1 2 3	C. Brooks Cutter (SBN 121407) Todd A. Walburg (SBN 213063) Margot P. Cutter (SBN 306789) CUTTER LAW, P.C. 4179 Piedmont Avenue, 3 rd Floor	ENDORSED FILE D San Francisco County Superior Count DEC 2 2 2017
4	Oakland, CA 94611 Mailing: 401Watt Avenue	OLEEK OF THE COURT
5	Sacramento, CA 95864 Telephone: (916) 290-9400	BY: KALENE APOLONIO Deputy Clerk
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9	CUREDIAN COURT FOR TU	IE STATE OF CALLEODNIA
10	SUPERIOR COURT FOR THE STATE OF CALIFORNIA COUNTY OF SAN FRANCISCO	
11		
12	PATRICIA YOUNG,	Case No. CGC -17-563332
13	Plaintiff,	COMPLAINT FOR DAMAGES
14	vs. BAYER HEALTHCARE	STRICT PRODUCTS LIABILITY: FAILURE TO WARN;
15	PHARMACEUTICALS INC.; BAYER PHARMA AG; BAYER CORPORATION;	2) NEGLIGENCE
16	BAYER HEALTHCARE LLC; McKESSON	DEMAND FOR JURY TRIAL
17	CORPORATION; McKESSON MEDICAL- SURGICAL INC.; MERRY X-RAY	DEMIAND FOR JUNE TRIAL
18	CHEMICAL CORPORATION; and DOES 1 through 50, inclusive,	BY FAX
19	Defendants.	
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21	COMES NOW Plaintiff, Patricia Young (hereinafte	er "Plaintiff"), and allege as follows:
22	<u>PARTIES</u>	
23	Plaintiff	
24	1. Plaintiff Patricia Young is a resident of the City of San Rafael, within Marin County, in	
25	the State of California.	
26	2. Because Plaintiff and three of the Defendants are residents of the State of California (no	
27	diversity jurisdiction), and because there is no federal question involved, this case should not be removed	
28	to federal court.	
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COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

- 3. Because two of the Defendants are residents of San Francisco County, this court is the appropriate venue for this case.
- 4. Plaintiff suffers from Gadolinium Deposition Disease ("GDD"). GDD is an incurable, painful disease. Plaintiff contracted GDD because of receiving MRIs/MRAs using intravenous injections of a gadolinium-based contrast agent known as Magnevist.

Manufacturing Defendants

- 5. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, Bayer Corporation, Bayer Healthcare LLC, and DOES 1 through 20, inclusive (collectively referred to as the "Manufacturing Defendants"), manufacture, market, and sell Magnevist, a gadolinium-based contrast agent ("GBCA") that was injected into Plaintiff's body.
- 6. Defendant Bayer Pharma AG is a foreign company domiciled in Germany. Bayer Pharma AG 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-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).
- 7. 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

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27 28 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).

- Defendant Bayer Corporation is an Indiana corporation with its headquarters located in 8. 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 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-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017). Defendant Bayer Corporation is duly authorized to conduct business in the State of California and does business in San Francisco County. Said Defendant has elected to establish an agent for service of process in the State of California.
- Defendant Bayer HealthCare LLC is a Delaware LLC with its headquarters located in 9. 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 California's state laws, and Plaintiff's claim arises out of Defendant's Specifically, Defendant conducted clinical trials of Magneyist within forum-related activities. 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-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017). Defendant Bayer HealthCare LLC is duly authorized to conduct business in the State of California and does business in San Francisco County. Said Defendant has elected to establish an agent for service of process in the State of California.
- At all times relevant to this complaint, the Manufacturing Defendants advertised, 10. promoted, marketed, distributed, and sold Magnevist in California and nationwide.

