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** *Wilma Daniels v. Pfizer Inc.*, **2:14-cv-01400-RMG**

PFIZER INC.'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Rules / Statutes

Other Authorities

Defendant Pfizer Inc. respectfully moves for summary judgment on all of Plaintiff's claims. A full explanation of the motion is provided in the supporting memorandum herein.

PRELIMINARY STATEMENT

Plaintiff Wilma Daniels is a 67-year-old resident of Colorado. She claims that her ingestion of Lipitor (atorvastatin), a statin medication prescribed to her in 1997 to treat her highly elevated cholesterol, caused her to develop Type 2 diabetes. Plaintiff alleges that she was diagnosed with diabetes in 1998. Daniels Short Form Compl. [Dkt. 62] ¶ 6. Her records also show, and her treating doctors have all confirmed, that she had multiple well-recognized risk factors for diabetes before she was prescribed Lipitor. Those risk factors included elevated blood glucose levels reaching the pre-diabetic range, a family history of diabetes, being overweight, progressive adult weight gain, high blood pressure, elevated triglycerides, low HDL (the "good cholesterol"), a long smoking history, and multiple sources of physical and emotional stress. She also met the criteria for having metabolic syndrome (characterized by having at least three metabolic risk factors, such as high triglycerides, low HDL, and high blood pressure), a condition that increases the risk of developing both diabetes and cardiovascular disease.

When Plaintiff was prescribed Lipitor in 1997, she had a total blood cholesterol level of 466 mg/dL and her LDL cholesterol (the "bad cholesterol") was 364 mg/dL. Both levels were significantly elevated above the normal range and considered alarmingly high by her physicians. Plaintiff's elevated cholesterol levels suggested that she had familial hypercholesterolemia, a genetic condition characterized by very high LDL, and they made her an appropriate candidate for treatment with Lipitor under its FDA-approved indications for lowering cholesterol and the prevailing cholesterol treatment guidelines. Each of her prescribing physicians testified that, based on her elevated cholesterol and other risk factors for heart disease, Lipitor was the most appropriate treatment option for her. Each testified that Lipitor was a potentially life-saving intervention and that there was no other medication available in 1997 that could achieve the cholesterol reduction Plaintiff needed.

Lipitor effectively reduced Plaintiff's cholesterol levels. Plaintiff was prescribed and took Lipitor 40 mg for nearly 16 years, from October 1997 until July 2013, when she switched for insurance reasons to Crestor (rosuvastatin), a statin she continues to take today. Although Plaintiff has a family history of cardiovascular disease, including a daughter who had a heart attack in her 30s, a brother who had a fatal heart attack, and another brother who has diabetes and heart disease, Plaintiff has never had a heart attack, stroke, or other cardiovascular event or procedure. Her physicians all credit Lipitor with reducing her risk of cardiovascular disease and providing her significant health benefits over the last two decades.

None of Plaintiff's physicians attributes her diabetes to Lipitor, and all agree she was at very high risk of being diagnosed with diabetes before she started taking Lipitor. All of Plaintiff's prescribing physicians stand by their decisions to prescribe Lipitor for her. Plaintiff and her physicians have successfully managed her diabetes through blood glucose monitoring and medication. She has been monitored for the development of diabetic complications, and no complications have been reported or documented by her physicians.

Summary judgment is warranted because Plaintiff has no competent evidence sufficient to raise any question of material fact regarding medical causation – that is, that Lipitor caused Plaintiff's diabetes. Medical causation is an essential element of each of Plaintiff's claims, and it is one that can be satisfied only through admissible and sufficient expert testimony. For the reasons set forth in Pfizer's Motion to Exclude Plaintiffs' Expert Testimony on the Issue of General Causation [Dkt. 972], Plaintiffs have not proffered any admissible expert testimony that Lipitor can cause diabetes, and, at a minimum, Plaintiffs should be excluded from offering expert testimony that Lipitor can cause diabetes at any dose below 80 mg. Plaintiff Daniels never took 80 mg of Lipitor; she took only the 40 mg dose. In addition, although Pfizer denies that Lipitor can cause diabetes and submits that Plaintiffs have no admissible expert testimony on general causation, the Court need not reach that issue to decide this motion. For the reasons set forth in Pfizer's concurrently filed Motion to Exclude the Specific Causation Testimony of Dr. Handshoe, the opinions of Plaintiff's only expert to testify that Lipitor caused Plaintiff to

develop diabetes are unreliable and inadmissible. Without admissible expert testimony that Plaintiff would not have developed diabetes if she had not taken Lipitor, Plaintiff cannot establish causation, and all of her claims should be dismissed.

Summary judgment is also warranted because Plaintiff cannot establish that any alleged failure to warn by Pfizer proximately caused her diabetes. Plaintiff alleges that Pfizer failed to provide adequate warnings to her prescribing physicians regarding an alleged risk of developing diabetes associated with Lipitor use. Plaintiff has no evidence that an additional or different warning would have changed her physicians' decisions to prescribe Lipitor for her. Drs. Kurt Wever, Wendy Day, and Phillip Pennington, the physicians who prescribed Lipitor for Plaintiff over a period of more than a decade, each testified that a different warning would not have altered his or her decision to prescribe Lipitor for Plaintiff. Without evidence that a different warning would have resulted in a different prescribing decision, Plaintiff cannot carry her burden to prove that the alleged failure to warn proximately caused her diabetes. Therefore, Pfizer is entitled to summary judgment on all of Plaintiff's claims.

Several of Plaintiff's causes of action are subject to summary judgment on other grounds. Her design defect claims are preempted by federal law, and she also cannot establish the necessary elements for those claims under state law. She cannot maintain her claims to the extent they allege that Lipitor is not effective for primary prevention in women and that Pfizer failed to disclose that information to her doctors both because she has no evidence that any of her prescribers would have changed his or her prescribing decision if that allegedly undisclosed information had been provided and because those claims are preempted by federal law. Plaintiff's claims for negligent misrepresentation, breach of express and implied warranties, fraud and misrepresentation, constructive fraud, and unjust enrichment should also be dismissed because Plaintiff cannot meet her burden of establishing required elements of these claims.

Finally, Plaintiff's punitive damages claim fails as a matter of law. In order to recover punitive damages under Colorado law, Plaintiff must prove *beyond a reasonable doubt* that Pfizer engaged in conduct that was fraudulent, malicious, or willful and wanton. In addition, the

Supreme Court's holding in *State Farm Mutual Auto Insurance Company v. Campbell*, 538 U.S. 408 (2003), requires Plaintiff to demonstrate that Pfizer's alleged misconduct has a "nexus" to her claimed injury. On the undisputed record, Plaintiff cannot show – and certainly cannot show beyond a reasonable doubt – that Pfizer acted fraudulently, maliciously, or wantonly or that there is a nexus between any alleged misconduct on the part of Pfizer and Plaintiff's diagnosis with diabetes. To the contrary, the record demonstrates – and Plaintiff's own experts agree – that Pfizer fully disclosed relevant Lipitor data to the FDA and at all times complied with FDA regulations. Accordingly, Plaintiff's claim for punitive damages should be dismissed.

