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

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION,	)	Master Docket: Misc. No. 21-1230
	)	MDL No. 3014
This Document Relates to:	)	
Amended Master Long Form Complaint for Personal Injuries and Damages, and Demand for Jury Trial (ECF No. 834)	)	

PLAINTIFFS' BRIEF IN OPPOSITION TO PHILIPS RS NORTH AMERICA LLC'S MOTION TO DISMISS PLAINTIFFS' AMENDED MASTER LONG FORM COMPLAINT FOR PERSONAL INJURIES AND DAMAGES FOR FAILURE TO STATE A CLAIM PURSUANT TO FED. R. CIV. P. 12(b)(6)

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I. INTRODUCTION

The primary purpose of multidistrict litigation ("MDL") is the promotion of "efficiency through the coordination of discovery." *In re Nuvaring Prods. Liab. Litig.*, 2009 WL 4825170, at *1 (E.D. Mo. Dec. 11, 2009) (citations omitted); 28 U.S.C. §1407(a). For that reason, courts readily acknowledge that case-specific rulings in an MDL "are neither the purpose, nor the forte, of a court presiding over a multidistrict litigation." *In re Skechers Toning Shoe Prod. Liab. Litig.*, 2014 WL 527703, at *1 (W.D. Ky. Feb. 7, 2014) (citations omitted). In this MDL, Philips[1] agreed to the establishment of procedures for the filing of a Master Complaint for Personal Injuries and Damages ("Master Complaint") and individual Short Form Personal Injury Complaints ("Short Form Complaints"),[2] which *together* are deemed the operative complaint for each Plaintiff alleging personal injuries resulting from the use of Philips' recalled devices. PTO 28 at §II.B.3.

Having consented to a specific process for pleading personal injury claims and having benefitted from that process, Philips baselessly challenges the Master Complaint for serving its purpose, and, in doing so, ignores the substance of the Short Form Complaints, the contents of which were agreed upon by the Parties. *See* PTO 28 at §II.B.2.a-m; ECF 834-1 (template for Short Form Complaint). Many of Philips' case-specific arguments are antithetical to the purpose of a Master Complaint and inappropriate for its dismissal. *See* PTO 28 at §II.C.4 (discussing motions to dismiss at bellwether stage); *Skechers*, 2014 WL 527703, at *1 (refraining from ruling on merits of motion to dismiss because an MDL court "typically does not rule on case-specific legal issues").

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[1] "Philips" refers to Defendants Philips RS North America LLC ("Philips RS"), Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., and Philips RS North America Holding Corporation. "Motion" is Philips RS's Motion to Dismiss for Failure to State a Claim (ECF 1345) and "Br." is its Mem. of Law in Support of the Motion (ECF 1346).

[2] *See generally* Pretrial Order #28 (ECF 783) ("PTO 28"), which was amended to include a process for resolving issues related to individual Plaintiffs' failure to timely file a Short Form Complaint. Amended Pretrial Order #28(a) (ECF 1594).

Philips designs, manufactures, markets, and sells CPAP, BiPAP, and ventilator devices intended to help patients with conditions such as sleep apnea or respiratory failure breathe better. ¶¶ 2, 73-81.[3] Philips sold 11.3 million of these devices in the U.S. from 2008 until they were recalled on June 14, 2021 because they contained polyester polyurethane ("PE-PUR") foam that is "susceptible to breaking down into particles which may then be inhaled or ingested by the user, and may emit VOCs that can also be inhaled, resulting in 'serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.'"[4] ¶¶ 3-6; *see also* ¶ 192 (FDA determination that the Devices posed an "unreasonable risk of substantial harm to the public health" and "were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture"). Despite knowing that the Devices were defective, Philips continued for many years to sell them to unsuspecting users, putting these individuals at great risk of suffering adverse health effects. Plaintiffs here are precisely those users whose Devices contained foam that degraded and off-gassed, releasing particles and causing Plaintiffs to sustain injuries.

Philips distorts the basis for Plaintiffs' claims by suggesting that Plaintiffs rely solely on Philips' voluntary recall of the Devices. Br. at 1. The fact that Philips recalled these Devices (many years *after* Philips knew they were defective) does not absolve Philips from liability. Its simplistic view ignores, among other things, that (i) Philips knew for years of the defect and the associated health consequences, ¶¶ 6-8, 10-12; (ii) users had no way of knowing themselves that foam in their Devices had degraded or off-gassed toxins, ¶ 144; (iii) Philips concealed the defect, ¶¶ 10-12; (iv) the toxins that resulted from the off-gassing caused by the defect were known to cause serious

[3] Paragraph citations ("¶") refer to the Amended Master Long Form Complaint for Personal Injuries and Damages, and Demand for Jury Trial (ECF 834).
[4] The devices are referred to as "Recalled Devices" or "Devices."

health effects, ¶¶ 132-65; and (v) Plaintiffs' use of the Devices caused them to suffer serious health effects, ¶¶ 21-24. Indeed, Plaintiffs were duped by Philips' representations regarding the products' quality, such as statements that the Devices were "clinically proven" "quality systems" that would help users to "[b]reathe easier, sleep more naturally," ¶¶ 128, 235, and by Philips' failure to disclose a material health and safety defect in the Devices, ¶¶ 10-12. Plaintiffs thought they were using a safe machine that would help treat their breathing issues, but instead were provided a Device that caused them serious harm. ¶¶ 22, 24. If Plaintiffs had known of the defect, they would not have used the Devices. ¶¶ 19, 380, 407, 493-94, 518, 547, 576, 630.

Accepting the allegations as true and considering all reasonable inferences in Plaintiffs' favor, Plaintiffs' claims are properly pled, and the Motion should be denied.

II. BRIEF SUMMARY OF ALLEGATIONS IN THE COMPLAINT

Philips used PE-PUR foam in the Devices even though it was widely known that this foam is susceptible to hydrolysis.[5] ¶¶ 91-94. Philips brought the Devices to market through the 510(k) clearance process,[6] which is less stringent than Pre-Market Approval ("PMA"). ¶¶ 116-20, 596-97. Having placed the Devices on the market, Philips had duties under federal and state law, including to investigate complaints and injuries and report adverse events. ¶¶ 122-24.

Philips sold the Devices as "clinically proven" treatments for sleep disorders, but they put users at risk of serious and debilitation injury. ¶¶ 128, 235. The Devices failed to comply with "current good manufacturing practice" requirements ("GMPs") and other obligations imposed by FDA regulations. ¶¶ 125-27. The foam in the Devices degrades and exposes patients to toxins, ¶¶ 6, 8, 135-48, some of which are known or suspected carcinogens. ¶¶ 149-65.

Beginning in 2008, Philips received hundreds of thousands of complaints of foam

[5] Poly***ether*** polyurethane foam, which is less prone to hydrolysis, was an alternative. ¶ 95.
[6] The E30 ventilator was marketed under an Emergency Use Authorization ("EUA"). ¶¶ 118-19.

degradation in the Devices and years later, received data confirming the defect. ¶¶ 7, 11, 168, 171-72. Instead of acting lawfully, Philips turned a blind eye to the problem and actively concealed it. ¶¶ 166-94, 204-06.

At no point before April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint there was a dangerous condition in its Devices. ¶ 235. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets," *id.*, promising consumers they will "[b]reathe easier, sleep more naturally." *Id.* Philips delayed recalling the Devices in order to first launch the DreamStation 2, which does not contain PE-PUR foam. ¶¶ 248-49. When it finally did issue a recall, on June 14, 2021, Philips advised CPAP and BiPAP users to "[d]iscontinue use of [their] device" and told ventilators users to discuss continued use with their physicians in light of the risks identified by Philips. ¶¶ 257-58. This confirmed the dangerous nature of the recalled products. ¶ 259. On July 22, 2021, the FDA upgraded the recall to Class I: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." *Id.* The recall did not effectively provide patients with notice of the risks, nor did it provide them with new devices. ¶¶ 285-90.

Plaintiffs are individuals who used the Devices and suffered injuries as a result.[7] ¶ 21. Plaintiffs have been diagnosed with serious injuries including cancer, COPD, kidney injuries, cardiac injuries, pulmonary injuries, liver damage, inflammation, respiratory issues, asthma, and other adverse health effects. ¶ 22.[8] As a proximate result of Philips' wrongful conduct, Plaintiffs have been severely harmed. ¶ 24.

[7] Some Plaintiffs may be the spouses or minor children of patients with consortium claims, or the estates and survivors of deceased patients with wrongful death claims. ¶ 23.
[8] Plaintiffs have also incurred economic losses. ¶ 25.

III. LEGAL STANDARD

On a motion to dismiss, the Court reviews the alleged facts "assuming their veracity, construing them in the light most favorable to the plaintiff, and drawing all reasonable inferences in the plaintiff's favor." *Tatel v. Mt. Lebanon Sch. Dist*., 2022 WL 15523185, at *7 (W.D. Pa. Oct. 27, 2022) (Conti, J.). A complaint "plausibly pleads a claim" when it "alleges 'enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of' the necessary elements of a claim[.]" *Id*.; *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). On a dismissal motion, "the court cannot consider the additional facts set forth in defendants' motions and briefs." *Tatel*, 2022 WL 15523185, at *7.

IV. ARGUMENT

A. Philips' Attacks on the "Deficiency" of the Master Complaint and Short Form Complaint Process that Philips Agreed to Should Be Rejected Out of Hand.

1. Philips' Argument Ignores the Procedures It Agreed to in this MDL.

Philips' challenges to the sufficiency of the Master Complaint and Short Form Complaints are nothing more than an attack on the processes it agreed to after many weeks of negotiations by the Parties regarding not only the filing of a Master Complaint and Short Form Complaints, *see* PTO 28, but also the completion of detailed and extensive Plaintiff Fact Sheets and production of supporting documents and Authorizations, *see* Pretrial Order #26(a) ("PTO 26(a)") (ECF 871).

PTO 28 is comprehensive. It specifies that "no personal injury claims may be asserted in current and future-filed cases in this MDL other than pursuant to the terms of this Order" and "in light of the inefficiencies of drafting unique personal injury complaints and individual answers to those complaints, the Parties have agreed to the following procedures related to the pleadings in personal injury cases." PTO 28 at §§I, II. The agreed-to order (1) establishes the timing for filing the Master Complaint and Short Form Complaints, (2) makes clear that the Master Complaint and

Short Form Complaint *together* are deemed the operative complaint for each Plaintiff, and (3) requires specific information in the Short Form Complaint, including: (a) Plaintiff's name; (b) whether Plaintiff is the person injured or the claim is being brought in a representative capacity; (c) Plaintiff's residency; (d) jurisdiction for a direct-filed action; (e) the specific Recalled Device used by Plaintiff, (f) Plaintiffs' alleged injuries, (g) the Defendants against whom Plaintiffs brings claims, and (h) additional allegations or causes of action not pled in the Master Complaint. *See id*. at §II.B.2.a-m; *see also* ECF 834-1. To the extent Philips is dissatisfied with the level of information that it agreed would be included in the Short Form Complaint, this Court implemented separate agreed-upon procedures for the completion by each Plaintiff of a nearly 50-page Plaintiff Fact Sheet ("Fact Sheet") with Authorizations and a signed Declaration, which must be produced within forty-five (45) days of the filing of any Short Form Complaint, along with the production of responsive documents within each Plaintiff's possession.[9] *See* PTO 26(a) at §V.B.

The Master Complaint and Short Form Complaint process was implemented so the Court could efficiently and effectively move forward the large number of personal injury cases anticipated in this MDL.[10] Philips took advantage of these efficiencies, being relieved of the obligation to file answers or motions against the individual complaints while collecting discovery from the Fact Sheets and documents expeditiously produced by Plaintiffs. Nevertheless, Philips has the temerity to now attack those procedures with a series of meritless arguments. For example,

[9] The existence of the Fact Sheet is revealing because it demonstrates that Philips understood that the information it now argues should be included in the Short Form Complaint was going to be forthcoming in a process that was agreed to by the Parties for the purpose of efficiency.

[10] As the court stated in *In re Trasylol Prod. Liab. Litig.*, 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009): "The purpose of the consolidated proceedings is to ensure that these cases, which have nearly identical discovery requirements, are resolved in a just and consistent manner." *See also Nuvaring*, 2009 WL 4825170, at *1 (similar); *In re Digitek Prod. Liab. Litig.*, 2009 WL 2433468, at *8 (S.D. W. Va. Aug. 3, 2009) (noting "[t]he administrative nature of a master complaint and its focus on facilitating management of the litigation").

Philips argues the Master Complaint does not appropriately allege standing because it does not allege "*specific* facts about any *specific* plaintiffs or *specific* injuries," Br. at 6-7 (emphasis in original), when PTO 28 quite clearly prescribes that "the Amended Master Personal Injury Complaint *together* with the Personal Injury Plaintiff's Short Form Complaint shall be deemed that Plaintiff's operative Complaint," PTO 28 at §II.B.3 (emphasis added). It is not possible or appropriate to evaluate an individual Plaintiff's Article III standing based solely upon the allegations contained in the Master Complaint. The entire purpose of Philips' argument is to support its contention that, because the Master Complaint needs the Short Form Complaints to complete its allegations, the claims from states where there are currently no filed Short Form Complaints should be dismissed.[11] Br. at 7. There is no deadline, however, for the filing of Short Form Complaints for any Plaintiff alleging personal injuries, other than for those Plaintiffs with actions on file in the MDL when the Master Complaint was filed. PTO 28 at §II.B.4.

Philips' argument ignores that PTO 28 applies to all "future-filed cases in this MDL." PTO 28 at §I. Because of the various tolling agreements between the Parties (*e.g.*, the previous tolling agreement and the current tolling-related Census Registry), Philips *knows* there are more than 30,000 potential claimants who have retained counsel, engaged in tolling, and may file suit.[12] Yet, seeking to circumvent PTO 28, Philips requests dismissal of any Plaintiffs' claims in those states *before* they have even filed their Short Form Complaints and possibly before they are even diagnosed with injuries related to use of the Recalled Devices. Nothing in PTO 28 or governing

[11] For example, Philips contends that causes of action for 13 states and D.C. should be dismissed because no Plaintiff residing in those jurisdictions has yet filed a Short Form Complaint.

[12] The Census Form requires potential claimants to provide their name, address, and counsel, if any. *See* Pretrial Order #25(a), Ex. A (ECF 870). Philips' counsel reported at the most recent status conference that there are over 30,000 potential claimants who have completed census registry forms as compared to several hundred Short Form Complaints filed. *See* Transcript of Status Conference Proceedings, dated Feb. 22, 2023 (attached hereto as Exhibit "1"), at 15:13-19.

law authorizes such action; on the contrary, dismissal of individual actions for personal injuries is deferred under the Court's order. *See* PTO 28 at §§II.C.5 and 6 (outlining answers and motions to dismiss). The purpose of the Master Complaint is to allow potential Plaintiffs to access the Master Complaint's allegations without forcing Defendants to answer or move to dismiss every complaint. If accepted, Philips' argument would require the Court to repeat this process when Short Form Complaints are filed from Plaintiffs in each of those jurisdictions.

Moreover, MDL courts routinely reject Philips' argument.[13] In *Trasylol*, 2009 WL 577726, at *8, the court denied a motion to dismiss the master complaint because it was drafted as a "compromise and attempt at efficiency," and the motion would "assess the sufficiency of plaintiffs' claims with substantial leniency." *Id.* The court found "the interests of justice" were best served by allowing plaintiffs' claims to go forward "and to be more appropriately addressed at the summary judgment stage." *Id.*; *see also In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, 2012 WL 3582708, at *3 (N.D. Ill. Aug. 16, 2012) (denying motion to dismiss and stating "that 'master' or 'consolidated' complaints must be interpreted in light of the 'primary purpose' of multidistrict litigation: 'to promote efficiency through the coordination of discovery.'") (quoting *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 1997 WL 109595, at *2 (E.D. Pa. Mar. 7, 1997)).

2. Philips' Case-Specific Attacks Are Inappropriate and Ignore the Allegations in the Master Complaint and Short Form Complaint.

Philips' case-specific attacks are inappropriate at the pleadings stage. They defeat the purpose of the bellwether process. *See* PTO 28 at §II.C.4 (a subsequent order at the bellwether stage will be implemented for dispositive motions and answers to Short Form Complaints); *Trasylol*, 2009 WL 577726, at *4; *Skechers*, 2014 WL 527703, at *1; *Nuvaring*, 2009 WL

[13] *See generally* LITIGATING MASS TORT CASES, *Pleading Requirements Under Iqbal* § 3:13.50 (June 2022) (collecting cases).

4825170, at *2-3.

Moreover, substantively, Philips' arguments are misguided. Philips contends that the Master Complaint and Short Form Complaints fail to allege that a Plaintiff was injured by Philips' conduct (*i.e*., standing is absent) because the Master Complaint concedes that the defect does not result in degradation and off-gassing in all Devices, Br. at 5-6, 8, and because the allegations do not establish how much exposure is necessary to cause harm, Br. at 5-6, 9. The allegations in the Master and Short Form Complaints, taken together, leave no question that the Complaints lay out in excruciating detail that the Devices were subject to foam degradation, which would release toxic particles and fumes that would be inhaled by users and cause serious injury and illness. With equal certainty, the Master Complaint alleges that the personal injury Plaintiffs are from the pool of users who did inhale such toxic particles and fumes and then suffered one or more of the very serious illnesses laid out in detail in the Master Complaint, *see, e.g*., ¶¶ 21-23, and identified with specificity for each Plaintiff in their Short Form Complaints, *see* PTO 28 at §II.B.2.h. Plaintiffs suffered an injury in fact (identified generally in the Master Complaint and specifically in the Short Form Complaint), that is fairly traceable to use of a Device, and likely to be addressed by a favorable determination of this Court. *Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338 (2016); *Sussino v. Work Out World Inc.,* 862 F.3d 346, 352 (3d Cir. 2017).[14]

Faced with this reality, Philips makes two arguments. First, it claims that the defect does not manifest in all of the Devices and, therefore, it is only a "*possible* injury." Br. at 8-9 (emphasis

[14] Philips' reliance on *In re Zofran (Ondansetron) Prod. Liab. Litig*., 2017 WL 1458193 (D. Mass. 2017) is misplaced. *Zofran* does not address Article III standing or the application of the 12(b)(6) pleading standard to standing allegations. Instead, it focuses on the application of Rule 9(b)'s heightened pleading standard. *Id*. at *5-7. Philips' suggestion that Plaintiffs need to show the circumstances of acquisition to state a fraud claim ignores Plaintiffs' fraudulent omission theory discussed *infra*.

in original). This argument ignores the requirement to assume each Plaintiff's allegations are true and draw all reasonable inferences in Plaintiff's favor, resulting in a conclusion that the defect did "manifest" in each given Plaintiff's Device. It also ignores the FDA determination that each of the Devices posed an "unreasonable risk of substantial harm." Second, Philips suggests that Plaintiffs cannot plead causation unless they allege the precise amount of their exposure to the foam toxins at issue and how much exposure is necessary to cause the specific injury at issue. Br. at 5-6, 9. In essence, Philips seeks to have the Complaints evaluated under a *Daubert* standard with respect to exposure and specific causation, which is clearly inappropriate at the pleading stage and contrary to the FDA's determination.[15] Philips' causation argument should be rejected until after the close of expert discovery. *See In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 127 F. Supp. 3d 1306, 1341 (N.D. Ga. 2015) (on summary judgment, evaluating under *Daubert* and denying the MDL defendant's motion to exclude one of plaintiff's specific causation experts for allegedly failing to "measure the levels at which exposure to chromium becomes toxic").

