UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation

MDL DOCKET NO. 1769

This Document Relates to ALL CASES LISTED ON EXHIBIT "A"

ASTRAZENECA'S MOTION FOR JUDGMENT ON THE PLEADINGS REGARDING THE STRICT LIABILITY "DESIGN DEFECT" CLAIMS AND RELATED "IMPLIED WARRANTY" CLAIMS ASSERTED BY PLAINTIFFS IN JURISDICTIONS THAT DO NOT RECOGNIZE THOSE CLAIMS IN THE PRESCRIPTION DRUG CONTEXT

I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 12(c), defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP ("AstraZeneca") move for judgment on the pleadings seeking dismissal of the strict liability "design defect" claims and/or "implied warranty" claims asserted by plaintiffs residing in jurisdictions that do not recognize such claims in the prescription drug context as a matter of law.

The complaints of 3,679 MDL plaintiffs haphazardly assert strict liability "design defect" claims against AstraZeneca based on Seroquel, a prescription drug, even though such claims are not cognizable under the governing laws of those states in which these plaintiffs reside. *See* Exhibit A (attached). Twenty-three states and the District of Columbia do not recognize "design defect" claims under strict liability theories in the prescription drug context,[1] and another three states do not recognize the doctrine of strict

[1] These twenty-three states are Alabama, California, Connecticut, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, and Wyoming.

products liability at all.[2] Consequently, AstraZeneca is entitled to judgment as a matter of law on each of these legally meritless claims. *See also* 3/2/07 Status Conference Transcript at 49:12-15 (plaintiff's liaison counsel admitting "there is no design defect claim that's really viable" in the "pharmaceutical prescription drug" context).

In addition, a number of these plaintiffs try to re-cast their legally meritless design-defect theories as claims for breach of implied warranty, but those efforts fail for the same reason. Courts in at least eleven jurisdictions relevant here have rejected similar efforts.[3] Accordingly, AstraZeneca is entitled to judgment on the pleadings as to those legally defective implied warranty claims as well.[4]

II. BACKGROUND

Plaintiffs in this MDL assert a series of state-law claims against AstraZeneca arising from their ingestion of the prescription drug Seroquel, an atypical antipsychotic approved by the FDA as safe and effective for indicated uses since 1997. Plaintiffs allege their use of Seroquel caused them to suffer injuries, most commonly diabetes. The

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[2] These three states are North Carolina, Virginia and Delaware.

[3] These eleven jurisdictions are California, District of Columbia, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Pennsylvania, Tennessee, Utah, and Wyoming.

[4] Apart from this Rule 12(c) motion, AstraZeneca in the subsequent summary judgment phase of dispositive motion practice in this MDL expects to present its further arguments supporting dismissal of *all* strict liability design-defect claims and related implied warranty claims asserted by the remaining plaintiffs – including, *inter alia*, contentions that such state-law claims are impliedly preempted by federal law because they fatally conflict with the FDA's authoritative regulatory determinations that Seroquel is sufficiently "safe and effective" to support its lawful distribution as a prescription drug in the United States despite the risks about which plaintiffs complain. *See, e.g.*, *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2006 WL 2472484, at *3 (N.D. Cal. Aug. 24, 2006); 71 Fed. Reg. 3922, 3935 (F.D.A. Jan. 24, 2006) (conflict preemption bars state claims that "encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public – the central role of FDA"). However, this Rule 12(c) motion focuses only on those plaintiffs that have asserted claims *not recognized by the underlying and governing state law*.

principal claims asserted, which sound in "failure to warn" theories, are not at issue here. Instead, this motion attacks plaintiffs' assertion of *design defect* theories pled as "strict liability" or "implied warranty" claims that are not recognized by the governing law.

Strict Liability "Design Defect" Claims: Thousands of plaintiffs in this MDL – including many individual complaints and all of the aggregated complaints filed by the Bailey, Perrin & Bailey firm[5] – indiscriminately assert a boilerplate strict liability "design defect" claim, alleging that:

- "Seroquel was defective in design" because the "risks of serious harm posed by the drug outweighed its alleged benefits" (Complaint, ¶ 28, *Aaron, et al. v. AstraZeneca L.P., et al.*, No. 06-cv-11847-NG (D. Mass. Oct. 11, 2006) ["*Aaron* Complaint"]); and/or
- Seroquel was "defective in design" because "the risks of serious harm posed by this drug was sufficiently great in relation to its alleged benefits" (Complaint, ¶ 84, *Campbell, et al. v. AstraZeneca Pharms., LP*, No. 06-cv-180 (E.D. Mo. Feb. 8, 2006)).[6]

By their own accounts, however, 3,679 plaintiffs reside in one of the twenty-seven jurisdictions that do *not* recognize such claims in the prescription drug context.

Breach of "Implied Warranty" Claims: Many of these plaintiffs also try to assert the same basic design defect theory re-cast as a claim for breach of the implied warranty of merchantability or fitness, variously alleging that:

- AstraZeneca breached "implied warranty of merchantability" and "fitness" because "Seroquel was defective" and "not fit for the ordinary purpose for which such drugs are used" in that it was not "reasonably safe for its intended use" (Complaint, ¶¶ 73-76, *Connor, et al., v. AstraZeneca Pharms., L.P., et al.*, No. 5:06-cv-16 (E.D. Tex. Jan. 30, 2006) (Count VII "Implied Warranty");

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[5] While the Court ordered plaintiffs to sever these improperly joined actions, the plaintiffs effectively re-filed identical complaints on a separate basis all of which still contain the same causes of action originally pled.