- 11. The true names and capacities of those Defendants designated as DOES 1-50 are unknown to Plaintiff. Plaintiff alleges on information and belief that DOES 1-20 manufactured gadolinium-based contrast agents that were injected into Plaintiff and/or manufactured MRI/MRA machines with which MRIs/MRAs were performed on Plaintiff using gadolinium-based contrast agents. Plaintiff alleges on information and belief that each of these fictitiously named defendants bears some legal responsibility for the events and damages set forth in this complaint.
- 12. Plaintiff alleges on information and belief that DOES 1-20 were and are companies authorized to do and doing business in the State of California and have regularly conducted business in the County of San Francisco, State of California.
- 13. Plaintiff will amend this Complaint if necessary to show the identity of each fictitiously named Defendant when they have been ascertained.
- 14. The Manufacturing Defendants, along with DOES 1-20, are collectively referred to as the Manufacturing Defendants.

Distributor Defendants

- 15. Defendant McKesson Corporation ("McKesson") distributes Magnevist and other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that McKesson distributed the Magnevist and/or other gadolinium-based contrast agents that were injected into Plaintiff.
- 16. Defendant McKesson Corporation is a Delaware corporation with its principal place of business and headquarters at One Post Street, San Francisco, San Francisco County, California.
- 17. McKesson Corporation is duly authorized to conduct business in the State of California and does business in San Francisco County.
- 18. At all times relevant to this complaint, McKesson Corporation sold Magnevist and/or other gadolinium-based contrast agents in San Francisco County and elsewhere.
- 19. Defendant McKesson Medical-Surgical, Inc. distributes Magnevist and other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that McKesson Medical-Surgical, Inc. distributed the Magnevist and/or other gadolinium-based contrast agents that were injected into Plaintiff.
 - 20. Defendant McKesson Medical-Surgical, Inc. is a Virginia corporation with its principal

place of business and headquarters at One Post Street, San Francisco, San Francisco County, California.

- 21. Defendant McKesson Medical-Surgical, Inc. is duly authorized to conduct business in the State of California and does business in San Francisco County.
- 22. At all times relevant to this complaint, Defendant McKesson Medical-Surgical, Inc. sold Magnevist and/or other gadolinium-based contrast agents in San Francisco County and elsewhere.
- 23. Defendant Merry X-Ray Chemical Corporation ("Merry X-Ray") distributes Magnevist and/or other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that Merry X-Ray distributed the Magnevist and/or other gadolinium-based contrast agents that were injected into Plaintiff.
- 24. Defendant Merry X-Ray Chemical Corporation is a California corporation with its principal place of business and headquarters at 4444 Viewridge Avenue, San Diego, California.
- 25. Merry X-Ray Chemical Corporation is duly authorized to conduct business in the State of California and does business in San Francisco County.
- 26. At all times relevant to this complaint, Merry X-Ray sold Magnevist and/or other gadolinium-based contrast agents in San Francisco County.
- 27. The true names and capacities of those Defendants designated as DOES 21-30 are unknown to Plaintiff. Plaintiff alleges on information and belief that DOES 21-30 distributed gadolinium-based contrast agents that were injected into Plaintiff. Plaintiff alleges on information and belief that each of these fictitiously named Defendants bear some legal responsibility for the events and damages set forth in this Complaint.
- 28. Plaintiff alleges on information and belief that DOES 21-30 were and are companies authorized to do and doing business in the State of California and have regularly conducted business in the County of San Francisco, State of California.
- 29. Plaintiff will amend this Complaint if necessary to show the identity of each fictitiously named defendant when they have been ascertained.
- 30. McKesson, McKesson Medical-Surgical, Inc., and Merry X-Ray, along with DOES 21-30, are collectively referred to as the Distributor Defendants.
 - 31. The Manufacturing Defendants and the Distributor Defendants are collectively referred

to as Defendants.