B. The Learned Intermediary Doctrine Does Not Bar Plaintiffs' Claims.

The learned intermediary doctrine raises two primary questions: (1) did the defendant provide an adequate warning to the prescriber; and (2) if not, did the inadequate warning cause plaintiff's harm.[16] *See Kline v. Zimmer Holdings, Inc.*, 2015 WL 4077495, at *24-25 (W.D. Pa.

[15] If the Court finds that the Complaints are lacking in some respect, the proper remedy would be to direct Defendants to file a motion for an order requiring Plaintiffs to replead pursuant to Rule 12(e). *See* Fed. R. Civ. P. 12(e) (permitting the court to "order[] a more definitive statement" where it finds the answering party "cannot reasonably prepare a response" to the complaint as pled); *see also In re Methyl Tertiary Butyl Ether ("MTBE") Prod. Liab. Litig.*, 2008 WL 2676278, at *4 (S.D.N.Y. July 8, 2008) (holding that "[b]ecause a more definite statement under Rule 12(e) will resolve the lack of specificity..., the motion to dismiss ... under Rule 12(b)(6) is denied."). Summarily dismissing the Master Complaint at this stage under Rule 12(b)(6) would be a manifest injustice to Plaintiffs and would defeat the administrative purpose of the MDL.

[16] Philips refers to its Memorandum of Law in Support of its Motion to Dismiss the Third Amended Complaint for Economic Losses (ECF 916) ("EL MTD Brief"), Br. at 10, containing a nearly identical argument. Plaintiffs incorporate by reference their Opposition to Philips' Motion to

July 6, 2015) (Conti, J.). Here, Philips gave *no warnings* to anyone (including physicians) and actively concealed the defect from everyone, ¶¶ 12, 305, 443, 566, 583, 611, 627, so it cannot invoke the doctrine. *E.g.*, *Walton v. Bayer Corp.*, 643 F.3d 994, 1001 (7th Cir. 2011) ("The learned-intermediary doctrine doesn't permit distributors to *conceal* a drug's adverse side effects from physicians, pharmacies, and consumers.") (citations omitted) (emphasis in original); *Green v. Ethicon, Inc.*, 497 F. Supp. 3d 364, 369-70 (C.D. Ill. 2020); *Grubbs v. Smith & Nephew, Inc*., 2020 WL 5305542, at *3-4 (S.D. Ohio Sept. 4, 2020). A non-existent warning can hardly be an adequate warning. *See Baker v. Bayer Healthcare Pharms., Inc.*, 2013 WL 6698653, at *5 (N.D. Cal. Dec. 19, 2013).

Philips' main argument is that Plaintiffs fail to allege specifically enough that their treating physicians would not have prescribed the Devices had they been informed that users risked breathing in toxic particles and fumes from the Devices. Br. at 11. Philips ignores Plaintiffs' allegations that "Philips intentionally concealed [the defect] from consumers, users, payors, *prescribers, and other healthcare providers*, including Plaintiffs and their physicians, because to do otherwise *would have resulted in users seeking safer alternatives to treat their breathing issues*." ¶¶ 566, 583, 611 (emphasis added); *see also* ¶¶ 569, 587 (Philips had a duty to disclose to physicians); ¶ 570 (Philips misled physicians into believing the Devices were safe). The Court can draw the reasonable inference from these allegations alone, and the Complaint as a whole, that if prescribing physicians had known about the defect, they would not have prescribed the Devices.

In addition, as noted above, where there were no warnings whatsoever, the learned intermediary doctrine simply does not apply. The point of this doctrine is that the doctor will relay the information to the patient. *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006) ("The doctrine

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Dismiss the Economic Loss Complaint (ECF 1566) ("EL Opp."), at 20-21.

of the 'learned intermediary' presupposes that the physician will act as an intermediary" and "inadequate labeling could be a 'producing' cause of the injury, because it effectively sabotages the function of the intermediary."); *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 775 (5th Cir. 2018) (discussing Texas law where "a jury *might* be allowed to presume a particular physician would respond 'reasonably' to fuller disclosure") (emphasis in original). Because Philips withheld the information from prescribing physicians, it interfered with this dynamic; and given the nature of the defect and availability of similar machines without toxic foam, ¶¶ 97, 262-63, no reasonable doctor would have prescribed the Devices had they known of the defect.

C. Plaintiffs' Claims Do Not Implicate Preemption or Primary Jurisdiction Doctrine.

1. The Standards Governing Preemption.

"Preemption is an affirmative defense that the defendant has the burden to prove." *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 705 (D.N.J. 2021) (citation omitted). Dismissal at the pleading stage on preemption grounds, therefore, is premature. Moreover, there is a presumption against preemption in areas where states have traditionally exercised their powers, including "matters of health and safety." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). "[T]he historic police powers of the States [a]re not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Lohr*, 518 U.S. at 485. Philips has not met that standard.[17]

Philips contends that most of Plaintiffs' claims are preempted because they "arise out of

[17] In *In re SoClean, Inc., Mkt., Sales Pracs. & Prod. Liab. Litig.*, MDL No. 3021 (W.D. Pa.), SoClean withdrew a similar motion to dismiss based on guidance from the Court. *See* Jan. 25, 2023 Hearing Transcript ("*SoClean* Tr."), attached as Ex. 1 to the EL Opp., at 3-23 (ECF 1544-1).

alleged fraud-on-the-FDA and purported non-compliance with the [Food, Drug, and Cosmetic Act ("FDCA")] and its implementing regulations." Br. at 12. Not only is Philips factually incorrect, its conclusion fails to provide any legal framework for a preemption analysis.[18] Although the FDCA, as amended by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §301, *et seq*., contains an express preemption provision, 21 U.S.C. §360k(a), Philips does not seriously suggest the claims are expressly preempted. That is likely because governing law makes clear that devices marketed pursuant to §510(k) clearance rather than the rigorous PMA process[19] "do not receive the benefit of express preemption." *Shuker*, 885 F.3d at 767 (citing *Lohr*, 518 U.S. at 492-94).

The touchstone of any preemption analysis begins with the statute's plain wording, which "necessarily contains the best evidence of Congress' preemptive intent." *Shuker*, 885 F.3d at 770 n.8 (citation omitted). The Court of Appeals for the Third Circuit adopted the Supreme Court's two-part preemption test: (1) have federal requirements been established regarding the specific device at issue, and (2) if so, are plaintiff's claims based on state law obligations that are "different from, or in addition to" the federal requirements and do they "relate to safety and effectiveness." *Shuker*, 885 F.3d at 771 (quoting *Riegel v. Medtronic, Inc*., 552 U.S. 312, 321-22 (2008)). When state duties merely parallel federal duties, the claims are not preempted. *Shuker*, 885 F.3d at 768; *Allergan*, 537 F. Supp. 3d at 706.

Philips' mention of the fact the MDA lacks a private right of action, Br. at 12, is of no import. As the Supreme Court observed in analyzing the importance of that provision, the MDA was intended "to provide for the safety and effectiveness of medical devices intended for human

[18] Philips refers to its EL MTD Brief (ECF 916), Br. at 4-10, containing a nearly identical argument. Therefore, Plaintiffs incorporate by reference their EL Opp. (ECF 1566) at 20-21.
[19] The E30 ventilator did not obtain §510(k) clearance but was marketed under an EUA which is less rigorous than PMA authorization. ¶¶ 118-19, 596.

use," and applying preemption broadly would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation." *Lohr*, 518 U.S. at 474, 487 (citing 90 Stat. 539). The Court held: "It is … 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.'" *Id.* at 487 (citation omitted).

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), relied upon by Philips, does not change the basic preemption analysis. The plaintiff there brought claims premised *solely* on fraudulent representations to the FDA. *Id*. at 343. The Court found that the claims "exist[ed] solely by virtue of the FDCA disclosure requirements" and did not arise from traditional state law duties. Thus, they were preempted. *Id*. at 352-53. Philips looks to expand this analysis arguing essentially that any complaint that cites to a defendant's violation of FDA regulations or is grounded in a defendant's deceit must *per se* be preempted. That broad reading of *Buckman* is not supportable.

The Supreme Court contrasted the claims in *Buckman* from those in *Lohr*, explaining that the claims in *Lohr* arose from an "alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." 531 U.S. at 352-53. Thus, courts find that *Buckman* reaffirmed that "certain state-law causes of actions that parallel federal safety requirements" are allowed. *Id*. at 353. *Buckman* "is often limited to 'fraud-on-the-agency' claims and not extended to claims based on state law tort principles." *Allergan*, 537 F. Supp. 3d at 711 1 (quoting *Mendez v. Shah*, 28 F. Supp. 3d 282, 291 (D.N.J. 2014)); *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010); *Bull v. St. Jude Med., Inc*., 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018).

Philips' assertion that Plaintiffs can only avoid preemption if their claims fit into a "narrow gap" is misplaced. Br. at 13. The "narrow gap" is that the claim is a violation of the FDCA but is

not based solely on the violation of the FDCA. *See Bausch*, 630 F.3d at 557-58. While several courts have adopted this "narrow gap" language, it is clear that the language was intended to do little more than "reflect[] the limits of both *Buckman* and *Lohr*." *Id.* at 558. When a "plaintiff claims breach of a well-recognized duty owed to her under state law—the duty of a manufacturer to use due care in manufacturing a medical device," her claims may proceed "so as long as she can show that she was harmed by a violation of applicable federal law. Her claim is not impliedly preempted by federal law." *Id*. Here, the traditional state law duties violated by Philips also violate the FDCA and, therefore, even under Philips' formulation, the claims fit into the "narrow gap."[20]

2. Plaintiffs' Claims Are Traditional State Law Claims that Do Not Arise Solely from Violations of Federal Regulations.

Philips argues that all of Plaintiffs' negligence-based claims as well as Plaintiffs' implied warranty, fraud, unjust enrichment and consumer protection claims are preempted, Br. at 12-16, but does not—and cannot—explain how these claims are based on duties that are "different from, or in addition to" federal obligations or how they arise *solely* from the cited regulatory violations.

The claims arise from long-standing state duties that do not implicate preemption concerns. *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 528-29 (1992) (claims based on generalized duty not to deceive or conspire to commit fraud not preempted); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, 2017 WL 1836443, at *7 (N.D. Ill. May 8, 2017) (claims grounded in traditional state law principles of liability, such as negligence, failure to warn, strict product liability, and fraud not preempted); *McDaniel v. Upsher-Smith Pharm., Inc*., 229 F. Supp. 3d 707, 711-12 (W.D. Tenn. 2017); *Alton v. Medtronic, Inc*., 970 F. Supp. 2d 1069,

[20] *Bell v. Boehringer Ingetheim Pharms., Inc*., 2018 WL 2447788, at *6 (W.D. Pa. May 31, 2018) (Conti, J.), Br. at 13, is inapposite. *Bell* involved claims involving prescription drug labelling (which the Court permitted to be amended) and claims that relied *solely* on the failure to communicate with the FDA (which the Court found preempted). Here, as noted above, Plaintiffs' claims do not rely solely on any FDA requirements and do not conflict with any FDA requirements.

1098 (D. Or. 2013) (state common law fraud claims based on intentional misrepresentation of health and safety information not preempted). To the extent the claims rely on violation of duties that mirror those imposed by the FDCA, they still arise from state law and impose no obligations that are different from, or in addition to those imposed by the FDCA. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 792 (3d Cir. 1999); *Allergan*, 537 F. Supp. 3d at 717.

Violations of regulatory obligations may be relevant in support of Plaintiffs' claims without giving rise to preemption. *See Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 993 (D. Ariz. 2013) ("[T]he mere fact that a federal court will have to interpret the MDA and FDCA at some point in evaluating a plaintiff's claim does not give rise to implied preemption."). There are reasons why those violations are relevant here beyond serving as the basis for a claim, including: (1) Philips' intent to hide the defect in the Devices, *Testosterone*, 2017 WL 1836443, at *8 ("reference to regulations regarding misbranding ... help establish [defendant's] intent and motive in connection with its marketing of [the product]"); (2) establishing the appropriate standard of care, *Allergan*, 537 F. Supp. 3d at 714-15; and (3) the fact the products were adulterated, *Bausch*, 630 F.3d at 557 ("evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient").[21]

Philips separately attacks Plaintiffs' negligence *per se* and negligent recall claims. Br. at

[21] The cases Philips cites are irrelevant and inapposite. *E.g., In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (PMA device and warranty claims required finding that could conflict with FDA approval); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (PMA device and theory of liability not based on traditional state tort law); *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021) (PMA device and plaintiffs failed to identify relevant state-law reporting duty); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (PMA device); *Caltagirone v. Cephalon, Inc.*, 190 A.3d 596, 599-600 (Pa. Super. Ct. 2018) (claims that "rely on asserted violations of the FDA's 'off-label' restrictions" are preempted); *Yimam v. Mylé Vape, Inc.*, 2020 WL 13614925, at *4 (D.C. Super. Ct. June 11, 2020) (requiring manufacturer to make additional disclosures on label would impose duty "different from, or in addition to" FDA's requirements).

15-16. Although Philips lumps them together, Plaintiffs separately plead negligence and negligence *per se* claims. Complaint at Counts I, XV. Philips argues that Plaintiffs' negligence *per se* claim fails because it relies upon the FDCA standards, Br. at 15, but its argument ignores that Plaintiffs' negligence *per se* claim is based also on equivalent parallel state law duties, ¶¶ 124, 597-98. Philips argues that Plaintiffs' negligent recall claim should fail because it "amount[s] to an attempt to enforce the FDCA, 'conflict[s] with the FDCA's enforcement scheme,' and would also interfere with the FDA's ongoing efforts." Br. at 15. However, the applicable statute refutes Philips' arguments because it expressly permits state and federal claims to proceed in the face of a recall. 21 U.S.C. §360h; *Riegel*, 552 U.S. at 339; 518(a) Notification Order (ECF 789-31).

3. The Court Should Not Invoke the Primary Jurisdiction Doctrine.[22]

Philips contends that Plaintiffs' negligent recall claim should be dismissed based on the primary jurisdiction doctrine. However, federal courts should only abstain from exercising their jurisdiction in "exceptional cases" because they "have a 'virtually unflagging obligation ... to exercise the jurisdiction given them.'" *Baykeeper v. NL Indus., Inc*., 660 F.3d 686, 691 (3d Cir. 2011) (citations omitted) (alternation in original). "The [primary jurisdiction] doctrine is a 'prudential' one, 'under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant Industry rather than by the judicial branch.'" *In re JUUL Labs, Inc., Mktg., Sales Pracs., and Prod. Liab. Litig*., 497 F. Supp. 3d 552, 579 (N.D. Cal. 2020) (citation omitted).

This doctrine is "reserved for a 'limited set of circumstances' that 'requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to

[22] The Court denied SoClean's motion to dismiss on primary jurisdiction grounds. *SoClean* Tr. at 22-40; *id*. at 25.

a regulatory agency.'" *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (quoting *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008)). Those circumstances do not exist here. Further, Congress has made explicit that an FDA recall does not relieve a manufacturer from claims under federal and state law. 21 U.S.C. §360h(d) ("[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law."). Accordingly, "courts generally do not defer jurisdiction where plaintiffs seek damages for injuries to their property or person." *In re Methyl Tertiary Butyl Ether ("MTBE") Prod. Liab. Litig.*, 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001). Philips' analysis of the four-factor primary jurisdiction test set forth in *Global Naps, Inc. v. Bell Atl.-N.J., Inc.*, 287 F. Supp. 2d 532, 549 (D.N.J. 2003), and repeated in *Baykeeper*, is misguided.

Factors 1 & 2. The recall-related claim does not require specific expertise. The main issues are whether Philips complied with its duties to adequately notify and promptly replace the Devices, which do not stray beyond a court's normal range of competence. As "'the matter is not one peculiarly within the agency's area of expertise but is one which the courts and jury are equally well-suited to determine, the court must not abdicate its responsibility.'" *Baykeeper*, 660 F.3d at 691 (citations omitted); *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, 2020 WL 7418006, at *12 (D.N.J. Dec. 18, 2020) (review of relevant scientific and technical data not outside a court's normal range of competence or purview).

Factors 3 & 4. There is no risk of inconsistent rulings. Plaintiffs do not seek to undermine any action taken by the FDA nor do they seek a remedy that conflicts with an FDA order. *Baykeeper*, 660 F.3d at 692. The FDA's ongoing review of the recall alone does not overcome the other factors weighing against abstention. *Cohen v. Subaru of Am., Inc.*, 2022 WL 721307, at *37 (D.N.J. Mar. 10, 2022) (initiation of recall "insufficient to justify abstention").

D. Plaintiffs' Negligent Failure to Recall Claim Is Viable.

Plaintiffs state a negligent failure to recall claim because they allege that as far back as 2008, Philips knew or reasonably should have known that the Devices were defective and exposed users to toxins as a result of the degradation and off-gassing of PE-PUR foam in the Devices. ¶ 416. Yet, despite that knowledge, Philips did not recall the Devices prior to June 14, 2021, long after any reasonable manufacturer under the same circumstances would have instituted a recall. ¶ 417.[23] Thereafter, Philips negligently implemented the Recall. ¶¶ 421-28. Philips contends that 10 states do not recognize negligent failure to recall as a separate cause of action.[24] Br. at 18. In all but 4 of those states, Philips is simply wrong because the state either has case law recognizing a negligent failure to recall claim or there is no case law definitively deciding the issue. *See* Chart-1.[25] *See also Lance v. Wyeth*, 85 A.3d 434, 460 (Pa. 2014) (discussing continuum of duty and noting that "we are convinced that a manufacturer or supplier has a duty to cease further distribution of a product at such point as it may know, or may reasonably be charged with knowledge that the commodity is too dangerous to be used by anyone"); *Smith v. Howmedica Osteonics Corp*., 251 F. Supp. 3d 844, 853 (E.D. Pa. 2017) (suggesting the Pennsylvania Supreme Court in *Lance* recognized the possibility of a negligent failure to recall claim).[26]

[23] Philips' counsel admitted that at least six months prior to the recall, in January 2021, Philips had engaged legal counsel that was "helping prepare the team for early custodial interviews" related to this litigation. *See* Tr. (Exhibit "1" hereto), at 19:17-25. Yet, Philips did not recall the defective Devices until June 14, 2021, allowing users to continue breathing in toxins during that period.