[6] *See also, e.g.*, Complaint, ¶¶ 87-93, *King v. AstraZeneca Pharms., L.P.*, No. 3:06-cv-620 (N.D. Cal. Jan. 30, 2006) (plaintiff, a Pennsylvania resident, asserts strict liability "design defect" claim based on allegation that Seroquel's "foreseeable risks exceeded the benefits associated with the design or formulation").

- "Plaintiff developed serious health problems" because Seroquel was not "of merchantable quality or safe or fit for [its] intended use" (Complaint, ¶¶ 82-87, *McAllister v. AstraZeneca Pharms., L.P.*, No. 3:06-cv-568 (N.D. Cal. Jan. 27, 2006) ("Implied Warranty" claim); *Aaron* Complaint, *supra*, ¶¶ 45-48 (same); and
- AstraZeneca "impliedly warranted Seroquel to be of merchantable quality" and sufficiently "safe," and that as a "result of [AstraZeneca's] breach of implied warranty, Plaintiff developed Diabetes Mellitus" (Complaint, ¶¶ 74-78, *Hogan v. AstraZeneca Pharms. LP*, No. 07-cv-234 (D.D.C. Feb. 26, 2007) (Count VIII "Breach of Implied Warranty")).

By their own accounts, however, 1,540 of these plaintiffs reside in one of the eleven jurisdictions in which such efforts fail as a matter of law.

Exhibit A contains a comprehensive list of those MDL plaintiffs whose complaints assert design defect theories cast as strict liability or implied warranty claims even though, by their own pleaded account and as confirmed by their verified PFS responses, they reside in jurisdictions in which one or both of these claims are not legally cognizable in this prescription drug context – including Alabama, California, Connecticut, Delaware, the District of Columbia, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wyoming.

III. STANDARD ON MOTIONS FOR JUDGMENT ON THE PLEADINGS UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(c)

A motion for judgment on the pleadings may be made at any time after the pleadings have closed. *See* Fed. R. Civ. P. 12(c). A Rule 12(c) motion should be granted where the claims on their face reveal that defendant is entitled to judgment "under the governing substantive law." 5C Wright & Miller, FEDERAL PRACTICE & PROCEDURE: CIVIL 3D, § 1367, at p. 242 (2004); *accord Hawthorne v. Mac Adjustment, Inc.*, 140 F.3d 1367, 1370 (11th Cir. 1998). Motions under Rules 12(c) and 12(b)(6) are treated

"identically." *First Merchants Collection Corp. v. Rep. of Arg.*, 190 F. Supp. 2d 1336, 1338 n.3 (S.D. Fla. 2002). Hence, a Rule 12(c) motion, like a Rule 12(b)(6) motion, is properly granted where – as here – the underlying substantive law does not recognize a cause of action or theory alleged in the complaint. *See*, *e.g.*, *Brown v. City of Clewiston*, 644 F. Supp. 1407, 1409 (S.D. Fla. 1986) (Rule 12(c) motion is "proper" to determine legal question whether complaint's allegations set forth a "cognizable" legal claim under governing law); *In re Eli Lilly & Co., Prozac Prods. Liab. Litig.*, 789 F. Supp. 1448, 1453-56 (S.D. Ind. 1992) (dismissing portion of strict liability and implied warranty claims against prescription drug manufacturer premised on non-cognizable "design defect" theories); *see also* 5C Wright & Miller, FEDERAL PRACTICE & PROCEDURE: CIVIL 3D, § 1369, at p. 264 (noting the "sound[ness]" of the conclusion that "principles of partial summary judgment [are] … applicable to a motion for judgment on the pleadings," which provides "the district judge greater flexibility and promot[es] efficiency and economy").

IV. ARGUMENT

The doctrine of strict products liability has been adopted by most, but not all, states within the United States. Section 402A of the Restatement (2d) of Torts "set[s] forth the strict products liability doctrine," *Brown v. Superior Court* (*Applied Labs.*), 751 P.2d 470, 474 n.1 (Cal. 1988), and provides:

> One who sells any product in a *defective condition unreasonably dangerous* to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user of consumer, or to his property, if (a) the seller is engaged in the business or selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Rest. (2d) of Torts § 402A (emphasis added).[7]

It is hornbook law that there are three types of product "defects" that may render a product actionable under this doctrine and, thus, three different types of strict products liability claims: (1) design defect claims; (2) manufacturing defect claims; and (3) failure-to-warn (or marketing defect) claims. *See, e.g.*, *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991) (citing Prosser & Keeton, THE LAW OF TORTS, § 99, at 695-98) (5th ed. 1984)); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 746 (W.D. Pa. 2004); *accord Brown*, 751 P.2d at 474.

This motion concerns the first category of claims, *i.e.*, design defect claims.[8] The premise of this distinct sort of strict liability claim is that the product's *design* itself is intrinsically flawed in a way that renders the product "unreasonably dangerous" and, thus, actionable under Restatement (2d) of Torts § 402A. *See, e.g.*, *Brown*, 751 P.2d at 474-75. Under the principal test that plaintiffs must satisfy to establish design defect claims, the trier of fact is asked to determine "whether, on balance, the benefits of the challenged design outweighed the risk of danger inherent in the design." *Id*. at 477; *see also* Prosser & Keeton, THE LAW OF TORTS, § 99, at 695, 698-700; W.P. Keeton, "The Meaning of Defect in Products Liability Law – A Review of Basic Principles," 45 MO. L. REV. 579, 592-93 (1980).

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[7] The theory underlying strict products liability is that manufacturers of defective and unreasonably dangerous products should be liable, without fault, for all injuries caused by the products – because they are in the best position either (i) to spread the costs of such injuries across all consumers by raising the price of the products and/or obtaining liability insurance, or (ii) to pull the product entirely from the market. *See, e.g.*, *Brown*, 751 P.2d at 478-80; Prosser & Keeton, THE LAW OF TORTS § 98, at pp. 692-94 (5th ed. 1984).

