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Attorneys for the Plaintiff SUSAN FISCHER

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

SUSAN FISCHER, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; BAYER HEALTHCARE LLC; BRACCO DIAGNOSTICS, INC.; GUERBET, LLC; MALLINCKRODT INC.; MALLINCKRODT LLC; and LIEBEL FLARSHEIM COMPANY LLC, Defendants.	Case No. **COMPLAINT FOR DAMAGES** 1. STRICT LIABILITY: FAILURE TO WARN; 2. NEGLIGENCE

COMES NOW Plaintiff, SUSAN FISCHER (hereinafter "Plaintiff"), and alleges as follows:

PARTIES

1. Plaintiff Susan Fischer is a resident of Scottsdale, Arizona. She was administered Gadolinium-Based Contrast Agents ("GBCAs") called Magnevist, MultiHance, and Optimark

2. Plaintiff Susan Fischer suffers from Gadolinium Deposition Disease ("GDD"). GDD is an incurable, painful disease. Plaintiff contracted GDD as a result of receiving MRIs and MRAs using intravenous injections of Magnevist, MultiHance, and Optimark.

Manufacturing Defendants

3. Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., Guerbet, LLC, Mallinckrodt Inc., Mallinckrodt LLC, and Liebel Flarsheim Company LLC (collectively referred to as the "Manufacturing Defendants"), manufacture, market, and sell Magnevist, MultiHance and/or Optimark, gadolinium-based contrast agents ("GBCA") that were injected into Plaintiff's body.

4. Defendant Bayer Healthcare Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business in New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the United States pharmaceuticals unit of Bayer Healthcare, LLC. Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This Court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of California's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of Magnevist within California, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17-cv-0244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

5. Defendant Bayer Corporation is an Indiana corporation with its headquarters located in Pennsylvania. Defendant Bayer Corporation is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of Magnevist within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

6. Defendant Bayer HealthCare LLC is a Delaware LLC with its headquarters located in New Jersey. Bayer HealthCare LLC is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of Magnevist within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See Dubose v. Bristol-Myers Squibb Co., No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

7. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. has elected to establish an agent for service of process in the State of California. Bracco Diagnostics, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of MultiHance within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17-cv-0244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

8. Defendant Guerbet, LLC is a Delaware corporation with its principal place of business in Indiana. Defendant, Guerbet, LLC engaged in the business of designing, licensing, manufacturing, distribution, selling, marketing, and/or introducing Optimark into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protection of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant

conducted clinical trials of Optimark within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17-cv-0244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

9. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business in Missouri. Defendant Mallinckrodt Inc. engaged in the business of designing, licensing, manufacturing, distribution, selling, marketing, and/or introducing Optimark into interstate commerce, either directly or indirectly through third parties or related entities This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protection of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of Optimark within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17-cv-0244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

10. Defendant Mallinckrodt, LLC. is a Delaware corporation with its principal place of business in Missouri. Defendant Mallinckrodt LLC engaged in the business of designing, licensing, manufacturing, distribution, selling, marketing, and/or introducing Optimark into interstate commerce, either directly or indirectly through third parties or related entities This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protection of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of Optimark within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17-cv-0244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

11. Defendant Libel-Flarsheim Company, LLC is a Delaware corporation with its principal place of business in Missouri. Defendant Libel-Flarsheim Company, LLC engaged in the business of designing, licensing, manufacturing, distribution, selling, marketing, and/or introducing Optimark into interstate commerce, either directly or indirectly through third parties or related entities This court has personal jurisdiction over said Defendant under the doctrine of specific

jurisdiction because said Defendant purposefully availed itself of the benefits and protection of Arizona's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of Optimark within Arizona, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17-cv-0244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

12. At all times relevant to this Complaint, the Manufacturing Defendants advertised, promoted, marketed, distributed, and sold Magnevist, MultiHance, and Optimark in Arizona and nationwide.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of Arizona. As ser forth more fully above, Defendant are entities organized in states other than the State of Arizona, and none of the Defendants is a citizen or resident of the State of Arizona. Additionally, the Manufacturing Defendants conducted clinical trials regarding the safety and efficacy of Magnevist, MultiHance, and Optimark in the State of Arizona.