[24] Plaintiffs do not challenge Philips' contention that Indiana, Mississippi, and Ohio law do not recognize a negligent failure to recall claim.

[25] Chart-[__] refers to the Charts of Case Citations, attached hereto.

[26] That Philips ultimately instituted a recall does not defeat Plaintiffs' negligent failure to recall claim, Br. at 18, because Plaintiffs allege that Philips breached its duty by failing to recall in a timely manner when it knew, or should have known, of the defect and associated health risks.

E. Certain States' Product Liability Acts Do Not Subsume Plaintiffs' Tort and Warranty Claims.

Philips argues, with no analysis or acknowledgement of the complexity of the issue, that 12 causes of actions for 9 (or 5) states are subsumed by those states' Product Liability Acts ("PLAs"). Br. at 18-19. The argument misses the-mark. While *some* of the acts cited by Philips possibly subsume, or perhaps prohibit, *some* of the causes of action challenged by Philips, few of them are as sweeping in nature as Philips suggests. For example, the Indiana PLA, cited by Philips as prohibiting both claims for personal harm and claims under consumer protection statutes, "has been found to subsume *neither* claims of violation of state consumer protection statutes *nor* claims of breach of express warranty or implied warranty," two claims for which Philips seeks dismissal. *See In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig*., 2021 WL 364663, at *13 (D.N.J. Feb. 3, 2021) (emphasis added). In addition, many of the acts in question do not eliminate "common-law substantive rights," but instead "merged [them] into one cause of action which has been created by statute." *See, e.g.*, *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 855-56 (2d Cir. 1994).

For an explanation of the nuances related to this issue in some of the states cited by Philips, *see* Chart-2. Because Philips makes no effort to establish precisely which claims it believes should be dismissed and why, its Motion should be denied. As the Court has noted, "'[i]t is not this court's responsibility to research and construct the parties' arguments.'" *Hubbell v. World Kitchen, LLC*, 688 F. Supp. 2d 401, 419 (W.D. Pa. 2010) (Conti, J.) (citation omitted). Even if some subset of the state PLAs cited by Philips required one unified claim, the proper remedy would be for Plaintiffs to amend the Master Complaint so that all theories were included under one PLA umbrella. However, because the application of any PLA is state- and claim-specific, this issue is more efficiently addressed at the bellwether phase or at summary judgment.

F. Plaintiffs' Warranty Claims Are Adequately Alleged

1. Plaintiffs Properly Plead Breach of an Express Warranty.

For breach of an express warranty, a plaintiff must plead that "the defendant breached or failed to meet its warranty promise, that the breach was the proximate cause of the plaintiff's harm and the amount of ensuing damages." *Roberts v. NVR, Inc*., 2015 WL 3745178, at *3 (W.D. Pa. June 15, 2015).[27] Plaintiffs properly allege these elements and attach an exemplar of the express warranties at issue. ¶¶ 486-510 & n.411. Philips argues the express warranty claims fail primarily because the warranty excludes design defect claims and consequential damages.[28] Br. at 19-21.

Philips Overstates Limitations in the Express Warranty. Philips argues its express warranty is limited to "defects of workmanship and materials," Br. at 19-20, and so design defects are not covered as a matter of law. *Id*. The express warranty is not so limited. Philips warranted that the Devices "will perform in accordance with the product specifications." ¶ 490. Philips presents no authority that a warranty of performance "in accordance with the product specifications" is only a manufacturing issue, and the term "specifications" evokes design. If Philips argues that "specifications" does not encompass design defects, the ambiguity should be construed against Philips. *See Daniel v. Ford Motor Co*., 806 F.3d 1217, 1225 (9th Cir. 2015).

Further, Philips is mistaken that all states' laws preclude design defect claims when the warranty is for "workmanship and materials." Br. at 19. The Pennsylvania Supreme Court, *e.g.*, affirmed a jury verdict for the plaintiff class on a breach of warranty claim *based on a design defect* where the warranty was for "material and workmanship." *Samuel-Bassett v. Kia Motors Am., Inc.*,

[27] While the precise elements required to state a breach of express warranty claim vary by jurisdiction, Plaintiffs have cited to the law of the forum, Pennsylvania, as an exemplar.
[28] Philips refers to its EL MTD Brief (ECF 916), Br. at 19 & 19 n.12, containing nearly identical arguments. Therefore, Plaintiffs incorporate by reference their EL Opp. (ECF 1566) at 14-20.

34 A.3d 1, 38 (Pa. 2011); *see also Parrish v. Volkswagen Group of Am., Inc*., 463 F. Supp. 3d 1043, 1066-67 (C.D. Cal. May 7, 2020) (discussing Pennsylvania law).[29]

Philips argues that even if the defect was covered under the express warranty, "Plaintiffs would need to allege that a defect actually manifested in their particular devices within the two-year limited warranty period, and that Respironics was timely notified of the defect." Br. at 20 n.16. However, taking each Plaintiff's allegations as true and taking all reasonable inferences in their favor, it is clear that the design defect did "manifest" in each Plaintiff's Device—indeed, each Device was made with the PE-PUR foam. That is the essence of the personal injury claims. Further, Plaintiffs allege the two-year time period is unconscionable and does not apply because: these are prescription breathing assistance devices; Philips knew that consumers seeking breathing assistance would risk inhaling toxic particles and VOCs if they used the Devices; Plaintiffs would not have used the Devices had they known of the defect; Philips intentionally hid the defect for many years; Philips delayed recalling the Devices until after it put a replacement product on the market that did not contain toxic foam; and users had no way of knowing of the defect or detecting when the foam degraded or off-gassed. ¶¶ 501-05.[30] This confluence of factors supports finding the two-year warranty period unconscionable. *Carlson v. General Motors Corp*., 883 F.2d 287, 296 (4th Cir. 1989) (explaining when unconscionability of a warranty period is pleaded, such a claim should "rarely be determined on the bare-bones pleadings" without presentation of relevant

[29] Philips attacks Plaintiffs' manufacturing defect claim related to the Trilogy EVO ventilators, Br. at 19 n.14. For the reasons set forth *infra*, Philips' argument is misguided.

[30] Philips' assertion that an unconscionability claim fails if a competing product is on the market is simply not true. Br. at 20 n.15 (citing *In re Gen. Motors Air Conditioning Mktg. & Sales Pracs. Litig*., 406 F. Supp. 3d 618, 629 (E.D. Mich. 2019)). In that case, plaintiff alleged unequal bargaining power, but the court found the automobile marketplace was one of the most competitive, with numerous options that included better warranties. That is not relevant here where there are no allegations regarding the number of competitors or the quality of their warranties, nor would Plaintiffs suspect they needed better warranties, considering the nature of the defect.

evidence and consideration of the totality of the circumstances). Finally, Philips' arguments about providing timely notice of the defect misconstrue the nature of the defect and ignore that Plaintiffs had no way to determine that the foam in their Devices degraded or off-gassed, or that they were thereby injured. ¶¶ 144, 332. And, they ignore that Philips was on notice of the defect and hid the same. Under the circumstances, no additional notice is required.

More importantly, the Court need not decide this issue at this time. The more prudent course would be to defer this determination until after discovery. *Winkworth v. Spectrum Brands, Inc.*, 2020 WL 3574687, at *4-5 (W.D. Pa. June 30, 2020) (finding determination of nature of defect could not be resolved at pleading stage).

Philips' Repair and Replacement Program Failed its Purpose. Philips argues that the express warranty claims fail because the warranty expressly disclaims liability for consequential damages, and Philips is repairing and replacing the Devices in any event. Br. at 21 & 21 n.19. Where warranty language limits the remedy to repair or replacement, the Third Circuit Court of Appeals has recognized that if there is a delay or inability to supply the remedy, a warranty limitation may '"fail of its essential purpose.'" *Demorato v. Carver Boat Corp.*, 304 F. App'x 100, 102 (3d Cir. 2008) (citations omitted). This is "a question of fact for the jury." *In re Caterpillar, Inc., C13 & c15 Engine Prod. Liab. Litig.*, 2015 WL 4591236, at *23 (D.N.J. July 29, 2015) (citation omitted). Philips' repair and replacement program was ineffective and inadequate. ¶¶ 412-32. There is also a bad faith exception that "can prevent enforcement of an otherwise valid limitation of damages clause." *Werner Kammann Maschinenfabrik, GmbH v. Max Levy Autograph, Inc*., 2002 WL 126634, at *4 (E.D. Pa. Jan. 31, 2002).

2. Plaintiffs Properly Allege Breach of Implied Warranties.

Every state has adopted the implied warranties of merchantability and usability, which require that goods be "fit for the ordinary purposes for which such goods are used." *E.g.*, 13 Pa.

C.S.A. §2314(b)(3); Uniform Commercial Code §2-314(2)(c). "The elements of a claim for breach of the implied warranty of merchantability do not vary across the states" even though some additional requirements may exist for certain states. *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 328 (D.N.J. 2014). The elements of the claims are set forth at ¶¶ 511-62. Philips argues they must be dismissed because: no Plaintiff alleges that a defect manifested; 7 jurisdictions require privity; certain claims fall outside the two-year warranty period; and Pennsylvania law bars implied warranty claims for medical devices. Br. at 19-23. Each of these arguments fails.

Direct Vertical Privity. The jurisdictions Philips challenges embrace applicable exceptions to any privity requirements, *e.g.*, *Weiss v. Gen. Motors LLC*, 418 F. Supp. 3d 1173, 1183 (S.D. Fla. 2019) (third-party beneficiary exception in Florida). *See* Chart-3. All prerequisites for these exceptions have been satisfied. ¶¶ 519-23, 548-52. Philips does not argue otherwise.

Time Limit. Philips argues 31 jurisdictions apply the durational limits in express warranties to related implied warranties. The durational limit here is unconscionable and should not be enforced. ¶¶ 501-04, 524-27. Further, limitations to the duration of implied warranties are not enforced when the language is not clear and conspicuous. *See Haft v. Haier US Appliance Solutions, Inc*., 578 F. Supp. 3d 436, 449-51 (S.D.N.Y. 2022) (Pennsylvania law). Here, the durational limit was printed on the final pages of lengthy User Manuals in regular font, subsumed in a larger paragraph with the limited warranty provision. ¶¶ 502, 525. A finding of unconscionability is well-supported by established precedent in the 31 jurisdictions at issue. *See* Chart-4. In addition, such issues are rarely determined at the pleading stage without a fully developed record. *Carlson*, 883 F.2d at 292; *see also Weinreich v. Toyota Motor Sales, U.S.A., Inc.*, 2019 WL 5684376, at *4 (D.S.C. Oct. 31, 2019); *McQueen v. Yamaha Motor Corp., U.S.A*.,

488 F. Supp. 3d 848, 862-63 (D. Minn. 2020); *Argabright v. Rheem Mfg. Co.*, 258 F. Supp. 3d 470, 483-84 (D.N.J. 2017).

Pennsylvania law. The Pennsylvania Supreme Court has not barred implied warranty claims for medical devices. Unless and until it "definitively states that no cause of action exists for breach of [express and implied] warranties when the object warranted is a medical device," the Court should "not dismiss these claims solely upon a prognostic basis." *Stevens v. C. R. Bard, Inc*., 2018 WL 692097, at *8 (W.D. Pa. Feb. 2, 2018).

3. Pre-Suit Notice Requirements Do Not Bar Plaintiffs' Warranty Claims.

Philips suggests certain warranty claims must be dismissed for a purported failure to provide pre-suit notice as required in 35 jurisdictions. Br. at 23-24. But a number of courts have found that such pre-suit notice requirements are procedural and do not apply in federal court. *See Chen v. Target Corp*., 2022 WL 1597417, at *4-5 (D. Minn. May 19, 2022) (citing *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co*., 559 U.S. 393, 407 (2010)). In addition, to the extent pre-suit notice was required, Plaintiffs have complied, substantially complied, or are excused from compliance, ¶¶ 506, 529, 558, 608, 620, because Philips is a remote manufacturer; Philips has had notice of its violations for over a year; and counsel for Plaintiffs sent multiple letters to Philips of Plaintiffs' demands. Philips' responses made clear it would not meet those demands, and any further notice would be futile or duplicative. These factual matters, going to the sufficiency of notice, should not be decided on a Rule 12(b)(6) motion.[31] *See, e.g.*, *In re Rust-Oleum Restore Mktg., Sales Pracs. & Prods. Liab. Litig.*, 155 F. Supp. 3d 772, 801-02 (N.D. Ill. 2016) (denying motion to dismiss warranty claims based on lack of pre-suit notice, noting that sufficiency and reasonableness of notice provided is usually a fact question for the jury, citing cases from New

[31] In addition, many of the jurisdictions cited by Philips, Br. 23-24, have exceptions to the pre-suit notice requirement. *See* Chart-5.

Jersey, Colorado, Alabama, Florida, Georgia, Illinois, Minnesota, New York, North Carolina, Ohio, and Texas; "an exhaustive review of the factual sufficiency of each Plaintiffs' allegations regarding notice under each applicable state law is not appropriate at this stage").

D. Plaintiffs Adequately Plead Claims for Strict Liability.[32]

1. Comment *k* of Restatement §402A Does Not Require Dismissal of Plaintiffs' Strict Liability Design Defect Claims.

Philips' argument that the laws of 15 jurisdictions apply the RESTATEMENT (SECOND) OF TORTS §402A, cmt. k ("comment *k*") to categorically bar strict liability claims for medical devices under a design defect theory is wrong. As a preliminary matter, the bulk of the states apply comment *k* on a case-by-case basis, and because its application is an issue of fact, it is best left for determination on a more developed factual record and not at the pleading stage. *See* Chart-6. In addition, at least one state does not apply comment *k* to injuries caused by medical devices such as the Recalled Devices, but rather limits it to "injuries caused by a *prescription medicine* or an *implanted medical product*," *Yalter v. Endocare, Inc.*, 2004 WL 5237598, at *4 (C.D. Cal. Nov. 8, 2004), *aff'd*, 220 F. App'x 657 (9th Cir. 2007), while other states expressly declined to extend comment *k* to medical devices or only applied it in the prescription drug context, *see* Chart-6.[33]

Philips' focus on Pennsylvania law is equally misplaced. Ignoring or minimizing recent developments, Philips argues that this Court should follow its decisions in *Killen v. Stryker Spine*, 2012 WL 4498865, at *3-4 (W.D. Pa. Sept. 28, 2012) and *Kline v. Zimmer Holdings, Inc.*, 2013 WL 3279797, at *1 (W.D. Pa. June 27, 2013) to find that Plaintiffs' strict liability design defect

[32] Plaintiffs do not contest Philips' argument that Delaware, Virginia, and North Carolina do not have strict liability regimes. Br. at 24.

[33] That some jurisdictions have not ruled on whether to apply comment *k* to medical devices should not counsel for dismissal, particularly on the pleadings. Given that Philips' argument is devoid of case law, the Court need not give it weight. *See Africa v. Digulielmo*, 2004 WL 2360419, *31 (E.D. Pa. Oct. 20, 2004) (the "court will not conduct legal research on behalf of [a party] ... to determine whether there is [authority] to support [his argument]").

claims are barred by comment *k*. Previously, the Pennsylvania Supreme Court had not extended or applied comment *k* to bar strict liability claims against medical device manufacturers, and this Court and others relied on the Pennsylvania Superior Court's decision in *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006), which extended the Pennsylvania Supreme Court's decision in *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) (applying comment *k* only to prescription drugs), to bar those claims. The Pennsylvania Supreme Court has since issued two opinions cautioning against "altering the common law of products liability," in both "general terms and with specific reference to *Hahn* and comment k." *Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 250 (E.D. Pa. Jan. 17, 2020) (referring to *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 396 (Pa. 2014) and *Lance*, 85 A.3d at 452 n.21).

These more recent cases "together, undermine *Creazzo*'s persuasive force and suggest that the Pennsylvania Supreme Court would not apply comment *k* to categorically exempt all prescription medical devices from strict liability claims." *Patchcoski v. W.L. Gore & Assocs., Inc.*, 2020 WL 4335016, at *9 (M.D. Pa. July 28, 2020). In *Tincher*, the Pennsylvania Supreme Court expressed skepticism of wholesale bars on the availability of the strict liability doctrine in products liability cases, reiterating that "[n]o product is expressly exempt and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Tincher*, 104 A.3d at 386. Further, in *Lance*, the Pennsylvania Supreme Court was doubtful about the reach of *Hahn*, explaining that "*Hahn* does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections." *Lance*, 85 A.3d at 452 n.21. Determining Pennsylvania law with the benefit of these two decisions, "there is little to support a prediction that the Pennsylvania Supreme Court would expand comment *k* to medical

devices as a categorical exemption from strict liability." *Spear v. Atrium Med. Corp.*, 2022 WL 3357485, at *1 (E.D. Pa. Aug. 12, 2022); *see also Cohen v. Johnson & Johnson*, 2022 WL 5109167, at *7 (W.D. Pa. Oct. 5, 2022) ("the Pennsylvania Supreme Court likely would conclude that strict liability claims are cognizable against medical device manufacturers, and that the extension of comment *k* to bar strict liability claims may only apply as to certain medical devices" when "evaluated on a case-by-case basis and only after consideration of the full and developed factual record.").

Because *Creazzo* offers no interpretive guidance in light of subsequent Pennsylvania Supreme Court decisions, Philips' Motion should be denied with respect to Pennsylvania law. In the alternative, Plaintiffs request that this Court defer ruling on the issue until there is a more developed factual record.[34] *Patchcoski*, 2020 WL 4335016, at *12; *Gross*, 434 F. Supp. 3d at 252.