[8] It also attacks claims premised on the same theories asserted as state-law "implied warranty" claims which, as explained below (*see* Part IV.B, *infra*), fail as a matter of law for the same reasons that plaintiffs' legally meritless design-defect claims must fail.

However, three states do not recognize the strict products liability doctrine at all. Twenty-three other states and the District of Columbia have held that, in the prescription drug context, manufacturers are not subject to strict liability "design defect" claims, but only claims premised on inadequate warning or manufacturing defect theories. Courts in these jurisdictions have reached that conclusion for at least one of three principal reasons.

First, these courts follow comment k to Restatement (2d) of Torts § 402A,[9] which they interpret as providing that prescription drugs are not "unreasonably dangerous" products, but rather are "unavoidably unsafe" in a way that *exempts* them from any design-defect theory under strict liability. *See Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996), *Brown*, 751 P.2d at 475; *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90-91 (2d Cir. 1980). While failure-to-warn or manufacturing-defect claims may be asserted against drug manufacturers, strict liability design-defect claims fail as a matter of law. *See, e.g., Schaerrer v. Stewart's Plaza Pharmacy, Inc*., 79 P.3d 922, 928 (Utah 2003).

Second, recognizing any state-law design defect claim would wrongly permit lay juries to second-guess the risk-utility balancing and judgments of the FDA, which regulates and ultimately approves prescription drugs as sufficiently safe and efficacious to warrant their availability in the United States. *See, e.g., Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (Texas law rejects design-defect claims in

[9] In relevant part, comment k provides: "*Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." Rest. (2d) of Torts § 402A, cmt. k (a "seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, *is not to be held strictly liable* for unfortunate consequences attending their use") (emphasis added). Notably, pharmaceutical drugs such as Seroquel are available only by physician prescription precisely because they are unavoidably unsafe products.

this context because "allow[ing] plaintiffs to sue for defective design of prescription drugs would . . . allow juries to second-guess the FDA's approval of the drugs for marketing"); *Grundberg*, 813 P.2d at 96-97 (same); *Sprague v. Upjohn Co.*, 1995 WL 376934, *2 (D. Mass. 1995) ("defective design claim is actually a claim that [the drug] should never have been designed or manufactured at all," and "[t]he role of the FDA should not be usurped by untrained courts and juries").[10]

Third, these courts also often emphasize several overriding *policy reasons* that support this "important distinction between prescription drugs and other products," which is premised in large part on "the broader public interest in the availability of drugs at an affordable price." *Brown*, 751 P.2d at 478-79. Such public policy considerations include concerns that: (1) allowing imposition of "strict liability for design defects" in the prescription drug context may "cause manufacturers to delay placing new products on the market, even after those products receive FDA approval," and thus deny "prompt availability of new pharmaceutical products" that may help consumers and save lives; (2) the "added expense of insuring against" strict liability design-defect claims may "cause the cost of medication to increase to the extent that it would no longer be affordable to consumers"; and (3) the specter of massive liability might force companies to "stop producing valuable drugs" due to enormous costs imposed by "lawsuits" claiming each drug's design was defective due to its side effects, and a corresponding "inability to secure adequate insurance." *Grundberg*, 813 P.2d 89, 93-95; *accord Brown*,

[10] While these courts employ this reasoning in refusing to recognize the claims as a matter of state law, the same premise illustrates why such claims are also barred by federal law under the doctrine of implied conflict preemption (*see* n. 4, *supra*).

751 P.2d at 479-81; *Hackett*, 246 F. Supp. 2d at 595.[11] The California Supreme Court in *Brown* cited real-world examples illustrating these concerns and showing the "connection between the cost and availability of pharmaceuticals and the liability imposed on their manufacturers for injuries resulting from their use." 751 P.2d at 480 n.10.

Regardless of the reason, however, what is dispositive here is that 3,679 plaintiffs in this Seroquel MDL have asserted strict liability "design defect" claims that are simply *not cognizable* under the governing laws of these twenty-seven jurisdictions. *See* Part IV.A., *infra*. Moreover, the law of at least eleven jurisdictions prohibits any effort to re-cast these legally meritless claims as claims for breach of an "implied warranty." *See* Part IV.B., *infra*. Thus, AstraZeneca is entitled to judgment on the pleadings with respect to these legally defective causes of action. *See* Part IV.C., *infra*.

A. Strict Liability "Design Defect" Claims Are Not Legally Cognizable In The Prescription Drug Context In Twenty-Seven Jurisdictions

1. Three States Do Not Recognize The Doctrine Of Strict Products Liability At All

No strict liability claim exists in North Carolina, Virginia, or Delaware.

Under North Carolina law, "[t]here shall be no strict liability in tort in product liability actions." N.C. Gen. Stat. Ann. § 99B-1.1 (2007); *see also*, *e.g.*, *Cowley v. Abbott Labs.*, 476 F. Supp. 2d 1053, 1061 (W.D. Wis. 2007) (applying North Carolina law in rejecting strict liability design defect claims against pharmaceutical company; "North Carolina law expressly rejects strict liability in products liability actions").

[11] Many of these courts have further emphasized that any other result would effectively threaten to make prescription drug manufacturers "insurers" against any adverse side effect or injury suffered by those using a drug, which is wrong as a matter of law and policy. *See, e.g.*, *Dunkin v. Syntex Labs., Inc.*, 443 F. Supp. 121, 125-26 (W.D. Tenn. 1977); *Fellows v. USV Pharm. Corp.*, 502 F. Supp. 297, 299-300 (D. Md. 1980).