14. This Court has personal jurisdiction over Defendants, each of which is licensed and/or is systematically and continuously conduction business in the State of Arizona, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including Magnevist, MultiHance, and Optimark, to the residents in this State.

15. Venue is proper in this District pursuant to 28 U.S.C § 1391(a), because Defendants marketed, advertised, and distributed the dangerous product in this District; Defendants do substantial business in the State of Arizona and within this District; and at all times relevant hereto, Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold Magnevist, MultiHance, and Optimark in interstate commerce.

FACTS

16. Plaintiff Susan Fischer had normal kidney function prior to developing Gadolinium Deposition Disease ("GDD"). Plaintiff Susan Fischer was subjected to several MRIs. At the time

of these procedures, Plaintiff was injected with the gadolinium-based contrast agent MultiHance. Unbeknownst to her, she developed GDD soon thereafter. Plaintiff Susan Fischer's symptoms of GDD included, but were not limited to the following: burning sensation; violent shaking; tremors; clouded mentation; confusion; weakness; fatigue; hypoglycemia; difficult, painful movement; low body temperature; inflammation, especially throughout her lymphatic system; muscle cramps; numbness; tingling sensation; aching joints; weight loss; hair loss; lumps and rashes on body, kidney damage; and osteoporosis.

17. Gadolinium Deposition Disease ("GDD") is the name for a disease process observed in people with normal or near-normal renal function who develop persistent symptoms that arise hours to months after the administration of gadolinium-based contrast agents. In these cases, no preexistent disease or subsequently developed disease of an alternate known process is present to account for the symptoms. People suffering from GDD experience symptoms consistent with the known toxic effects of retained gadolinium. Typical clinical features of GDD include persistent headaches, bone and joint pain, and clouded mental activity. People with GDD often experience subcutaneous soft-tissue thickening that clinically appears somewhat spongy or rubbery. Tendons and ligaments in a comparable distribution may also be painful and have a thickened appearance. People with GDD often experience excruciating pain, typically in a distal distribution, of the arms and legs but may also be in the torso or generalized in location. This pain is often described as feeling like sharp pins and needles, cutting, or burning. GDD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. GDD is a progressive disease for which there is no known cure.

18. GDD is a man-made disease. It only occurs in patients who have received a gadolinium-based contrast agent for an MRI or an MRA.

19. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.

20. Because gadolinium is toxic, it must be coated to keep it from coming into contact with human tissue when used in connection with MRIs or MRAs. This coating process is called

chelation.

21. The gadolinium-based contrast agents (Magnevist, MultiHance, and Optimark) injected into Plaintiff were manufactured by the Manufacturing Defendants.

22. During the years that Defendants have manufactured, marketed, distributed, sold, and administered gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer-reviewed literature, and other clinical data that have described and/or demonstrated GDD in connection with the use of gadolinium-based contrast agents. In addition, there has been a significant number of publicized complaints and comments from those individuals afflicted with GDD and others seeking to help these individuals. This information was all available to the Defendants several years ago, and put them on notice of the issues that give rise to Plaintiff's causes of action alleged herein.

23. Plaintiff Susan Fischer received MRIs utilizing gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark).

24. During the time period when Plaintiff received injections of the Manufacturing Defendants' gadolinium-based contrast agents, Defendants knew or should have known that the use of gadolinium-based contrast agents created a risk of serious bodily injury, even in patients with normal or near-normal kidney function.

25. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with gadolinium-based contrast agents (including Magnevist, MultiHance and Optimark), and failed to disclose the fact that there were safer alternatives.

26. As a direct and proximate result of receiving injections of gadolinium-based a contrast agent manufactured, distributed, marketed, and/or sold by Defendants (including Magnevist, MultiHance, and Optimark), Plaintiff developed GDD.