2. Plaintiffs' Manufacturing Defect Claim Is Appropriate.

Plaintiffs properly plead a manufacturing defect claim for "Recalled Devices, including certain recalled Trilogy Evo ventilators." ¶¶ 455-56. The Trilogy Evo was not included in the June 14, 2021 recall, but the FDA subsequently issued a recall of certain Trilogy Evo devices for the same foam degradation defect as the Devices in the earlier recall.[35] In an effort to limit its exposure, Philips is putting form over substance by trying to distinguish between Philips' CPAP devices

[34] Contrary to Philips' argument, *Creazzo* does not require or deserve substantial deference. *See Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 652 (E.D. Pa. 2020) ("The Court gives little persuasive weight to *Creazzo*; it is supported by scant reasoning and in the fourteen years since *Creazzo*, the Pennsylvania Supreme Court has not relied on it.").

[35] *Philips Respironics Recalls Certain Trilogy EVO Ventilators for Potential Health Risks from PE-PUR Foam*, U.S. FOOD & DRUG ADMIN. (last updated Jan. 26, 2022), https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-trilogy-evo-ventilators-potential-health-risks-pe-pur-foam; *Update: Certain Philips Respironics Ventilators, BiPAP Machines, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, U.S. FOOD & DRUG ADMIN. (last updated Feb. 9, 2023), https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due.

recalled in June 2021 and Philips' devices recalled in December 2021, both due to PE-PUR foam that "may off-gas certain chemicals."[36] There is no legitimate reason to preclude these claims, and doing so would unnecessarily thwart judicial and case management efficiencies.

While the Conditional Transfer Order does not explicitly include Trilogy Evo Ventilators, this Court has the authority to determine the scope of this MDL through the CTO process. *See In re Exactech Polyethylene Orthopedic Prod. Liab. Litig*., 2022 WL 5408779, at *1 (J.P.M.L. Oct. 7, 2022) (noting that in instances of an expanded recall, the MDL court has the authority to include expanded devices); *see also In re Hill's Pet Nutrition, Inc., Dog Food Prod. Liab. Litig*., 2020 WL 996802, at *9 (D. Kan. Mar. 2, 2020) (declining to create two separate litigation tracks for recalled and non-recalled dog foods that had the same contamination). Philips offers little support for its position. *In re Mortg. Elec. Registration Sys. (Mers) Litig*., 2016 WL 3931820, at *5 (D. Ariz. July 21, 2016), *aff'd sub nom*. *In re Mortg. Elec. Registration Sys., Inc., Litig*., 719 F. App'x 550 (9th Cir. 2017), is inapposite. There, the court analyzed the jurisdictional question whether a plaintiff can be added to a consolidated complaint without having first filed or transferred his own case into the MDL, a fundamentally different question than the management of different but related products. Requiring a separate MDL for the Trilogy Evo Ventilator would be wholly inefficient.

E. Plaintiffs Properly Plead a Negligent Manufacturing Claim.

Plaintiffs adequately allege a negligent manufacturing claim because the Master Complaint lays out in detail not only Philips' conduct with respect to the Devices and the injuries flowing from that conduct, but also how the manufacturing of the Devices violated federal and state duties

[36] *Class 1 Device Recall Trilogy EVO*, U.S. FOOD & DRUG ADMIN. (Jan. 22, 2022), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=190988; *Class 1 Device Recall DreamStation, DreamStation Go, Dorma 400, Dorma 500, and REMstar SE Auto*, U.S. FOOD & DRUG ADMIN. (July 13, 2021), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187815.

and other ways the manufacture of the Devices fell below reasonable standards. *See, e.g.*, ¶ 125 (FDA determined that the Devices failed to comply with GMPs and were therefore adulterated); ¶ 192 (518(b) Notice stating the FDA found "there are reasonable grounds to believe" that certain Recalled Devices were "not properly manufactured with reference to the state of the art"); ¶ 312 (Philips knew or should have known that the Devices did not comply with best manufacturing practices and regulatory requirements). These allegations are more than adequate to properly state a negligent manufacturing claim. *See, e.g.*, ¶¶ 468-85; *see also Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) (allegations adequate where plaintiff alleged the device caused his injury and device was adulterated due to violations of federal regulations); *Bausch*, 630 F.3d at 549-60 (allegations adequate where plaintiff alleged violations of federal law with respect to manufacturing and inspection processes).[37]

In addition, manufacturing defect claims are better decided after discovery, as "information related to the manufacturer's intention is within the sole possession of the manufacturer." *Cummings v. FCA US LLC*, 401 F. Supp. 3d 288, 314 (N.D.N.Y. 2019).

F. Plaintiffs Properly Plead Negligent Misrepresentation and Common Law Fraud by Omission

Plaintiffs properly allege each element of common law fraud, and negligent misrepresentation by omission. ¶¶ 563-92.[38] *Slippery Rock Area Sch. Dist. v. Tremco, Inc.*, 2016 WL 3198122, *8 (W.D. Pa. 2016) (Conti, J.) (citing elements of common law fraud). The elements of the two causes of action are nearly identical with negligent misrepresentation requiring a lesser mental state for the plaintiff to succeed. *See Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*,

[37] Philips' cases do not support dismissal. *See Foge, McKeever LLC v. Zoetis Inc.*, 565 F. Supp. 3d 647, 654 (W.D. Pa. 2021) (allegations of manufacturing defect purely inferential); *Smith v. Howmedica*, 251 F. Supp. 3d at 853 (allegations only about product, not defendant's conduct).
[38] Here, detailed allegations specifying the defect, the associated health and safety risks, and Philips' knowledge, concealment, and intent are prevalent. *E.g.*, ¶¶ 2-19, 125-246.

417 F. Supp. 3d 531, 563 (E.D. Pa. 2019). Philips challenges only proximate cause and its duty to Plaintiffs under the laws of several states. Br. at 29-32.

Rule 9(b) requires pleading "with particularity the 'circumstances' of the alleged fraud in order to place defendants on notice of the precise misconduct with which they are charged," *Foge, McKeever LLC v. Zoetis Inc.*, 605 F. Supp. 3d 682, 694 (W.D. Pa. 2022) (citation omitted), but that heightened standard is "somewhat relaxed" in the context of fraudulent omissions. *Majdipour v. Jaguar Land Rover N. Am., LLC*, 2013 WL 5574626, at *15 (D.N.J. Oct. 9, 2013) (citation omitted); *In re Takata Airbag Prod. Liab. Litig.*, 464 F. Supp. 3d 1291, 1303 (S.D. Fla. 2020). Rule 9(b) does not apply to negligent misrepresentation claims. *See Sims v. Viacom, Inc.*, 2009 WL 3856667, at *2 (E.D. Pa. Nov. 17, 2009).

1. Plaintiffs Plead Actionable Omissions.

The omissions. The gravamen of Plaintiffs' fraud and negligent misrepresentation claims is that Philips marketed the Devices as a "clinically proven" treatment for sleep disorders that would help users breathe, ¶¶ 128, 235, when it knew they were defective because they contained toxic PE-PUR foam that posed serious health risks to users, ¶¶ 566, 583. This serious health risk is material. *Takata*, 464 F. Supp. 3d at 1303. Philips intentionally concealed that material information from consumers, payors, prescribers, and other healthcare providers for years because disclosing it would have caused them to seek safe alternatives. ¶¶ 566-68, 583-84. In addition, while the Master Complaint focuses on fraud by omission, the Short Form Complaint provides each Plaintiff an opportunity to allege additional facts that could expand the fraud and negligent misrepresentation allegations. ECF 834-1. For that reason alone, dismissal should wait until the bellwether process when each Plaintiff's Short Form Complaint can be viewed on its own.

Causation. Philips concedes that Plaintiffs allege they were harmed but dismisses those allegations as "threadbare" and argues that any omission would not matter because Plaintiffs relied

on their doctors.[39] Br. at 30-31. This is nonsensical. First, Plaintiffs allege that Philips' failure to disclose the defect made all manner of its marketing of the Devices misleading, leaving Plaintiffs and their physicians to "believ[e] that the Recalled Devices were safe for use." *E.g.*, ¶¶ 566-573, 583-586. Second, had Philips disclosed the defect to healthcare providers, the providers would have relayed the information to the Plaintiffs (and mostly likely, never would have prescribed the Devices). *E.g.*, ¶¶ 566, 583. Plaintiffs allege that if they had known the truth, they would not have used the Devices. *E.g.*, ¶ 576. *See, e.g., McNeil*, 462 F.3d at 373. Third, the FDA determined that the Devices posed an "unreasonable risk of substantial harm."

Duty to Disclose. Philips argues that certain states impose a duty to disclose only where there is "a confidential or fiduciary relationship." Br. at 31-32. But in each of these states, a duty to disclose exists "absent a confidential or fiduciary relationship" where: (1) one party has superior knowledge; (2) the defect goes to health and safety; or (3) the defendant partially disclosed facts but withheld information that would have been material. *See* Chart-7. Plaintiffs allege all of these elements. *E.g.*, ¶¶ 191-92 (health and safety), 235 (partial disclosure), 567, 569, 584, 587 (superior knowledge/health and safety).

2. Negligent Misrepresentation is Viable in Most Jurisdictions.

Philips' challenge to Plaintiffs' negligence misrepresentation claims in 8 jurisdictions is not only legally incorrect, it is premature and unnecessary. First, Philips' challenge to 2 states ignores the RESTATEMENT (SECOND) OF TORTS, §311 ("Negligent Misrepresentation Involving Risk of Physical Harm"), which allows Plaintiffs to bring negligent misrepresentation claims for personal injury. Second, even though the other 6 states have not yet adopted §311, these states allow

[39] Philips' suggestion that the allegations in Plaintiffs' negligent misrepresentation count are less robust than the fraud count, Br. at 30, misses the point—all allegations in the Master Complaint must be read together with reasonable inferences being construed in Plaintiffs' favor. *E.g.*, ¶ 581.

negligent misrepresentation claims either as a separate cause of action or as part of their negligence claim. *See* Chart-8. Under either circumstance, these claims will be a part of each Plaintiff's case. This is a case-specific issue better left for the bellwether process.

G. Plaintiffs Properly Plead Claims Under State Consumer Protection Statutes.

Philips seeks dismissal of Plaintiffs' claims under 65 state consumer protection statutes. With little or no analysis, Philips makes 12 cursory arguments, failing to satisfy its burden to show there is no claim stated as a matter of law.[40] *In re: Domestic Drywall Antitrust Litig. Civ. Action*, 2016 WL 3769680, at *11 (E.D. Pa. July 13, 2016) ("To the extent Defendants' one-paragraph argument is an invitation for the Court to comb through all of Plaintiffs' consumer protection claims and determine whether the elements have been adequately pleaded, the Court respectfully declines the invitation."). Such underdeveloped arguments are typically waived. *Brock v. Belleville*, 2018 WL 2320511, at *6 (S.D. Ill. May 22, 2018); *see also SoClean* Tr. at 40-43.[41]

Philips appears to contend that the 65 state consumer protection claims are pled so similarly that they cannot state unique claims, Br. at 32-33; however, Philips ignores that there is substantial overlap in the required elements of these claims because many states use the same model act or adopt another state's act. *SoClean* Tr. at 41-42, 44, 46, 58 (denying motion to dismiss claims under PA act which is "a uniform law" with the kind of similar provisions in many other jurisdictions.").

[40] Philips refers to its EL MTD Brief (ECF 916), Br. at 33 n.37, containing most of the same arguments. Plaintiffs incorporate by reference their EL Opp. (ECF 1566) at 28-40.

[41] The Court should reject any attempt by Philips to flesh out the specific law and offer new reasoning in reply. Courts recognize that such sandbagging is prejudicial. *In re BlackRock Mut. Funds Advisory Fee Litig.*, 327 F. Supp. 3d 690, 736 n.42 (D.N.J. 2018), *aff'd*, 816 F. App'x 637 (3d Cir. 2020) ("[C]ourts ordinarily decline to consider arguments raised for the first time in a reply brief, on the grounds that consideration of the same would prejudice the non-moving party.").

1. Philips' Repeated Arguments Fare No Better with Respect to Consumer Protection Claims.

Preemption: Philips again argues for preemption, misstating the nature of Plaintiffs' claims, and its argument fails for the same reasons. Beyond that, with a single sentence, Philips declares that the consumer protection statutes of 12 jurisdictions expressly preclude claims in areas subject to regulatory oversight. Br. at 33. But these statutes do not wholesale exempt matters subject to regulatory oversight, but rather, only exempt matters when the conduct being challenged has been specifically approved by a regulatory agency. *See* Chart-9. This does not apply here.

Rule 9(b): Philips argues all claims fail Rule 9(b)'s particularity requirement, Br. at 33, incorrectly assuming that all state consumer protection claims sound in fraud. *See, e.g.*, *Pleasant v. McDaniel*, 550 S.W.3d 8, 12 (Ark. App. 2018) (ADTPA action "not a 'fraud' action"; Rule 9 is not the proper pleading standard). Philips addresses only two states which is insufficient because the same standard does not apply to all 63 counts. *See Brackbill v. Ruff*, 2018 WL 2322014, at *6 (M.D. Pa. May 22, 2018) (declining to address undeveloped argument). Notwithstanding that, Plaintiffs' consumer protection claims satisfy Rule 9(b), as discussed above.

Causation: Philips incorrectly argues that Plaintiffs fail to allege causation and/or reliance. Br. at 33-34. First, Philips overstates the reliance requirement in many states. *See* Chart-10. More importantly, the Master Complaint contains allegations that show, among other things, that Philips' deceptive conduct caused Plaintiffs to use a Device they would not otherwise have used. *See* ¶¶ 605-24; *see also* ¶¶ 25, 566, 583, 611, 627. That is sufficient to allege causation and reliance. In one sentence at the end of this paragraph, Philips challenges Plaintiffs' allegations of scienter. Br. at 34. This hardly qualifies as an argument, but to the extent it does, Plaintiffs meet even the most stringent standard alleging knowledge and intent throughout the Master Complaint. *E.g.*, ¶ 611; *see also* ¶¶ 166-234, 248-50; Chart-11 (scienter requirements).

2. The State Consumer Protection Statutes Permit Recovery Here.

Viewing the allegations in their entirety as true and giving all reasonable inferences to Plaintiffs, there is no doubt they have stated claims for violations of the state consumer protection acts challenged by Philips. None of Philips' myriad undeveloped challenges changes that fact.

Personal Injury. Philips argues that recovery for personal injury is precluded by the consumer protection statutes of 14 states. Br. at 35. The proper inquiry here is by statute (some states have multiple statutes), and the law is less clear than Philips asserts in some of the states it cites. *See* Chart-12 (addressing select states cited by Philips).

Damages Barred: Philips' contention that 5 state statutes prohibit actions for money damages, Br. at 35, does not support its request for dismissal. Dismissal is not warranted because all of the statutes permit actions for injunctive/equitable relief. *See* Chart-13; ¶ 624.

Limited to Direct Purchasers. Philips contends privity is required in 15 jurisdictions. Br. at 35. But, the plain language and purpose of the statutes, along with relevant case law, say otherwise. *See* Chart-14; *see also* RIGHT TO PRIVATE ACTION UNDER STATE CONSUMER PROTECTION ACT – PRECONDITIONS TO ACTION, 117 A.L.R.5th 155, §2[a] (2004) (state acts intended to, among other things, "eliminat[e] certain technical barriers to filing actions, such as horizontal privity requirements").

Prescription Medical Devices Excluded. Philips' argument that the Devices are not goods for "personal, family, or household use" as required in 24 jurisdictions, Br. at 35, is wrong. These statutes do not exclude personal-use medical devices, like the Devices, from their scope. Chart-15. The cases cited by Philips are irrelevant because they involve implanted medical devices, where the hospital or surgeon is the "consumer," and not devices provided directly to, sold to, and used by patients. *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 435 (2d Cir. 2015); *Williams v. Boston Sci. Corp.*, 2013 WL 1284185, at *6 (N.D. Ohio Mar. 27, 2013) (implant of vaginal

sling).[42]

Subsumed. Philips argues that consumer protection claims are subsumed by state product liability acts in 5 jurisdictions. Br. at 35-36. Philips overstates the law. *See* Chart-2. In 3 of the 5 jurisdictions,[43] whether a claim is subsumed is subject to analysis by the Court. *Id*. Philips offers no analysis as to why it believes these claims should be subsumed.

In-State Conduct. Philips' argument that Plaintiffs fail to allege that conduct occurred within a given jurisdiction, Br. at 36, simply ignores specific allegations about the business conducted in each jurisdiction, *e.g.*, ¶ 610, and other allegations about the scope of Philips' business. *See* Chart-16; *e.g., Lewis v. Mercedes-Benz USA, LLC*, 530 F. Supp. 3d 1183, 1233 (S.D. Fla. 2021) (out-of-state defendants made false statements in materials for sales in the state).

Pre-Suit Notice. Philips argues certain claims should be dismissed for failure to satisfy pre-suit notice requirements. Br. at 36. Philips' argument is merely a citation to its table that cites statutes with no analysis of any state's actual application of the relevant law because the state laws referenced by Philips provide for many forms of notice and exceptions. *See* Chart-17. Even if any of these statutes applied in part or whole, Plaintiffs have complied, and their allegations are sufficient on the pleadings. *E.g.*, ¶¶ 506, 529, 558, 608. Philips attaches some, but not all, of the notices they received from Plaintiffs, in an improper attempt to have this Court make an evidentiary ruling. *See Francis v. Gen. Motors, LLC*, 504 F. Supp. 3d 659, 691-92 (E.D. Mich. 2020).

Philips did not acknowledge the notices and refused to acknowledge and cure the violations

[42] Philips' Citation Table F(8) is not insightful because, although it cites to a statute or case for each jurisdiction, it provides no explanation as to why the devices in question would not constitute a consumer good. *See* Chart-15 for authorities contradicting Philips' position.

[43] Plaintiffs do not contest that Plaintiffs' consumer protection claims under Louisiana law are likely subsumed by the Louisiana Product Liability Act ("LPLA"). Consumer protection claims are not subsumed by the Indiana PLA. *See Valsartin*, 2021 WL 364663, at *13.

in a manner that would compensate Class members. Any additional notice would be futile and duplicative.[44] In all events, Plaintiffs would be entitled an opportunity to cure.

Finally, Philips throws in, as an afterthought, the blanket assertion that Plaintiffs' consumer protection claims should be dismissed because of preemption, Rule 9(b), and the learned intermediary doctrine, all of which the Plaintiffs have discussed at length above.

