en banc) (per curiam). I reject this invitation. *Diaz* has received significant judicial criticism, *see id.* at 907 (Gould, J., dissenting); *Evans v. City of Chicago,* 434 F.3d 916, 931 n. 26 (7th Cir. 2006), *overruled on other grounds by Hill v. Tangherlini*, 724 F.3d 965 (7th Cir. 2013); *Bougopoulos v. Altria Grp., Inc.*, 954 F. Supp. 2d 54, 66 (D.N.H. 2013), and I find its reasoning unpersuasive.

RICO claims under § 1964(c) "to the extent they can prove a measure of damages distinct from personal injuries"). Indeed, the remedies provided by § 1964(b) and § 1964(c) are so distinct that "the United States government does not have standing to sue for damages to its business or property" under § 1964(b). *United States v. Bonanno Organized Crime Family of La Cosa Nostra*, 683 F. Supp. 1411, 1456 (E.D.N.Y. 1988), *aff'd*, 879 F.2d 20 (2d Cir. 1989). *Philip Morris* is simply not relevant to determining whether plaintiffs have adequately pled injuries to their business or property as required by the statute.

Even if plaintiffs' personal injuries were cognizable under RICO, I would have to dismiss their claims because plaintiffs have not plausibly alleged that they were injured "by reason of" a RICO violation. 18 U.S.C. § 1964(c). In addition to requiring a plaintiff to plead an injury to his business or property, RICO's cause of action requires a plaintiff to plead that this injury was proximately caused by the defendant's RICO violation. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1386–87 (2014) (citing *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265–68 (1992)); *id.* at 1391 n.6 (citing *Iqbal*, 556 U.S. at 678–79). Here, the lynchpin of plaintiffs' RICO theory is that Dr. Hamburg "willfully covered up" the FDA's April 2013 report linking Levaquin to mitochondrial toxicity as part of defendants' alleged conspiracy to inflate J&J's stock price. Am. Compl. ¶ 34; *see also* Tr. of Mot. Hr'g 40–41 [Dkt. #46]; Pls.' Supp. to Oral Arg. 2–3. According to plaintiffs, the "causal chain" linking the alleged cover up to their injuries "is extremely direct and simple. Defendants engaged in a conspiracy to willfully suppress the deadly effects of Levaquin to Plaintiffs, physicians, and the public at large, and as a direct result, Plaintiffs consumed Levaquin and were seriously injured." Pls.' Mem. of

Law in Opp'n to J&J Defs.' Mot. to Dismiss 15 ("Opp'n to J&J") [Dkt. #32]. But there is a major kink in this chain. The amended complaint states that David Melvin, the last of the five plaintiffs to be injured by Levaquin, "became unable to work on or around 2012." Am. Compl. ¶ 81. That is the year *prior* to the alleged suppression of the FDA report. Barring some sort of temporal paradox, *see* H.G. Wells, *The Time Machine* 22–23 (1895), there is no way that suppression of an FDA report in 2013 could have caused plaintiffs to be injured in 2012 or earlier. Because plaintiffs' "allegations, taken as true, are insufficient to establish proximate causation," their federal RICO counts "must be dismissed." *Lexmark*, 134 S. Ct. at 1391 n.6.[5]

2. Arizona RICO Claims

Plaintiffs also allege violations by all defendants of Arizona's civil racketeering statute, Ariz. Rev. Stat. § 13-2314.04. Am. Compl. ¶¶ 172–78. "Arizona's RICO act is patterned after the federal RICO act." *Rosier v. First Fin. Capital Corp.*, 889 P.2d 11, 13–14 (Ariz. Ct. App. 1994). "[T]o state a cause of action for civil damages under [Arizona's] RICO, the plaintiff's damages must be proximately caused by the defendant's violation of a predicate RICO act." *Id.* at 15; *see also First United Funding, LLC v. Four Corners Dev., LLC*, No. 1 CA-CV 15-0377, 2016 WL 6080599, at *4 (Ariz. Ct. App. Oct. 18, 2016) (unpublished) (affirming dismissal). As discussed above, plaintiffs have failed to plead