The strict product liability doctrine also is not recognized under Virginia law. *See, e.g., Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 374 S.E.2d 55, 57 n.4 (Va. 1988) ("Virginia law has not adopted § 402A of the Restatement (Second) of Torts and does not permit tort recovery on a strict-liability theory in products-liability cases.").

Likewise, Delaware does not recognize strict products liability claims. *Cline v. Prowler Indus. of Md., Inc.*, 418 A.2d 968, 978-80 (Del. 1980). As the Delaware Supreme Court held, it was the Delaware legislature's "clear intent" "to treat consumer injuries by defective products through the medium of sales warranty law," which precludes judicial "adoption of the doctrine of strict tort liability." *Id*. After *Cline*, the Delaware legislature has never adopted the strict liability doctrine by legislation.

In short, no "strict products liability" claim exists in North Carolina, Virginia, or Delaware. Thus, any effort to assert such claims under the laws of these states fails.

2. Twenty-Four Jurisdictions Do Not Recognize Strict Liability "Design Defect" Claims In The Prescription Drug Context

Although the following jurisdictions recognize the strict liability doctrine, they do *not* recognize strict liability "design defect" claims in the prescription drug context.

***Alabama*:** Under Alabama law, no strict liability "design defect" claims will lie in the prescription drug context. In *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301 (Ala. 1984), the Alabama Supreme Court confirmed that prescription drugs are considered "unavoidably unsafe" products under Alabama law, and fall within the "exception to the strict liability [doctrine]" provided under "Comment k" to Restatement (2d) of Torts § 402A. *Id*. at 1303. Hence, in Alabama, a prescription drug may be deemed "defective" on an inadequate-warning theory, *id*. at 1304, but not any design-

defect theory. *See also Bodie v. Purdue Pharma Co.*, 2007 U.S. App. LEXIS 12725, at *17-*18 (11th Cir. June 1, 2007) (applying Alabama law).

***California*:** California law categorically precludes any "design defect" claims in the prescription drug context under its strict products liability regime. *Brown*, *supra*, 751 P.2d 470, 473-83 (Cal. 1988) ("a drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability"). In *Brown*, the California Supreme Court adopted and followed comment k to Restatement (2d) of Torts § 402A, which it interpreted categorically to shield *all* prescription drugs from *any* strict liability "design defect" claim, while also citing overriding public policy considerations in support of its conclusion. *Id*. at 475-79.

***Connecticut*:** Under Connecticut law, "prescription drugs are unavoidably unsafe products"; a drug manufacturer's liability may be established only on failure-to-warn theories, and *not* any strict liability design-defect theory. *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836 (Conn. 2001); *accord Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 783 (Conn. 2006); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2d Cir. 1969). Thus, in the prescription drug context, no strict liability "design defect" claim is recognized under Connecticut law.

District of Columbia: The law of the District of Columbia categorically rejects strict liability design-defect claims in the prescription drug context. *Fisher v. Sibley Mem. Hosp.*, 403 A.2d 1130, 1134 (D.C. 1979); *accord Dyson v. Winfield*, 113 F. Supp. 2d 35, 39-40 (D.D.C. 2000); *Raynor v. Richardson-Merrell, Inc.*, 643 F. Supp. 238, 247 (D.D.C. 1986). Following the "exception to the strict liability rule for products such as drugs" in "comment k," District of Columbia law deems prescription drugs "unavoidably

unsafe," *Raynor*, 643 F. Supp. at 247, and thus not subject to strict liability "design defect" claims, as opposed to failure-to-warn claims.

***Indiana*:** Under Indiana law, prescription drugs are deemed "unavoidably unsafe" products and are not subject to strict liability design-defect claims. *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 545-46 (Ind. Ct. App. 1979). Prescription drug manufacturers may thus be held strictly liable to consumers only under failure-to-warn or manufacturing-defect theories, not design-defect theories. *Id*. at 546.

Iowa: Under Iowa law, prescription drugs are "deemed 'unavoidably unsafe products'" and are "not held to be defective or unreasonably dangerous 'so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects.'" *Moore v. Vanderloo*, 386 N.W.2d 108, 117 (Iowa 1986); *accord Petty v. United States*, 740 F.2d 1428, 1439 (8th Cir. 1984) (applying Iowa law). No strict liability "design defect" claim exists in the prescription drug context under Iowa law.

***Kentucky*:** Following comment k, the Kentucky Supreme Court has categorically rejected strict liability design-defect claims in the prescription drug context. *See Larkin v. Pfizer*, 153 S.W.3d 758, 761-62 (Ky. 2004) ("that a particular drug might produce unfortunate side effects makes it 'unavoidably unsafe' but not '*unreasonably* dangerous' (emphasis added), and strict liability will not obtain if 'proper warning is given, where the situation calls for it'") (internal citations omitted).[12]

***Louisiana*:** Under Louisiana law, prescription drugs are categorically treated as "unavoidably unsafe" products and, thus, are not subject to strict liability design-defect

[12] Although an older line of federal decisions in diversity cases suggested more equivocation on the issue in Kentucky (*see, e.g.*, *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 540 (6th Cir. 1993)), the Kentucky Supreme Court's subsequent decision in *Larkin* controls over any federal-court decision on this question of Kentucky law.

claims. *Kinney v. Hutchinson*, 468 So.2d 714, 718 (La. Ct. App. 1985), *writ denied*, 472 So.2d 35 (La. 1985); *accord Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 575, 577 (W.D. La. 1988) (applying Louisiana law), *aff'd without opinion*, 864 F.2d 789 (5th Cir. 1988). Instead, a drug manufacturer's liability in Louisiana is solely "a question of the adequacy of the warnings" rather than defective design. *Kinney*, 468 So.2d at 718.