I. FACTUAL OVERVIEW

A. Plaintiff's Medical History Before Lipitor

Before she was first prescribed Lipitor in October 1997, in addition to having highly elevated cholesterol and elevated triglycerides, Plaintiff had multiple well-recognized risk factors for both diabetes and cardiovascular disease. She had substantial weight gain as an adult and was overweight to obese in the years before taking Lipitor. [redacted] Plaintiff also has a long history of high blood pressure that pre-dated her use of Lipitor, Daniels Tr. (Ex. 1) at 118:7-20, and she has been prescribed and taken medications for high blood pressure over the last 20 years. Further, Plaintiff smoked up to a pack of cigarettes a day for more than 30 years, stopping shortly before she started taking Lipitor. *Id.* at 132:10-133:2, 133:12-17; *see also* WDANIELS-8CSHP-CO-00108 (Ex. 12).

Plaintiff also had multiple elevated blood sugar levels in the pre-diabetic range before she was first prescribed Lipitor. [redacted]

[redacted]

In addition, Plaintiff has a family history of both diabetes and heart disease. Two of her brothers were diagnosed with diabetes, one of whom died of a heart attack around age 50, and the other of whom has Type 2 diabetes, high cholesterol, and heart disease. Daniels Tr. (Ex. 1) at 91:24-92:3; Lottig 5/15 Tr. (Ex. 5) at 28:16-25, 56:22-57:23. One of Plaintiff's daughters had a sudden heart attack when she was only in her mid-30s and has also been diagnosed with Type 2 diabetes. Daniels Tr. (Ex. 1) at 78:16-79:8, 81:1-6. Plaintiff also testified that her paternal grandmother may have had diabetes. *Id.* at 89:14-90:21.

[redacted]

B. Plaintiff Was Prescribed Lipitor to Reduce Her Highly Elevated Cholesterol

Plaintiff's family care practitioner, Dr. Wever, prescribed Lipitor for Plaintiff on October 1, 1997, after laboratory tests drawn on September 3, 1997, showed that she had:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

Lipitor was approved by the FDA in December 1996 to lower elevated cholesterol, including in patients with genetic or familial high cholesterol. When Dr. Wever prescribed Lipitor for Plaintiff in 1997, it was the newest statin on the market and considered the most efficacious because clinical trials had demonstrated that it lowered LDL more than other statins.

[redacted]

With the exception of a brief period in 1998 when she was switched to another statin, Plaintiff was prescribed and took Lipitor through 2013. Plaintiff was prescribed Lipitor by Dr. Day from 1998 to 1999, Dr. Pennington from 1999 to 2008, and Ms. Navarro, a physician's assistant, from 2009 to 2013, when Plaintiff switched to Crestor for insurance reasons. Navarro Tr. (Ex. 6) at 51:8-17, 54:15-55:3. [redacted]

[redacted] Navarro Tr. (Ex. 6) at 26:22-27:8, 34:3-6, 37:20-39:8, 47:13-24.

[redacted]

C. Plaintiff's Physicians Stand by Their Prescribing Decisions

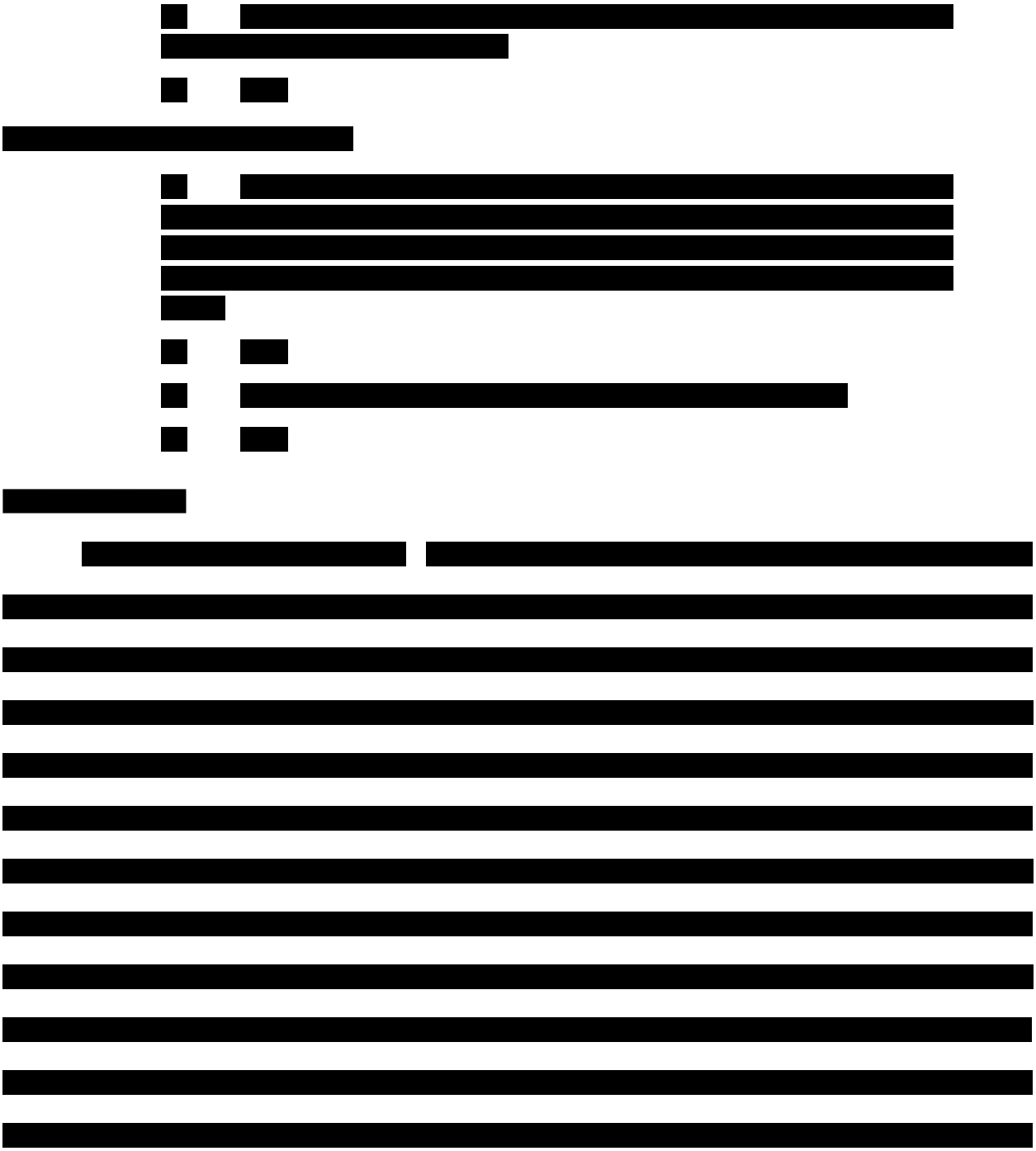
Each of Plaintiff's prescribing physicians has unequivocally reaffirmed his or her decision to prescribe Lipitor for Plaintiff based on her elevated cholesterol and high risk for cardiovascular disease. They have done so notwithstanding Plaintiff's allegations that Lipitor can and did cause diabetes and that Pfizer should have provided different or additional information or warnings to prescribing physicians relating to blood glucose or diabetes.

