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Attorneys for Plaintiff CHERYL MAHNKE

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CHERYL MAHNKE,

Plaintiffs,

vs.

BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER HEALTHCARE PHARMACEUTICALS, INC.; MCKESSON CORPORATION; MCKESSON MEDICAL-SURGICAL, INC.; and DOES 1 through 20, inclusive,

Defendants.

Case No.:

COMPLAINT FOR DAMAGES

1) STRICT PRODUCTS LIABILITY: FAILURE TO WARN
2) STRICT PRODUCTS LIABILITY: DESIGN DEFECT
3) STRICT PRODUCTS LIABILITY: MISREPRESENTATION
4) NEGLIGENCE
5) BREACH OF EXPRESS WARRANTY
6) BREACH OF IMPLIED WARRANTY
7) NEGLIGENT MISREPRESENTATION
8) FRADULENT MISREPRESENTATION
9) CONSUMER PROTECTION VIOLATIONS

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff CHERYL MAHNKE ("Plaintiff") and alleges as follows:

INTRODUCTION

1. This action arises out of Plaintiff Cheryl Mahnke's injuries and damages, which were directly and proximately caused by her exposure to Defendants' Magnetic Resonance Imaging ("MRI") prescription Gadolinium-based Contrast Agents ("GBCAs") in the State of California. Plaintiff's damages are a direct and proximate result of Defendants' and/or their corporate predecessors negligent, willful, and wrong conduct in connection with the research, development, design, testing, licensing, manufacturing, distribution, supply, labeling, marketing and/or sale of GBCAs.

PARTIES

2. Plaintiff Cheryl Mahnke, at all relevant times, was a resident and citizen of the State of California.

Defendant Bayer Corporation

3. Defendant Bayer Corporation is, and at all relevant times has been, engaged in the research, development, design, testing, licensing, manufacturing, distribution, supply, labeling, marketing, and sale of the prescription GBCAs: Magnevist, Eovist, and Gadavist.

4. Defendant Bayer Corporation is, and at all relevant times has been, engaged in the distribution, supply, marketing, and sale of Magnevist, Eovist, and Gadavist in the State of California. 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 laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

5. Defendant Bayer Corporation is a for-profit corporation that is incorporated under the laws of Indiana.

6. Defendant Bayer Corporation contends that its principal place of business is in New Jersey.

7. Defendant Bayer Corporation may be served with process by serving its registered agent, CSC – Lawyers Incorporating Services, located at 2710 Gateway Oaks Drive,

Suite 150 N, Sacramento, CA 95833.

Defendant Bayer HealthCare, LLC

8. Defendant Bayer HealthCare LLC is, and at all relevant times has been, engaged in the research, development, design, testing, licensing, manufacturing, distribution, supply, labeling, marketing, and sale of the prescription GBCAs: Magnevist, Eovist, and Gadavist.

9. Defendant Bayer HealthCare LLC is, and at all relevant times has been, engaged in the distribution, supply, marketing, and sale of Magnevist, Eovist, and Gadavist in the State of California. 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 laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

10. Defendant Bayer HealthCare LLC is a for-profit limited liability company organized under the laws of Delaware.

11. Defendant Bayer HealthCare LLC contends that its principal place of business is in New Jersey.

12. Defendant Bayer HealthCare LLC consists of nine (9) members, which are as follows:

(a) NippoNex, Inc., a Delaware corporation with its principal place of business in New Jersey;

(b) Bayer West Coast Corporation, a Delaware corporation with its principal place of business in New Jersey;

(c) Bayer Essure Inc., a Delaware corporation with its principal place of business in New Jersey;

(d) Bayer Medical Care Inc., a Delaware corporation with its principal place of business in the Commonwealth of Pennsylvania;

(e) Bayer Consumer Care Holdings LLC, a limited liability company, the sole member of which is Bayer East Coast LLC and the sole preferred member of which is Bayer HealthCare US Funding LLC. Bayer East

Coast LLC's sole member is Bayer US Holding LP, and Bayer HealthCare US Funding LLC's members are Bayer AG, Bayer Pharma AG, and Bayer World Investments B.V. Bayer US Holding LP is a limited partnership in which Bayer World Investments B.V. is the sole General Partner and Bayer Solution B.V. is the sole limited partner. Bayer Solution B.V. is a private company with limited liability organized under the laws of the Netherlands and is wholly-owned by Bayer World Investments B.V. Bayer World Investments B.V. is a private company with limited liability organized under the laws of Netherlands and is wholly owned by Bayer AG. Bayer AG and Bayer Pharma AG are German Aktiengesellschafts organized under the laws of Germany whose stock is publicly traded in Germany, and their principal places of business are in Germany;

(f) Dr. Scholl's LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;

(g) Coppertone LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;

(h) MiraLAX LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC; and

(i) Bayer HealthCare US Funding LLC, a limited liability company, whose members are Bayer AG, Bayer Pharma AG, and Bayer World Investments B.V.