***Maine*:** Maine follows, and has effectively adopted, comment k to Restatement (2d) of Torts § 402A. *St. Germain v. Husqvarna Corp.*, 544 A.2d 1283, 1287 n.3 (Me. 1988) (noting that Maine statute 14 M.R.S.A. § 221 is "an almost verbatim recitation of section 402A of the Restatement (Second) of Torts"); *Tardy v. Eli Lilly & Co.*, 2004 WL 1925536, *3 (Me. Super. 2004) (applying comment k of Rest. (2d) of Torts § 402A). No strict liability "design defect" claim has been recognized in the prescription drug context.

***Maryland*:** Strict liability claims under design defect theories have not been recognized in the prescription drug context under Maryland law. *See Fellows v. USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980). Rather, Maryland has generally adopted and followed Restatement (2d) of Torts § 402A, *see Phipps v. General Motors Corp.*, 363 A.2d 955, 958-59 (Md. 1976), including "the substance of Comment k" to section 402A. *Miles Lab, Inc., Cutter Lab. Div. v. Doe*, 556 A.2d 1107, 1116-17, 1121 (Md. 1989) (rejecting strict liability design-defect claims in medical blood products context, and following Rest. (2d) of Torts § 402A, cmt. k). Thus, under Maryland law, no strict liability design-defect claim may be asserted because prescription drugs are deemed "unavoidably unsafe" products under comment k; the manufacturer is exempt from strict liability "unless [it] has failed to provide adequate warnings of the drug's possible dangers." *Fellows*, 502 F. Supp. at 300.

***Massachusetts*:** The Massachusetts Supreme Judicial Court has explicitly adopted a "policy [of] rejecting strict liability" in the prescription drug context "for drug related injuries," following the principles of comment k to Restatement (2d) of Torts § 402A. *Payton v. Abbott Labs.*, 437 N.E.2d 171, 189-90 (Mass. 1982); *see also Sprague v. Upjohn Co*., 1995 WL 376934, at *3 (D. Mass. May 10, 1994) (*Payton* "recognized that prescription drug cases must be evaluated under the principles of negligence"). Thus, "defendant pharmaceutical companies" are entitled to judgment as a matter of law where plaintiffs assert strict "products liability" claims "under the common law of Massachusetts." *Lareau v. Page*, 840 F. Supp. 920, 933 (D. Mass. 1993) (applying Rest. (2d) of Torts § 402A, cmt. k).[13]

***Michigan*:** Under Michigan law, prescription drugs "are characterized as 'unavoidably unsafe' products" within the meaning of comment k to Restatement (2d) of Torts § 402A, *Nichols v. McNeilab, Inc*., 850 F. Supp. 562, 570 (E.D. Mich. 1993), and no court applying Michigan law has ever recognized a strict liability claim under any "design defect" theory. In fact, Michigan statutory law (*see* Mich. Comp. Laws § 600.2946(5)) "confers broad immunity upon pharmaceutical companies in cases where the drug at issue has been approved for sale by the FDA." *Zammit v. Shire US, Inc*., 415 F. Supp. 2d 760, 765 (E.D. Mich. 2006); *accord Garcia v. Wyeth-Ayerst Labs*., 385 F.3d

[13] In fact, there exists no "strict liability tort" claim in Massachusetts "in product liability cases." *Kelly v. Ely Lilly & Co*., 2007 U.S. Dist. LEXIS 31052, at *25 (D.D.C. Apr. 27, 2007) (applying Massachusetts law); *see also Mason v. General Motors*, 490 N.E. 437, 441-42 (Mass. 1986) (refusing judicially to create strict liability tort claims). Although Massachusetts does not recognize strict liability design-defect claims, it does recognize claims for breach of implied warranty, but such claims are "'congruent in nearly all respects with the principles expressed in Restatement (Second) of Torts § 402A'" and its comments. *Correia v. Firestone Tire & rubber Co.*, 446 N.E.2d 1033, 1039 (Mass 1984) (citation omitted).

961, 963 (6th Cir. 2004) (affirming dismissal of all products liability claims against drug manufacturer based on § 600.2946(5)'s "statutory immunity"). Under section 600.2946(5), prescription drugs are "not defective or unreasonably dangerous" where, as here, they have received FDA approval; and their manufacturers are "not liable" in product liability suits under Michigan law. Mich. Comp. Laws § 600.2946(5); *accord Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127, 129-30 (Mich. 2003). Thus, in Michigan, no strict liability "design defect" claim exists in the prescription drug context.

***New York*:** Under New York law, "prescription drugs are 'unavoidably unsafe products'" within the meaning of comment k to Restatement (2d) of Torts § 402A. *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61 (N.Y. App. Div. 1979). No strict liability claim under any design-defect theory will lie against a prescription drug manufacturer because "a prescribed drug, accompanied by adequate warnings, is 'not defective, nor is it unreasonably dangerous.'" *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993) (citation omitted); *accord Wolfgruber*, 72 A.D.2d at 60-61 (any "legally viable" products liability claim against drug manufacturers "is dependent upon," and "directly related to," "the adequacy of the warning").

