IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 2:14-mn-02502-RMG**
	This Document Relates to:
	Barbara J. Coffey v. Pfizer Inc., No. 2:14-cv-1945-RMG *Giesla Conner v. Pfizer Inc.*, No. 2:14-cv-1847-RMG *Vivian Elliott v. Pfizer Inc.*, No. 2:14-cv-1712-RMG *Judy A. Jones v. Pfizer Inc.*, No. 2:14-cv-0589-RMG *Victory Moseley v. Pfizer Inc.*, No. 2:14-cv-3087-RMG *Chinh Nguyen v. Pfizer Inc.*, No. 2:14-cv-0922-RMG *Silvia C. Orellana v. Pfizer. Inc.*, No. 2:14-cv-3483-RMG *Rosie Rivas v. Pfizer Inc.*, No. 2:14-cv-1338-RMG *Yukimi Trujillo et al. v. Pfizer Inc.*, No. 2:14-cv-0966-RMG *Pamela Williams v. Pfizer Inc.*, No. 2:14-cv-3249-RMG

DEFENDANT PFIZER INC.'S MOTION FOR JUDGMENT ON THE PLEADINGS AND MEMORANDUM IN SUPPORT

Defendant Pfizer Inc. ("Pfizer") respectfully submits this motion for judgment on the pleadings under controlling Texas law, pursuant to Federal Rule of Civil Procedure 12(c), and this supporting memorandum of law.[1]

[1] Pursuant to Local Civil Rules 7.04 and 7.05, D.S.C., Pfizer states that a full explanation of the motion is provided herein and, therefore, a separate supporting memorandum

PRELIMINARY STATEMENT

Plaintiffs Barbara J. Coffey, Giesla Conner, Vivian Elliott, Judy A. Jones, Victory Moseley, Chinh Nguyen, Silvia C. Orellana, Rosie Rivas, Yukimi Trujillo, and Pamela Williams are Texas residents who allege that they sustained personal injuries as a result of ingesting Lipitor, a prescription medication manufactured by Pfizer.[2] Plaintiffs allege that they were prescribed and ingested Lipitor in Texas and that they were diagnosed with type 2 diabetes in Texas. As a result, under well-established choice-of-law rules, Texas law applies to all of Plaintiffs' claims. Under settled Texas law, Plaintiffs' claims are barred by Texas Civil Practice & Remedies Code § 82.007 (the "Texas Act"). *See Lofton v. McNeil Consumer & Specialty Farm.*, 672 F.3d 372 (5th Cir. 2012).

Plaintiffs allege that Pfizer failed to warn of the potential risk of the injuries they claim they sustained from ingestion of Lipitor. The Texas Act creates a statutory presumption that a manufacturer of a prescription medication is not liable for product liability claims if the medication is accompanied by warnings that were approved by the FDA. It is undisputed that the Lipitor prescribed to Plaintiffs came with an FDA-approved warning label. Plaintiffs' claims do not fall within any statutory exception to the Texas Act because Plaintiffs do not allege that the FDA has ever revoked Lipitor's approval or ordered its withdrawal or that Pfizer bribed an FDA official to gain approval for Lipitor. Nor do Plaintiffs allege that Pfizer recommended, promoted, or advertised Lipitor for any off-label use or that their physicians prescribed Lipitor

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would serve no useful purpose. In addition, Pfizer states that it has filed the instant motion in these exemplar cases involving Plaintiffs whose claims are governed by Texas law. Pfizer submits that the arguments set forth herein apply to and warrant dismissal of other actions in the MDL and any future-filed actions involving claims governed by Texas law. Pfizer reserves its right to move to dismiss in those cases to the extent that the Court determines that Texas law directs dismissal here.

[2] Plaintiff Yukimi Trujillo is joined in her suit by Ernest J. Trujillo, her husband.

for any off-label use, much less that any off-label promotion or use caused their alleged injuries. Moreover, Plaintiffs do not allege that FDA approval for Lipitor was the result of fraud on the FDA, an allegation that would, in any case, be preempted by federal law. *See Lofton*, 672 F.3d at 379-80. Under these circumstances, Plaintiffs' claims are barred and Pfizer is entitled to judgment on the pleadings.