13. Defendant Bayer HealthCare LLC may be served with process by serving its registered agent, CSC – Lawyers Incorporating Services, located at 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833.

Defendant Bayer HealthCare Pharmaceuticals, Inc.

14. Defendant Bayer HealthCare Pharmaceuticals, Inc. is, and at all relevant times has been, engaged in the research, development, design, testing, licensing, manufacturing,

distribution, supply, labeling, marketing, and sale of the prescription GBCAs: Magnevist, Eovist, and Gadavist.

15. Defendant Bayer HealthCare Pharmaceuticals, Inc. is, and at all relevant times has been, engaged in the distribution, supply, marketing, and sale of Magnevist, Eovist, and Gadavist in the State of California. 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 laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

16. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a for-profit corporation that is incorporated under the laws of Delaware.

17. Defendant Bayer HealthCare Pharmaceuticals, Inc. contends that its principal place of business is in New Jersey.

18. Defendant Bayer HealthCare Pharmaceuticals, Inc. may be served with process by serving its registered agent, CSC – Lawyers Incorporating Services, located at 2710 Gateway Oaks Drive, Sacramento, CA 95833.

Defendant McKesson Corporation

19. Defendant McKesson Corporation ("McKesson") distributes Magnevist and other GBCAs in California and elsewhere. Plaintiff alleges that McKesson distributed Magnevist and/or other GBCAs that were injected into Plaintiff.

20. Defendant McKesson Corporation is a for-profit Delaware corporation with its principal place of business and headquarters in Irving, Texas.

21. Defendant McKesson Corporation is, and at all relevant times has been, engaged in the distribution of Magnevist and other GBCAs in the State of California. 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 laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

22. Defendant McKesson Corporation may be served with process by serving its registered agent, CSC – Lawyers Incorporating Services, located at 2710 Gateway Oaks Drive,

Sacramento, CA 95833.

Defendant McKesson Medical-Surgical, Inc.

23. Defendant McKesson Medical-Surgical, Inc. distributes Magnevist and other GBCAs in California and elsewhere. Plaintiff alleges that McKesson Medical-Surgical, Inc. distributed Magnevist and/or other gadolinium-based contrast agents that were injected into Plaintiff.

24. Defendant McKesson Medical-Surgical, Inc. is a Virginia corporation with its principal place of business and headquarters in Irving, Texas.

25. Defendant McKesson Corporation is, and at all relevant times has been, engaged in the distribution of Magnevist and other GBCAs in the State of California. 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 laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

26. Defendant McKesson Corporation may be served with process by serving its registered agent, CSC – Lawyers Incorporating Services, located at 2710 Gateway Oaks Drive, Sacramento, CA 95833.

Defendant Does 1-20

27. The true names and capacities of those Defendants designated as DOES 1-20 are unknown to Plaintiff. Plaintiff alleges on information and belief that DOES 1-20 manufactured, marketed and/or distributed gadolinium-based contrast agents that were injected into Plaintiff and that these fictitiously named defendants bear some legal responsibility for the events and damages set forth herein. 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 laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Plaintiff will amend this complaint if necessary to show the identity of each fictitiously named Defendant when they have been ascertained.

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JURISDICTION AND VENUE

28. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds the jurisdictional minimum of this Court, 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 California. As set forth more fully above, all Defendants are entities organized in states other than the State of California, all Defendants have their principal place of business in a state other than the State of California, and none of the Defendants is a citizen or resident of the State of California.

29. This Court has personal jurisdiction over all Defendants because they supplied, distributed, shipped, and delivered their GBCAs to healthcare providers throughout the United States, including, upon information and belief, to Plaintiff's healthcare providers in the State of California.

30. This Court has personal jurisdiction over all Defendants because Defendants have engaged in continuous, systematic, and substantial business activities in the State of California including but not limited to the marketing, sale and distribution of their GBCAs throughout the State of California.

31. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants marketed, advertised, and distributed the GBCAs in this District, Defendants do substantial business in the State of California and within this District, and Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold GBCAs, including Magnevist, Eovist, and Gadavist in interstate commerce.