[5] In light of my conclusion that plaintiffs have not adequately pled standing or causation as required by § 1964(c), it is unnecessary for me to reach defendants' arguments that plaintiffs have not pled facts sufficient to allege substantive violations of §§ 1962(a)-(d). *See* Mem. of Law in Supp. of the Renaissance Defs.' Mot. to Dismiss the Am. Compl. 19–37 ("Renaissance Mem.") [Dkt. #24-7]; J&J Mem. 16–20. For the same reason, I need not reach Dr. Hamburg's argument that she is protected from suit by the doctrine of qualified immunity. *See* Mem. of Law in Supp. of Dr. Margaret A. Hamburg's Mot. to Dismiss the Am. Compl. 15–24 [Dkt. #23-1].

facts that make possible—let alone plausible—the conclusion that the alleged cover up by defendants was the proximate cause of plaintiffs' injuries. Thus, assuming *arguendo* that plaintiffs as a group have a sufficient connection with Arizona to invoke her RICO statute—an issue defendants contest—their claims fail for the same reason as under the federal statute.

3. Lanham Act Claims

Plaintiffs allege that the J&J defendants violated the Lanham Act, 15 U.S.C. § 1125(a), by making "false and/or misleading statements" concerning Levaquin that "deceived and/or had the capacity to deceive consumers." Am. Compl. ¶ 267. The Supreme Court has held that "to come within the zone of interests in a suit for false advertising under § 1125(a), a plaintiff must allege an injury to a *commercial interest* in reputation or sales." *Lexmark*, 134 S. Ct. at 1390 (emphasis added). Consumer claims are therefore not cognizable. "A consumer who is hoodwinked into purchasing a disappointing product may well have an injury-in-fact cognizable under Article III, but he cannot invoke the protection of the Lanham Act[.]" *Id.* In light of this clear and binding authority, I decline plaintiffs' invitation to engage in a wholesale reconstruction of the statute, *see* Opp'n to J&J 34, and will dismiss their Lanham Act claim.

4. Common Law Claims

Plaintiffs, who reside in Maryland, Pennsylvania, Arizona, Illinois, and California, assert nine common law claims sounding in tort and contract law against Johnson & Johnson, a citizen of New Jersey. One of these claims, for unjust enrichment, is also asserted against Renaissance, a company organized under the laws of Delaware and with

its principle place of business in New York. Although plaintiffs did not bring these claims under the law of any particular jurisdiction, they now contend that the common law of the District of Columbia applies, or in the alternative, the common law of the States where each individual plaintiff resides. Opp'n to J&J 16–17. Defendants are willing to concede, for purpose of analysis, that District of Columbia law applies. J&J Mem. 23; Renaissance Mem. 40 n.9.[6] In light of the parties' stance, and given the paucity of factual allegations in the amended complaint that would be necessary to a proper choice of law analysis, I will apply D.C. law to plaintiffs' common law claims in deciding the motions to dismiss. *See In re APA Assessment Fee Litig.*, 766 F.3d 39, 45–46 (D.C. Cir. 2014).

a. Products Liability

Three counts in the amended complaint allege that Levaquin was "defective" and assert that the J&J defendants are strictly liable and liable for negligence. Am. Compl. ¶¶ 186–202, 255–63. In the District of Columbia, a product may be found defective "if it has one of three shortcomings: (1) a manufacturing defect; (2) an absence of sufficient warnings or instructions; or (3) an unsafe design." *Warner Fruehauf Trailer Co. v. Boston*, 654 A.2d 1272, 1274 (D.C. 1995); *accord* Restatement (Third) of Torts: Products Liability § 2 (1998) ("A product is defective when, at the time of sale or distribution, it contains a

[6] The J&J defendants suggest, but appear unwilling to commit to, the position that under a choice of law analysis New Jersey law would govern the claims brought against them. *See* J&J Mem. 24 ("Assuming *arguendo*, that New Jersey law governs . . . ."). Under New Jersey law, nearly all of plaintiffs' common law claims would presumably be subsumed by the New Jersey Products Liability Act, which "encompass[es] virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litig.*, 924 A.2d 484, 503 (N.J. 2007). I will not decide whether New Jersey law applies, however, because the J&J defendants "do not ask." *Fisher v. Univ. of Texas at Austin*, 133 S. Ct. 2411, 2419 (2013); *see id.* at 2422 (Scalia, J., concurring).

manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings."). The amended complaint fails to state a plausible claim under any recognized products liability theory.