1. Dr. Wever

Dr. Wever, who prescribed Lipitor for Plaintiff from 1997 to 1998, testified that he stands by his prescribing decision:

2. Dr. Day

Dr. Day, who prescribed Lipitor for Plaintiff from 1998 to 1999, similarly testified that additional information or warnings would not have changed her decision to prescribe Lipitor for Plaintiff:



[redacted]

3. **Dr. Pennington**

Dr. Pennington, who prescribed Lipitor for Ms. Daniels from 1999 through 2008, testified that additional information or warnings would not have changed his decision to prescribe Lipitor for Ms. Daniels:

[redacted]

[redacted] Pennington 12/14 Tr. (Ex. 9) at 76:5-78:18.

[redacted]

4. Lisa Navarro

Lisa Navarro, the physician's assistant who prescribed Lipitor for Plaintiff from 2009 through 2013, when Plaintiff switched to Crestor for insurance reasons, likewise confirmed that she had no reason to second guess her decision to prescribe Lipitor for Plaintiff:

> Q: Do you stand by your decisions with respect to the medications that you have prescribed to Ms. Daniels over the years?
>
> A: I do.
>
> Q: And have you ever had any reason to second-guess any of the prescriptions that you authorized for Ms. Daniels?
>
> A: No.
>
> Q: Did you prescribe Lipitor to Ms. Daniels because, in your best professional judgment, it was a medication that she needed and benefited from?
>
> MS. BURKE: Objection to the form.
>
> Q: You can answer.
>
> A: Yes. And she came on it – she came into – came to me on it. And it appeared to be working, so I didn't see a reason to change.
>
> Q: As we sit here today, in your best professional judgment, does Ms. Daniels still need to be on a statin medication?
>
> A: Yes.

Navarro Tr. (Ex. 6) at 78:20-79:14. Like Drs. Wever, Day, and Pennington, Ms. Navarro has not changed her Lipitor prescribing practices, *id.* at 18:2-19:3, still prescribes Lipitor and considers it an effective medication, *id*., and believes Lipitor was effective for Plaintiff. *Id*. at 26:22-27:8, 34:3-6, 37:20-39:8, 47:13-24.

D. Plaintiff's History of Diabetes

While the diabetes disease process generally takes at least ten years to progress to the point of diagnosis, [redacted] Plaintiff's medical records reflect that she was prescribed diabetes medication as early as 2000. [redacted]

[redacted] *see also* Navarro Tr. (Ex. 6) at 27:9-15, 34:18-25, 39:14-22, 45:15-20, 59:3-6, 63:14-18, 64:7-17.

II. SUMMARY JUDGMENT STANDARD

A court shall grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). In other words, summary judgment should be granted "when it is clear that there is no dispute concerning either the facts of the controversy or the inferences to be drawn from those facts." *Pulliam Inv. Co. v. Cameo Props.*, 810 F.2d 1282, 1286 (4th Cir. 1987). In determining whether a genuine issue has been raised, a court must construe all inferences and ambiguities against the movant and in favor of the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962); *HealthSouth Rehab. Hosp. v. Am. Nat'l Red Cross*, 101 F.3d 1005, 1008 (4th Cir. 1996). The party seeking summary judgment bears the initial burden of demonstrating to the court that there is no genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

Once the moving party has made this threshold demonstration, then the burden shifts to the non-movant to set forth specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324. To survive summary judgment, the non-moving party may not rest on the allegations of the pleadings, but rather must offer evidence demonstrating that specific facts exist that give rise to a genuine issue. *Id.* "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

III. COLORADO LAW GOVERNS PLAINTIFF'S STATE LAW CLAIMS

As the parties previously agreed and this Court has observed, the choice-of-law rules of Colorado, the state of the transferor court, apply here. Under those rules, the substantive law of Colorado, Plaintiff's home state, governs her claims. *See* CMO 36 [Dkt. 941] at 4.

IV. PLAINTIFF CANNOT ESTABLISH MEDICAL CAUSATION

Each of Plaintiff's claims is subject to summary judgment because she cannot meet her burden to prove medical, or factual, causation. Plaintiff claims that Lipitor caused her to develop diabetes and asserts causes of action for negligence, negligent misrepresentation, negligent design, design defect, failure to warn, breach of express and implied warranties, fraud and misrepresentation, constructive fraud, and unjust enrichment. Daniels Short Form Compl. [Dkt. 62] ¶ 10. To prevail on each of these claims, Plaintiff must demonstrate both general causation – that Lipitor can cause diabetes – and specific causation – that it did cause Plaintiff's diabetes. *See Norris v. Baxter Healthcare Corporation*, 397 F. 3.d. 878, 881 (10th Cir. 2005); *In re Bausch & Lomb Inc. Contacts Lens Solution Prod. Liab. Litig.*, 693 F. Supp. 2d 515, 518 (D.S.C. 2010). Under Colorado law, Plaintiff must show that Lipitor was "a cause without which [Plaintiff's diabetes] would not have occurred." *Reigel v. SavaSeniorCare L.L.C.*, 292 P.3d 977, 987 (Colo. Ct. App. 2011). In addition, because the medical causation issues in this case are complex, Plaintiff cannot establish causation without scientifically reliable expert testimony. *See Howell v. Centric Group, LLC*, 508 Fed. Appx. 834, 836 (10th Cir. 2013); *Mathison v. United States*, 2015 WL 854476, at *2-3 (D. Colo. Feb. 26, 2015); *Bausch & Lomb*, 693 F. Supp. at 518.

As set out in Pfizer's Motion to Exclude Plaintiffs' Expert Testimony on the Issue of General Causation and Pfizer's Motion to Exclude the Specific Causation Testimony of Dr. Handshoe, Plaintiff's experts' opinions on both general and specific causation are unreliable and should be excluded under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. Pfizer's *Daubert* motions establish that Plaintiffs have no reliable, admissible expert evidence that Lipitor 40 mg, the dosage Plaintiff took, can cause diabetes in anyone, much less any reliable, admissible expert evidence that Lipitor 40 mg was a "but for" cause or "a

necessary component of" a cause of Plaintiff's diabetes. *Reigel*, 292 P.3d at 987; *accord June v. Union Carbide Corp.*, 577 F.3d 1234, 1244-45 (10th Cir. 2009).

If this Court grants either of Pfizer's *Daubert* motions on medical causation, Plaintiff cannot establish medical causation, and summary judgment should be granted as to all of her claims. To decide the dispositive issue of specific causation, this Court need not even reach the issue of the admissibility of Plaintiff's general causation experts' opinions. Even if Plaintiff could proffer admissible expert evidence on general causation, her only expert on specific causation, Dr. Handshoe, has not applied a reliable methodology and should be excluded from opining that if Plaintiff had not taken Lipitor, she would not have developed diabetes.

Moreover, although Dr. Handshoe's expert report purports to meet the causation standard by opining that "**but for** her ingestion of Lipitor, Ms. Daniels would not have developed Type 2 Diabetes Mellitus," Handshoe Rpt. (Ex. 10) at 4 (emphasis added), Dr. Handshoe conceded during his deposition that he cannot actually offer that opinion and that no one can: "Q. … You cannot say that but for taking Lipitor, [Ms. Daniels] wouldn't have been diagnosed with diabetes at some point? A. **Nobody can say that**." Handshoe Tr. (Ex. 11) at 276:12-16 (emphasis added). Thus, in addition to failing to apply a reliable methodology to derive his causation opinion, Dr. Handshoe by his own admission cannot offer testimony that would establish medical causation under Colorado law. Without such testimony, there is no genuine issue of material fact as to Plaintiff's ability to prove medical causation, and summary judgment is warranted as to all of her claims. *See Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271, 1303-06 (M.D. Fla. 2009).