NATURE OF ACTION

32. Gadolinium (Gd) is a rare earth metal.

33. Gadolinium-based Contrast Agents ("GBCAs") are chemical compounds that are introduced into the body prior to an MRI procedure in order to enhance the imaging.

34. The instant action arises from Plaintiff's exposure to Defendants' GBCA products by way of having undergone MRI procedures as detailed *infra*.

35. Plaintiff's exposure to Defendants' GBCAs has resulted in retention of Gadolinium in Plaintiff's body, directly and proximately causing Plaintiff to develop Gadolinium toxicity, manifested by symptoms including brain fog, joint pain and skin problems.

36. Plaintiff's development of Gadolinium toxicity has caused Plaintiff pain and suffering, and mental anguish.

37. Plaintiff brings this action, sounding in, *inter alia*, strict products liability, negligence, and fraud, seeking recovery of compensatory and punitive damages demands a trial by jury.

FACTUAL BACKGROUND:

GADOLINIUM AND GADOLINIUM-BASED CONTRAST AGENTS (GBCAs)

38. Gadolinium (Gd) is a chemical element. It sits in the lanthanide metal series of the periodic table and carries atomic number 64 and a relative atomic mass of 157 u.

39. In its natural state, gadolinium exists only in oxidized form as Gd^{3+}, which is a cation (an ion with more protons than electrons and hence a positive charge).

40. The gadolinium atom contains seven unpaired electrons in its 4f orbit, which is the highest possible number of unpaired electron spins that an atom can contain.

41. These unpaired electrons are what makes gadolinium highly paramagnetic, and consequently, uniquely effective for use in Magnetic Resonance Imaging (MRI or MR imaging).

42. MR imaging is a medical diagnostic procedure that employs radiofrequency (RF) waves and a strong magnetic field to temporarily realign protons found in body tissue being targeted in the particular imaging.

43. Once RF is applied, the protons in the body's tissue produce signals captured by a receiver and are generated into a "picture" of the target area by the MRI machine.

44. Prior to the 1980s, magnetic resonance MRI was ordinarily performed in the clinical setting without the use of contrast agents.

45. Eventually, research revealed that introducing a contrast agent into a patient prior to MRI might safely alter the magnetic properties of target tissues and serve to enhance the imaging.

46. Today, Gadolinium-based Contrast Agents (GBCAs) are the most widely used contrast agents in MR imaging.

47. GBCAs shorten what are called the T1 and T2 "relaxation" times of the target tissue, with the net result of higher intensity MR signaling and a clearer MR picture. Gadolinium has the strongest relaxation rate of all the paramagnetic elements.

48. But gadolinium is toxic. It does not occur naturally in the body, and it is well accepted in the medical and scientific community that "free" gadolinium is toxic in biological systems.

49. Because gadolinium cannot be safely introduced into the body by itself, GBCAs instead are comprised of "chelated" gadolinium—*i.e.*, Gd^{3+} that is complexed (or "bound") by a ligand.

50. "Chelate" is Latin for "claw," and a simple understanding of the nature of chelated gadolinium is that the ligand serves as a claw holding onto the gadolinium as it passes through the body.

51. Thus, the gadolinium in a GBCA is intended to remain chelated as it passes through and eventually is eliminated from the body, mainly by the kidneys, after the MRI.

52. There are currently nine (9) GBCAs that have been approved by the Food and Drug Administration (FDA) for use in the United States, and they fall into one of two categories based on the nature of their chelation: linear or macrocyclic.

53. Linear chelates are elongated ligand structures that wrap around the Gd^{3+} ion, like a coil around a cylinder. In contrast, macrocyclic chelates are cage-like structures that trap the Gd^{3+} ion more securely in a center cavity.

54. Because of the structure of GBCAs, there is a risk of "de-chelation," a process whereby gadolinium can become unbound or freed from its chelate. De-chelation is due in part to the fact that other substances in the body will "compete" with gadolinium for its chelate, including zinc, copper, and iron. In fact, the bond in a GBCA can become very weak and separate very easily in low pH conditions, such as those found in many compartments of the human body including extracellular fluid spaces.

55. Once de-chelated, the freed, highly reactive cation Gd^{3+} will immediately—within femtoseconds—bind to another substance in the body, and there are a variety of substances in the human body that are available to, and known to bind with, de-chelated Gd^{3+}, including proteins, phosphates and other compounds.