H. Plaintiffs' Properly Plead Unjust Enrichment Claims

Plaintiffs adequately state an unjust enrichment claim by alleging: they conferred a benefit on Philips by using Devices that were purchased or leased on their behalf; they would not have done so had they known about the defect and related health risks; Philips concealed the defect and health risks; Philips was unjustly enriched as a result of its wrongful conduct; Philips accepted and retained the benefits to Plaintiffs' detriment and expense; there is no justification for Philips' enrichment; and Philips' retention of the benefits would be unjust and inequitable. ¶¶ 628-634; *see, e.g.*, RESTATEMENT (FIRST) OF RESTITUTION § 1 (1937). Philips incorporates five arguments it made in prior briefing without argument or citation to authority,[45] but raises one new argument—Plaintiffs cannot bring unjust enrichment claims in a personal injury case. Br. at 37. Philips does not offer any citation in support, nor could it because an unjust enrichment claim is appropriate in the tort context. *See, e.g.*, *Bostic v. Ethicon Inc.*, 2022 WL 952129, at *15 (E.D. Pa. Mar. 29, 2022) ("'In the tort setting, an unjust enrichment claim is essentially another way of stating a traditional tort claim.'") (citations omitted); *Robinson v. Colorado State Lottery Div.*, 179 P.3d 998 (Colo. 2008) (en banc) (unjust enrichment claims premised on tortious misconduct are valid).

[44] *See In re Ranbaxy Generic Drug Application Antitrust Litig.*, 2020 WL 2308839, at *3 (D. Mass. May 8, 2020) (under Maine law, failure to comply with notice did not require dismissal); *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 589-90 (E.D. Pa. 2018) (plaintiffs satisfied notice obligation under WV law, even though notice was provided 3 months after filing the complaint).
[45] Br. at 37 (citing the EL MTD Brief (ECF 916) at 32-33). Therefore, Plaintiffs incorporate by reference their EL Opp. (ECF 1566) at 26-28. *See also* Chart-5; Chart-6; and Chart-7 thereto.

I. Plaintiffs Properly Plead a Claim for Battery.

The Master Complaint is rife with allegations that Philips knew of the defect and associated health risks but concealed the defect and continued to sell the Devices anyway, resulting in harm to the Plaintiffs. *See, e.g.*, ¶¶ 7-8, 134, 141, 230, 433-47. This conduct supports a claim for battery. *See, e.g.*, *Johnson v. Sunoco, Inc. (R&M)*, 2018 WL 925009, at *4 (E.D. Pa. Feb. 15, 2018) (stating elements for battery under Pennsylvania law, finding allegations defendant placed contaminated product in stream of commerce knowing and intending plaintiffs to use it supported battery claim).

Philips attacks Plaintiffs' battery claim arguing they fail to allege requisite intent. But Plaintiffs need not allege that Philips sold the recalled devices with the *sole* intent to commit an offensive touching; they need only allege Philips intended to take action that it knew was likely to result in harmful or offensive contact.[46] *See, e.g., Field v. Philadelphia Elec. Co*., 565 A.2d 1170, 1178 (Pa. Super. Ct. 1989) (intent extends "to the consequences substantially certain to follow from the act."); *Adams v. Dole Food Co.*, 323 P.3d 122, 136 (Haw. App. 2014). Plaintiffs have adequately alleged intent.

Philips also makes the bizarre argument that even if it is alleged that it had "knowledge of the alleged defect," Plaintiffs did not allege that Philips "knew that any particular plaintiff was 'substantial[ly] certain' to experience a harmful contact." Br. at 38 (alteration in original). Having placed a harmful product into the stream of commerce knowing *some* users would be subjected to adverse health effects, Philips' suggestion that it cannot be held liable for battery unless it knew *specifically which* users would be subjected to those health effects is clearly not the law.

[46] Philips' citation to *Acosta Orellana v. CropLife Int'l*, 711 F. Supp. 2d 81 (D.D.C. 2010), is inapposite. The court there found plaintiffs failed to allege the requisite intent, but the case dealt with a crop and not with a product that was intended for human use. *Id*. at 90-91.

J. Negligence *Per Se* Is Viable in each Jurisdiction.

Philips' challenge to Plaintiffs' negligence *per se* claims is unnecessary and premature. *First*, as Philips notes, the states' laws it references do not prohibit negligence *per se*; they simply integrate negligence *per se* into a negligence claim. Br. at 38. *Second*, even there, plaintiffs are sometimes required to plead negligence *per se* separately. *See, e.g., Nelson v. Inman Homes, Inc*., 2014 WL 2094327, at *2 (E.D. Tenn. Apr. 17, 2014) (even though "[t]he negligence *per se* doctrine does not create a new cause of action.... [A] plaintiff still has an obligation to specifically plead or assert a claim for negligence *per se*."). *Third*, resolution of this case-specific issue is better left for the bellwether process where the applicable law is determined, because under each state's law negligence *per se* will play some role in each Plaintiff's action.

K. Medical Monitoring Is Available in each Jurisdiction.

Philips' argument for dismissal of Plaintiffs' medical monitoring count is unnecessary and premature. Importantly, Philips only argues that dismissal is warranted because there are some states that treat medical monitoring as an "independent claim"; Philips *does not argue* that Plaintiffs have failed to allege facts that could support medical monitoring relief. Br. at 39. The fact remains that Plaintiffs are entitled to medical monitoring, either as a measure of damages or a separate cause of action.[47] Philips' argument is an oversimplification of a complex and nuanced issue that is discussed in full in the briefing with respect to Philips RS's Motion to Dismiss Plaintiffs' Consolidated Second Amended Class Action Complaint for Medical Monitoring for Failure to State a Claim Pursuant to Fed. R. Civ. P. 12(b)(6).[48] For purposes of this Motion, medical monitoring will be a part of each Plaintiff's case and, therefore, Philips' request to dismiss

[47] Philips makes no efforts to discuss the jurisdictions where medical monitoring is an appropriate form of relief, focusing solely on the "independent cause of action" argument. Br. at 39-40.
[48] ECF 1351; ECF 1352. Pls.' Br. in Opp., filed March 7, 2023, is incorporated herein by reference.

medical monitoring claims in all but 7 jurisdictions should be denied. This issue can be addressed more effectively and efficiently in the bellwether process where the applicability of medical monitoring, either as its own cause of action or an element of relief, can be addressed on a case-specific basis.

L. Punitive Damages Are Available in each Jurisdiction.

Philips attempts to dismiss Plaintiffs' claim for punitive damages for the sole reason that it is "not an independent claim." Br. at 40. Notably, Philips does not contest that punitive damages are an appropriate remedy for Plaintiffs' causes of actions or that Plaintiffs have alleged facts to support a punitive damages claim. Philips also does not attempt any state-by-state analysis reflecting which states permit punitive damages as a separate cause of action. Nonetheless, whether it is included as part of the remedy or as its own cause of action, the punitive damages paragraphs serve the purpose of identifying facts, incorporated throughout the Master Complaint, that support a claim for punitive damages. Because these damages will be part of each Plaintiff's case, the determination of their appropriateness is best left for the bellwether process. *See, e.g., N. Side Foods Corp. v. Bag-Pack, Inc.*, 2007 WL 954106 at *5 (W.D. Pa. Mar. 28, 2007) (Conti, J.) (declining to dismiss punitive damages at early stage).

M. Philips' Motion Related to Loss of Consortium and Survivorship and Wrongful Death Claims Should Be Denied.

Philips asks the Court to dismiss loss of consortium and survivorship and wrongful death claims "because those claims are derivative of Plaintiffs' other causes of action, which fail," Motion at 11, but offers no argument in support of this assertion. As such, the Motion should be denied without consideration. Second, the factual premise of its argument fails because, as set forth above, Plaintiffs have adequately pled numerous claims.

V. CONCLUSION

The Motion should be denied, but if granted, Plaintiffs request leave to file an amendment.

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Respectfully submitted,

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APPENDIX

Chart 1 – Negligent Failure to Recall Claim Is Viable

State	Authority
AK	*Blake v. Guthy-Renker, LLC*, 965 F. Supp. 2d 1076, 1082-84 (D. Alaska 2013) (various claims premised on failure to recall allowed to proceed); *Hiller v. Kawasaki Motors Corp., U.S.A.*, 671 P.2d 369, 371 (Alaska 1983) (plaintiff's failure to recall claim, among others, went to jury verdict)
IL	*Smith v. BOC Grp. PLC*, 2001 WL 477237, at *5 (N.D. Ill. May 4, 2001) ("If Defendants did know or should have known of any such danger, they may very well be found liable for their failure to warn or recall....")
NE	*Dubas v. Clark Equip. Co.*, 532 F. Supp. 3d 819, 829 (D. Neb. 2021), cited by Philips, acknowledges that post-sale duties have not been ruled on by the Nebraska Supreme Court; *Stahlecker v. Ford Motor Co*., 667 N.W.2d 244, 252, 258 (Neb. 2003) (acknowledging plaintiff had alleged facts to support a negligence finding is a case that included negligent failure to recall allegations)
OK	*Wicker ex rel. Est. of Wicker v. Ford Motor Co.*, 393 F. Supp. 2d 1229, 1236-37 (W.D. Okla. 2005), cited by Philips, deals with a post-sale duty to retrofit under distinguishable facts; *see In re: Gen. Motors LLC Ignition Switch Litig*., 154 F. Supp. 3d 30, 37-41 (S.D.N.Y. 2015) (discussing whether Oklahoma law imposes a duty to recall and finding that it did "grounded in the duty of ordinary care that the common law demands from all actors")
PA	*Lance v. Wyeth*, 85 A.3d 434, 459-60 (Pa. 2014) ("the law of negligence establishes a duty, on the part of manufacturers, which can be viewed on a continuum from the requirements of: a warning of dangers, ... through non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in light of its relative risks"); *Smith v. Howmedica Osteonics Corp*., 251 F. Supp. 3d 844, 853 (E.D. Pa. 2017) (suggesting the Pennsylvania Supreme Court in *Lance* recognized the possibility of a negligent failure to recall claim)
TX	*Syrie v. Knoll Int'l*, 748 F.2d 304, 311 (5th Cir. 1984) (noting that "a manufacturer's liability for a post-marketing failure to warn or to recall products that the state of the art has made defective is cognizable under a negligence theory")

Chart 2 – Product Liability Acts Do Not Subsume All Claims

State	Authority
CT	Philips asserts that the CPLA subsumes all common law and consumer protection claims. This is an overstatement. *See, e.g., Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 775-76 (Conn. 2003) (CUTPA claims for personal injury, death, or property damage are subsumed by the CPLA; claims for financial injury are not)
IN	Philips asserts that the IPLA subsumes all common law and consumer protection claims. There are exceptions. *See In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig*., 2021 WL 364663, at *13 (D.N.J. Feb. 3, 2021) (exceptions for breach of express warranty, breach of implied warranty, and consumer protection claims)

State	Authority
KS	Philips asserts that the KPLA subsumes all common law claims. It does not impact consumer protection claims. *See Mattos v. Eli Lilly & Co.*, 2012 WL 1893551, at *2 (D. Kan. May 23, 2012) (KPLA consolidates all product liability actions except KCPA claims)
LA	Philips asserts that the LPLA subsumes all common law and consumer protection claims. The LPLA does not subsume all claims. *See Stroderd v. Yamaha Motor Corp., U.S.A.*, 2005 WL 2037419, at *2 (E.D. La. Aug. 4, 2005) (LPLA's exclusivity provision does not bar claims arising under the redhibition articles.)
MS	Philips asserts the MPLA subsumes all common law claims. It does not mean that common law theories are unavailable to the plaintiff. *See Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 687 (MPLA providing exclusive remedy "does not mean that common law negligence or breach of implied warranty claims are disallowed.... Instead, they must be evaluated under the framework of the MPLA").
NJ	Philips asserts the NJPLA subsumes all common law claims except breach of express warranty and all consumer protection claims. It does not impact consumer protection claims. *See Valsartan,* 2021 WL 364663, at *7 (exception for certain CFA claims)
OH	Philips asserts the OPLA subsumes all common law and consumer protection claims. There are exceptions. *See Hollar v. Philip Morris Inc.*, 43 F. Supp. 2d 794, 808 (N.D. Ohio 1998) (common law fraud claim exception); *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) (UCC breach of warranty claims exception)
TN	Philips asserts the TPLA subsumes all common law claims. It does not impact consumer protection claims. *See Valsartan,* 2021 WL 364663, at *19 (TPLA subsumes common law claims except claims for violation of state consumer protection statutes)
WA	Philips asserts the WPLA subsumes common law claims. It does not subsume all claims. *See* Wash. Rev. Code §7.72.010(4) (common-law claims for fraud and intentional torts, like battery, are expressly excluded as beyond the reach of the WPLA); *Cutter v. Biomet, Inc.*, 2019 WL 2450785, at *1 (W.D. Wash. June 12, 2019) (fraud exception)

Chart 3 – Implied Warranty: Direct Vertical Privity Not Required

State	Authority
AZ	*Naiman v. Alle Processing Corp.*, 2020 WL 6869412, at *3 (D. Ariz. Nov. 23, 2020) (public health exception); *Crystal Coca-Cola Bottling Co. v. Cathey*, 317 P.2d 1094, 1097 (Ariz. 1957) (public health exception)
FL	*Weiss v. Gen. Motors LLC*, 418 F. Supp. 3d 1173, 1183 (S.D. Fla. 2019) (third-party beneficiary exception); *Sanchez-Knutson v. Ford Motor Co.*, 52 F. Supp. 3d 1223, 1233-34 (S.D. Fla. 2014) (third-party beneficiary law)
GA	*Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1326 (M.D. Ga. 2011) (privity exists when manufacturer expressly warrants product will meet certain standards)
ID	*Am. W. Enters. v. CNH, LLC*, 316 P.3d 662, 668 (Idaho 2013) (lack of privity excused where enforcing privity requirement "would have the effect of unfairly prejudicing the plaintiff")
KY	*Levin v. Trex Co.*, 2012 WL 7832713, at *3 (W.D. Ky. Mar. 5, 2012) (privity exists when manufacturer expressly warrants product will meet certain standards)
OR	*Smith v. Ethicon Inc.*, 2021 WL 3578681, at *8 (D. Or. May 13, 2021) (end-users of medical devices satisfy privity requirements for breach of implied warranty claims)

State	Authority
WI	*Grams v. Milk Prod., Inc.*, 685 N.W.2d 172, 2004 WL 1418010, at *2-4 (Wis. Ct. App. June 17, 2004) (third-party beneficiary exception for privity requirement)

Chart 4 – Implied Warranty: Unconscionable Durational Limits Not Applied

State	Authority
AL	*Roberson v. Money Tree of Ala., Inc.*, 954 F. Supp. 1519, 1524 (M.D. Ala. 1997)
AZ	*Wilson v. Volkswagen Grp. of Am., Inc.*, 2018 WL 4623539, at *5 (S.D. Fla. Sept. 26, 2018); *Argabright v. Rheem Mfg. Co.*, 258 F. Supp. 3d 470, 483-84 (D.N.J. 2017)
AR	*Perez v. Volkswagen Grp. of Am., Inc.*, 2013 WL 1661434, at *4 (W.D. Ark. Apr. 17, 2013)
CA	*LaChapelle v. Omni Hotels Mgmt. Corp.*, 2021 WL 3373337, at *3 (N.D. Cal. Aug. 3, 2021)
CO	*In re Porsche Cars N. Am., Inc.*, 880 F. Supp. 2d 801, 824 (S.D. Ohio 2012)
DE	*James v. Nat'l Fin., LLC*, 132 A.3d 799, 814 (Del. Ch. 2016)
FL	*Barnext Offshore Ltd. v. Ferretti Group USA, Inc.*, 2011 WL 13223746, at *11 (S.D. Fla. May 16, 2011)
GA	*NEC Techs., Inc. v. Nelson*, 478 S.E.2d 769, 773 (Ga. 1996)
IL	*Federico v. Freedomroads RV, Inc.*, 2010 WL 4740181, at *7 (N.D. Ill. Nov. 10, 2010)
IN	*Castagna v. Newmar Corp.*, 2016 WL 3413770, at *6 (N.D. Ind. June 22, 2016)
KY	*CK Franchising, Inc. v. SAS Servs. Inc.*, 398 F. Supp. 3d 163, 175 (E.D. Ky. 2019)
LA	*Iberia Credit Bureau, Inc. v. Cingular Wireless LLC*, 379 F.3d 159, 167 (5th Cir. 2004)
MA	*Wright v. Marjem Recovery, LLC*, 2014 WL 4274528, at *5 (D. Mass. Aug. 27, 2014)
MI	*Ambrose v. Gen. Motors LLC*, 2022 WL 3701946, at *12 (E.D. Mich. Aug. 26, 2022); *Porsche*, 880 F. Supp. 2d at 822-24
MN	*McQueen v. Yamaha Motor Corp., U.S.A.*, 488 F. Supp. 3d 848, 865 (D. Minn. 2020)
MO	*Singh v. Lenovo (U.S.) Inc.*, 510 F. Supp. 3d 310, 321 (D. Md. 2021)
MT	*Beneficial Commercial Corp. v. Cottrell*, 688 P.2d 1254, 1257 (Mont. 1984)
NJ	*Haft v. Haier US Appliance Sol., Inc.*, 578 F. Supp. 3d 436, 449-51 (S.D.N.Y. 2022)
NY	*Haft*, 578 F. Supp. 3d at 449-51
NC	*Bussian v. DaimlerChrysler Corp.*, 411 F. Supp. 2d 614, 623 (M.D.N.C. 2006)
OH	*Goodyear Tire & Rubber Co. v. Chiles Power Supply, Inc.*, 7 F. Supp. 2d 954, 966 (N.D. Ohio 1998)
OK	*API Enters., Inc. v. Am. Standard, Inc.*, 2008 WL 819335, at *2 (W.D. Okla. Mar. 25, 2008)
PA	*Haft*, 578 F.Supp.3d at 449-51
SC	*Weinreich v. Toyota Motor Sales, U.S.A., Inc.*, 2019 WL 5684376, at *4 (D.S.C. Oct. 31, 2019)
TN	*Anderson v. Amazon.com, Inc.*, 490 F. Supp. 3d 1265, 1274 (M.D. Tenn. 2020)
TX	*Porsche*, 880 F. Supp. 2d at 822-24
VT	*KPC Corp. v. Book Press, Inc.*, 636 A.2d 325, 328 (Vt. 1993)

State	Authority
VA	*King v. Flinn & Dreffein Eng'g Co.*, 2012 WL 3133677, at *11 n.10 (W.D. Va. Jul. 30, 2012)
WA	*AMC, LLC v. Northwest Farm Food Coop.*, 481 F. Supp. 3d 1153, 1174 (D. Or. 2020)
WV	*Murphy v. Setzer's World of Camping, Inc.,* 2021 WL 302744, at *4 (S.D. W. Va. Jan. 29, 2021)
WI	*Carando Gourmet Frozen Foods Corp. v. Axis Automation, LLC*, 458 F. Supp. 3d 60, 70 (D. Mass. 2020)