V. PLAINTIFF CANNOT ESTABLISH PROXIMATE CAUSATION

Each of Plaintiff's claims is also subject to summary judgment because she cannot prove proximate (or legal) causation.

A. Plaintiff Must Prove a Different Warning Would Have Changed Her Physicians' Decision to Prescribe Lipitor

The focus of each of Plaintiff's claims are her allegations that Pfizer failed to adequately warn of an alleged risk of diabetes with Lipitor use or otherwise misrepresented the safety profile of Lipitor. *See, e.g.*, Master Compl. ¶¶ 67, 74-75, 80, 112, 114, 120, 125, 139, 141, 154, 157, 163, 177-79, 195, 205. To prevail on any of her claims under Colorado law, "[P]laintiff must show that [Pfizer's] failure to warn was a proximate cause of her injury." *Peterson v. Parke Davis & Co.*, 705 P.2d 1001, 1004 (Colo. App. 1985); *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281 (Colo. Ct. App. 2010).

In cases involving prescription medicines and medical devices, Colorado applies the learned intermediary doctrine, under which "the manufacturer's duty to warn has been limited to an obligation to advise the prescribing physician," not individual patients, "of any potential dangers that may result from the drug's use." *O'Connell*, 250 P.3d at 1281; *Haffner v. Stryker Corp.*, 2014 WL 4821107 at *4 (D. Colo. Sept. 29, 2014). "It is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a particular course of treatment." *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992); *accord O'Connell*, 250 P.3d at 1281. Accordingly, the proximate cause analysis focuses on the actions of the prescribing physician and whether the alleged failure to warn affected his or her prescribing decision. Where the evidence shows that an additional or different warning would not have changed the prescribing decision, summary judgment is warranted. *See, e.g.*, *In re Nuvaring Litig.*, 2013 WL 1874321, *26 (N.J. Super. L. Div. Apr. 18, 2013) (applying Colorado law); *In re Trasylol Prods. Liab. Litig.-MDL-1928*, 2013 WL 1192300, at *14 (S.D. Fla. Mar. 22, 2013) (applying Colorado law); *Wollam v. Wright Med. Grp., Inc.*, 2012 WL 4510695, at *6 (D. Colo. Sept. 30, 2012).

In *Nuvaring*, for example, a New Jersey court applying Colorado law in a case involving a prescription birth control product granted defendant's summary judgment motion based on lack of evidence of proximate cause where plaintiff failed to establish an issue of fact as to whether

her doctor would have changed his decision to prescribe the product if defendant had provided additional or stronger warnings about the alleged risk. *In re Nuvaring Litig.*, 2013 WL 1874321, at *26. The court observed that plaintiff's prescriber testified that he "continues to prescribe NuvaRing®, and would not have (or at the very least, "did not know" whether he would have) changed his decision to prescribe based on Plaintiffs[']questions at the deposition." *Id.* (citations omitted). It held: "This evidence does not sufficiently raise any issues of fact as to whether the physician would have changed his decision to prescribe NuvaRing®, therefore Plaintiff has not established issues of material fact." *Id.* Similarly, in the *Trasylol* MDL, the court "note[d] that the Plaintiffs present no evidence whatsoever that the doctor who made the decision to use Trasylol … would not have made the decision to use Trasylol with a different warning." *In re Trasylol*, 2013 WL 1192300, at *15 n.27.

Summary judgment is warranted under Colorado law in a prescription medication failure-to-warn case where, as here, a plaintiff fails to introduce evidence that a different warning would have caused her treating physician to change his or her decision to prescribe the medication at issue. Colorado law is aligned with the law of numerous other states, and courts around the country routinely grant summary judgment in prescription pharmaceutical and device cases where there is no evidence that a different warning would have changed the physician's prescribing decision. *See, e.g., Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203, 2014 (5th Cir. 2008) (Texas law); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1024 (10th Cir. 2001) (Oklahoma law); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1004 (4th Cir. 1992) (South Carolina law); *Garrison v. Novartis Pharm. Corp.*, 30 F. Supp. 3d 1325, 1335 (M.D. Ala. 2014) (Alabama law); *D'Agnese v. Novartis Pharm. Corp.*, 952 F. Supp. 2d 880, 891 (D. Ariz. 2013) (Arizona law); *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1486 (E.D. Okla. 1997) (Oklahoma law). The prescribing physician's decision in such cases "breaks the causal chain as to the allegedly inadequate warnings." *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1130 (D. Kan. 2002) (Kansas law).

B. Plaintiff Has No Evidence That Additional Warnings Would Have Changed Her Physicians' Prescribing Decisions

Plaintiff cannot satisfy her burden to establish proximate cause because she has no evidence that any additional or different warning would have led any of her prescribing physicians to change their decision to prescribe Lipitor for her. [redacted] Navarro Tr. (Ex. 6) at 78:20-79:10. [redacted] Navarro Tr. (Ex. 6) at 17:22-19:3. Therefore, Plaintiff cannot establish that an allegedly inadequate warning proximately caused her alleged injury, and summary judgment should be granted.

C. Testimony that a Physician Might Have Changed Counseling Practices Is Insufficient to Establish Proximate Cause

Based on questions Plaintiff's counsel asked during the depositions of Drs. Wever, Day, and Pennington, Plaintiff may argue that proximate cause may be established through evidence that the prescriber may have changed his or her treatment in other ways, such as by offering different patient counseling, even if he or she would have made the same prescribing decision. Under the law discussed above, proximate cause requires proof that the learned intermediary would have made a different prescribing decision, which is proof Plaintiff lacks.

Although Dr. Wever testified that he might have offered different counseling or glucose monitoring, there is no evidence to support an inference that this would have changed the outcome of his prescribing Lipitor for Plaintiff. [redacted]

[redacted] Pennington 12/14/ Tr. (Ex. 9) at 82:18-88:6.

In short, even if Plaintiff could show that her physicians' treatment might have changed in other ways independent of the ultimate prescribing decision, it is legally immaterial. Plaintiff cannot show that an additional or different warning would have changed the result in her case.[1]

[1] As discussed in Section IV above, and in Pfizer's concurrently filed Motion to Exclude the Specific Causation Testimony of Dr. Handshoe, Plaintiff can offer no admissible evidence that taking Lipitor caused Plaintiff to develop diabetes. None of Plaintiff's prescribing physicians have attributed Plaintiff's development of diabetes to her use of Lipitor, and [redacted]

[redacted] For each of Plaintiff's prescribing physicians, prescribing Lipitor was the only responsible course of action considering her highly elevated cholesterol and risk for cardiovascular disease. Plaintiff cannot establish proximate causation consistent with this testimony.

VI. PLAINTIFF'S DESIGN DEFECT CLAIMS FAIL AS A MATTER OF LAW

Plaintiff's design defect claims (Master Compl. ¶¶ 77-116) are subject to summary judgment under federal preemption and Colorado state law standards.