***North Dakota*:** North Dakota has generally followed Restatement (2d) of Torts § 402A and its comments, *see, e.g., Butz v. Werner*, 438 N.W.2d 509, 517 (N.D. 1989) (following section 402A and comment j), and has never recognized any strict liability design-defect claim in the prescription drug context. In a related context, the U.S. Court of Appeals for the Eighth Circuit has predicted that the North Dakota Supreme Court would adopt the learned intermediary doctrine just as it "has adopted other comments from section 402A." *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1017 (8th Cir. 2004)

(citing cases). Given that "the North Dakota Supreme Court has discussed and adopted comments to section 402A on several occasions," *id*., North Dakota's broad adoption of section 402A to govern strict liability claims indicates that it would also adopt comment k, under which prescription drugs are unavoidably unsafe products subject to liability only under failure-to-warn or manufacturing-defect theories and not design-defect theories. *Cf. Fellows, supra*, 502 F. Supp. 297, 300 (D. Md. 1980).[14]

***Ohio*:** Under Ohio statutory law, prescription drugs are "not defective in design or formulation because some aspect of it is unavoidably unsafe," so long as the drug's manufacturer "provides [an] adequate warning." Ohio Rev. Code Ann. § 2307.75(D). Moreover, the Ohio Supreme Court has adopted Restatement (2d) of Torts § 402A to govern strict liability claims, *Temple v. Wean United, Inc*., 364 N.E.2d 267, 271 (Ohio 1977), including "comment k," which it interprets categorically to provide "that a drug manufacturer will not be held strictly liable for injuries caused by an unavoidably dangerous drug, such a prescription drugs, if the warning is adequate." *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991); *accord Seley v. G.D. Searle & Co*., 423 N.E.2d 831, 835-36 (Ohio 1981). Ohio law has never recognized any strict liability "design defect" claims in the prescription drug context.

***Oklahoma*:** The Oklahoma Supreme Court has held that, under comment k to Restatement (2d) of Torts § 402A, prescription drugs are exempt from strict liability design-defect claims. *See Edwards v. Basel Pharms.*, 933 P.2d 298, 300 (Okl. 1997); *McKee v. Moore*, 648 P.2d 21, 23-24 (Okl. 1982). Under Oklahoma law, prescription

[14] A federal district court sitting in diversity has a duty to predict how the state's highest court would rule if faced with the issue, and may properly follow other federal court decisions on the issue. *See, e.g., State Farm Fire & Cas. Co. v. Steinberg*, 393 F.3d 1226, 1231-32 (11th Cir. 2004).

drugs are "unavoidably unsafe products" within the meaning of comment k to section 402A and, thus, "are not deemed defective or unreasonably dangerous if they are accompanied by proper directions for use and adequate warnings concerning potential side effects." *McKee*, 648 P.2d at 23-24. No strict liability "design defect" claim has been recognized under Oklahoma law in the prescription drug context.

***Pennsylvania*:** The Pennsylvania Supreme Court has adopted comment k to Restatement (2d) of Torts § 402A, and interpreted it to shield prescription drugs from any "strict liability" claim. *Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996). Although all "prescription drugs" are "dangerous in that they are not without medical risks," under comment k to section 402A, they "are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Id*. Thus, no strict liability claim is cognizable in the prescription drug context under Pennsylvania law. *See also Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006) (stating that *Hahn* "adopted comment k, to conclude that strict liability could not be applied to prescription drugs").[15]

***South Dakota*:** South Dakota has adopted Restatement (2d) of Torts § 402A to govern its strict liability doctrine, *see, e.g.*, *Engberg v. Ford Motor Co*., 205 N.W.2d 104, 109 (S.D. 1973); *Smith v. Smith*, 278 N.W.2d 155 (S.D. 1979), but has yet to decide any case involving prescription drugs. Federal courts applying South Dakota law, however, have consistently applied comment k to section 402A and held that "prescription drugs" fall within its "exemption" as "'unavoidably unsafe' products." *McElhaney v. Eli Lilly & Co*., 575 F. Supp. 228, 230-31 (D.S.D. 1983), *aff'd.* 739 F.2d 340, 340-41 (8th Cir.

[15] In fact, in Pennsylvania, even "where the adequacy of warnings associated with prescription drugs is at issue," "negligence" – not strict liability – "is the *only* recognized basis of liability" under Pennsylvania law. *Hahn*, 673 A.2d at 889-90 (emphasis added).

1984); *see also Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 161-61 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969). No court applying South Dakota law has recognized any strict liability "design defect" claim in the prescription drug context.

***Tennessee*:** The Tennessee Supreme Court has adopted and applied comment k to Restatement (2d) of Torts § 402A in holding that "prescription drugs" are "unavoidably unsafe products." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994). Hence, under Tennessee law, prescription drug manufacturers are not subject to strict liability claims except under failure-to-warn theories. *Id*. at 428 ("[m]anufacturers of prescription drugs . . . may discharge their duty by distributing the drugs with proper directions and adequate warnings"); *see also Laws v. Johnson*, 799 S.W.2d 249, 252 (Tenn. App. 1990) (applying comment k). No strict liability "design defect" claim is recognized under Tennessee law.

***Texas*:** Texas law follows comment k to section 402A, and exempts prescription drugs from strict liability design-defect claims. In Texas, "all FDA-approved prescription drugs are unavoidably unsafe as a matter of law"; thus, prescription drug manufacturers "can only be held strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings." *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002); *accord Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1273-75 (5th Cir. 1974) (applying Texas law); *McNeil v. Wyeth Labs.*, 2005 U.S. Dist. LEXIS 3477, *19-20 (N.D. Tex. 2005), *rev'd on other grounds*, 462 F.3d 364 (5th Cir. 2006). No strict liability "design defect" claim exists in the prescription drug context.

***Utah*:** The Utah Supreme Court has adopted comment k to section 402A, and interpreted it to provide "a broad grant of immunity from strict liability claims based on

design defects" for all "FDA-approved prescription drugs" under Utah law, while also citing broad public policy considerations in support of this conclusion. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95-99 (Utah 1991). In Utah, "all prescription drugs" are "classified as unavoidably dangerous in design" and, thus, exempt from any strict liability design-defect claim. *Id.* at 95; *accord Schaerrer v. Stewart's Plaza Pharmacy, Inc*., 79 P.3d 922, 928 (Utah 2003) ("under Utah law, comment k shields manufacturers and sellers of prescription drugs from strict liability based on allegations of a design defect").