Chart 5 – Warranty: Standards to Satisfy Notice and Exceptions

State	Authority
AL	*Hobbs v. Gen. Motors Corp.*, 134 F. Supp. 2d 1277, 1285 (M.D. Ala. 2001) (filing of complaint constitutes notice)
AR	*Jarrett v. Panasonic Corp. of N. Am.*, 8 F. Supp. 3d 1074, 1083 (E.D. Ark. 2013) (no specific form of notice required)
CA	*In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs. & Prods. Liab. Litig.*, 754 F. Supp. 2d 1145, 1180 (C.D. Cal. 2010) (no notice required to manufacturer)
CO	*Gregorio v. Ford Motor Co.*, 522 F. Supp. 3d 264, 285 (E.D. Mich. 2021) (filing of complaint constitutes notice)
CT	*Gerrity v. R.J. Reynolds Tobacco Co.*, 399 F. Supp. 2d 87, 91-3 (D. Conn. 2005) (no notice required to manufacturer)
FL	*In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1270 (D.N.M. 2017) (no notice required to manufacturer)
GA	*Pulmonary Assocs. of Charleston PLLC v. Greenway Health, LLC*, 508 F. Supp. 3d 1268, 1275 (N.D. Ga. 2020) (filing of complaint constitutes notice)
IL	*In re Rust-Oleum Restore Mktg., Sales Practices & Prods. Liab. Litig.*, 155 F. Supp. 3d 772, 799-801 (N.D. Ill. 2016) (seller's knowledge)
IN	*Anderson v. Gulf Stream Coach, Inc.,* 662 F.3d 775, 781-82 (7th Cir. 2011) (seller's knowledge of defect constitutes notice)
IA	*In re MyFord Touch Cons. Litig.*, 46 F. Supp. 3d 936, 977 (N.D. Cal. 2014) (no notice required to manufacturer)
MD	*Firestone Tire & Rubber Co. v. Cannon*, 452 A.2d 192, 197-98 (Md. Ct. Spec. App. 1982), *aff'd*, 456 A.2d 930 (Md. 1983) (no notice required to manufacturer)
MA	*In re Ford Motor Co. E-350 Van Prods. Liab. Litig. (No. II)*, 2010 WL 2813788, at *78 (D.N.J. July 9, 2010) (filing of complaint constitutes notice)
MI	*Ford Motor*, 2010 WL 2813788, at *65 (filing of complaint constitutes notice)
MN	*In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160, at *13 (D.N.J. May 8, 2017) (seller's knowledge of defect constitutes notice)
MS	*Albright v. Sherwin-Williams Co.*, 2019 WL 5307068, at *3 (N.D. Ohio Jan. 29, 2019) (no specific form of notice required)
NJ	*Strzakowlski v. General Motors Corp.*, 2005 WL 2001912, at *3 (D.N.J. Aug. 16, 2005) (filing of complaint constitutes notice)
NM	*Santa Fe*, 288 F. Supp. 3d at 1271-72 (filing of complaint constitutes notice)
NY	*Panda Capital Corp. v. Kopo Int'l, Inc.*, 242 A.D.2d 690, 692 (N.Y. App. Div. 1997) (filing of complaint constitutes notice)

State	Authority
NC	*Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 786 (W.D.N.C. 2008) (filing of complaint constitutes notice)
OH	*Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624, 638 (Ohio 1989) (filing of complaint constitutes notice)
PA	*Bednarski v. Hideout Homes & Realty, Inc., A Div. of U.S. Homes & Properties, Inc.*, 709 F. Supp. 90, 92 (M.D. Pa. 1988) (filing of complaint constitutes notice)
SC	*Lessin v. Ford Motor Co.*, 2021 WL 3810584, at *6 (S.D. Cal. Aug. 25, 2021) (no specific form of notice required)
TN	*In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 155 F. Supp. 2d 1069, 1111 (S.D. Ind. 2001) (filing of complaint constitutes notice)
TX	*Vintage Homes, Inc. v. Coldiron*, 585 S.W.2d 886, 888 (Tex. App. 1979) (notice not required to manufacturer)
VA	*MyFord*, 46 F. Supp. 3d at 978-79 (filing of complaint constitutes notice)

Chart 6 – Restatement (Second) of Torts §402A, Comment *k*

State	Authority
CA	Comment *k* has been applied only to prescription drugs and *implanted* medical devices. *See, e.g.*, *Sukonik v. Wright Med. Tech., Inc.*, 2015 WL 10682986, at *9 (C.D. Cal. Jan. 26, 2015) ("there is an exception [to strict liability] in the context of prescription drugs and implanted medical devices")
DC	Applying cmt. *k* in some contexts but not yet determined on prescription medical devices. *See, e.g., Dyson v. Winfield*, 113 F. Supp. 2d 35, 39-40 (D.D.C. 2000) (applying comment *k* to prescription drugs); *Fisher v. Sibley Memorial Hosp.*, 403 A.2d 1130, 1134 (D.C. 1979) (applying comment *k* to blood transfusion)
IA	Applying cmt. *k* in some context but not yet determined on prescription medical devices. *See, e.g.*, *Moore v. Vanderloo*, 386 N.W.2d 108, 117 (Iowa 1986) (applying comment *k* to a prescription drug); *Petty v. United States*, 740 F.2d 1428, 1439 (8th Cir. 1984) (applying Iowa law to find that comment *k* applied to a vaccine)
IN	*Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290 (7th Cir. 1972) (discussing Indiana law and cmt. *k* application only to some prescription drugs); *Koehler by Koehler v. Wyeth Lab'ys Div. of Am. Home Prod. Corp.*, 1987 WL 47831, at *4 (S.D. Ind. Sept. 8, 1987) (discussing what qualifies as "unavoidably usafe")
MD	*Conway v. Am. Med. Sys., Inc.*, 2021 WL 6126293, at *8 n.13 (D. Md. Dec. 28, 2021) (explaining that Maryland courts have "never held that all prescription medications and medical devices are unavoidably unsafe")
MA	*Taupier v. Davol, Inc.*, 490 F. Supp. 3d 430, 444 (D. Mass. 2020) ("Because the SJC has adopted a risk-utility balancing test in product liability cases, it likely would not apply comment *k* to categorically bar liability for a design defect.")
MT	*Dalbotten v. C. R. Bard, Inc.*, 2023 WL 157735, at *5 (D. Mont. Jan. 11, 2023) (declining to extend comment *k* to medical devices under Montana law)

State	Authority
NM	*McDonald v. Zimmer Inc.*, 461 P.3d 930, 945 (N.M. Ct. App. 2019) (explaining that New Mexico's iteration of comment *k* "expressly adopts a case-by-case inquiry")
NY	*Arruda v. C.R. Bard, Inc.*, 2020 WL 4569436, at *6 (N.D.N.Y. Aug. 6, 2020) (denying medical device manufacturer's request to categorically apply comment *k* to medical devices because New York state courts have not extended the unavoidably unsafe products exception to all medical devices) (citation omitted); *Williamson v. Stryker Corp.*, 2013 WL 3833081, at *8 (S.D.N.Y. July 23, 2013) (refusing to dismiss design defect claims under the "unavoidably unsafe products" exception where plaintiffs stated a cognizable "failure to warn" claim)
OH	*Thompson v. DePuy Orthopaedics, Inc.*, 2015 WL 7888387, at *15 (S.D. Ohio Dec. 4, 2015) (explaining that "not all prescription medical devices are deemed unavoidably unsafe" under Ohio law); Ohio Rev. Code Ann. §2307.71(A)(16)
PA	*Cohen v. Johnson & Johnson*, 2022 WL 5109167, at *7 (W.D. Pa. Oct. 5, 2022) ("Reading *Lance* and *Tincher* together, this Court is persuaded that comment *k* likely would not be applied by the Pennsylvania Supreme Court to categorically bar the applicability of strict liability principles as to all medical devices."); *Moultrie v. Coloplast Corp.*, 2020 WL 1249354, at *8 (W.D. Pa. Mar. 16, 2020); *Patchcoski v. W.L. Gore & Assocs., Inc.*, 2020 WL 4335016, at *9 (M.D. Pa. July 28, 2020); *Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 252 (E.D. Pa. 2020); *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 465 (W.D. Pa. 2019)
SD	Applying cmt. *k* in some context but not yet determined on prescription medical devices. *See, e.g.*, *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228, 231 (D.S.D. 1983), *aff'd*, 739 F.2d 340 (8th Cir. 1984) (applying comment *k* to a prescription drug)
TN	*Nolen v. C.R. Bard Inc.*, 533 F. Supp. 3d 584, 592 (M.D. Tenn. 2021) (whether a medical device was inherently unsafe was an issue of fact that defeated defendant's summary judgment motion as to the plaintiff's defective design-based claims).
TX	*In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 772 (5th Cir. 2018) (explaining the Texas Supreme Court has never "expressly extended" the immunity of comment *k* to medical devices on either a categorical or product-by-product basis and refusing to apply it to a medical implant device)
WY	Applying cmt. *k* in some context but not yet determined on prescription medical devices. *See, e.g.*, *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 852 (10th Cir. 2003) (referencing comment *k* when discussing the learned intermediary doctrine in a case against the manufacturer of the drug nefazodone); *Van Dyke v. GlaxoSmithKline*, 2006 WL 8430904, at *6 (D. Wyo. Nov. 1, 2006) (denying plaintiff's motion for summary judgment where the manufacturer of Paxil pled comment *k* as an affirmative defense)

Chart 7 – Fraud/Negligent Misrepresentation: Duty to Disclose Exceptions

(exceptions: (1) one party has "superior knowledge"; (2) the defect goes to "health and safety"; or (3) the defendant "partially disclosed" facts but withheld information that would have been material)

State	Authority
AL	*Freightliner, L.L.C. v. Whatley Contract Carriers, L.L.C.*, 932 So.2d 883, 895 (Ala. 2005) (partial disclosure); *Hughes v. Hertz Corp.*, 670 So. 2d 882, 887-88 (Ala. 1995) (health and safety exception)
AR	*Holiday Inn Fran., Inc. v. Hotel Assocs., Inc.*, 382 S.W.3d 6, 14 (Ark. Ct. App. 2011) (party has superior knowledge); *Zimpel v. Trawick*, 679 F. Supp. 1502, 1509 (W.D. Ark. 1988) (partial disclosure)
CT	*Wedig v. Brinster*, 469 A.2d 783, 788 (Conn. App. 1983) (partial disclosure)
DE	*Arcelik, A.S. v. E.I. Du Pont de Nemours & Co.*, 2022 WL 3139086, at *8 (D. Del. Aug. 5, 2022) (partial disclosure); Delaware Pattern Civil Jury Instructions § 16.3, DEL. P.J.I. CIV. § 16.3 (2000) (active concealment); *Rohm & Haas Elec. Materials, LLC v. Honeywell Int'l, Inc.*, 2009 WL 1033651, at *7 (D. Del. Apr. 16, 2009) (defendant's knowledge is the "only" difference for negligent misrepresentation and fraud)
FL	*Nessim v. DeLoache*, 384 So. 2d 1341, 1344 (Fla. App. 1980) (one party has superior knowledge); *Nicholson v. Kellin*, 481 So. 2d 931, 936 (Fla. App. 1985) (partial disclosure); *S.K.Y. Mgmt. LLC v. Greenshoe, Ltd.*, 2007 WL 9701121, at *3 (S.D. Fla. Mar. 11, 2007) (superior knowledge); *BVS Acquisition Co., LLC v. Brown*, 649 F. App'x 651, 665 (11th Cir. 2016)
GA	*Amin v. Mercedes-Benz USA, LLC*, 301 F. Supp. 3d 1277, 1296 (N.D. Ga. 2018) (one party has superior knowledge); *Jordan v. Flynt*, 240 S.E.2d 858, 863 (Ga. 1977) (partial disclosure); *McCabe v. Daimler AG*, 948 F. Supp. 2d 1347, 1368-69 (N.D. Ga. 2013) (health and safety exception); *Hightower v. Century 21 Farish Realty*, 448 S.E.2d 271, 273 (Ga. App. 1994) ("same principles apply to both fraud and negligent misrepresentation cases.")
IA	*Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 177 (Iowa 2002) (partial disclosure); *Cornell v. Wunschel*, 408 N.W.2d 369, 376 (Iowa 1987) (superior knowledge); *Union Cnty., IA v. Piper Jaffray & Co.*, 741 F. Supp. 2d 1064, 1089 (S.D. Iowa 2010) (recognizing fraud and negligent misrepresentation claims are "similar")
IL	*Van Zeeland v. Rand McNally*, 532 F. Supp. 3d 557, 572-73 (N.D. Ill. 2021) (one party has superior knowledge); *Toulon v. Cont'l Cas. Co.*, 877 F.3d 725, 737 (7th Cir. 2017) (partial disclosure); *Carlen v. Coloplast Corp.*, 2020 WL 3050752, at *6 (S.D. Ill. June 8, 2020) (partial disclosure)
MD	*Brass Metal Prod., Inc. v. E-J Enter., Inc.*, 984 A.2d 361, 387 n.22 (Md. 2009) (partial disclosure)
MA	*First Choice Armor & Equip., Inc. v. Toyobo Am., Inc.*, 717 F. Supp. 2d 156, 162 (D. Mass. 2010) (one party has superior knowledge); *Stolzoff v. Waste Sys. Int'l, Inc.*, 792 N.E.2d 1031, 1044 (Mass. Ct. App. 2003) (partial disclosure); *Broderick v. PNC Mortg. Corp.*, 2013 WL 6909531, at *2 (D. Mass. Dec. 30, 2013) (partial disclosure); *Lynch v. Cotton*, 780 N.E.2d 488 (Mass. Ct. App. 2002) (superior knowledge)

State	Authority
MS	*Poe v. Summers*, 11 So. 3d 129, 134 (Miss. 2009) (one party has superior knowledge); *Welsh v. Mounger*, 883 So. 2d 46, 49 (Miss. 2004) (partial disclosure); *Shelter Mut. Ins. Co. v. Brown*, 345 F. Supp. 2d 645, 652 (S.D. Miss. 2004) (superior knowledge and partial disclosure)
NC	*Hardin v. KCS Int'l, Inc.*, 682 S.E. 726, 773 (N.C. App. 2009) (active concealment and superior knowledge); *Silicon Knights, Inc. v. Epic Games, Inc.*, 2011 WL 1134453, at *13 (E.D.N.C. Jan. 25, 2011), *report and recommendation adopted*, 2011 WL 1134447 (E.D.N.C. Mar. 24, 2011) (principal difference in fraud and negligent misrepresentation is "intent to deceive")
NJ	*Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 234 (D.N.J. 2020) (partial disclosure); *Amato v. Subaru of Am., Inc.*, 2019 WL 6607148, at *21 (D.N.J. Dec. 5, 2019) (patrial disclosure)
NV	*Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 110 (Nev. 1998), *abrogated on other grounds by GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001) (one party has superior knowledge); *Nelson v. Heer*, 163 P.3d 420, 426 (Nev. 2007) (partial disclosure)
NY	*In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160, at *21 (D.N.J. May 8, 2017) (superior knowledge)
OH	*Stuckey v. Online Res. Corp.*, 819 F. Supp. 2d 673, 686-87 (S.D. Ohio 2011) (partial disclosure); *Andersons, Inc. v. Consol, Inc.*, 348 F.3d 496, 506 (6th Cir. 2003) (applying Ohio law, defendant cannot make an affirmatively false statement)
OR	*Gregory v. Novak*, 855 P.2d 1142, 1144 (Or. Ct. App. 1993) (partial disclosure)
PA	*Gaines v. Krawczyk*, 354 F. Supp. 2d 573, 586 (W.D. Pa. 2004) (one party has superior knowledge); *Volkswagen*, 2017 WL 1902160, at *19-20 (applying Pennsylvania law) (partial disclosure)
SC	*Volkswagen*, 2017 WL 1902160, at *18 (applying South Carolina law) (one party has superior knowledge); *Pitts v. Jackson Nat. Life Ins. Co.*, 574 S.E.2d 502, 510 (S.C. Ct. App. 2002) (partial disclosure); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 823 (D.S.C. 2011) (health and safety exception)
SD	*Maybee v. Jacobs Motor Co.*, 519 N.W.2d 341 (S.D. 1994) (partial disclosure)
TX	*White v. Zhou Pei*, 452 S.W.3d 527, 537-38 (Tex. App. 2014) (one party has superior knowledge); *Yoon v. Yoo*, 2016 WL 4801314 (N.D. Tex. Feb. 24, 2016) (partial disclosure); *Highland Crusader Offshore Partners, L.P. v. Lifecare Holdings, Inc.*, 2009 WL 1065212, at *6 (N.D. Tex. Apr. 21, 2009) (health and safety exception); *Kirkbride v. Kroger Co.*, 2022 WL 2703960, at *8 (S.D. Ohio July 12, 2022) (applying Texas law, partial disclosure); *Conestoga Tr. Servs., LLC, Tr. of Conestoga Tr. v. Focus Med. Underwriters, LLC*, 2022 WL 599344, at *3 (Tex. App. Mar. 1, 2022) (superior knowledge)
VA	*Sonneveldt v. Mazda Motor of Am., Inc.*, 2021 WL 4813753, at *6 (C.D. Cal. July 29, 2021) (applying Virginia law) (superior knowledge); *Price Auto. II, LLC v. Mass Mgmt.*, 2015 WL 300418, at *4 (W.D. Va. Jan. 22, 2015) ("Constructive fraud [i.e., negligent misrepresentation] differs from actual fraud in that the misrepresentation of material fact is not made with the intent to mislead, but is made innocently or negligently although resulting in damage to the one relying on it.")