56. In short, when de-chelated, gadolinium from GBCAs will bind with, deposit, and remain in the cells and tissue of various organs in the body.

57. Since as early as 1984, medical and scientific literature have reported on the deposition of toxic gadolinium in animal tissue.

58. In 1988, Bayer's Magnevist, a linear GBCA, was the first GBCA to gain FDA approval for marketing and sale in the United States, and by that time, Bayer was aware of the evidence of gadolinium deposition in biological systems.

59. September 1989 may have marked the very first report of the retention of toxic gadolinium in a human, when Tien et al. reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)." *See* Tien, R.D., et al., *Cerebral Erdheim-Chester Disease: persistent enhancement with Gd-DTPA on MR images*, Radiology, 1989; Vol. 172, No. 3, p. 791-92. Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue.

60. In 1993, shortly after FDA's approval of another linear GBCA, General Electric's Omniscan, preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies showed that quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.

61. Throughout the 1990s, evidence showing retention of gadolinium in human patients with renal (kidney) insufficiency was mounting, and by 2004, evidence clearly began to show deposition of gadolinium in human patients *without* compromised renal function.

62. Indeed, by 2004, gadolinium had been shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies. Since then, studies have continued to indicate that gadolinium from GBCAs remains within people's bodies

long after their suggested half-lives.

63. Because of their structure, macrocyclic GBCAs are more stable and less prone to de-chelation—and hence deposition—in the body. Indeed, laboratory (*in vitro*) studies assessing the stability of various GBCAs in human blood have demonstrated that, over time, greater percentages of gadolinium are released from linear agents as compared to the macrocyclic agents.

64. As direct consequence of the skyrocketing use of GBCAs in MRI in the 1980s and 1990s, by the early 2000s, the medical and scientific community began to take note of a never-before-seen disease that was arising in patients with compromised renal function who had been exposed to GBCAs.

65. The disease is characterized by fibrosis of the skin and/or internal organs. Initially the condition was called "nephrogenic fibrosing dermopathy," but eventually came to be known as it is today: nephrogenic systemic fibrosis, or "NSF."

66. The disease was uncovered and understood only by the attentive clinical observation and work of dermatologists, nephrologists, and other scientists, who connected the administration of *linear* GBCAs to this rapidly progressive, debilitating and often fatal condition.

67. There were over 500 cases of NSF reported, and it was estimated there were well over a thousand non-reported cases.

68. Eventually, the emergence of NSF prompted the FDA to require GBCA manufacturers, including all Defendants, to strengthen the class product labeling for GBCAs to include a "black box" warning, which first went into the labeling in 2007:

> **WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)**
>
> ***See full prescribing information for complete boxed warning.***
>
> **Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities.**
>
> **• Do not administer Magnevist to patients with:**
>
> **o chronic, severe kidney disease (GFR < 30 mL/min/1.73m2), or**

o acute kidney injury.

• Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension, or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

69. Because of the black box warning and the medical community's awareness of the clear causal connection between GBCAs and NSF in renally impaired patients, the incidence of NSF has all but disappeared, as healthcare practitioners have universally changed MRI prescription habits.

70. It is now settled in the medical community that GBCAs are a cause of NSF. Authoritative and reliable medical literature has reported that the relative risk for development of the disease in renally impaired patients exposed to GBCAs might be as high 41 (a 4,000% increased risk over baseline) compared to baseline. *See* Wagner, B., et al. *Pathophysiology of gadolinium-associated systemic fibrosis*, Am. J. Physiol. Renal Physiol., 311(1): p. F1-F11 (2016).

71. To be sure, the kidneys play a central role in the body's clearance of GBCAs, but the name "nephrogenic" systemic fibrosis is misleading, as there is in fact no evidence that this systemic fibrotic condition is in any way *caused* by the kidneys.

72. Instead, the kidneys are simply a catalyst, insofar as impaired renal function results in the body's prolonged exposure to a GBCA dose from an imaging event.

73. Indeed, by 2017, FDA and industry were forced to acknowledge that gadolinium retention is not a problem only in patients with renal impairment, but instead, that the evidence is now unequivocal that GBCA exposure results in gadolinium being retained in the bodies—tissue and organs, including the skin, bones, liver, and brain—of patients who do not suffer from clinically diagnosed renal impairment.

74. In September 2017, FDA and the GBCA industry collaborated in an advisory committee meeting—the Medical Imaging Drugs Advisory Committee (MIDAC)—and the committee voted thirteen to one in favor of adding statements on the GBCA class product labeling that would reveal to doctors for the first time that gadolinium can be retained in the

body even in patients with healthy kidneys.