Judgment in Pfizer's favor is also consistent with a large body of case law in which federal and state courts in Texas and other states examining virtually identical product liability claims and the same or similar statutes have reached the "inescapable conclusion that [the plaintiff's] claims should be dismissed" with prejudice. *Del Valle v. PLIVA, Inc.*, B-11-113, 2012 WL 4747259, at *8 (S.D. Tex. Sept. 12, 2012), *aff'd sub nom Lashley v. Pfizer, Inc.*, 12-60861, 2014 WL 661058 (5th Cir. Feb. 21, 2014); *see also McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 906 (W.D. Tex 2013), *aff'd*, 13-50404, 2014 WL 2198544 (5th Cir. May 27, 2014); *Willis v. Schwarz-Pharma, Inc.*, 2014 WL 3703418, at *7 (E.D. Tex. July 23, 2014); *Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556, 571 (D.N.J. 2013).

FACTUAL BACKGROUND

A. Barbara J. Coffey

Plaintiff Barbara J. Coffey filed her action directly into the MDL in the District of South Carolina on May 15, 2014. Plaintiff alleges that she is a resident of Texas. *Coffey* Compl. ¶ 2. Plaintiff alleges that she was diagnosed with type 2 diabetes in or about August 2010, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 22, 25. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL") and as a primary prevention measure to decrease her risk of developing cardiovascular disease ("CVD")." *Id.* ¶ 19. Plaintiff asserts product

liability claims, including claims for failure to warn, negligence, breach of implied warranty, fraud, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶¶ 26-85.

In May 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by physicians in Texas and obtained Lipitor from a pharmacy in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

B. Giesla Conner

Plaintiff Giesla Conner filed her action directly into the MDL in the District of South Carolina on May 8, 2014. Plaintiff alleges that she is a resident of Texas. *Conner* Compl. ¶ 2. Plaintiff alleges that she was diagnosed with type 2 diabetes in or about July 2012, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 22, 25. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL") and as a primary prevention measure to decrease her risk of developing cardiovascular disease ("CVD")." *Id.* ¶ 19. Plaintiff asserts product liability claims, including claims for failure to warn, negligence, breach of implied warranty, fraud, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶¶ 26-85.

In May 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by a physician in Texas and obtained Lipitor from pharmacies in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

C. Vivian Elliott

Plaintiff Vivian Elliott filed her action directly into the MDL in the District of South Carolina on April 29, 2014. Plaintiff alleges that she is a resident of Texas. *Elliott* Compl. ¶ 2. Plaintiff alleges that she was diagnosed with type 2 diabetes in or about October 28, 2008, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 22, 25. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL") and as a primary prevention measure to decrease her risk of developing cardiovascular disease ("CVD")." *Id.* ¶ 19. Plaintiff asserts product liability claims, including claims for failure to warn, negligence, breach of implied warranty, fraud, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶¶ 26-85.

In May 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by a physician in Texas and obtained Lipitor from a pharmacy in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

D. Judy A. Jones

Plaintiff Judy A. Jones filed her action in the Southern District of Texas on November 18, 2013. Plaintiff alleges that she is a resident of Texas. *Jones* Compl. ¶ 2. Plaintiff alleges that she was diagnosed with type 2 diabetes in or about October 2009, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 22, 24. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL") and as a primary prevention measure to decrease her risk of developing cardiovascular disease ("CVD")." *Id.* ¶ 19. Plaintiff asserts product liability claims, including

claims for failure to warn, negligence, breach of implied warranty, fraud, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶¶ 25-84.

In June 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by physicians in Texas and obtained Lipitor from pharmacies in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

E. Victory Moseley

Plaintiff Victory Moseley filed her action directly into the MDL in the District of South Carolina on August 1, 2014. Plaintiff alleges that she is a resident of Texas. *Moseley* Short Form Compl. ¶ 1. Plaintiff alleges that she was diagnosed with type 2 diabetes on August 9, 2007, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 6-7. Plaintiff asserts product liability claims, including claims for negligence, negligent misrepresentation, negligent design, design defect, failure to warn, breach of express warranty, breach of implied warranties, fraud and misrepresentation, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶ 10.