A. Plaintiff's Design Defect Claims are Preempted by Federal Law

Plaintiff's design defect claims are preempted by federal law under the Supreme Court's decision in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), because they would require that Pfizer change the FDA-mandated composition of Lipitor. In *Bartlett*, the Court held that "state-law design-defect claims … that place a duty on manufacturers to render a drug safer by … altering its composition … are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition." *Id.* at 2479. Following *Bartlett*, courts have dismissed design defect claims like Plaintiff's here, observing that the Supreme Court "held that state-law causes of action for the alleged defective design of a drug regulated and approved by the FDA were preempted by federal law. Specifically, the Court held that because a drug manufacturer could not simultaneously comply with FDA requirements mandating the specific design of an approved drug and state law requirements mandating that the design be altered, the state-law requirements were preempted by federal law." *Amos v. Biogen*

[redacted] *see also* Navarro Tr. (Ex. 6) at 77:24-78:19 (testifying that she was never asked to determine the cause of Plaintiff's diabetes and would not engage in this type of analysis in her clinical practice).

Idec Inc., 28 F. Supp. 3d 164, 168-69 (W.D.N.Y. 2014) (citing *Bartlett*, 133 S. Ct. at 2477); *see also Yates v. Ortho-McNeil Pharm., Inc.*, 2015 WL 66423, at *5 (N.D. Ohio Jan. 5, 2015); *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 874-75 (N.D. Ohio 2014); *accord Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1013-14 (E.D. Mo. 2014).

Prescription drugs are complex chemical compounds with immutable chemical properties. As such, drugs are incapable of having alternative designs because a different design of a chemical molecule is by definition a different molecule. *See, e.g.*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001). A different molecule is a different drug that has a different risk-benefit profile and would need to be separately studied, reviewed, and approved by the FDA. The Supreme Court's holding in *Bartlett* confirms that, for this reason, design defect claims like Plaintiff's are preempted.

As the *Yates* court recently explained in dismissing similar design defect claims in an MDL case involving allegations that a birth control patch caused plaintiff to have a stroke, even though *Bartlett* involved a generic drug and certain labeling issues that related to generic manufacturers, the Supreme Court's holding on design defect claims is not limited to generic drugs: "The Supreme Court specifically stated that '[o]nce a drug – *whether generic or brand name* – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'" *Yates*, 2015 WL 66423, at *5 (quoting *Bartlett*, 133 S. Ct. at 2471 (emphasis added, citation omitted)). Similarly, in *Booker*, the same court observed: "As the Supreme Court explained [in *Bartlett*], when a state imposes a 'duty to ensure that one's products are not unreasonably dangerous,' it also involves a duty to make one or several changes to the composition of the drug, which conflicts with federal law prohibiting alteration of an FDA-approved design." *Booker*, 54 F. Supp. 3d at 875 (quoting *Bartlett*, 133 S. Ct. at 2480). Here, under *Bartlett* and as in *Amos*, *Yates*, and *Booker*, Plaintiff's design defect claims should be dismissed as preempted by federal law because they would require Pfizer to

change the design of Lipitor (*see, e.g.*, Master Compl. ¶¶ 86, 100-01), an action that conflicts with the federal regulatory regime governing the design and approval of prescription medicines.

B. Plaintiff's Design Defect Claims Cannot Satisfy Colorado State Law

In cases involving prescription drugs and devices, Colorado courts have applied both the Restatement (Second) of Torts Section 402A and, more recently, the Restatement (Third) of Torts: Products Liability, Section 6. *See Haffner*, 2014 WL 4821107, at *2-3. At a minimum, under comment *k* to Section 402A of the Restatement (Second), which establishes a defense to design defect claims for manufacturers of prescription medicines, Plaintiff's Fourth Cause of Action (Strict Products Liability – Design Defect) is subsumed by her negligent failure-to-warn claim and should be dismissed for all of the reasons set forth above in Section V. *See id.* at *2.

As the *Haffner* court observed, however, recent Colorado precedent, including *O'Connell*, 250 P.3d at 1281, supports an analysis of design defect claims in drug and device cases under the Restatement (Third) of Torts. *Haffner*, 2014 WL 4821107, at *2. Section 6 of the Restatement (Third) "establishes a different test for design defect with respect to prescription drugs and medical devices." *Id.* at *3. It provides that a prescription drug is not defectively designed unless there is no class of patients to whom a reasonable physician would prescribe it:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Id. (quoting Restatement (Third) of Torts § 6(c)). This rule has been adopted or applied in a number of states. *See Harrison v. Howmedica Osteonics Corp.*, 2008 WL 906585, at *21-22 (D. Ariz. Mar. 31, 2008); *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999), *aff'd*, 15 F. App'x 540 (9th Cir. 2001); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 n.9, 258 (E.D.N.Y. 1999).

The Reporters to the Restatement (Third) of Torts have explained that the rule adopted in section 6(c) "reflects the judgment that, as long as a given drug or device provides net benefits

for a class of patients, it should be available to them, accompanied by appropriate warnings and instructions. Learned intermediaries must generally be relied upon to see that the right drugs and devices reach the right patients." Restatement (Third) of Torts: Products Liability § 6, cmt. *f* (1998). Similarly, the Reporters commented that "a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." *Id.* at cmt. *b*; *Haffner*, 2014 WL 4821107, at *3.

This rule is compatible with both a rebuttable presumption of non-defectiveness that applies in Colorado to claims involving products that comply with federal or state regulations, Colo. Rev. Stat. § 13-21-403, and with Colorado's "risk-utility" standard for design defect claims in product liability cases like this. *See Haffner*, 2014 WL 4821107, at *2 (citing *Armentrout v. FMC Corp.*, 842 P.2d 175, 183 (Colo. 1992)); *see also Kokins v. Teleflex, Inc.*, 621 F.3d 1290, 1296 (10th Cir. 2010). Plaintiff has not presented evidence that could satisfy the test under section 6(c) of the Restatement (Third) or otherwise establish that an alleged increased risk of diabetes with Lipitor outweighs its utility. Lipitor and atorvastatin remain approved by the FDA and continue to be widely prescribed today. Plaintiff's own experts and prescribing physicians concede that Lipitor provides benefit to multiple classes of patients; none of them have opined that it should be withdrawn from the market or that Pfizer could have changed the composition or delivery of Lipitor to make a safer version of itself. "[A]n allegation," like Plaintiff's here (e.g., Master Compl. ¶¶ 86), "that [a manufacturer] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect." *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013), *reconsideration denied*, 18 F. Supp. 3d 423 (S.D.N.Y. 2014), *appeal withdrawn* (Dec. 8, 2014). Plaintiff has not demonstrated and cannot demonstrate that the utility of Lipitor is outweighed by the risk she alleges, and her design defect claims should be dismissed. *Haffner*, 2014 WL 4821107, at *3.

VII. PLAINTIFF CANNOT MAINTAIN CLAIMS OF NO EFFICACY IN WOMEN

Plaintiff has inserted throughout her Complaint as part of her various causes of action allegations that Lipitor is not effective for primary prevention of cardiovascular disease in women and that Pfizer failed to adequately disclose that information. *See, e.g.*, Master Compl. ¶¶ 1, 18, 55, 59, 60, 62, 67, 80, 114, 124, 125, 127, 134, 141, 157, 163, 177. As an initial matter, Plaintiff has not presented evidence that different information about primary prevention in women would have affected any of her physicians' decisions to prescribe Lipitor for her, and indeed, she was not prescribed Lipitor for primary prevention. Rather, her physician first prescribed Lipitor for her in 1997 for the separate approved use of treating her highly elevated cholesterol. This was before the first primary prevention trials of Lipitor were completed and before Lipitor was approved for primary prevention use in 2004.