To begin with, the allegations of manufacturing defect in the amended complaint are nothing more than conclusory statements. Plaintiffs insert some form of the word "manufacture" into numerous lists throughout the amended complaint which purport to describe the actions of the J&J defendants, including, among other things, that the J&J defendants "manufacture," "manufactured," or are the "manufacturer" of, Levaquin. *E.g.*, Am. Compl. ¶¶ 12, 17, 22, 30, 123, 187–88, 195, 204, 256–57. But for all these recitals of the term "manufacture" and its derivatives, plaintiffs plead no facts "that would appear to relate to manufacturing *defects* in the [Levaquin] doses taken by [plaintiffs]." *Rollins v. Wackenhut Servs.*, 802 F. Supp. 2d 111, 122 (D.D.C. 2011) (emphasis added) (dismissing claim against drug manufacturer under D.C. law), *aff'd*, 703 F.3d 122 (D.C. Cir. 2012). Plaintiffs never allege, for example, that the doses of Levaquin they took deviated from other doses manufactured by J&J, or from their FDA-approved design. The pleading is thus plainly inadequate to support a claim for manufacturing defect.

I must also reject as inadequately pled plaintiffs' allegations that the J&J defendants failed to warn sufficiently of "the hidden, dangerous risk posed by Levaquin." Am. Compl. ¶¶ 196, 197. To state a failure to warn claim with plausibility, the plaintiff must plead facts "affording a reasonable basis for the belief that appellants' failure to provide adequate warnings was a substantial factor in bringing about the harm at issue." *E. Penn Mfg. Co. v. Pineda*, 578 A.2d 1113, 1124 (D.C. 1990) (emphasis deleted); *accord* Restatement

(Third) of Torts: Product Liability § 15, cmt. a (1998) (restating "[r]equirement of causal connection between defect and harm"). The amended complaint here does not allege any facts that, when taken as true, support a plausible inference that Levaquin's warning labels were a substantial factor in causing plaintiffs' injuries. *See Iqbal*, 556 U.S. at 678. "Nowhere," for example, "does the complaint recite the contents of the warning label . . . at the time of the administration of the drug" or explain "how the contents of the label were inadequate." *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 609 & n.13 (11th Cir. 2008) (affirming dismissal of failure to warn claim). Nor does it plead "facts about the timing of [each plaintiff's] use of [Levaquin], the onset of [their injuries], or how the alleged distinctions in the warnings would have had a causal effect." *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 752 (W.D. Pa. 2011) (dismissing failure to warn claim); *see also Rollins*, 802 F. Supp. 2d at 123–24 & n.8. Indeed, the amended complaint is entirely vague as to when each individual plaintiff was prescribed Levaquin, what injuries each individual plaintiff experienced, and why they think Levaquin was the cause of these injuries—let alone why they think inadequate *warnings* contributed to their injuries. To be sure, as plaintiffs point out, the amended complaint *does* assert that if the J&J defendants had "used an alternative warning which fully disclosed the hidden deadly risks posed by Levaquin, Plaintiffs would not have ingested Levaquin and Plaintiffs[']] physicians, on information and belief, would not have prescribed Levaquin to Plaintiffs." *See* Opp'n to J&J 21 nn.29–30 (citing Am. Compl. ¶ 197); *see also* Am. Compl. ¶¶ 91–92, 198. But without factual allegations supporting this claim, it is nothing more than "a legal conclusion couched as a

factual allegation." *Iqbal*, 556 U.S. at 678. As such, it is insufficient to state a claim for product defect based upon failure to warn.