In September 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor for treatment of high cholesterol by physicians in Texas and obtained Lipitor from a pharmacy in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

F. Chinh Nguyen

Plaintiff Chinh Nguyen filed her action in the Northern District of Texas on February 27, 2014. Plaintiff alleges that she is a resident of Texas. *Nguyen* Compl. ¶ 1. Plaintiff alleges that she was diagnosed with type 2 diabetes on July 10, 2009, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 31, 34. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL") and/or as a primary prevention measure to decrease her risk of developing cardiovascular disease ("CVD")." *Id.* ¶ 28. Plaintiff asserts product liability claims, including claims for negligence, negligent misrepresentation, failure to warn, design defect and breach of express and implied warranties, fraud and misrepresentation, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶¶ 39-119.

In May 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by a physician in Texas and obtained Lipitor from pharmacies in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

G. Silvia C. Orellana

Plaintiff Silvia C. Orellana filed her action directly into the MDL in the District of South Carolina on August 28, 2014. Plaintiff alleges that she is a resident of Texas. *Orellana* Short Form Compl. ¶ 1. Plaintiff alleges that she was diagnosed with type 2 diabetes in November 2012, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 6-7. Plaintiff asserts product liability claims, including claims for negligence, negligent misrepresentation, negligent design, design defect,

failure to warn, breach of express warranty, breach of implied warranties, fraud and misrepresentation, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶ 10.

In September 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor for treatment of high cholesterol by a physician in Texas and obtained Lipitor from a pharmacy in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

H. Rosie Rivas

Plaintiff Rosie Rivas filed her action in the Southern District of Texas on February 25, 2014. Plaintiff alleges that she is a resident of Texas. *Rivas* Compl. ¶ 2. Plaintiff alleges that she was diagnosed with type 2 diabetes on or about May 17, 2012, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 20, 23. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL")." *Id.* ¶ 19. Plaintiff asserts product liability claims, including claims for failure to warn, negligence, breach of implied warranty, fraud, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶¶ 24-83.

In May 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by a physician in Texas and obtained Lipitor from a pharmacy in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

I. Yukimi Trujillo

Plaintiff Yukimi Trujillo filed her action in the Northern District of Texas on February 11, 2014 and is joined by Ernest J. Trujillo, her husband. Plaintiff alleges that she is a resident of Texas. *Trujillo* Compl. ¶ 7. Plaintiff alleges that she was diagnosed with type 2 diabetes in or about September 2004, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor, and that her injuries are permanent. *Id.* ¶¶ 26, 30. Plaintiff alleges that she was prescribed Lipitor "to lower her levels of low-density lipoprotein ("LDL") and as a primary preventive measure to decrease her risk of developing cardiovascular disease ("CVD")." *Id.* ¶ 24. Plaintiff and her husband assert product liability claims, including claims for negligence, failure to warn, misrepresentation, negligent misrepresentation, breach of implied warranty, fraud, violation of Texas's Deceptive Trade Practices-Consumer Protection Act (DTPA), Tex. Bus. & Com. Code Ann. § 17.50, *et seq.*, loss of consortium, and punitive damages. *Id.* ¶¶ 38-117.

In May 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor by physicians in Texas and obtained Lipitor from pharmacies in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

J. Pamela Williams

Plaintiff Pamela Williams filed her action directly into the MDL in the District of South Carolina on August 13, 2014. Plaintiff alleges that she is a resident of Texas. *Williams* Short Form Compl. ¶ 1. Plaintiff alleges that she was diagnosed with type 2 diabetes on August 13, 2012, that she sustained physical and emotional injuries as a result of her ingestion of Lipitor,

and that her injuries are permanent. *Id.* ¶¶ 6-7. Plaintiff asserts product liability claims, including claims for negligence, negligent misrepresentation, negligent design, design defect, failure to warn, breach of express warranty, breach of implied warranties, fraud and misrepresentation, constructive fraud, unjust enrichment, and punitive damages. *Id.* ¶ 10.

In September 2014, Plaintiff signed and swore to a Plaintiff Fact Sheet confirming that: Plaintiff is a resident of Texas; Plaintiff was prescribed Lipitor for treatment of hypercholesterolemia by a physician in Texas and obtained Lipitor from pharmacies in Texas; and Plaintiff was diagnosed with and treated for type 2 diabetes in Texas. The Fact Sheet does not identify any witnesses who are located in, or any events that took place in, any other state.