27. Defendants have repeatedly and consistently failed to advise consumers and/or their healthcare providers of the causal relationship between gadolinium-based contrast agents and GDD. Defendants knew or should have known of the risk of GDD posed by gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) to individuals with normal or near-normal kidney function.

28. Had Plaintiff and/or her healthcare providers been warned about the risks associated with gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark), she would not have been administered gadolinium-based contrast agents and would not have been afflicted with GDD.

29. As a direct and proximate result of Plaintiff's being administered gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark), she has suffered severe physical injury and pain and suffering, including, but not limited to, the effects of GDD.

30. As a direct and proximate result of being administered gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark), Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

31. As a direct and proximate result of being administered gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark), Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

APPLICATION OF THE DISCOVERY RULE AND THE HISTORY OF DEFENDANTS' CONCEALMENT OF INFORMATION

32. The nature of Plaintiff Susan Fischer's injuries and damages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs (including MultiHance), was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than two years before the filing of this Complaint. At a certain time, Plaintiff became aware that she had retained gadolinium from the gadolinium-based contrast agents that were injected into her. However, she was not aware of the connection between her symptoms and gadolinium retention until a later date.

33. Plaintiff became aware of GDD in or around August 2016 upon publication of "Gadolinium in Humans: A Family of Disorders," in Volume 207:2 of the American Journal of Roentgenology.

34. Magnevist was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988. There are two basic types of contrast agents differentiated by their

chemical structure which include linear agents and macrocyclic agents. The main difference is that the linear agents do not fully surround the gadolinium ion, whereas the macrocyclic agents form a complete ring around gadolinium ion which creates a much more difficult bond to break. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE Healthcare), Optimark (manufactured by Guerbet), and MultiHance (manufactured by the Manufacturing Defendants). Greater safety due to the stronger bonds of the macrocyclic contrast agents as compared to their linear contrast counterparts has been well established by scientists (Huckle, et al. 2016).

35. Then, coincidentally again in 1988, it was recognized that gadolinium was breaking free from the bonds in the linear-based contrast agents, and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron (Huckle, et al. 2016). Furthermore, emerging science showed that the bond between toxic gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH conditions such as those found in many compartments of the human body, including extracellular fluid spaces.

36. Stability differences among gadolinium-based contrast agents have long been recognized in laboratory (in vitro), and deposition of toxic gadolinium in tissues has been described in animal models since at least 1984. The first major study that showed deposition in humans appeared in 1998 regarding patients with renal failure, and later in 2004 in patients with normal renal function (Huckle, et al. 2016).

37. The laboratory (in vitro) studies assessing the stability of each gadolinium-based contrast agent in human blood were performed and demonstrated that, over time, greater percentages of gadolinium were released from linear agents as compared to the macrocyclic agents which showed superior stability. The lack of stability seen within the linear agents was not considered to be a problem as long as the contrast agent was excreted out of the body according to the claimed drug's half-life, before the chelate could release the toxic gadolinium. However, it was later noted that other conditions could cause prolonged retention of the contrast agents, thus allowing more toxic gadolinium to be released in the bodies of patients. In addition, a delayed elimination phase

of the gadolinium-based contrast agents would later be discovered.

38. Peer-reviewed articles on the deposition of gadolinium in animals with normal renal function, some illustrating deleterious consequences, have been published as early as 1984.

39. Three months after the FDA approval of Omniscan (a linear contrast agent with a similar structure to MultiHance) the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies demonstrated that while toxic gadolinium was no longer detectable in the blood seven days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.

40. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over one year after the approval of Magnevist. Authors Tien, et al. reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)." Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue. After this report, however, there was no further mention of gadolinium retention in humans until 1998.

41. The Manufacturing Defendants knew that their product, MultiHance, did not have very stable bonds and could come apart easily causing significant toxicity in humans.