Nor can plaintiffs state a claim for design defect. In *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2479 (2013), the Supreme Court held "that state-law design-defect claims . . . that place a duty on [pharmaceutical] manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling" and are therefore preempted. The amended complaint expressly pleads that the J&J defendants should have used "other designs." Am. Compl. ¶¶ 199, 260. Nevertheless, plaintiffs contend that *Mutual Pharmaceutical* does not control because its conflict preemption reasoning applies only to "generic drugs and not 'brand name' drugs" like Levaquin. Opp'n to J&J 19. Plaintiffs are mistaken. *Mutual Pharmaceutical* expressly found that "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to [its formulation]" by federal law. 133 S. Ct. at 2471. Thus, even though *Mutual Pharmaceutical* arose from a state-law design-defect claim against a manufacturer of a generic drug, its holding applies to both types of drugs, and plaintiffs' design-defect claim must be dismissed.[7]

[7] This result is not, as plaintiffs claim, "bizarre" or "nonsensical." Opp'n to J&J 19–20. It is in fact fully consistent with the well-established tort law principle, "especially common in the field of drugs," that an unavoidably unsafe product is "not defective, nor is it unreasonably dangerous" where it is "properly prepared, and accompanied by proper directions and warning." Restatement (Second) of Torts § 402A, cmt. k (1965); *see also Rollins* 703 F.3d at 130 n.2.

b. Fraud and Misrepresentation

Plaintiffs also assert three common law fraud and misrepresentation theories. Am. Compl. ¶¶ 203–20, 234–54. As noted at the outset, Federal Rule of Civil Procedure 9(b) requires such claims to "state the time, place and content of the false misrepresentations" and to "identify individuals allegedly involved in the fraud." *Martin-Baker*, 389 F.3d at 1256. The amended complaint fails to comply with these requirements.

To begin with, plaintiffs fail to state with particularity the "time" of the alleged fraud. *Id.* The amended complaint states that defendants have "made misrepresentations" about Levaquin's safety "[s]ince at least 1996." Am. Compl. ¶ 236; *see also* Opp'n to J&J 24 (relying on this allegation). However, that allegation spans the more than twenty-year period that Levaquin has been on the market, and therefore is insufficient "to allow for preparation of a response" by defendants. *Martin-Baker*, 389 F.3d at 1256; *accord U.S. ex rel. Gage v. Davis S.R. Aviation, L.L.C.*, 623 F. App'x 622, 627 (5th Cir. 2015) (finding allegations that defendant engaged in fraudulent activity "between 2009 and 2011 . . . not specific enough to comply with Rule 9(b)"). Nor does the amended complaint adequately allege the "place" of the fraud. *Martin-Baker*, 389 F.3d at 1256. Plaintiffs have not alleged, for example, "whether each individual Plaintiffs [encountered the misrepresentations] and purchased [Levaquin] in their state of residence." *Mouzon v. Radiancy, Inc.*, 85 F. Supp. 3d 361, 381 (D.D.C. 2015) (dismissing action).

"The complaint also fails to identify with specificity who precisely was involved in the fraudulent activity." *Martin-Baker*, 389 F.3d at 1257. Plaintiffs' allegations of common law fraud and misrepresentation are directed at three corporate entities—Johnson

& Johnson, Johnson & Johnson Pharmaceutical Research & Development, and Ortho-McNeil-Janssen Pharmaceuticals. Am. Compl. ¶¶ 203, 234, 247. Not only do plaintiffs fail to "identify individuals" associated with these companies, *Martin-Baker*, 389 F.3d at 1257, they do not even specify which corporate entity they believe was responsible, *cf. Anderson v. USAA Cas. Ins. Co.*, 221 F.R.D. 250, 255 (D.D.C. 2004) (dismissing negligent misrepresentation claim for "advancing nothing more than what appears to be a blanket belief that the defendants as a group 'misrepresented or withheld material and significant facts'"). In sum, plaintiffs fall woefully short of pleading any specific allegations that would support a claim of fraud or misrepresentation.