As demonstrated above, Plaintiff's prescribing physicians unanimously agree that Lipitor was effective for Plaintiff, and they stand by their prescribing decisions. Plaintiff has not shown and cannot show that any alleged failure to disclose to her prescribing physicians that Lipitor is not effective for primary prevention in women, even if such information were accurate (and it is not), would have caused any of them to not prescribe Lipitor for her, much less that Plaintiff would not have developed diabetes if such a disclosure had been made. Thus, Plaintiff cannot maintain her no efficacy claims for the same reasons as those set forth in Section V above.

In addition, as Pfizer has established in its Motion to Exclude Expert Testimony and Claims that Lipitor Is Not Effective for and Should Not Be Approved for Primary Prevention in Women [Dkt. 970], those claims conflict directly with the FDA's approval of Lipitor for that use based on the very same data on which Plaintiffs rely, and they are therefore preempted by federal law. For the reasons set forth in that motion, including Sections I.B and III, Plaintiff's claims that Lipitor is not effective for primary prevention in women are preempted and they should be dismissed or stricken from any cause of action that includes such allegations.

VIII. PLAINTIFF'S SECOND, SIXTH, SEVENTH, EIGHTH, NINTH, AND TWELFTH CAUSES OF ACTION SHOULD BE DISMISSED FOR ADDITIONAL REASONS

Plaintiff's Second, Sixth, Seventh, Eighth, Ninth, and Twelfth causes of action assert claims for negligent misrepresentation, breach of express warranty, breach of implied warranties, fraud and misrepresentation, constructive fraud, and unjust enrichment (Daniels Short Form Compl. [Dkt. 62] ¶ 10) that should be dismissed for the further reason that Plaintiff cannot meet her burden of establishing required elements of these causes of action.

A. Colorado Law Does Not Recognize Negligent Misrepresentation in the Personal Injury Context

Colorado does not recognize the claim of negligent misrepresentation outside the context of business transactions, such as in the personal injury context. *See Denver Health & Hosp. Auth. v. Beverage Distributors Co., LLC*, 843 F. Supp. 2d 1171, 1178 (D. Colo. 2012); *Allen v. Steele*, 252 P.3d 476, 483 (Colo. 2011). Plaintiff's action alleges personal injury based on her ingestion of Lipitor and does not involve alleged negligent misrepresentation in a business transaction. Her Second Cause of Action (Negligent Misrepresentation) should be dismissed.

B. Plaintiff's Fraud-Based Claims Should Be Dismissed Because There Is No Evidence She Relied on Any Representations by Pfizer

Plaintiff asserts causes of action for Fraud and Misrepresentation and Constructive Fraud. Each of these causes of action requires the plaintiff to prove, among other elements, that Pfizer made a misrepresentation to Plaintiff and Plaintiff relied on that representation. For example, "[t]o establish a prima facie case of fraud," under Colorado law, "a plaintiff must present evidence that the defendant made a false representation of a material fact; that the party making the representation knew it was false; that the party to whom the representation was made did not know of the falsity; that the representation was made with the intent that it be acted upon; and that the representation resulted in damages." *Brody v. Bock*, 897 P.2d 769, 775–76 (Colo. 1995); *accord Shaw v. 17 West Mill St.*, LLC, 307 P.3d 1046, 1050 n. 5 (Colo. 2013); *see also* Colo. Jury Instr., Civil 19:1. Similarly, to establish a claim for strict product liability involving a misrepresentation about a product, the plaintiff must prove: (1) the defendant made a

misrepresentation of a material fact concerning the character or quality of a product; (2) the misrepresentation was made to the public; and (3) physical harm resulted to plaintiff from justifiable reliance upon the misrepresentation. *Am. Safety Equip. Corp. v. Winkler*, 640 P.2d 216, 222 (Colo. 1982); Restatement (Second) of Torts § 402B (1965); C.R.S. § 13-21-401(3) (definition of seller); Colo. Jury Instr., Civil 14:22. Likewise, "[t]o establish a claim for constructive fraud, a plaintiff must show (1) the existence of a duty due to a relationship between the parties; (2) violation of the duty by making deceptive material representations of past or existing facts or remaining silent when a duty to speak exists; (3) reliance thereon by the complaining party; (4) injury to the complaining party proximately caused thereby; and (5) the gaining of an advantage by the party to be charged at the expense of the complaining party." *Barnett v. Elite Properties of Am., Inc.*, 252 P.3d 14, 23–24 (Colo. App. 2010).

Plaintiff cannot satisfy the representation or reliance elements of these causes of action. There is no evidence that Pfizer made any express statement or representation directly to Plaintiff, nor that Plaintiff relied upon any such alleged statement. To the extent Plaintiff's fraud-based claims are based on an alleged non-disclosure, these claims must fail because Pfizer had no "duty to speak" directly to Plaintiff. "To succeed on a claim for fraudulent concealment or non-disclosure," the Colorado Supreme Court has held that, "a plaintiff must show that the defendant had a duty to disclose material information." *Mallon Oil Co. v. Bowen/Edwards Associates, Inc.*, 965 P.2d 105, 111 (Colo. 1998). Under the learned intermediary doctrine, Pfizer had no duty to warn Plaintiff directly. *See Caveny*, 818 F. Supp. at 1406. Therefore, Pfizer is entitled to summary judgment on Plaintiff's Eighth (Fraud and Misrepresentation) and Ninth (Constructive Fraud) Causes of Action.

C. Plaintiff Has Not Established the Elements of Her Express Warranty Claim

To maintain a claim for breach of express warranty, Plaintiff must prove (1) the existence of a warranty, (2) breach of the warranty, (3) the breach proximately caused the losses claimed as damages, and (4) defendant received timely notice of the breach. *Scott v. Honeywell Int'l Inc.*,

2015 WL 1517527, at *3 (D. Colo. Mar. 30, 2015). An express warranty is an "affirmation of fact or promise" relating to the goods that became "part of the basis of the bargain." C.R.S. § 4-2-313(1)(a). As discussed above in connection with Plaintiff's fraud-based claims, there is no evidence that Pfizer made any express statement to the Plaintiff that could have become "part of the basis of the bargain." Absent any such express statement by Pfizer, Plaintiff's claim for breach of express warranty is subject to summary judgment.[2] Further, Plaintiff alleges that Lipitor was not safe for its intended use in violation of an express warranty. Therefore, Plaintiff's breach of express warranty fails because, as discussed above in Section V, Plaintiff cannot satisfy the causation requirement. For all these, Pfizer is entitled to summary judgment on Plaintiff's Sixth Cause of Action (Breach of Express Warranty).

D. Plaintiff Has Not Established the Elements of Her Implied Warranty Claim

To sustain a claim for breach of an implied warranty under Colorado law, Plaintiff must prove that the breach of the asserted implied warranty was the cause of her injuries. *Trust Dep't of First Nat. Bank of Santa Fe, Colorado Branch v. Burton Corp.*, 2013 WL 4884483, at *6 (D. Colo. Sept. 11, 2013). Plaintiff alleges that Lipitor was not safe for its intended use by virtue of the fact that the warnings Pfizer provided were allegedly inadequate. Therefore, Plaintiff's breach of implied warranty claim fails because, as discussed above in Section V, Plaintiff cannot satisfy the causation requirement. Accordingly, Pfizer is entitled to summary judgment on Plaintiff's Seventh Cause of Action (Breach of Implied Warranties).