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JURISDICTION AND VENUE

- 32. Jurisdiction and venue are both proper in San Francisco County Superior Court, in the State of California.
 - 33. This Court has personal jurisdiction over all parties named herein, as described above.
- 34. Plaintiff is a resident of the State of California. Three of the Defendants are residents of the State of California.
- 35. Many of the acts and omissions related to the liability of the Defendants occurred in California.
- 36. Diversity jurisdiction, as is required in federal district court for a case of this nature, does not exist here. Diversity jurisdiction requires "complete diversity," which does not exist if any plaintiff is from the same State as any defendant. 28 U.S.C. § 1332. Here, Plaintiff is a California resident. Defendants McKesson Corporation, McKesson Medical-Surgical, Inc., and Merry X-Ray are also California residents. Therefore, there is not complete diversity of the parties and diversity jurisdiction does not apply.
 - 37. Removal of this case to federal court would be improper due to the lack of diversity.
- 38. Furthermore, this venue (particularly the San Francisco Superior Court Complex Civil Litigation Department which handled the previous gadolinium litigation) is convenient to the parties and is an appropriate venue for a multiple party product liability action.

FACTS

- 39. Plaintiff Patricia Young had normal kidney function prior to developing Gadolinium Deposition Disease ("GDD"). Plaintiff Patricia Young, was subjected to one or multiple MRIs/MRAs. At the time of these procedures, Plaintiff was injected with the gadolinium-based contrast agent, Magnevist. Unbeknownst to her, she developed GDD soon thereafter. Plaintiff Patricia Young's symptoms of GDD include but are not limited to the following: numbness and tingling sensation throughout body, severe fatigue, anemia, a restless leg-type syndrome, memory loss, and cognitive impairment.
 - 40. Gadolinium Deposition Disease ("GDD") is the name for a disease process observed in

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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 like Magnevist. 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 softtissue 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.

- 41. GDD is a man-made disease. It only occurs in patients who have received a gadoliniumbased contrast agent for an MRI or an MRA.
- Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. 42. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.
- Because gadolinium is toxic, it must be coated to keep it from coming into contact with 43. human tissue when used in connection with MRIs or MRAs. This coating process is called chelation.
- 44. The gadolinium-based contrast agents (including Magnevist) injected into Plaintiff were manufactured by the Manufacturing Defendants and distributed by the Distributor Defendants.
- 45. 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

- 46. Plaintiff received MRIs/MRAs utilizing gadolinium-based contrast agents, including Magnevist.
- 47. 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 in patients with normal or near-normal kidney function.
- 48. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with gadolinium-based contrast agents, including Magnevist, and failed to disclose the fact that there were safer alternatives.
- 49. As a direct and proximate result of receiving injections of gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, including Magnevist, Plaintiff developed GDD.
- 50. 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, to individuals with normal or near-normal kidney function.
- 51. Had Plaintiff and/or her healthcare providers been warned about the risks associated with gadolinium-based contrast agents, including Magnevist, she would not have been administered gadolinium-based contrast agents and would not have been afflicted with GDD.
- 52. As a direct and proximate result of Plaintiff's being administered gadolinium-based contrast agents, including Magnevist, she has suffered severe physical injury and pain and suffering, including, but not limited to, the effects of GDD.
- 53. As a direct and proximate result of being administered gadolinium-based contrast agents, including Magnevist, 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.
- 54. As a direct and proximate result of being administered gadolinium-based contrast agents, including Magnevist, 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

- 55. The nature of Plaintiff's injuries and damages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, including Magnevist, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until less than two years before the filing of this Complaint. On or about December 23, 2015, Plaintiff became aware that she had retained gadolinium from the Magnevist gadolinium-based contrast agent that was injected into her.
- 56. Plaintiff became aware of the disease, GDD, in August 2016 upon publication of "Gadolinium in Humans: A Family of Disorders," in volume 207:2 of the American Journal of Roentgenology.
- 57. In 1984--prior to FDA approval-- the inventors of gadolinium-based contrast agents claimed that their product Gd-DTPA did not cross the blood-brain barrier and that the bonds between the toxic gadolinium and its protective coating did not break inside the body. Additionally, they claimed that there would be no toxic gadolinium residue left behind to cause illness.
- 58. 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 Manufacturing Defendants) along with Omniscan (manufactured by GE Healthcare), Optimark (manufactured by Guerbet), and Multihance (manufactured by Bracco). 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).
- 59. Also 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.