75. In May 2018, the FDA's and industry's statements were formally issued, and advised healthcare providers, *inter alia*, that:

(j) gadolinium is retained for months or years in brain, bone, skin, and other organs in patients with normal renal function;

(k) the highest concentrations of retained gadolinium are found in bone, followed by other organs (brain, skin, kidney, liver, and spleen);

(l) the duration of gadolinium retention is longest in bone and varies by organ;

(m) retention is greater in patients administered linear GBCAs than in those administered macrocyclic GBCAs;

(n) there have been reports of pathological skin changes in patients with normal renal function; and

(o) there have adverse event reports involving multiple organ systems in patients with normal renal function.

76. However, and notwithstanding the overwhelming evidence of causal association between GBCAs and NSF, the FDA and the GBCA industry have cast the issue of retention as separate from the medical community's experience with NSF, coming short of acknowledging any untoward health effects from gadolinium retention in non-renal patients.

77. Indeed, to date, the FDA and the GBCA industry have refused to acknowledge that GBCAs can cause NSF in renal patients but also can cause, in non-renal patients, a variety of NSF-like injuries and symptoms along a continuum, ranging from minor to severe.

78. Plaintiff, who prior to GBCA exposure had never been diagnosed with kidney disease or been treated for compromised kidney function, alleges that the injuries Plaintiff suffered, detailed *infra*, were the direct and proximate result of exposure to Defendants' GBCAs and were on a NSF-like continuum, and Plaintiff brings this complaint to recover damages for those injuries.

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FACTUAL BACKGROUND:

PLAINTIFF'S GBCA EXPOSURE AND INJURIES

79. Upon information and belief, on or around the following dates, Plaintiff was exposed to GBCA-enhanced MRIs over twenty (20) times, including but not limited to the following:

09/17/2010:	Magnevist
	MRI Spine
	Radiology Associates MRI of San Luis Obispo
	San Luis Obispo, CA – San Luis Obispo County
12/15/2010:	Magnevist
	MRI Spine
	Radiology Associates MRI of San Luis Obispo
	San Luis Obispo, CA – San Luis Obispo County
08/06/2014:	Magnevist
	MRI Brain, Cervical Spine, Lumbar Spine, and Thoracic Spine
	Selma Carlson Diagnostic Center
	San Luis Obispo, CA – San Luis Obispo County
05/01/2015:	Magnevist
	MRI Brain
	Selma Carlson Diagnostic Center
	San Luis Obispo, CA – San Luis Obispo County

80. Prior to Plaintiff's exposure to Defendants' GBCAs as outlined above, Plaintiff had never been diagnosed with kidney disease or been treated for compromised kidney function.

81. As a direct and proximate result of Plaintiff's exposure to Defendants' GBCAs, Plaintiff now suffers from gadolinium toxicity, or Gadolinium Deposition Disease (GDD), as characterized by a multitude of symptoms, ailments, injuries, and adverse health effects that she has suffered and continues to suffer, including but not necessarily limited to: neurological and

cognitive issues; body, bone, joint and muscle pain; skin issues including paresthesia and rashes; and extreme fatigue.

FEDERAL STANDARDS AND REQUIREMENTS

82. Upon information and belief, the Defendants have or may have failed to comply with all federal standards and requirements applicable to the sale of GBCAs including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations.

CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY: FAILURE TO WARN

(*all Defendants*)

83. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

84. Defendants' linear GBCAs were manufactured, sold, marketed, distributed, supplied, and/or placed into the stream of commerce by Defendants and were defective at the time they left Defendants' control in that the drugs failed to include proper and adequate warnings, instructions and directions relating to the risks associated with the use of linear GBCAs.

85. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers yet Defendants failed to adequately warn consumers and their healthcare providers of such risks.

86. Defendants failed to provide proper and adequate warnings to healthcare providers and users, including Plaintiff and Plaintiff's healthcare providers, of the increased risk of gadolinium retention and resulting injuries associated with linear GBCAs. The defect or defects made the GBCAs unreasonably dangerous to those persons, such as Plaintiff, who could reasonably be expected to use and rely upon the product.

87. Prescribing physicians, healthcare providers and patients, including Plaintiff and Plaintiff's healthcare providers, neither knew nor had reason to know at the time of their use of Defendants' linear GBCAs, of the existence of the lack of proper and adequate warnings.