E. Unjust Enrichment Is Inapplicable Where Plaintiff Has a Remedy at Law.

Under Colorado law, unjust enrichment is a "purely equitable remedy." *Jorgensen v. Colorado Rural Properties, LLC*, 226 P.3d 1255, 1259 (Colo. Ct. App. 2010). When a plaintiff has an adequate remedy at law, equitable relief is not available. *Mahoney Mktg. Corp. v. Sentry*

[2] Colorado law also requires that a buyer asserting an express warranty claim provide timely notice of the breach to the seller. C.R.S. § 4-2-607. Plaintiff has not offered any evidence that she provided notice prior to filing this suit, and her express warranty claim fails for this reason as well.

Builders of Colorado, Inc., 697 P.2d 1139, 1140 (Colo. App. 1985). In support of this cause of action, Plaintiff alleges that she did not receive a safe and effective drug for which she paid and that it would be inequitable for Pfizer to retain the money it received from her purchase. The facts on which Plaintiff's unjust enrichment claim is based are identical to those on which her product liability claims are based, and the recovery she seeks is a subset of the remedies she seeks under her legal claims. Accordingly, Pfizer is entitled to summary judgment on Plaintiff's Twelfth Cause of Action (Unjust Enrichment).

IX. PLAINTIFF CANNOT MAINTAIN CLAIMS FOR PUNITIVE DAMAGES

A. Colorado Law Requires Proof Beyond a Reasonable Doubt of Fraudulent, Malicious, or Willful and Wanton Conduct to Impose Punitive Damages

In Colorado, punitive damages "are a creature of statute." *Mince v. Butters*, 616 P.2d 127, 128 (Colo. 1980); *accord Alley v. Gubser Devel. Co.*, 785 F.2d 849, 855 (10th Cir. 1986). Section 13-21-102(1)(a) of Colorado's Revised Statutes allows punitive damages only when "the injury complained of is attended by circumstances of fraud, malice, or willful and wanton conduct." C.R.S. § 13-21-102(1)(a). The statute defines "willful and wanton conduct" as "conduct purposefully committed which the actor must have realized as dangerous, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly the plaintiff." *Id.* § 13-21-102(1)(b). Conduct that is merely negligent cannot serve as the basis for a punitive damages award. *Alley*, 785 F.2d at 855; *Tri-Aspen Constr. Co. v. Johnson*, 714 P.2d 484, 488 (Colo. 1986).

In order to recover punitive damages, a plaintiff must prove *beyond a reasonable doubt* that the defendant's conduct was fraudulent, malicious, or willful and wanton. *Id.* § 13–25–127(2). This burden is "by definition a heavy one." *Juarez v. United Farm Tools, Inc.*, 798 F.2d 1341, 1342 (10th Cir. 1986) (quoting *Tri-Aspen*, 714 P.2d at 486). Whether the evidence in a particular case is sufficient to justify an award of punitive damages is a question of law for the Court. *Tri-Aspen*, 714 P.2d at 486; *Mince*, 616 P.2d at 129. In light of the heavy burden of proof imposed by Colorado statute, the Colorado Supreme Court has repeatedly denied punitive

damages as a matter of law. *See Tri-Aspen*, 714 P.2d at 486, 488; *Pizza v. Wolf Creek Ski Dev. Corp.*, 711 P.2d 671, 685 (Colo. 1985); *Rosenbaum v. Mathews*, 156 P.2d 843, 844 (Colo. 1945); *Reyher v. Mayne*, 10 P.2d 1109, 1111 (Colo. 1932). The Tenth Circuit, applying Colorado law, has also denied punitive damages as a matter of law. *See Juarez*, 798 F.2d at 1344-45; *Alley*, 785 F.2d at 856.

B. Plaintiff Cannot Recover Punitive Damages Because Pfizer's Alleged Tortious Conduct Has No Nexus to Her Alleged Injury

The U.S. Supreme Court has held that, to comport with due process, punitive damages may be awarded only where the defendant's conduct has "a nexus to the specific harm suffered by the plaintiff." *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003). Stated otherwise, a defendant may be punished only for "conduct that harmed the plaintiff." *Id*. at 423; *see also, e.g., Philip Morris USA v. Williams*, 549 U.S. 346, 354-55 (2007); *White v. Ford Motor Co.*, 500 F.3d 963, 972 (9th Cir. 2007). Under *State Farm*, therefore, as a matter of due process, "courts cannot award punitive damages to plaintiffs for wrongful behavior that they did not themselves suffer." *Williams v. ConAgra Poultry Co.*, 378 F.3d 790, 797 (8th Cir. 2004); *accord In re Simon II Litig.*, 407 F.3d 125, 139 (2d Cir. 2005). Likewise, tortious conduct that is unrelated to the plaintiff's injury is an insufficient basis for an award of punitive damages. *See IGEN Int'l, Inc. v. Roche Diagnostics GmbH*, 335 F.3d 303, 313-14 (4th Cir. 2003).

Here, Plaintiff's claim for punitive damages fails because she cannot make the required showing under *State Farm* that Pfizer's alleged misconduct has a nexus with her injury.

1. Post-Diagnosis Conduct Is Inadmissible as to Punitive Damages

As a threshold matter, any alleged misconduct by Pfizer that occurred after Plaintiff was diagnosed with diabetes could not conceivably have any nexus to Plaintiff's alleged injury. Put simply, Pfizer's conduct *after* Plaintiff developed diabetes could not have *caused* Plaintiff to develop diabetes. Consequently, evidence of post-diagnosis conduct is generally inadmissible for the purpose of awarding punitive damages because consideration of such conduct would violate due process. *See, e.g., Gober v. Ralphs Grocery Co.*, 128 Cal. App. 4th 648, 661 (Cal.

App. 4th Dist. 2005), *review granted on other grounds and otherwise denied*, 2005 Cal. App. LEXIS 8231 (Cal. July 27, 2005); *Wohlwend v. Edwards*, 796 N.E.2d 781, 787 (Ind. Ct. App. 2003); *see also State Farm*, 538 U.S. at 422-23.

Plaintiff alleges that she was diagnosed with diabetes in 1998. Daniels Short Form Compl. [Dkt. 62] ¶ 6. However, Plaintiff's expert Dr. Handshoe has opined that Plaintiff's lab results did not support a diagnosis of "full-fledged diabetes" until November 2003. Handshoe Rpt. (Ex. 10) at 5. Even assuming the later date for Plaintiff's diagnosis, any alleged misconduct by Pfizer that occurred after November 2003 would be inadmissible as a matter of constitutional due process for the purposes of determining whether punitive damages are warranted in this case.[3]

2. Pfizer's Pre-Diagnosis Conduct Was Not Fraudulent, Malicious, or Willful and Wanton

With respect to Pfizer's pre-diagnosis conduct – regardless of whether Plaintiff's diagnosis occurred in 1998 or 2003 – the evidence does not permit a finding, and certainly not a finding beyond a reasonable doubt, that Pfizer's behavior was fraudulent, malicious, or willful and wanton. Instead, the evidence demonstrates that Pfizer conducted extensive studies of Lipitor, fully disclosed relevant data to FDA, and at all times complied with FDA regulations.