c. Breach of Express or Implied Warranties

Plaintiffs also assert claims against the J&J defendants for breach of express and implied warranties. Am. Compl. ¶¶ 221–33. Plaintiffs' claim for breach of express warranty must be dismissed because "Plaintiff[s] ha[ve] not adequately pleaded any express promises made by Defendant[s]" as required by D.C. law. *Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 465 (D.D.C. 1997) (dismissing claim). To be sure, the amended complaint asserts that "Defendants expressly warranted that Levaquin was safe" and that "Plaintiffs either directly or indirectly through Plaintiffs' prescribing physicians did in fact see and hear these representations and justifiably relied on these representations." Am. Compl. ¶¶ 222–23. But these allegations are insufficient without more factual content supporting them. Courts in other jurisdictions have found that to state a claim for breach of express warranty in cases involving prescription drugs, "Plaintiff[s] must allege facts demonstrating that Defendants' affirmations formed the basis of the

bargain, i.e., facts regarding how the warranties were made to Plaintiff's physician, and that Plaintiff's specific physician relied on them." *Hammarlund v. C.R. Bard, Inc.*, No. 215CV05506SVWJEM, 2015 WL 5826780, at *5 (C.D. Cal. Oct. 2, 2015); *see also Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 1001 (D. Ariz. 2013) (similar). I find these decisions persuasive, and plaintiffs' failure to move beyond labels and conclusions by providing specific allegations is fatal to their express warranty claim.

As for plaintiffs' breach of implied warranty claim, little analysis is necessary. Defendants argue that this claim is duplicative, and in any event, cannot be independently maintained in a case involving prescription drugs. J&J Mem. 33–34. Plaintiffs do not contest these arguments, and therefore have conceded them. *See Buggs v. Powell*, 293 F. Supp. 2d 135, 141 (D.D.C. 2003) (arguments not addressed in an opposition may be treated as conceded) (citing *FDIC v. Bender*, 127 F.3d 58, 67–68 (D.C. Cir. 1997)).

d. Unjust Enrichment

Rounding out their common law claims, plaintiffs allege that the J&J defendants and the Renaissance defendants have unjustly enriched themselves through the sale of Levaquin. Am. Compl. ¶¶ 179–85. All parties agree that "[u]njust enrichment occurs when: (1) the plaintiff conferred a benefit on the defendant; (2) the defendant retains the benefit; and (3) under the circumstances, the defendant's retention of the benefit is unjust." *Bregman v. Perles*, 747 F.3d 873, 876 (D.C. Cir. 2014); *see* Renaissance Mem. 39–40; Opp'n to Renaissance 39; J&J Mem. 36; Opp'n to J&J 26. Both sets of defendants contend, for different reasons, that this claim should be dismissed because the amended complaint

does not, in their view, allege enough facts for me to draw the reasonable inference that any benefit was conferred on them by plaintiffs.[8]

The Renaissance defendants have the easier argument to make in this regard. According to plaintiffs, the Renaissance defendants received a benefit because, as minority stockholders in publically traded Johnson & Johnson, they must have "earned profits" from the sale of Levaquin to plaintiffs. Opp'n to Renaissance 39. However, any such earnings are far too remote and speculative to support an unjust enrichment claim. *Cf. Prime Mover Capital Partners L.P. v. Elixir Gaming Techs., Inc.*, 898 F. Supp. 2d 673, 697 (S.D.N.Y. 2012) (dismissing claim because the "indirect benefit from [plaintiffs'] stock purchases" was "insufficient to sustain an unjust enrichment claim"), *aff'd*, 548 F. App'x 16 (2d Cir. 2013). As such, I have no trouble dismissing this count against the Renaissance defendants.

Plaintiffs' theory is less attenuated in regard to the J&J defendants; obviously, the manufacturer of a product obtains some benefit when its product is sold or resold to consumers. It remains a bridge too far, however, because plaintiffs have not pled that *they* conferred a benefit on the J&J defendants. As the J&J defendants correctly point out, the amended complaint does not allege "that Plaintiffs paid any money for Levaquin, rather than relying on an insurer, as most patients do." J&J Mem. 36. This omission is significant because there is "no authority demonstrating that benefits received from third-parties can

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[8] In addition, the J&J defendants assert that I should dismiss plaintiffs' claim because plaintiffs have pled various other legal theories and unjust enrichment is a common law equitable claim available only where there is no adequate remedy at law. J&J Mem. 35. This argument misapprehends Rule 8, which expressly permits pleading in the alternative. Fed. R. Civ. P. 8(d)(2); *see also* 1-2 James Wm. Moore et al., *Moore's Federal Practice* § 2.03 (Matthew Bender 3d ed.) ("It is not generally a ground for dismissal of a complaint asserting equitable claims that the plaintiff has an adequate remedy at law.").