- 60. Stability differences among gadolinium 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).
- 61. 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.
- 62. 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.
- 63. Three months after the FDA approval of Omniscan (a linear contrast agent with a similar structure to Magnevist) 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 7-days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.
- 64. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over 1 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.

- 65. Manufacturing Defendants knew that their product, Magnevist, did not have very stable bonds and could come apart easily causing significant toxicity in humans.
- 66. 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 Magnevist, 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 Magnevist, 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 were patients' skin and vital organs 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 multi-million-dollar verdict for Mr. Decker. Unfortunately, Mr. Decker passed away from his gadolinium-triggered disease before the verdict was reached.
- 67. 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.
- 68. 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 because 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 several

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.

- 69. 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.
- 70. 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.
- 71. 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.
- 72. 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.
- 73. In July of 2015, and in direct response to the Mayo Clinic study's findings, the FDA issued a new public safety alert. The FDA is 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.
- 74. 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 in the brain, even in patients with healthy kidneys.

- 75. On December 19, 2017 the FDA announced that it is requiring a new class warning and other safety measures for all gadolinium-based contrast agents for MRI concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs.
- 76. Defendants have known about the risks that gadolinium-based contrast agents, including Magnevist, pose to people with normal kidney function for many years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function. In 2004, gadolinium was shown to be deposited in the resected femoral heads of people who had undergone gadolinium-chelate enhanced MRI studies. Since then, studies have continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.
- 77. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their product, Magnevist. 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.
- 78. 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.
- 79. Defendants are estopped from asserting a statute of limitations defense because all Defendants concealed from Plaintiff the nature of Plaintiff's injuries and the connection between their injuries and all Defendants' tortious conduct.

FIRST CAUSE OF ACTION

(Against All Defendants)

STRICT PRODUCTS LIABILITY: FAILURE TO WARN

- 80. Plaintiff incorporates by reference and realleges each paragraph set forth above.
- 81. Defendants' gadolinium-based contrast agents, including Magnevist, were defective due

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.

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Code Section 3294(c)(1).

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(Against All Defendants)

NEGLIGENCE

product of the serious safety risks of the product. This allegation is sufficient to show despicable conduct

carried on with a willful and conscious disregard of the rights and safety of others per California Civil

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

SECOND CAUSE OF ACTION

increasing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

The foregoing acts, conduct and omissions of Defendants were vile, base, willful,

- 85. Plaintiff incorporates by reference and realleges each paragraph set forth above.
- 86. 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. They had a duty to ensure that their products did not pose an unreasonable risk of bodily harm and adverse events.
 - 87. Defendants failed to exercise reasonable care in the design, formulation, manufacture,

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sale, testing, marketing, or distribution of gadolinium-based contrast agents, including Magnevist, 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.

- Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast agents, including Magnevist, 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
- Even though Defendants knew or should have known that gadolinium-based contrast agents, including Magnevist, 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, and failed to exercise reasonable care with respect to post-sale warnings
- 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.
- 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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

- Compensatory damages more than 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;
- Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
- 3. Punitive damages as to the First Cause of Action in an amount to be determined at trial of this action;
 - 4. Pre-judgment and post-judgment interest;
 - 5. Attorneys' fees, if applicable, expenses, and costs; and

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1	6. Such further relief as this Court deems necessary, just, and proper.		
2	DEMAND FOR JURY TRIAL		
3	In addition to the above, Plaintiff hereby demands a trial by jury for all causes of action ar		
4	issues that can be tried by a jury.		
5	Respectfully submitted this 22nd day of December 2017.		
6	CUTTER LAW, P.C.		
7	Add I M		
8	By: Todd A. Walburg		
9	C. Brooks Cutter (SBN 121407)		
10	Todd A. Walburg (SBN 213063)		
11	Margot P. Cutter (SBN 306789) CUTTER LAW, P.C. 4179 Piedmont Avenue, 3 rd Floor		
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