Chart 8 – Negligent Misrepresentation

State	Authority
AR	*See* RESTATEMENT (SECOND) OF TORTS, §311 (Negligent Misrepresentation Involving Risk of Physical Harm); *Holguin v. Celebrity Cruises*, 2010 WL 11602745, at *1 (S.D. Fla. June 4, 2010) ("section 552 applies only in cases that do not involve physical harm.... When, as here, a plaintiff suffers physical harm from a negligent misrepresentation, section 311 governs her negligent misrepresentation claim."). *See also Holiday Inn Fran., Inc. v. Hotel Assocs., Inc.*, 382 S.W.3d 6, 14 (Ark. Ct. App. 2011) (party with superior knowledge has a tort duty to plaintiffs based on knowledge of the risk of the harm)
FL	*See Holguin*, 2010 WL 11602745, at *1 (apply § 311 under Florida law); Also, for personal injury claims involving medical devices, Florida law has allowed claims for negligent misrepresentation. *See, e.g., Barrow v. Bristol-Myers Squibb*, 1998 WL 812318, at *45 (M.D. Fla. Oct. 29, 1998); *Albertson v. Richardson-Merrell, Inc*., 441 So. 2d 1146, 1150 (Fla. 4th DCA 1983)
ID	*Clark v. Int'l Harvester*, 581 P.2d 784, 794 (Idaho 1978) (noting that Idaho law allows a products liability action sounding in negligence (which would include negligent misrepresentation) under circumstances where there is personal injury or damage to property alleged); *Packer v. Riverbend Commc'ns, LLC*, 468 P.3d 1283, 1287 (Idaho 2020) (recognizing negligent misrepresentation involving risk of physical harm, RESTATEMENT (SECOND) OF TORTS § 311)
IN	*In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160, at *21 (D.N.J. May 8, 2017) (recognizing Indiana allows claims to proceed when the tort claim (negligent misrepresentation) is based on conduct that is either independent of a contract or where there is a *risk* of personal injury
ME	Maine allows for a claim for negligent misrepresentation under § 311. *See Dow v. Maier*, 2000 WL 33675683, *3 (Me. Super. Ct. Mar. 15, 2000) (finding under § 311 there is no requirement of a business purpose with respect to the misrepresentation)
MN	Minnesota has not adopted, nor rejected, § 311. *See also Cantonis v. Stryker Corp*., 2010 WL 6239354, at *4 (D. Minn. Nov. 23, 2010), *report and recommendation adopted*, 2011 WL 1084971 (D. Minn. Mar. 21, 2011) (allowing a claim for negligence to be stated that involved statements and omissions regarding a medical device)
NC	*Hunter v. Guardian Life Ins. Co. of Am.*, 593 S.E.2d 595, 600 (N.C. Ct. App. 2004) (stating "North Carolina 'expressly recognizes a cause of action in negligence based on negligent misrepresentation.'" (quoting *Stanford v. Owens*, 265 S.E.2d 617, 622 (N.C. App. 1980), *disc. review denied*, 301 N.C. 95 (1980))
VA	*Barrigan v. Elite Funding*, 2009 WL 54514, at *4 (E.D. Va. Jan. 6, 2009), *aff'd*, 353 F. App'x 813 (4th Cir. 2009) (finding that Virginia recognizes a claim for negligent misrepresentation)

Chart 9 – Consumer Protection: Limits of State Regulatory Oversight Statutes

State	Authority
AK	Alaska Stat. §45.50.481(c) ("The exemption in (a)(1) ... does not apply to an act or transaction listed in [§]45.50.471(b)."; *White v. NYLIFE Sec., LLC*, 551 F. Supp. 3d 974, 980-81 (D. Alaska 2021) (to get exemption, defendant must show: "that its conduct is subject to *ongoing, careful regulation*"; "that such regulation prohibits the conduct alleged"; the regulations "must 'prohibit the *specific* conduct at issue.'") (emphasis in original)
CO	Colo. Rev. Stat. Ann. §6-1-106(1) (standard UDPTA exclusion that does not broadly exclude claims arising out of conduct subject to regulatory oversight but instead narrowly applies to conduct that is expressly allowed and in compliance with other statutes and regulations); *Shostrom v. Ethicon, Inc.*, 2021 WL 778994, at *9-10 (D. Colo. Mar. 1, 2021) (denying motion for summary judgment on CCPA claim where plaintiff alleged that defendant's misrepresentations were not in compliance with any federal law)
CT	Conn. Gen. Stat. Ann. §42-110c(a)(1)); *Connelly v. Hous. Auth.*, 567 A.2d 1212, 1216 (Conn. 1990) (Supreme Court holding that exclusion applies where the actions of the defendant "are expressly authorized and pervasively regulated."); *Patane v. Nestlé Waters N. Am., Inc.*, 478 F. Supp. 3d 318, 329-31 (D. Conn. 2020) (summary judgment denied because fact issue as to whether conduct was "expressly authorized and pervasively regulated" where no conclusive evidence that regulators had "specifically approved" the sale at issue)
GA	O.C.G.A. §10-1-396(1) (FBPA) (protecting action "*specifically authorized* under laws administered by or rules and regulations promulgated by any regulatory agency of this state or the United States.") (emphasis added); O.C.G.A. §10-1-374(1) (UDTPA) (exception for "Conduct in compliance with the orders or rules of or a statute administered by a federal, state, or local government agency."); *Barge v. Bristol-Myers Squibb Co.*, 2009 WL 5206127, at *8 (D.N.J. Dec. 30, 2009) (noting exception inapplicable if the promotional materials were not in compliance or not the type specifically monitored)
IL	815 Ill. Comp. Stat. Ann. 510/4(1) ("This Act does not apply to ... conduct in compliance with the orders or rules of or a statute administered by a Federal, state or local governmental agency."); *Tri-Plex Tech. Servs., Ltd. v. Jon-Don, LLC*, 2022 WL 16709517, *5 (Ill. Ct. App. Nov. 4, 2022) ("To trigger these exemptions, a regulatory body must be acting within its statutory authority and *the challenged conduct must be 'specifically authorized' by that regulatory body*.") (emphasis added)
ME	Me. Rev. Stat. tit. 10, §1214(1)(A) (exception for "conduct in compliance with the orders or rules of, or a statute administered by, a federal, state or local governmental agency."); *Patane*, 478 F. Supp. 3d at 333-36 (denying defendant's motion for summary judgment based on Maine's exemption in Nestle spring water case)
MA	Mass. Gen. L. Ch. 93A §3 ("Nothing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States."); *Com. v. Fremont Inv. & Loan*, 897 N.E.2d 548, 561 (Mass. 2008) (exception applies only when there is "more than the mere existence of a related or even overlapping regulatory scheme" but rather "a defendant must show that such [regulatory] scheme affirmatively permits the practice which is alleged to be unfair or deceptive.") (quoting *Fleming v. Nat'l Union Fire Ins. Co.*, 837 N.E.2d 1113, 1121 (Mass. 2005))

State	Authority
MI	Mich. Comp. Laws Ann. §445.904(1)(a) (exception for "[a] transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States."); *Robertson v. State Farm Fire & Cas. Co.*, 890 F. Supp 671, 676 (E.D. Mich. 1995) ("[T]he inquiry under §1(a) is not whether the conduct is subject to regulation, but rather whether the conduct is 'specifically authorized.'"
NE	Neb. Rev. Stat. §59-1617(1) (exception for "actions or transactions otherwise permitted, prohibited, or regulated under laws administered by the Director of Insurance, the Public Service Commission, the Federal Energy Regulatory Commission, or any other regulatory body or officer acting under statutory authority of this state or the United States."); *Hage v. Gen. Serv. Bureau*, 306 F. Supp. 2d 883 (D. Neb. 2003) ("particular conduct is not immunized from the operation of the Consumer Protection Act merely because the actor comes within the jurisdiction of some regulatory body.")
NM	N.M. Stat. Ann. §57-12-7 (statute cited by Philips is clear on its face that it does not apply here: "Nothing in the Unfair Practices Act shall apply to actions or transactions *expressly permitted* under laws administered by a regulatory body of New Mexico or the United States, *but all actions or transactions forbidden by the regulatory body, and about which the regulatory body remains silent, are subject to the Unfair Practices Act*.") (emphasis added); *Truong v. Allstate Ins. Co.*, 227 P.3d 73, 83 (N.M. 2010)
OK	15 Okla. Stat. §754(2) (exception for "[a]ctions or transactions regulated under laws administered by the Corporation Commission or any other regulatory body or officer acting under statutory authority of this state or the United States."); *Money v. Bristol-Myers Squibb Co.*, 2009 WL 5216987, at *6 (D.N.J. Dec. 30, 2009) (stating if challenged materials "were not authorized by the FDA's regulatory scheme ... the statutory exemption would be inapplicable" and noting the exemption not "applicable merely because the promotion and marketing of prescription drugs are generally regulated").
RI	6 R.I. Gen. Laws Ann. §6-13.1-4(a) (mirroring the MA statute: "Nothing in this chapter shall apply to actions or transactions permitted under laws as administered by the department of business regulation or other regulatory body or officer acting under statutory authority of this state or the United States.")

Chart 10 – Consumer Protection: Reliance Presumed or Not Required

State	Authority
CA	*Wilson v. Frito-Lay N. Am., Inc*., 260 F. Supp. 3d 1202, 1208 (N.D. Cal. 2017) (presumption of reliance with material misrepresentation)
CO	*Hall v. Walter*, 969 P.2d 224, 237 (Colo. 1998) (no reliance required)
CT	*Hinchliffe v. Am. Motors Corp*., 440 A.2d 810, 815-16 (Conn. 1981) (neither causation nor reliance required)
IL	*Connick v. Suzuki Motor Co*., 675 N.E.2d 584, 593, 595 (Ill. 1996) (no reliance required)
KY	*Brown v. Tax Ease Lien Servicing, LLC*, 2015 WL 7431044, at *11 (W.D. Ky. Nov. 20, 2015) (no reliance required)
MD	*Est. of Morgan v. BWW L. Grp., LLC*, 2019 WL 2869286, at *3 (D. Md. July 3, 2019) (neither causation nor reliance required)
NJ	*Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 366 (N.J. 1997) (no reliance required)
NM	*Lohman v. Daimler-Chrysler Corp*., 166 P.3d 1091, 1098 (N.M. Ct. App. 2007) (no reliance required)

Chart 11 – Consumer Protection: Scienter Not an Essential Element

State	Authority
AR	*Curtis Lumber Co. v. Louisiana Pac. Corp*., 618 F.3d 762, 776 (8th Cir. 2010) (Arkansas law) (not all consumer protection theories require knowledge)
AZ	*Powers v. Guar. RV, Inc*., 278 P. 3d 333, 338 (Ariz. Ct. App. 2012) (does not require knowledge or intent)
IL	*Barrett v. Brian Bemis Auto World*, 408 F. Supp. 2d 539 (N.D. Ill. 2005) (does not require knowledge or intent)
MD	*McCormick v. Medtronic, Inc*., 101 A.3d 467, 493 (Md. App. 2014) (not all consumer protection theories require knowledge)
NV	*Poole v. Nev. Auto Dealership Invs., LLC*, 449 P.3d 479 (Nev. App. 2019) (does not require intent)
PA	*Pa. v. Navient Corp*., 354 F. Supp. 3d 529, 565-66 (M.D. Pa. 2018), *aff'd*, 967 F.3d 273 (3d Cir. 2020) (does not require intent)

Chart 12 – Consumer Protection: Recovery of Personal Injury Damages

State	Authority*
FL	Plaintiffs assert claims under Fla. Stat. Ann. §501.201, *et seq*. (DUTPA), and Fla. Stat. Ann. §817.06, 817.41, *et seq*. Philips challenges only claims under the DUTPA. Plaintiffs do not contest Philips' position
ME	Plaintiffs assert claims under Me. Rev. Stat. tit. 5, §205A, *et seq*. (UTPA), and Me. Rev. Stat. tit. 10, §1211, *et seq*. Philips challenges only the claims under the UTPA. *See Kilroy v. Northeast Sunspaces, Inc*., 930 A.2d 1060 (Me. 2007) (permitting UTPA claims alleging damages for personal injuries)
NE	Plaintiffs assert claims under Neb. Rev. Stat. §59-1601, *et seq*. (CPA), and Neb. Rev. Stat. §87-301, *et seq*. Philips challenges only claims under the CPA. Plaintiffs do not contest Philips' position
NM	N.M. Stat. Ann. §57-12-1, *et seq*. The issue has not been decided in New Mexico. *See Pena v. Scrip, Inc*., 2013 WL 12334164, at *3 (D.N.M. Mar. 22, 2013) ("Neither the New Mexico Supreme Court nor the New Mexico Court of Appeals has ruled on whether personal injury damages are recoverable under the UPA. In fact, those courts have manifestly avoided deciding whether the UPA extends to non-economic damages.").
OH	Ohio Rev. Code Ann. §1345.01, *et seq*. *Whitaker v. M.T. Auto., Inc.*, 855 N.E.2d 825, 833 (Ohio 2006) (claims only barred if the statutory violation requires proof of a personal injury; claims permitted where a plaintiff's injuries are the result of a violation).
SC	S.C. Code Ann. §39-5-10, *et seq*. *Little v. Brown Williamson Tobacco Corp*., 1999 WL 33291385, at *11 (D.S.C. Mar. 3, 1999) (under the UTPA "plaintiffs may have an action to recover their medical costs, lost earnings, and any other alleged out-of-pocket expenses.")

* Plaintiffs do not contest Philips' position with the remainder of the states cited in its Citation Table F(4)

Chart 13 – Consumer Protection: Availability of Damages/Injunctive Relief

State	Authority
ALL	*In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 510, 553-54 (N.D. Ill. 2019) (denying motion to dismiss based on unavailability of damages because plaintiff can still proceed where injunctive relief is permitted under statute)
DE	Damages *are* available. *See* Del. Code Ann. tit. 6, §2533(c) ("If damages are awarded to the aggrieved party under the common law or other statutes of this State, such damages shall be treble the amount of the actual damages proved."); *see also* Del. Code. Ann. tit. 6, §2533(a) (permitting action for injunctive relief)
GA	O.C.G.A. §10-1-373 (permitting action for injunctive relief); *Rickman v. BMW of N. Am.*, 2020 WL 3468250, at *16 (D.N.J. June 25, 2020) (denying motion to dismiss Georgia UDTPA claim because claim requested injunctive relief, which was available)
IL	815 Ill. Comp. Stat. Ann. 510/3 (permitting action for injunctive relief)
ME	Me. Rev. Stat. tit. 10, §1213 (permitting action for injunctive relief)
NE	Neb. Rev. Stat. §87-303 (permitting action for injunctive relief)

Chart 14 – Consumer Protection: Privity Not Required

State	Authority
AL	Ala. Code §8-19-3 (no direct purchase requirement and no case is cited by Philips); Ala. Code §8-19-5 proscribes a variety of wrongdoing that naturally extends beyond direct seller including "[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce."
AZ	*Watts v. Medicis Pharm. Corp*., 365 P.3d 944, 953 (Ariz. 2016) (plaintiff need not allege "direct merchant-consumer transaction" to succeed on consumer fraud claim, but rather must show "a false promise or misrepresentation made in connection with the sale or advertisement of 'merchandise,'" including prescription pharmaceuticals); *Sullivan v. Pulte Home Corp*., 306 P.3d 1, 2 (Ariz. 2013), cited by Philips, is distinguishable as it dealt with construction defects, brought by the subsequent purchaser of the house, who never had a contract with the homebuilder. The court never made a ruling regarding whether a subsequent purchaser had a claim under the Arizona consumer fraud act. *Id.*
DC	D.C. Code §28-3901 (no direct purchase requirement in statute, no case cited by Philips)
GA	No direct purchase requirement in the GFBPA. *Zeeman v. Black*, 273 S.E.2d 910, 914 (Ga. App. 1980) (limited to the consumer marketplace). *Lewis v. Ally Financial, Inc.*, 2022 WL 1286587, at *10 (N.D. Ga. Feb. 9, 2022), cited by Philips, is inapposite. Claims dismissed because they were conclusory, nothing in *Lewis* suggests a direct purchase requirement under the GFBPA.
ID	*BCBSM, Inc. v. Walgreen Co.*, 512 F. Supp. 3d 837, 857 (N.D. Ill. 2021) (finding lack of direct privity did not preclude claims; claim needed to be based on a contract but there did not need to be privity). *Dreyer v. Idaho Dep't of Health & Welfare*, 455 F. Supp. 3d 938, 952 (D. Idaho 2020), cited by Philips, is unhelpful because it discussed contractual requirement but did not find privity under those facts.
KY	*Neeley v. Wolters Kluwer Health, Inc.*, 2013 WL 3929059, at *17 (E.D. Mo. July 30, 2013) (no direct purchase requirement under KCPA). *Skinner v. Ethicon, Inc.*, 2021 WL 640809, at *4 (E.D. Ky. Feb. 18, 2021), cited by Philips, is factually distinguishable. Here, privity is not required. *See Naiser v. Univlever U.S., Inc.*, 975 F. Supp. 2d 727, 743 (W.D. Ky. 2013).
ME	Me. Rev. Stat. tit. 5, §213(1) (no direct purchase requirement in statute and no case cited by Philips); Me. Rev. Stat. tit. 5, §206(3) explicitly states that "'[t]rade' and 'commerce' shall include ... any trade or commerce directly or indirectly affecting the people of this State."
MS	Miss. Code Ann. §75-24-15(1), cited by Philips, expressly recognizes claims against not only the seller or lessor, but also the "manufacturer" committing a prohibited act or practice; *see also* Miss. Code Ann. §75-24-5.
MO	The MMPA prohibits the "act, use or employment by any person" of any unfair or deceptive practice "in connection with the sale or advertisement of any merchandise ... whether committed before, during or after the sale, advertisement or solicitation." Mo. Rev. Stat. §407.020.1. *Pleasant v. Noble Finance Corp.*, 54 F. Supp. 3d 1071, 1078 (W.D. Mo. 2014), cited by Philips, does not hold that a plaintiff must purchase directly. In fact, the court recognized that "the defendant's actions must have some relationship to the sale but ... the defendant need not necessarily be the seller."