be the proper subject of an unjust enrichment claim." *Council on Am.-Islamic Relations Action Network, Inc. v. Gaubatz*, 82 F. Supp. 3d 344, 358–59 (D.D.C. 2015) (granting summary judgment for defendant where "Plaintiffs have identified only benefits that Defendants have received from third parties"); *see also Sabre Int'l Sec. v. Torres Advanced Enter. Sols., LLC*, 60 F. Supp. 3d 36, 41–42 (D.D.C. 2014) (dismissing claim where plaintiff failed to allege that "it conferred any benefit on the Individual Defendants directly"); *Snyder v. Farnam Companies, Inc.*, 792 F. Supp. 2d 712, 724 (D.N.J. 2011) ("When consumers purchase a product from a third party, they confer a benefit on that third party, not on the manufacturer."). Plaintiffs' only response when confronted with this pleading defect is to argue that I should blind myself to the common sense reality of how prescription drugs are ordinarily purchased at risk of "improperly insert[ing] facts and presumptions contrary to the standard set forth in *Iqbal*." Opp'n to J&J 27. Plaintiffs are mistaken. *Iqbal* teaches that "[d]etermining whether a complaint states a plausible claim for relief" is "a context-specific task that requires the reviewing court to draw on its *judicial experience and common sense*." 556 U.S. at 679 (emphasis added). Where, as here, "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting Fed. Rule Civ. Proc. 8(a)(2)). Because plaintiffs have not pleaded any facts showing that they paid for Levaquin, I must dismiss their unjust enrichment claim against the J&J defendants.

4. State Consumer Fraud Claims

The amended complaint also asserts seven state law consumer fraud claims against the J&J defendants under the statutes of D.C., New York, Maryland, Pennsylvania, Illinois, Arizona, and California. Am. Compl. ¶¶ 271–318. Each count fails to state a claim.

First, courts construing the consumer fraud statutes of six of these seven jurisdictions have held that the statutes do not apply to the types of claims plaintiffs assert here. These courts have held either that the statutes do not apply to personal injury claims, *see Arndt v. Johnson & Johnson*, 67 F. Supp. 3d 673, 682 (E.D. Pa. 2014) ("[P]ersonal injury claims are not permitted under the Pennsylvania statute[.]"); *Harshbarger v. Philip Morris, Inc.*, No. 02-05267, 2003 WL 23342396, at *6 (N.D. Cal. Apr. 1, 2003) ("Personal injuries . . . are not compensable under [the California B & P Code]."), or more commonly, that they do not apply to claims involving prescription drugs, *see Pease v. Abbott Labs., Inc.*, No. CIV. 12-1844, 2013 WL 174478, at *2 (D. Md. Jan. 16, 2013) ("[P]rescription drugs are not 'consumer goods' under the [Maryland Consumer Protection Act]."); *Kester v. Zimmer Holdings, Inc.*, No. 210-CV-00523, 2010 WL 2696467, at *14 (W.D. Pa. June 16, 2010) ("[A] plaintiff does not have a viable [Pennsylvania Unfair Trade Practices and Consumer Protection Law] cause of action against a manufacturer of prescription drugs."); *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014) ("[A]ny alleged deceptive act related to the issuance of those [drug] warnings is not a 'consumer oriented' act actionable under Section 349 of the New York General Business Law."); *Barkley v. D.C. Water & Sewer Auth.*, 2013 CA 003811 B, 2016 D.C. Super. LEXIS 1, at *30 (D.C. Super. Ct. 2016) (recognizing the D.C. Consumer Protection Procedures Act does "not

grant individuals a private right to sue for 'damages for personal injury of a tortious nature'"); *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001) (holding Illinois Consumer Fraud Act exempts "highly regulated" pharmaceutical companies from liability). Arizona is the lone exception. *See Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 953 (Ariz. 2016) ("[T]he [Arizona Consumer Fraud Act] applies to prescription pharmaceuticals.").[9]