42. Over the next 18 years, more evidence was forthcoming and research began to flourish regarding the release of toxic gadolinium from the linear contrast agents such as MultiHance, and its long-term retention in the bodies of animals and humans. Nephrologists and other scientists connected the administration of linear gadolinium-based contrast agents including MultiHance, to a rapidly progressive debilitating and often fatal condition called Gadolinium-induced Nephrogenic Systemic Fibrosis (NSF), prompting the Food and Drug Administration (FDA) to issue a black box warning on all gadolinium based contrast agents in 2006. NSF is a horrible disease in which patients' skin and vital organs would fibrose, becoming wood-like. There were over 500 NSF cases reported and estimated to be well over a thousand non-reported. Over 500 lawsuits were filed against gadolinium-based contrast manufacturers. All of them settled before trial except Decker vs. GE (Omniscan), which resulted in a five-million-dollar verdict for

Mr. Decker. Unfortunately, Mr. Decker passed away from his Gadolinium-triggered disease before the verdict was reached.

43. Because obvious signs of clinical pathology associated with NSF were only seen in patients who had severely reduced renal function, it was widely (and wrongly) assumed by the public that people with normal renal function were not getting sick and there were no other concerns. However, research continued to report evidence that toxic gadolinium was being stored in people with normal renal function.

44. Although many patients with debilitating symptoms who had normal renal function that received injections with gadolinium-based contrast agents had already been reporting adverse reactions for years to the FDA, manufacturers, and poison control, no link between gadolinium and their symptoms were ever officially made publicly. This is partially due to the fact that blood and urine testing for gadolinium only became available recently. Additionally, most doctors were not aware of any disease that was associated with gadolinium other than NSF, which is said to only occur in patients with renal failure. Gadolinium toxicity is an underreported and underdiagnosed condition. Over the past six years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients with normal renal function have been forming advocacy groups and coming forward to create awareness for their condition. Symptomatic patients often have documentation of high levels of gadolinium in their blood and urine several days, weeks, months and even years after their exposure to gadolinium-based contrast agents. Many patients even had tissue biopsies of various parts of their body that showed additional evidence of retained gadolinium years after their exposure.

45. Patients sent several strongly worded letters with scientifically-supported research data to the FDA, warning about the occurrence of gadolinium toxicity in those with normal renal function following injections of gadolinium-based contrast agents. Correspondence was confirmed in 2012.

46. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents up to several years

prior. They found that the brain had hyperintense signals in critical areas of the brain. These were very alarming findings.

47. These findings were confirmed by scientists at the Mayo Clinic in 2014 when autopsy studies were performed on 13 deceased individuals, all of whom had normal or near normal renal function and who had received six or more injections of gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.

48. As these new findings emerged, the entire radiology community was put on high alert, with several large universities conducting research to further address this concern.

49. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a safety alert. The FDA said that it was evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents use in MRI's and they now have their National Center for Toxicological Research team working on determining the exact consequences of these new findings. However, to this day, the FDA continues to publicly deny that gadolinium deposition has caused any injuries.

50. In September 2017, the FDA's medical advisory committee voted 13 to 1 in favor of adding a warning on labels that gadolinium can be retained in some organs, including the brain, even in patients with healthy kidneys.

51. In May 2018, the Manufacturing Defendants jointly issued a new drug warning admitting that:

a. "Gadolinium is retained for months or years in several organs."

b. "Linear GBCAs cause more retention than macrocyclic GBAs."

c. "There are rare reports of pathologic skin changes in patients with normal renal function. Adverse events involving multiple organ systems have been reported in patients with normal renal function…"

52. "While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at a higher risk. These include

patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions."

53. Defendants have known about the risks that gadolinium-based contrast agents (including Magnevist, MultiHance and Optimark) pose to people with normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[1] In 2004, gadolinium was shown to be deposited in the resected femoral heads of people who had undergone gadolinium-chelate enhanced MRI studies.[2] Since then, studies have continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.

54. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the labels of their products, MultiHance. In 2012, Defendants corrected their label to include contraindications for use in people with kidney disease and acute kidney injury. Yet, Defendants have failed to update their label to reflect the extensive evidence of gadolinium retention in people with normal renal function.

55. Defendants were also involved in prior litigation (in the San Francisco Superior Court Complex Civil Litigation Department and a federal MDL) involving this very product, and have made statements about this product denying that it causes the types of injuries alleged in this complaint.

56. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between her injuries and all Defendants' tortious conduct.

FIRST CAUSE OF ACTION
(Against All Defendants)
STRICT LIABILITY: FAILURE TO WARN

[1] Schumann-Giampieri G, Krestin G. Pharmacokinetics of Gd-DTPA in patients with chronic renal failure. *Invest Radiol.*, 1991; 26:975-979.

[2] Gibby WA, Gibby KA, Gibby WA. Comparison of Gd DTPA-BMA (Omniscan) versus Gd HP-DO3 (ProHance) retention in human bone tissue by inductively coupled plasma atomic emission spectroscopy. *Invest Radiol.*, 2004; 39:138-142.

57. Plaintiff incorporates by reference and realleges each paragraph set forth above.

58. Defendants' gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark), were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

59. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) are the legal cause of Plaintiff's serious physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the future.

60. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

SECOND CAUSE OF ACTION
(Against All Defendants)
NEGLIGENCE

61. Plaintiff incorporates by reference and realleges each paragraph set forth above.

62. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) and the MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents. In particular, they had a duty to ensure that their products did not pose an unreasonable risk of bodily harm and adverse events.

63. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) and the MRI machines and products designed to be used in

conjunction with gadolinium-based contrast agents in that they knew or should have known that the products could cause significant bodily harm or death and were not safe for use by certain types of consumers.

64. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) and the labeling of MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury due to the use of gadolinium-based contrast agents (including Magnevist, MultiHance and Optimark) and the MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents.

65. Despite the fact that Defendants knew or should have known that gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) and the MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Manufacturing and Distributor Defendants unreasonably continued to manufacture and market gadolinium-based contrast agents (including Magnevist, MultiHance, and Optimark) and the MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents, and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

66. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff would suffer injury as a result of their failure to exercise ordinary care as described above.

67. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

a) Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

b) Past and future medical expenses, loss of income, and other economic damages in an amount to be determined at trial of this action;

c) Punitive damages in an amount to be determined at trial of this action (only applicable to the Defendants and Causes of Action noted above);

d) Pre-judgment and post-judgment interest;

e) Attorneys' fees, expenses, and costs; and

f) Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

In addition to the above, Plaintiff Susan Fischer hereby demands a trial by jury for all causes of action and issues that can be tried by a jury.

Dated: June 8, 2018

CUTTER LAW, P.C.

By: _____
Todd A. Walburg

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Attorneys for the Plaintiff SUSAN FISCHER

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): **SUSAN FISCHER**

County of Residence: Maricopa

County Where Claim For Relief Arose: Maricopa

Plaintiff's Atty(s):

Todd A. Walburg
Cutter Law P.C.
401 Watt Ave.
Sacramento, California 95864
9162909400

Defendant(s): **BAYER HEALTHCARE PHARMACEUTICALS INC., et al.**

County of Residence: Outside the State of Arizona

Defendant's Atty(s):

II. Basis of Jurisdiction: **1. U.S. Government Plaintiff**

III. Citizenship of Principal Parties **(Diversity Cases Only)**

Plaintiff:- **1 Citizen of This State**
Defendant:- **5 Non AZ corp and Principal place of Business outside AZ**

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **367 Health Care/Pharmaceutical Personal Injury Product Liability**

VI.Cause of Action: **28 U.S.C. Section 1332 Strict Liability, Failure to Warn, Negligence**

VII. Requested in Complaint

Class Action: **No**
Dollar Demand:
Jury Demand: **Yes**

VIII. This case **is not related** to another case.

Signature: Todd A. Walburg

Date: 6/8/18

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014