***Vermont*:** The Vermont Supreme Court has "adopted the doctrine of strict liability set forth in the Restatement (Second) of Torts § 402A," *Webb v. Navistar Intern. Transp. Corp*., 692 A.2d 343, 346-47 (Vt. 1996) (citing *Zaleski v. Joyce*, 333 A.2d 110, 113 (1975)), including comment k. *Id*. No court applying Vermont law has recognized a strict liability "design defect" claim in the prescription drug context. Instead, under comment k to section 402A, prescription drugs are treated as unavoidably unsafe products and not subject to strict liability claims except under inadequate warning or manufacturing defect theories. *See* Rest. (2d) of Torts § 402A, cmt. k.

***Washington*:** The Washington Supreme Court has adopted comment k to Restatement (2d) of Torts § 402A, and held that manufacturers of "prescription drugs," as well as other prescription-only medical devices and products, may be held liable only on failure-to-warn theories adjudged under a negligence standard, not strict liability. *See Young v. Key Pharms., Inc*., 922 P.2d 59, 64-65 (Wash. 1996); *Rogers v. Miles Labs., Inc*., 802 P.2d 1346, 1350-53 (Wash. 1991); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 977-80 (Wash. 1978). Under Washington law, prescription drugs (and other prescription-only medical devices) are categorically treated as "unavoidably unsafe products" within

the protection of comment k, *ibid*., and are not subject to any strict liability design-defect claims as a matter of law. Indeed, in Washington, the only potentially viable claim in this context is one premised on an inadequate-warning theory, but even then, the manufacturer's "liability," if any, sounds "in negligence and not in strict liability." *Rogers*, 802 P.2d at 1352-53; *accord Young*, 922 P.2d at 63-64.

***Wyoming*:** The Wyoming Supreme Court has adopted Restatement (2d) of Torts § 402A and "its official comments" to govern "strict liability" claims in the state. *Ogle v. Caterpillar Tractor Co.*, 716 P.2d 334, 341-42 (Wyo. 1986); *see also Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851-52 (10th Cir. 2003) (Wyoming "has adopted [section 402A] in its entirety," including "Comment k"). Under Wyoming law, prescription drugs are treated as unavoidably unsafe products within the meaning of comment k; hence, prescription drugs are not subject to strict liability claims, and are not "considered unreasonably dangerous," except under inadequate-warning theories. *Jacobs v. Dista Prods.*, 693 F. Supp. 1029, 1031 (D. Wyo. 1988) ("whether strict liability is available as a cause of action" in Wyoming turns on the "adequacy of the warning provided"). No strict liability "design defect" claim exists in the prescription drug context.

B. Eleven Jurisdictions Reject Any Effort To Re-Cast Legally Meritless Strict Liability Design-Defect Claims As Breach of "Implied Warranty" Claims

1,540 plaintiffs have tried to re-cast their legally meritless strict liability "design defect" causes of action as claims for breach of implied warranty of merchantability or fitness for general or particular purposes, even though they reside in jurisdictions where such efforts necessarily fail as a matter of law. *See* Exh. A. The gravamen of these claims is that AstraZeneca impliedly warranted that Seroquel was sufficiently "safe," but

breached that implied warranty because plaintiffs allegedly contracted diabetes and related injuries after ingesting Seroquel. *See* pp. 3-4, *supra* (citing complaints). In eleven of the jurisdictions at issue on this motion, these claims can and should be dismissed on this motion for judgment on the pleadings.

Specifically, six of these jurisdictions – California, Kentucky, Maryland, Pennsylvania, Tennessee, and Wyoming – have squarely refused to recognize such implied warranty claims in the prescription drug context for the same reason these jurisdictions reject strict liability "design defect" claims; namely, prescription drugs are "unavoidably unsafe" products. *Brown*, *supra*, 751 P.2d at 484 (California's rule barring strict liability "design defect" claims in prescription drug context also bars claims for beach of implied warranty); *McMichael v. American Red Cross*, 532 S.W.2d 7, 11 (Ky. Ct. App. 1975) (Kentucky's "policy" that the "unavoidable unsafeness" that "is a basis for denying strict liability" under design defect theories in prescription drug context also "prevail[s] with respect to liability under implied warranty" claims); *Fellows*, *supra*, 502 F. Supp. 297, 299-300 (D. Md. 1980) (implied warranty claim in prescription drug context is "untenable" in Maryland for same reason "strict liability" design-defect claims are not recognized; prescription drugs are inherently unsafe, and to "impose liability on manufacturers of prescription drugs [under implied warranty theories] when the ultimate consumer suffers any harmful side effects" would wrongly make drug manufacturers "'insurer[s] of the drug user's health'") (citation omitted); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752-53 (E.D. Pa. 2004) ("Pennsylvania courts have held that the nature of prescription drugs precludes claims for breaches of implied warranty for similar reasons" that strict liability design-defect claims are not recognized in Pennsylvania,

pursuant to comment k to Rest. (2d) of Torts § 402A) (citing cases); *Dunkin v. Syntex Labs., Inc.*, 443 F. Supp. 121, 125-26 (W.D. Tenn. 1977) (under Tennessee law, no viable claim for breach of implied warranties of merchantability or fitness exists in prescription drug context for similar reasons that "no viable strict liability claim" exists; "[t]o hold otherwise would make the drug manufacturer an insurer of the drug user's health," which is not the law); *Jacobs v. Dista Prods. Co.*, 693 F. Supp. 1029, 1030-31, 1036 (D. Wyo. 1988) (under Wyoming law, drug manufacturers "are insulated from liability premised upon a breach of [implied] warranty theory" for same reasons strict liability design-defect claims fail due to "Wyoming's acceptance of comment k" to Rest. (2d) of Torts § 402A).