State	Authority
NM	The NMUPA contains no direct purchase requirement. N.M. Stat. Ann., §§57-12-2, 57-12-10. The UPA's definition of an "unfair or deceptive trade practice" does not require privity of contract between the plaintiff and the defendant; rather, the statute refers to false or misleading representations that may, tend to, or do "deceive or mislead any person." N.M. Stat. Ann., §57-12-2(D). *Amco Ins. Co. v. SimplexGrinnell LP*, 2016 WL 4425095, at *8 (D.N.M. Feb. 29, 2016), cited by Philips, does not state otherwise.
PA	73 Pa. Stat. Ann. §201-9.2(a) (no direct purchase requirement in statute and there is no such requirement under the UTPCPL). *See Johnson v. MetLife Bank, N.A.*, 883 F. Supp. 2d 542, 547-48 (E.D. Pa. 2012) ("[P]laintiff need not be in direct privity with a defendant to bring an action under the [PA] UTPCPL....")
RI	6 R.I. Gen. Laws §6-13.1-1(3) (no direct purchase requirement and broadly defining what can be considered a person for standing). *R.I. Laborers' Health & Welfare Fund ex rel. Trustees v. Philip* Morris, Inc., 99 F. Supp. 2d 174, 189 (D.R.I. 1999), cited by Philips, does not discuss a direct purchaser requirement rather rejected claims where the plaintiff was not a purchaser of defendants' goods for personal, family, or household use.
TN	Tenn. Code Ann. §47-18-103 (no direct purchase requirement in statute and there is no such requirement under the TCPA). *See Westgate Resorts, Ltd. v. Wesley Fin. Grp., LLC*, 2021 WL 794878, at *4-6 (M.D. Tenn. Mar. 2, 2021) (collecting cases; TCPA is not limited to consumers, but rather applies to "any person," who suffered an injury); Tenn. Code Ann. §47-18-109(a)(1) ("Any person who suffers an ascertainable loss....")
VT	Vt. Stat. Ann. tit. 9, §2451a contains no direct purchase requirement and the Vermont Supreme Court has held that there is no privity requirement. *Elkins v. Microsoft Corp.*, 817 A.2d 9, 12-13 (Vt. 2002) (Act contained "no privity requirement" and was "clearly intended ... to have as broad a reach as possible.")
WV	W. Va. Code Ann. §46A-6-106(a) (no direct purchase requirement in statute; statute authorizes "any person" to bring suit). Philips cites no case is support of its position.

Chart 15 – Consumer Protection: The Devices Qualify As Consumer Goods

State	Authority
ALL	Philips relies on state statutes in F(7) that *do not* exclude personal use medical devices such as CPAPs from their scope (the handful of cases it cites are distinguishable, many because they involve surgical implants typically purchased by doctor and not consumer)
AL	Ala. Code §8-19-3(4) ("Consumer" is "[a]ny natural person who buys goods or services for personal, family, or household use"). Ala. Code §8-19-3(14) (trade or commerce includes any good or article without limitation). Philips cites *Collins v. Davol*, 56 F. Supp. 3d 1222, 1232 n.9 (N.D. Ala. 2014) (surgical implant, *see* above)
AK	Philips cites *Aloha Lumber Corp. v. Univ. of Alaska*, 994 P.2d 991, 1002 (Ala. 1999) (involved sale of trees/timber, plainly not a consumer good for personal use)
CA	Cal. Civ. Code §1761 ("Goods" are "tangible chattels bought or leased for use primarily for personal, family, or household purposes"); *Wang v. Massey Chevrolet*, 118 Cal. Rptr. 2d 770, 779 (Cal. Ct. App. 2002) (CLRA must be "liberally construed and applied to promote its underlying purposes … to protect consumers against unfair and deceptive business practices"); *In re Vioxx, Class Cases*, 103 Cal. Cptr. 3d 83 (Cal. Ct. App. 2009) (applying CLRA to pharmaceutical products); *Steroid Hormone Prod. Cases*, 104 Cal. Rptr. 3d 329 (Cal. Ct. App. 2010) (same)

State	Authority
DC	D.C. Code Ann. §28-3901(a)(2) ("anything that ... [a] person ... would ... normally use for personal, household, or family purposes"); *see also generally Ctr. of Inquiry Inc. v. Walmart, Inc.*, 283 A.3d 109 (D.C. App. 2022) (applying CCPA to sale of homeopathic and OTC drugs); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, 2018 WL 7197233, at *39 (S.D.N.Y. Dec. 26, 2018) (noting members' use prescription drugs for "personal, family, or household purposes" under §28-3901(a)(2)(B)(i))
GA	O.C.G.A. §10-1-392(a)(10) ("Consumer transactions" include "sale, purchase, lease, or rental of goods, services, or property, real or personal, primarily for personal, family, or household purposes"); *see also Georgia ex. rel. Carr v. Elite Integrated Medical, LLC*, 533 F. Supp. 3d 1303 (N.D. Ga. 2021) (Georgia Attorney General brought suit under FBPA against regenerative medical products seller)
HI	Haw. Rev. Stat. §480-1 ("Consumer" is "a natural person who, primarily for personal, family, or household purposes, purchases ... goods or services"); *see also People v. Med. Device Bus. Servs. f/k/s Depuy*, 2019 N.Y. Misc. LEXIS 12666, at *3-6 & n.2 (N.Y. Sup. Ct. Feb. 5, 2019) (settlement in medical device case brought by New York Attorney General including claims under Hawaii's UDTPA)
IL	815 Ill. Comp. Stat. Ann. 505/1(e) ("consumer" is "any person who purchases ... for his use or that of a members of his household"); 815 Ill. Comp. Stat. Ann. 505/1(f) ("advertising, offering for sale, sale [of] any property ... and any other article, commodity, or thing of value directly or indirectly affecting the people of this State"); *De Bouse v. Bayer AG*, 922 N.E.2d 309 (Ill. 2009) (analyzing, on the merits, ICFA claims brought by purchasers of prescription drug Baycol against drug manufacturer)
IN	Ind. Code Ann. §24-5-0.5-2(a) ("'Consumer transaction' means a sale, lease [] of an item of personal property ... for purposes that are primarily personal, familial, charitable, agricultural, or household"); *In re Actiq Sales & Mktg. Practices Litig.*, 790 F. Supp. 2d 313, 325-26 (E.D. Pa. 2011); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 495 F. Supp. 2d 1027, 1036-37 (N.D. Cal. 2007)
KY	Ky. Rev. Stat. Ann. §367.220(1) ("any person who purchases or leases goods or services primarily for personal, family or household purposes"); *Neeley*, 2013 WL 3929059, at *17 (purchasers of drug Reglan and its generic version stated claim under KCPA)
LA	La. Stat. Ann. §51:1402(3) ("'Consumer transaction' means any transactions involving trade or commerce to a natural person, the subject of which transaction is primarily intended for personal, family, or household use"); La. Stat. Ann. §51:1405 ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."); La. Stat. Ann. §51:1409(A) ("Any person who suffers any ascertainable loss of money ... as a result of ... an unfair or deceptive method, act, or practice declared unlawful by R.S. 51:1405, may bring an action")
ME	Me. Rev. Stat. tit. 5, §213 ("Any person who purchases or leases goods, services or property ... primarily for personal, family, or household purposes"); Me. Rev. Stat. tit. 5, §207 ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."). Philips cites *Herzog v. Arthrocare Corp*, 2003 WL 1785795, at *10 (D. Me. Mar. 21, 2003) (surgical tool purchased by surgeon)

State	Authority
MD	*Mayor of Baltimore v. GlaxoSmithKline, LLC*, 2022 WL 537004, *9 (Md. Cir. Ct. Balt. City Jan. 28, 2022) (allowing a city to sue under the MCPA against the pharmaceutical companies because the city purchased ranitidine "through various City-funded insurance and healthcare programs administered for the benefit of Baltimore residents")
MI	Mich. Comp. Laws Ann. §445.902(g) ("'Trade or commerce' means the conduct of a business providing goods . . . primarily for personal, family, or household purposes"); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 495 F. Supp. 2d 1027, 1032-34 (N.D. Cal. 2007) (purchase of drugs which gave rise to TPP's claims, "were primarily for personal purposes, that is, the personal use of the patients.")
MS	Miss. Code Ann. §75-24-15(1) ("any person who purchases or leases goods or services primarily for personal, family or household purposes"); Miss. Code Ann. §75-24-3(b) ("'Trade' and 'commerce' mean the advertising, offering for sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situated ... and any trade or commerce directly or indirectly affecting the people of this state")
MO	Mo. Rev. Stat. §407.025.1 ("Any person who purchases or leases merchandise primarily for personal, family or household purposes"); §407.010.4 ("Merchandise" means "any objects, ware, goods..."). Courts have held "merchandise" includes prescription drugs. *Plubell v. Merck & Co., Inc.*, 289 S.W.3d 707 (Mo. Ct. App. 2009)
MT	Mont. Code Ann. §30-14-102 ("'Consumer' means a person who purchases or leases goods ... primarily for personal, family, or household purposes."). *See generally Vinion v. Amgen, Inc.*, 2004 WL 6057351, at *4 (D. Mont. Aug. 30, 2004) (court rejected plaintiffs' (drug study participants) MCPA claims but suggested claims would lie if drugs were purchased "primarily for personal purposes" instead of "for the benefit of the study")
OH	Ohio Rev. Code Ann. §1345.01 ("'Consumer transaction' means a sale, lease ... of goods ... for purposes that are primarily personal, family, or household"); *State ex rel. Dewine v. Janssen Pharm., Inc.*, 2012 Ohio Misc. LEXIS 17878, at *2 (Ohio Ct. Com. Pl. Franklin Cnty. Sept. 10, 2012) (settlement order recognizing that Janssen, engaged in trade affecting consumers, within the meaning of the CSPA)
OR	Or. Rev. Stat. §646.605(6)(a) ("goods" means "those that are or may be obtained primarily for personal, family or household purposes"); *Fowler v. Cooley*, 245 P.3d 155, 159 (Or. Ct. App. 2010) ("If goods are customarily bought by a substantial number of purchasers for personal, family or household uses and were, in fact, bought by the plaintiff for his or someone else's use and not for resale, the [OUTPA] applies.")
PA	*Comm. v. TAP Pharm. Prods., Inc.*, 885 A.2d 1127, 1142-43 (Pa. Commw. Ct. 2005) ("[T]he drugs are ultimately used for a personal, family or household purpose.... Based upon the foregoing... that the purchases the programs made were for personal. family, or household use under *Valley Forge*"). Philips cites a distinguishable Learned Intermediary case.

State	Authority
RI	6 R.I. Gen. Law. §6-13.1-5.2 ("Any person who purchases or leases goods or services primarily for personal, family, or household purposes"); 6 R.I. Gen. Law. §6-13.1-2 ("[U]nfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful."); 6 R.I. Gen. Law. §6-13.1-1(5) ("'Trade' and 'commerce' means the advertising, offering for sale ... any property ... or thing of value [in] any trade or commerce directly or indirectly affecting the people of this state."); *Long v. Dell, Inc*., 93 A.3d 988, 1000 (R.I. 2014) ("The DTPA is a remedial act and it should be liberally construed.")
VT	Vt. Stat. Ann. tit. 9, §2451a(1) ("'Consumer' means any person who purchases, leases, contracts for ... goods or services ... for the person's use or benefit or the use or benefit of a member of the person's household"); *In re Wellbutrin XL Antitrust Litig*., 260 F.R.D. 143, 156 (E.D. Pa. 2009) (standing for insurers because "[r]eimbursement for the purchase of drugs, ... constitutes a monetary injury to the plaintiffs")
VA	Va. Code Ann. §59.1-198 (includes transactions involving goods "to be used primarily for personal, family or household purposes"); *Wingate v. Insight Health Corp.*, 2013 WL 9564175, at *5-7 (Va. Cir. Ct. Oct. 31, 2013) (denying motion to dismiss claims under VCPA for misrepresentations concerning steroid injection drug); *Com. Ex rel. Herring v. Teva Pharm. USA, Inc.,* 2020 WL 12991889 (Va. Cir. Ct. Nov. 13, 2020).
WV	*W. Va. ex rel. McGraw v. Johnson & Johnson*, 704 S.E.2d 677, 683-84 (W. Va. 2010) (State sued Johnson & Johnson for violations of the CCPA for its allegedly deceptive and misleading promotion of two of its prescription drugs); *but see Wyeth v. White*, 705 S.E.2d 828 (W. Va. 2010) (distinguishable because CPAPs are personal use devices)
WY	Wyo. Stat. Ann. §40-12-102(a)(ii) ("'Consumer transactions' means the advertising, offering for sale, sale or distribution of any merchandise to an individual for purposes that are primarily personal, family or household"); Wyo. Stat. Ann. §40-12-102(a)(vi) ("'Merchandise" includes any service or any property, tangible or intangible, real, personal or mixed, or any other object, ware, good, commodity, or article of value wherever situated.")

Chart 16 – Consumer Protection: Criteria for Activity to be "Within the State"

State	Authority
AZ	*Cheatham v. ADT Corp.*, 161 F. Supp. 3d 815, 825 (D. Ariz. 2016) (statute "broadly prohibits fraudulent, deceptive, or misleading conduct in connection with the sale or advertisement of consumer goods and services")
CT	*Izzarelli v. R.J. Reynolds Tobacco Co.*, 117 F. Supp. 2d 167, 176 (D. Conn. 2000)
DE	*Arcelik A.S v. E. I. du Pont De Nemours & Co.*, 2018 WL 1401327, at *8 (D. Del. Mar. 20, 2018)
DC	*Ctr. for Inquiry Inc. v. Walmart, Inc.*, 283 A.3d 109, 120 (D.C. 2022)
FL	*Lewis v. Mercedes-Benz USA, LLC*, 530 F. Supp. 3d 1183, 1233 (S.D. Fla. 2021) (claim survived motion to dismiss where out-of-state manufacturers allegedly "represent[ed]" in marketing/advertising campaigns that their products were of a quality they were not)
GA	*Amin v. Mercedes-Benz USA, LLC*, 301 F. Supp. 3d 1277, 1290 (N.D. Ga. 2018)
ID	*State ex rel. Kidwell v. Master Distributors, Inc.*, 615 P.2d 116, 127 (Idaho 1980) (out-of-state manufacturer liable where it "knowingly distributed its products in Idaho")
IL	*Dyson, Inc. v. Bissell Homecare, Inc.*, 951 F. Supp. 2d 1009, 1029 (N.D. Ill. 2013)
KS	*Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233, 1247 (D. Kan. 2007) (plaintiff stated claim against out-of-state defendants who "introduced their products into the national stream of commerce, including Kansas," and "market[ed]" their products in-state)
MA	*O'Hara v. Diageo-Guinness, USA, Inc.*, 306 F. Supp. 3d 441, 463 (D. Mass. 2018)
MN	*Cleveland v. Whirlpool Corp.*, 550 F. Supp. 3d 660, 675 (D. Minn. 2021)
MO	*Hawkins v. Nestle U.S.A. Inc.*, 309 F. Supp. 3d 696, 701-06 (E.D. Mo. 2018) (plaintiff stated claim against out-of-state manufacturer based on allegation that manufacturer packaged its product in a deceptive manner and distributed product in the state)
NE	*S&H Distribution, LLC v. Meyer Lab., Inc.*, 2022 WL 5255323, at *3 (D. Neb. Oct. 6, 2022) (declining to dismiss UDTPA claim where out-of-state manufacturer allegedly made deceptive statements on its "product labels and website")
NV	*R.J. Reynolds Tobacco Co. v. Eighth Jud. Dist. Ct. in & for Cnty. of Clark*, 514 P.3d 425, 427 (Nev. 2022) (claim stated where they alleged "that they were directly harmed by [an out-of-state manufacturer's] false and misleading advertising" of its products)
NH	*Bougopoulos v. Altria Grp., Inc.*, 954 F. Supp. 2d 54, 64-65 (D.N.H. 2013)
NY	*Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 292-93 (S.D.N.Y. 2015) (claim stated where out-of-state manufacturer of medical products used deceptive advertisements and product labels and distributed its products for sale in the state)
OH	*Traxler v. PPG Indus., Inc.*, 158 F. Supp. 3d 607, 627-28 (N.D. Ohio 2016)
OK	*Hampton v. Gen. Motors, LLC*, 2022 WL 4538440, at *6 (E.D. Okla. Sept. 28, 2022)
SC	*State ex rel. Wilson v. Ortho-McNeil-Janssen Pharms., Inc.*, 777 S.E.2d 176, 195-96 (S.C. 2015) (affirming judgment against out-of-state drugmaker based on deceptive labeling and false information provided to prescribing physicians in the state)
TN	*Orr v. Ethicon, Inc.*, 2020 WL 9073528, at *3-5 (E.D. Tenn. Sept. 11, 2020)
TX	*GJP, Inc. v. Ghosh*, 251 S.W.3d 854, 885 (Tex. Ct. App. 2008) (affirming judgment against out-of-state seller of defective product and explaining that "courts generally apply the Texas [consumer protection statute] to suits involving damages to Texas consumers, regardless of where the defendant maintains his business")

Chart 17 – Consumer Protection: Standards to Satisfy Notice and Exceptions

State	Authority
AL	Ala. Code §8-19-14 ("The demand requirements of this subsection shall not apply if the prospective respondent does not maintain a place of business or does not keep assets within the state.")
AK	No authority identified applying Alaska Stat. §45.50.535(b) to dismiss claim for lack of pre-suit notice as incurable defect
CA	*Rosales v. FitFlop US, LLC*, 882 F. Supp. 2d 1168, 1177 (S.D. Cal. 2012) (Cal. Civ. Code §1782 does not apply to injunctive relief, and even as to damages claims, is not a basis for dismissal with prejudice, but rather is curable by amended pleading)
GA	O.C.G.A. §10-1-399(b**)** ("The demand requirements of this subsection shall not apply if the prospective respondent does not maintain a place of business or does not keep assets within the state.")
IN	Ind. Code Ann. §24-5-0.5-5 (excluding pre-suit notice when violation is "incurable" as defined by statute, as alleged in this case)
MA	Mass. Gen. L. Ch. 93A §1-9; *See, e.g.*, *York v. Sullivan*, 338 N.E.2d 341, 347 (Mass. 1975) ("even if the first suit could be treated as a suit under c. 93A, subject to dismissal because it was begun too soon, such a dismissal should not ordinarily bar a suit brought after the thirty days had run.... Even if dismissal were proper, it should not be 'on its merits' or 'with prejudice.'")
ME	*In re Ranbaxy Generic Drug Application Antitrust Litig.*, 2020 WL 2308839, at *3 (D. Mass. May 8, 2020) ("failure to comply with the MUTPA's pre-suit notice and demand requirement does not require dismissal.")
TX	Tex. Bus. & Com. Code Ann. §17.505; In re Alford Chevrolet-Geo, 997 S.W.2d 173, 178 (Tex. 1999) (affirming finding that abatement was not necessary despite plaintiffs' failure to provide 60-day pre-suit notice because case was automatically abated and when trial court issued its ruling, more than 60 days had passed since plaintiffs provided notice)
UT	*Nunes v. Rushton*, 299 F. Supp. 3d 1216, 1241 n.6 (D. Utah 2018) ("section 13-11a-4(5) creates a notice requirement only for an 'action for injunctive relief.'")
WV	*In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 589-90 (E.D. Pa. 2018) (notice obligation satisfied under WV law even though notice wasn't provided until 3 months after filing of complaint because the notice provision contemplated post-suit notice)
WY	Wyo. Stat. Ann. §40-12-109 (reads primarily as a limitations period and does not state any specific period of pre-suit notice required)

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on this 7th day of March 2023, and is available for download by all counsel of record.

/s/ D. Aaron Rihn
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