Two of Plaintiff's expert witnesses address alleged misconduct by Pfizer in the relevant time frame: Dr. G. Alexander Fleming and Dr. John Abramson. Dr. Fleming, the expert whom Plaintiff designated to testify about "Pfizer's ability and duty to update the Lipitor label to disclose the increased risk of diabetes and increased glucose," Fleming Tr. (Ex. 16) at 22:10-23, could not point to any intentional or wanton misconduct on Pfizer's part. Instead, Dr. Fleming testified that:

- Pfizer fully disclosed and did not hide any relevant data from the FDA in the NDA it submitted for Lipitor in 1996 (*id*. at 147:22-148:9);

[3] Pfizer reserves the right to move in limine to exclude evidence of post-diagnosis conduct on other grounds.

- in fact, in the NDA, Pfizer highlighted for the FDA that studies of Lipitor had shown an imbalance in reporting rates of hyperglycemia in those taking Lipitor versus placebo (*id*. at 148:11-25);
- Pfizer met with the FDA to discuss the appropriate way to organize the data in the NDA so that it could be analyzed for safety (*id*. at 132:24-133:18);
- Pfizer complied with relevant FDA regulations regarding the listing of adverse events, including hyperglycemia, in the label (*id*. at 126:10-127:16);
- Pfizer did not violate any FDA regulations (*id*. at 128:23-129:11); and
- Pfizer did not withhold from the FDA any relevant data or information regarding the ASCOT study (*id*. at 224:11-14).

Far from opining that Pfizer deliberately misrepresented or concealed information regarding Lipitor, Dr. Fleming's testimony suggests only that Plaintiff and Dr. Fleming disagree with the conclusions that Pfizer and the FDA reached about Lipitor's safety. As to the NDA, Dr. Fleming conceded that Pfizer and the FDA addressed the issue of a glucose imbalance seen in patients taking Lipitor versus placebo, but he stated that he disagreed with Pfizer's *and* the FDA's analysis of the safety data and thought their methodology was flawed. *Id*. at 154:18-157:5.

With respect to Pfizer's conduct after the submission of the NDA, Dr. Fleming conceded that the FDA did not request that Pfizer conduct additional testing regarding the potential risks of hyperglycemia and diabetes in patients taking Lipitor. *Id*. at 169:1-25. Nevertheless, Dr. Fleming noted that Pfizer made a "reasonable attempt" at such additional testing in the form of the ASCOT study. *Id*. at 170:1-171:8. Dr. Fleming stated that Pfizer "could have done more," but nowhere suggested that the company acted maliciously or wantonly. *Id*.

Finally, Dr. Fleming opined that Pfizer should have, but did not, disclose to the FDA the 2003 addition of language to the Japanese label for Lipitor indicating that Lipitor could increase the risk of diabetes or aggravate diabetes. *Id*. at 171:18-24. However, as Dr. Fleming conceded, the FDA does not require pharmaceutical manufacturers to provide information about foreign labeling changes. *Id*. at 205:25-206:9. Dr. Fleming further conceded that (i) he did not know whether the Japanese label change was justified, (ii) the labeling process in Japan is very different from the one in the United States, and (iii) portions of the Japanese label were "silly" and inconsistent with FDA recommendations about statin use. *Id*. at 194:16-23, 195:22-196:1,

207:25-208:14. [redacted] Moreover, nothing in the record remotely suggests that not directing the FDA to the Japanese label change – in circumstances where the FDA's regulations did not require Pfizer to do so and where the FDA already had access to vast amounts of information regarding the safety profile of Lipitor – was motivated by malice or fraudulent intent or amounted to willful and wanton misconduct.

Dr. Abramson similarly does not offer any evidence that Pfizer acted fraudulently, maliciously, or wantonly. As to the NDA, Dr. Abramson opined only that evidence from short-term trials included in the NDA "should have alerted" Pfizer to the "possibility" that Lipitor could increase the risk of being diagnosed with diabetes – a statement that suggests, at most, negligence. Abramson Rpt. (Ex. 17) at ¶ 65. Like Dr. Fleming, he simply takes issue with the methodology Pfizer used to analyze the glucose imbalance data: he conceded that the FDA agreed with Pfizer's analysis of the data, but noted that his analysis "disagrees" with Pfizer's and the FDA's conclusions. Abramson Tr. (Ex. 18) at 436:10-438:18. [redacted] *Id.* at 21:13-22:1, 27:2-13, [redacted]

Dr. Abramson's report points to three alleged misrepresentations in the time-frame relevant here. [redacted]; (ii) the April 2003 Lancet article that published the results of the ASCOT trial misrepresented Lipitor's effectiveness in reducing cardiovascular events in women, principally by combining results for women and men, *id.* at ¶¶ 191-202; and (iii) a September 2003 article in

the American Journal of Cardiology did not reference a statistically significant increased risk of hyperglycemia associated with Lipitor, *id*. at ¶ 90.

Critically, Dr. Abramson does not point to any evidence that these alleged misrepresentations were intentional or wanton or suggest that Pfizer deliberately hid any relevant data. Indeed, Dr. Abramson conceded that he could not opine regarding Pfizer's intent. Abramson Tr. (Ex. 18) at 469:17-472:24. He instead speculates that Pfizer interpreted the data the same way that he does and thus was "aware" of his (flawed) understanding of that data. Dr. Abramson does not tie his assertions to any concrete evidence that Pfizer actually interpreted the data that way and, based on that interpretation, made a decision to conceal or misrepresent any information. [redacted]

In the face of these disclosures – and Pfizer's full disclosures to the FDA – Dr. Abramson's allegations of misconduct represent nothing more than a difference of opinion about the way that Pfizer interpreted and presented data regarding hyperglycemia and the ASCOT trial results to doctors. Dr. Abramson's mere disagreement with Pfizer's presentation of certain data does not even approach the requirement for punitive damages of fraudulent, malicious, or wanton conduct beyond a reasonable doubt.

The evidence that Plaintiff has put forward regarding Pfizer's alleged misconduct is plainly insufficient as a matter of law to support an award of punitive damages. The testimony of Plaintiff's own experts – that Pfizer provided all relevant information to the FDA and complied with FDA regulations – does not remotely approach the requisite evidentiary standard under Colorado law. In short, there is no proof that Pfizer deliberately misrepresented or concealed material information about Lipitor. Accordingly, there is no basis to support a finding beyond a reasonable doubt that Pfizer acted fraudulently, maliciously, or wantonly.

3. There Is No Connection Between Pfizer's Alleged Misconduct And Plaintiff's Doctors' Decisions To Prescribe Lipitor

Any alleged misconduct by Pfizer does not have a nexus to Plaintiff's injury for the additional reason that all three of Plaintiff's prescribing physicians – [redacted] *see also supra* Sections I.C and V. The record thus does not support a connection between Pfizer's alleged misconduct, Plaintiff's claimed injury, and the decisions of Plaintiff's treating physicians to prescribe Lipitor to Plaintiff. Accordingly, as a matter of law, there is no basis for any award of punitive damages against Pfizer.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that this Court grant summary judgment and dismiss this action with prejudice.

DATED: August 7, 2015

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CERTIFICATE OF SERVICE

I hereby certify that, this 7th day of August 2015, I have electronically filed a copy of the above and foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to counsel of record.

/s/ Mark S. Cheffo
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