LEGAL STANDARD

A party's motion for judgment on the pleadings under Federal Rule of Civil Procedure Rule 12(c) should be granted when "accepting the facts set forth in the pleadings, the case can be decided as a matter of law." *Crutchfield v. Pfizer Inc.*, CIV.A. 2:12-1462-RMG, 2013 WL 2897023, at *3 (D.S.C. June 13, 2013) (citing *Tollison v. B. & J Machinery Co., Inc.*, 812 F. Supp. 618, 619 (D.S.C. 1993)). A motion under Federal Rule of Civil Procedure Rule 12(c) "is assessed under the same standards as a Rule 12(b)(6) motion." *Faile v. Lancaster Cnty., S.C.*, CA 0:11-2206-CMC, 2013 WL 786447, at *1 (D.S.C. Mar. 1, 2013); *see also Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999); *Deutsche Bank Nat'l Trust Co. v. I.R.S.*, 361 F. App'x 527, 529 (4th Cir. 2010) (a "Rule 12 (c) motion for judgment on the pleadings is decided under the same standard as a motion to dismiss under Rule 12(b)(6)"). To survive a motion to dismiss for failure to state a claim under Rule 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). Under *Iqbal*, the pleading standard "demands more than an unadorned, the-defendant-unlawfully-

harmed-me accusation," and "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action' will not do." *Id.* (citations omitted); *see also Twombly*, 550 U.S. at 554–55. Further, while the court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the plaintiff, *Adcock v. Freightliner LLC*, 550 F.3d 369, 374 (4th Cir. 2008), "bare assertions devoid of further factual enhancement fail to constitute well-pled facts for Rule 12(b)(6) purposes." *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009).

In addition, "Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law." *Neitzke v. Williams*, 490 U.S. 319, 326 (1989). "This procedure, operating on the assumption that the factual allegations in the complaint are true, streamlines litigation by dispensing with needless discovery and factfinding." *Id.* at 326–27. Where, as here, a complaint does not contain either direct or inferential allegations with respect to every material element necessary to support liability, "a claim must be dismissed." *Id.* at 327; *see also McLean v. United States*, 566 F.3d 391, 399 (4th Cir. 2009).

ARGUMENT

I. Texas Law Governs Plaintiffs' Claims

A. Texas Law Governs the Claims of Plaintiffs Jones, Nguyen, Rivas, and Trujillo, Whose Cases Originated in the District of Texas

Texas law governs the claims of Plaintiffs Judy A. Jones, Chinh Nguyen, Rosie Rivas, and Yukimi Trujillo under Texas' choice-of-law rules, which apply to these cases that were transferred to this MDL from the Northern and Southern Districts of Texas. *See Volvo Const. Equip. N. Am., Inc. v. CLM Equip. Co., Inc.*, 386 F.3d 581, 600 (4th Cir. 2004) (citing *Van Dusen v. Barrack*, 376 U.S. 612, 632–37 (1964)). Texas applies the "most significant relationship" test to tort claims. *See Jackson v. W. Telemarketing Corp. Outbound*, 245 F.3d

518, 523 (5th Cir. 2001). When applying the most significant relationship test, a court is to look to "(1) the place where the injury occurred, (2) the place where the conduct causing the injury occurred, (3) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (4) the place where the relationship, if any, between the parties is centered." *Burleson v. Liggett Grp. Inc.*, 111 F. Supp. 2d 825, 828 (E.D. Tex. 2000). These factors follow the Restatement (Second) of Conflict of Laws § 145, and "with respect to tort causes of action, the Restatement emphasizes, but does not mandate, the choice of state substantive law with greatest connection to the injury plaintiff seeks to remedy." *Jelec USA, Inc. v. Safety Controls, Inc.*, 498 F. Supp. 2d 945, 952 (S.D. Tex. 2007); *see also Black v. Toys R US-Delaware, Inc.*, 4:08-CV-3315, 2010 WL 4702344 at *10 (S.D. Tex. Nov. 10, 2010) ("As the most significant relationship test instructs, the location of the injury is an important contact which weighs in favor of applying [the law of the place of injury].")

Here, the place of Plaintiffs' alleged injuries is Texas, Plaintiffs' home state. Texas is where: Plaintiffs were allegedly prescribed, purchased, and ingested Lipitor; their physicians allegedly received inadequate warnings about the medicine; and Plaintiffs allegedly sustained and were diagnosed with their claimed injuries. Accordingly, Texas is also the place where the relationship between the parties is centered. Although Pfizer is headquartered in New York and incorporated under Delaware law, the balance of the choice-of-law factors directs that Texas law should govern Plaintiffs' claims. *See Black*, 2010 WL 4702344 at *16 (in products liability action, finding the state with the most significant relationship to be the state where the alleged injury occurred); *accord O'Neal v. Bumbo Int'l Trust*, 959 F. Supp. 2d 972, 976 (S.D. Tex. 2013).