In the other five jurisdictions – the District of Columbia, Louisiana, Massachusetts, Michigan, and Utah – strict liability "design defect" claims and claims for breach of "implied warranty" are substantively indistinguishable and subject to the same doctrinal rules. *See Bowler v. Stewart-Warner Corp.*, 563 A.2d 344, 347-48 (D.C. 1989) (District of Columbia law); *Correia v. Firestone Tire & Rubber Co.*, 446 N.E. 2d 1033, 1039 (Mass. 1983) (Massachusetts law); *Berry v. Crown Equipt. Corp.*, 108 F. Supp. 2d 743, 756-57 (E.D. Mich. 2000) (Michigan law); *Ernest W. Hahn, Inc. v. Armco Steel Co.*, 601 P.2d 152, 159 (Utah 1979) (Utah law); *see also Jefferson v. Lead Industries Ass'n, Inc.*, 106 F.3d 1245, 1250-51 (5th Cir. 1997) (applying Louisiana law; reviewing the Louisiana Products Liability Act, which eliminates implied warranty as a cognizable theory of recovery). In each of these jurisdictions, the same reasons that compel dismissal of strict liability design-defect claims mandate rejection of claims for breach of

implied warranty. *See, e.g.*, *Berry*, 108 F. Supp. 2d at 756-57 (failure of plaintiff's "design defect claim eviscerates her claim of breach of implied warranties[] as well").[16]

C. AstraZeneca Is Entitled To Judgment On The Pleadings With Respect To Each Strict Liability "Design Defect" Claim And "Implied Warranty" Claim Asserted By Plaintiffs Residing In States That Do Not Recognize Those Claims In The Prescription Drug Context

Each of the 3,679 plaintiffs listed on Exhibit A asserts strict liability design-defect and/or implied warranty claims even though, by their own accounts, they reside in one of the jurisdictions in which such claims are *not legally cognizable* causes of action in the prescription drug context. The law of the plaintiffs' state of residency properly applies to each individual's products liability claims – given that it is presumptively the jurisdiction in which each of these plaintiffs were prescribed Seroquel, ingested the drug, and allegedly suffered injury. *See, e.g.*, *Phillips v. General Motors Corp.*, 995 P.2d 1002, 1012 (Mont. 2000) (concluding that state of plaintiff's residency has overriding interest in ensuring its "product liability laws" govern strict liability claims asserted by state residents); *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 776 (N.J. 2007) (holding that state where plaintiff in strict liability case resides, received an FDA-approved drug, and allegedly sustained injuries is state with overriding interest in having its substantive law applied); *Nelson v. Sandoz Pharms. Corp.*, 288 F.3d 954, 965 (7th Cir. 2002) (same); *accord Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608, 613 (6th Cir. 1984); *Bearden*

[16] In Massachusetts, implied warranty claims in the prescription drug context fail under comment k to Restatement (2d) of Torts § 402A, given that prescription drugs are unavoidably unsafe products. *See, e.g.*, *Lareau v. Page*, 840 F. Supp. 920, 933 (D. Mass. 1993) (applying Massachusetts law).

v. Wyeth, 482 F. Supp. 2d 614, 620 (E.D. Pa. 2006); *Harwell v. American Medical Systems, Inc.*, 803 F. Supp. 1287, 1295 (M.D. Tenn. 1992).[17]

As detailed above, the claims at issue here simply are *not viable* in the jurisdictions relevant here. Hence, as a matter of law, AstraZeneca is entitled to judgment on the pleadings with respect to each of the legally meritless claims asserted by the plaintiffs identified in Exhibit A. *See In re Eli Lilly & Co., Prozac Prods. Liab. Litig.*, 789 F. Supp. at 1453-55; *Brown v. City of Clewiston*, 644 F. Supp. at 1409.

[17] Over 3,000 plaintiffs subject to this motion originally filed their claims in federal court in Massachusetts, even though *none* allege to have resided in that state. While Massachusetts product-liability law certainly does not apply to these plaintiffs' claims, even if it did these claims would necessarily fail as a matter of law (*see* pp. 14, 22-23 & n.16, *supra*). But this MDL court applies the choice-of-law rules of the transferor courts, *In re Managed Care Litigation*, 298 F. Supp. 2d 1259, 1296 (S.D. Fla. 2003), and courts under Massachusetts choice-of-law rules have repeatedly applied the substantive law of the state in which a products liability plaintiff resided and suffered the alleged injury. *See*, *e.g.*, *Cosme v. Whitin Mach. Works*, 632 N.E.2d 832, 833-36 (Mass. 1994) (applying products liability law of "plaintiffs' place of residence," which has overriding "significant interest in seeing that its" products liability law applies to claims of a "resident plaintiff"); *Kramer v. Acton Toyota*, 2004 WL 2697284, at *3 (Mass. Super. 2004) ("the relevant policy" of plaintiff's state of residence "must be given significant weight"). Hence, either way, *these* plaintiffs' claims are not cognizable as a matter of law, and this motion should be granted.

V. CONCLUSION

For the foregoing reasons, AstraZeneca's motion for judgment on the pleadings should be granted.

Respectfully submitted,

DATED: July 31, 2007,

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CERTIFICATE OF SERVICE

I hereby certify that, on July 31, 2007, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system through which all participating parties are deemed served. I further certify that, by using the CM/ECF, the foregoing has been served on plaintiffs' liaison counsel, who is charged with serving any non-CM/ECF participants on the attached Service List.

/s/ *Elliot M. Gardner*

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MDL Docket No. 1769

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