Second, plaintiffs have not adequately pled their claims under the consumer fraud statutes of any of these States, including Arizona's. As discussed above, claims based on fraud must be pled "with particularity." Fed. R. Civ. P. 9(b); *see also Mouzon*, 85 F. Supp. 3d at 378–79 (applying Rule 9(b) to consumer fraud claims brought under California, D.C., Illinois, Maryland, and Pennsylvania statutes). Plaintiffs contend that they have satisfied this heightened pleading standard in regard to their statutory claims because the amended complaint alleges that "Defendants made false and/or misleading statements of fact in commercial advertisements, productions, and reports about Levaquin," and that "Defendants advertised and represented Levaquin without providing warning of the risks and dangers of ingesting Levaquin." Opp'n to J&J 29–30 (quoting Am. Compl. ¶¶ 272, 277, 278). But these conclusory statements are not enough for me to avoid finding that

[9] In addition, plaintiffs' claims under the D.C. and New York statutes must be dismissed because neither statute applies extraterritorially and the amended complaint does not allege that any of the plaintiffs reside in, were prescribed Levaquin in, consumed Levaquin in, or suffered injury in, either jurisdiction. *See Shaw v. Marriott Int'l, Inc.*, 605 F.3d 1039, 1045 (D.C. Cir. 2010) (holding plaintiff "cannot state a claim under the [D.C. Consumer Protection Procedures Act]" where he "is not a citizen of the District" and the defendant "is [not] a business entity located in the District"); *Goshen v. Mut. Life Ins. Co. of N.Y.*, 774 N.E.2d 1190 (N.Y. 2002) ("[T]o qualify as a prohibited act under [General Business Law § 349], the deception of a consumer must occur in New York.").

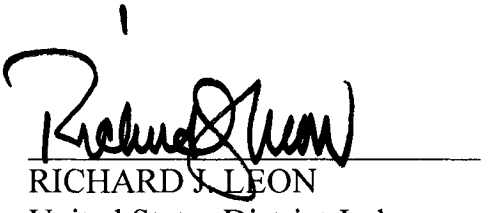
"Plaintiffs have not alleged the basic circumstances under which they were exposed to the [misrepresentations] and purchased [Levaquin], which the Court would expect the individual Plaintiffs to recall." *Mouzon*, 85 F. Supp. 3d at 381. As I stated above in regard to plaintiffs' common law fraud claims, the "missing basic facts include whether each individual Plaintiff [encountered the misrepresentations] and purchased [Levaquin] in their state of residence." *Id.* In addition, because plaintiffs suggest in each statutory count that they relied upon their doctors' decisions to prescribe Levaquin, Am. Compl. ¶¶ 273–74, 279–80, 285–86, 292–93, 299–300, 306–017, 316–17, the circumstances of those prescription decisions, and plaintiffs' reliance on them, are particularly important—yet plaintiffs allege no information about them. "[T]he absence of detail about Plaintiffs experiences leads to the conclusion that Plaintiffs have not pleaded these claims with the requisite particularity." *Mouzon*, 85 F. Supp. 3d at 381; *see also Jefferson v. Collins*, 905 F. Supp. 2d 269, 290 (D.D.C. 2012) (dismissing claim where "the amended complaint offers no details concerning when and where this [fraudulent] statement was made, who made it, and what the plaintiffs gave up or retained as a consequence of it").

CONCLUSION

The medical symptoms and conditions experienced by plaintiffs Terry Aston, John Fratti, Linda Martin, David Melvin, and Jennifer Wilcox are "tragic and evoke[] deep sympathy." *Mutual Pharm.*, 133 S. Ct. at 2480. Nevertheless, the decision to let their case go forward or to dismiss it at the pleading stage "ultimately depends not on [their] condition, but on [their] complaint." *McElroy v. Amylin Pharm., Inc.*, 573 F. App'x 545, 546 (6th Cir. 2014). Because the amended complaint "pleads facts that are merely

consistent with defendant[s'] liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Iqbal,* 556 U.S. at 678 (quotation marks omitted). Accordingly, the Court will GRANT the motions and DISMISS the amended complaint.

An Order consistent with this decision accompanies this Memorandum Opinion.



RICHARD J. LEON
United States District Judge