B. Texas Law Governs the Claims of Plaintiffs Coffey, Conner, Elliott, Moseley, Orellana, and Williams, Who Filed Directly Into the MDL

Texas law also governs the claims of Plaintiffs Barbara J. Coffey, Giesla Conner, Vivian Elliott, Victory Moseley, Silvia C. Orellana, and Pamela Williams, who filed their actions directly into the MDL. South Carolina's choice-of-law rules apply in such actions. *See Mizell v. Eli Lilly & Co.*, 526 F. Supp. 589, 594, n. 5 (D.S.C. 1981). In personal injury cases like these, South Carolina's choice-of-law rules direct that "the substantive law . . . is determined by the lex loci delicti, the law of the state in which the injury occurred." *Nash v. Tindall Corp.*, 650 S.E.2d 81, 83 (S.C. Ct. App. 2007) (quoting *Boone v. Boone*, 546 S.E.2d 191, 193 (S.C. 2001)); *accord Thorton v. Cessna Aircraft Co.*, 886 F.2d 85, 87 (4th Cir. 1989) ("Under South Carolina law when an action is brought in one jurisdiction for a tort which caused injury in another jurisdiction, the substantive law is determined by the law of the state in which the injury occurred . . . ."). Here, Texas is where: Plaintiffs were allegedly prescribed, purchased, and ingested Lipitor; their physicians allegedly received inadequate warnings about the medicine; and Plaintiffs allegedly sustained and were diagnosed with their claimed injuries. Accordingly, Texas substantive law governs.

II. Plaintiffs' Claims Are Barred by Texas Law

A. The Texas Act Applies to Plaintiffs' Claims

Plaintiffs' claims are barred as a matter of law under the Texas Act. *See Lofton*, 672 F.3d at 372. The Act provides, in pertinent part:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act.

Tex. Civ. Prac. & Rem. Code § 82.007(a). The Fifth Circuit has confirmed that the Act "presumptively insulates from liability, for failure to warn, defendants who made, prescribe, or sell drugs in accord with FDA standards." *Lofton*, 672 F.3d at 379; *see also Phares v. Actavis-Elizabeth, LLC*, 892 F. Supp. 2d 835, 846 (S.D. Tex. 2012) (holding "based on the applicable products liability statute and relevant case law," plaintiff could not prevail on any of her claims against defendant).

Because Plaintiffs' alleged claims fall within the ambit of the Texas Act, they are barred as a matter of law. *See Anderson v. Abbott Labs.*, No. 3:11-CV-1825, 2012 WL 4512484, at *5-7 (N.D. Tex. Sept. 30, 2012) (dismissing with prejudice plaintiffs' product liability claims alleging injuries from the prescription medicine Humira under Section 82.007(a) of the Texas Act); *see also Del Valle*, 2012 WL 4747259, at *8 ("Even if the brand name defendants owed [plaintiff] a duty to warn, Texas statutes afford a presumption that any warnings were adequate and lead to the inescapable conclusion that [plaintiff]'s claims should be dismissed.").

First, it is undisputed that the FDA approved Lipitor and its accompanying labeling and warnings. Second, Plaintiffs' actions are "products liability action[s] alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product." Tex. Civ. Prac. & Rem. Code§ 82.007(a). The Texas Act defines "[p]roducts liability action" broadly to mean "any action against a manufacturer or seller for recovery of damages arising out of personal injury . . . allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." *Id.* § 82.001(2).

This definition encompasses all of Plaintiffs' causes of action, regardless of their labels or legal theories, because they are all premised on Pfizer's alleged failure to provide adequate warnings with regard to the alleged risks of Lipitor. *See Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 977 (S.D. Tex. 2012), *reconsideration denied* (May 2, 2012) (dismissing as a matter of law negligence, strict liability, and breach of warranty claims pursuant to § 82.007(a)(1) because they all "arise from failure to warn").

B. Plaintiffs Cannot Rebut the Texas Act Presumption

Plaintiffs cannot meet their burden to rebut the presumption under the Texas Act. Indeed, Plaintiffs have not alleged any facts that could implicate any exception to the Texas Act. The Texas Act enumerates that it can only be rebutted in these narrow circumstances: (1) the manufacturer "withheld from or misrepresented to the [FDA] required information that was material and relevant to" the medication's performance and "causally related to the claimant's injury"; (2) the medication was sold or prescribed after the FDA ordered a withdrawal or withdrew approval for the medication; (3) the manufacturer recommended, promoted, or advertised the medication for an off-label use, the medication was prescribed for that use, *and* "the claimant's injury was causally related" to that off-label prescription; (4) a defendant physician prescribed the medication for an off-label use, the medication was used as prescribed, *and* "the claimant's injury was causally related" to that off-label prescription; or (5) the manufacturer made an illegal payment to an FDA official or employee that caused the warning to be inadequate. Tex. Civ. Prac. & Rem. Code § 82.007(b)(1)–(5).

The second, third and fourth bases for rebutting the presumption that an FDA-approved label was adequate are easily rejected here. It is undisputed that the FDA has never revoked Lipitor's approval or ordered it to be withdrawn from the market. *See id.* § 82.007(b)(2). Nor do Plaintiffs allege that Pfizer recommended, promoted, or advertised Lipitor for any off-label use

or that their physicians prescribed Lipitor for any off-label use, much less that any off-label use caused the alleged injuries at issue. *See id.* § 82.007(b)(3)–(4); *see also Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 777 (S.D. Tex. 2008) (§ 82.007(b)(3) does not apply where "[p]laintiff has not offered any evidence to establish that [the prescribing physician] was influenced by the alleged overpromotion marketing scheme"), *aff'd on other grounds*, 321 F. App'x 350 (5th Cir. 2009); *McKay*, 934 F. Supp. 2d at 906 (§ 82.007(b)(3) does not apply where plaintiffs have provided "insufficient evidence to establish that any off-label promotion . . . actually reached and influenced [the prescribing physician]"); *Holland v. Hoffman-La Roche, Inc.*, No. 3-06-CV-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15, 2007). Plaintiffs have not made such allegations and cannot overcome the presumption of adequacy. To the contrary, Plaintiffs have alleged that they were prescribed Lipitor to lower their levels of low-density lipoprotein, which is an on-label, or approved, use of Lipitor. *See Coffey* Compl. ¶ 19; *Conner* Compl. ¶ 19; *Elliott* Compl. ¶ 19; *Jones* Compl. ¶ 19; *Moseley* Plaintiff Fact Sheet at 4; *Nguyen* Compl.¶ 28; *Orellana* Plaintiff Fact Sheet at 4; *Rivas* Compl.¶ 19; *Trujillo* Compl. ¶ 24; *Williams* Plaintiff Fact Sheet at 4.

1. The Fraud-on-the-FDA Basis for Rebuttal Is Preempted by Federal Law

Plaintiffs also cannot satisfy the other two bases for rebutting the Texas Act presumption, which involve claims of bribery or fraud on the FDA. First, Plaintiffs have not asserted claims that Pfizer bribed any FDA employee to gain approval for Lipitor, as would be required by Tex. Civ. Prac. & Rem. Code § 82.007(b)(5). Second, under the U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, a claim that a manufacturer committed fraud on the FDA is impliedly preempted by the federal Food, Drug, and Cosmetic Act. *See Buckman*, 531 U.S. 341, 350–53 (2001). In *Lofton*, the Fifth Circuit applied this holding to the Texas Act,

ruling that "because § 82.007(b)(1) requires a Texas plaintiff to prove fraud-on-the-FDA to recover for failure to warn, this requirement invokes federal law supremacy according to *Buckman*." *Lofton*, 672 F.3d at 379; *accord Murthy*, 847 F. Supp. 2d at 976 (§ 82.007(b)(1) is preempted); *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-md-1760, 2008 WL 2944910 at *5 (M.D. Tenn. July 25, 2008) (same). Thus, under the Texas Act, a plaintiff can only rebut the presumption that a warning was adequate if "the FDA *itself* finds fraud." *Lofton*, 672 F.3d at 380 (emphasis added); *see also Lashley*, 2014 WL 661058, at *5 (5th Cir. Feb. 21, 2014) (noting that "the FDA has not made such a finding [of fraud] and, therefore, that avenue for overturning the brand defendants' presumption of non-liability is foreclosed"); *Willis*, 2014 WL 3703418, at *7 (E.D. Tex. July 23, 2014) ("In order to rely on the fraud exception, the plaintiff must show that the FDA itself has found fraud."); *Solomon*, 916 F. Supp. 2d at 571 (D.N.J. 2013) (applying Texas law and finding plaintiff's failure to present evidence establishing fraud on the FDA was "fatal to his failure-to-warn claim").

The Fifth Circuit's holding in *Lofton* is consistent with the Sixth Circuit's reasoning in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004). Garcia involved Michigan's analogous product liability statute that also limits product liability actions against manufacturers of FDA-approved prescription medications. Mich. Comp. Laws § 600.2946(5); *see Lofton*, 672 F.3d at 375; *Murthy*, 847 F. Supp. 2d at 974; *accord Marsh v. Genentech, Inc.*, 693 F.3d 546, 554-55 (6th Cir. 2012). The Sixth Circuit held that the fraud-on-the-FDA exception to Michigan's drug product liability statute was preempted unless plaintiffs could show that "the FDA *itself* determine[d] that a fraud ha[d] been committed on the agency during the regulatory-approval process." *Garcia*, 385 F.3d at 966 (emphasis in original); *accord Miller v. Mylan Inc.*, No. 12-11684, 2012 WL 5300721, at *4 (E.D. Mich. Oct. 25, 2012), *rev'd on other grounds*, 741

F.3d 674 (6th Cir. 2014); *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1029 (W.D. Mich. 2008); *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006); *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1322–27 (S.D. Fla. 2010).

Here, Plaintiffs do not allege, nor can they, that the FDA has ever made a determination of fraud regarding Lipitor, much less that Pfizer fraudulently obtained FDA approval for Lipitor. Lipitor remains on the market and continues to be widely prescribed. Therefore, because Plaintiffs cannot rebut the presumption that Lipitor's warning was adequate, the Texas Act compels judgment on the pleadings in Pfizer's favor. *See Murthy*, 847 F. Supp. 2d at 976; *Thurston v. Merck & Co.*, 415 F. App'x 585, 586 (5th Cir. 2011) (dismissal as a matter of law was warranted where plaintiff failed to "plead facts sufficient to meet any of the exceptions" to the presumption that an FDA-approved warning was adequate), *cert. denied*, 132 S. Ct. 192 (2011).

2. Plaintiffs Have Not Pleaded Fraud With the Required Particularity

In addition to the fact that any claim of fraud on the FDA is preempted, Plaintiffs would also not be able to proceed under such a claim because they have not pleaded fraud with the required particularity. *See Phares*, 892 F. Supp. 2d at 838 ("Plaintiff's fraud claims are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), which requires . . . 'the who, what, when, where, and how to be laid out.'" (quoting *Benchmark Elecs., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. 2003) (internal quotation marks omitted)); *see also DeVore v. Pfizer Inc.*, 58 A.D.3d 138, 143-44 (N.Y. App. Div. 1st Dep't 2008) (affirming dismissal of a Lipitor action under the analogous Michigan products liability statute). Plaintiffs, like plaintiffs in *DeVore*, set forth no claims that Pfizer fraudulently obtained FDA approval for Lipitor, much less with "the requisite particularity for a fraud claim," and, as the court held in

DeVore, Plaintiffs cannot rely on bare allegations of fraudulent concealment "to proceed with discovery on a claim of fraud in the agency approval process." *Id.* at 143; *see also id.* at 144 ("Plaintiffs will not be allowed to use pretrial discovery as a fishing expedition when they cannot set forth a reliable factual basis for what amounts to, at best, mere suspicions.") (citation omitted).

CONCLUSION

For the foregoing reasons, Texas law governs Plaintiffs' actions under well-settled choice-of-law rules and bars their claims as a matter of law. Accordingly, Pfizer respectfully requests that this Court grant it judgment on the pleadings.

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CERTIFICATE OF SERVICE

I hereby certify that, this 3rd day of October, 2014, I have electronically filed a copy of the above and foregoing with Clerk of the Court using the ECF system, which sent notification of such filing to counsel of record.

s/ Mark S. Cheffo