88. Ordinary consumers would not have recognized the potential risks or side effects for which Defendants failed to include appropriate warnings, and which Defendants concealed, including the risk of gadolinium retention in multiple organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

89. At all times alleged herein, Defendants' linear GBCAs were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants. The GBCAs injected into Plaintiff's body were neither misused nor materially altered.

90. Defendants' failure to warn includes but is not limited to failure to warn as to the following:

(a) Failing to adequately and correctly warn the Plaintiff, the public, and the medical and healthcare communities of the dangers of their linear GBCAs with respect to the risk of gadolinium retention;

(b) Failing to disclose their knowledge that gadolinium is retained for months to years in several organs;

(c) Failing to disclose their knowledge that higher concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);

(d) Failing to disclose their knowledge that gadolinium retention is longest in bone and varies by organ;

(e) Failing to disclose their knowledge that linear GBCAs cause more retention than macrocyclic GBCAs;

(f) Failing to disclose their knowledge about adverse event reports involving multiple organ systems in patients with normal renal function;

(g) Failing to disclose their knowledge that certain patients are at higher risk of adverse effects from linear GBCAs; and

(h) Failing to disclose their knowledge that gadolinium has a tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

91. Had Plaintiff and Plaintiff's medical providers been adequately warned of the risks associated with their linear GBCAs, Plaintiff would not have used, and/or Plaintiff's healthcare providers would not have administered, Defendants' linear GBCAs and Plaintiff's injuries would have been avoided.

92. Defendants' failure to warn was a factual and proximate cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

COUNT II – STRICT PRODUCTS LIABILITY: DEFECTIVE DESIGN

(*all Defendants*)

93. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

94. Defendants' linear GBCAs were manufactured, sold, marketed, distributed, supplied, and/or placed into the stream of commerce by Defendants and were defective at the time they left Defendants' control in that the drugs were defective in their design.

95. At all times alleged herein, Defendants' linear GBCAs were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants. The GBCAs injected into Plaintiff's body were neither misused nor materially altered.

96. Under the "consumer expectation test," Defendants' linear GBCAs are defective because they failed to perform as safely as an ordinary consumer would have expected them to perform when used in an intended, or unintended but reasonably foreseeable way.

97. Under the "risk utility test," Defendants' linear GBCAs are defective because a reasonable person would conclude that the possibility and seriousness of the harm pleaded herein, *passim*, outweighed the burden or cost of making the product safe.

98. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the product with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of Plaintiff and others similarly situated.

99. Defendants' GBCAs are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable use, and do not meet or perform to the expectations of consumers.

100. The foreseeable risks associated with the design or formulation of linear GBCAs include, but are not limited to, retention of gadolinium in organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), resulting fibrosis in organs, bone, and skin, and gadolinium's tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

101. The foreseeable risks associated with Defendants' design of linear GBCAs, including the risks of retention of gadolinium in tissues and organs, outweigh their utility for the foreseeable uses for which they are prescribers to patients like Plaintiff.

102. There are GBCAs on the market, including macrocyclic GBCAs, with safer alternative designs in that they provide equal or greater efficacy and far less risk.

103. These safer alternatives would have prevented or significantly reduce the risk of injury to Plaintiff, without substantially impairing their utility.

104. These safer alternatives were both technologically and economically feasible when Defendants' GBCAs left the control of Defendants.

105. Defendants' defective design of their linear GBCAs was a factual and proximate cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and

mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

COUNT III—NEGLIGENCE

(*all Defendants*)

106. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

107. At all times relevant hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff and Plaintiff's prescribing physician, herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of their linear GBCAs, and post-marketing vigilance regarding same.

108. Defendants knew or should have known that injecting their linear GBCAs into the bodies of patients created an unreasonable risk of dangerous side effects, including gadolinium retention and resultant injuries, such as those suffered here by Plaintiff.

109. Defendants breached their duty of reasonable care to Plaintiff in that they negligently designed, developed, promoted, marketed, distributed, continued to sell, and/or labeled their linear GBCAs, including but not limited to the following conduct:

(a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of their linear GBCAs;

(b) In failing to adequately or correctly warn Plaintiff, the public, and the medical and healthcare communities, including Plaintiff's healthcare providers, of the dangerous and defective characteristics of their linear GBCAs;

(c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for their linear GBCAs;

(d) In promoting their linear GBCAs in an overly aggressive, deceitful, and fraudulent manner, despite evidence of their defective and dangerous characteristics in causing irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), resulting in fibrosis

in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

(e) In representing that linear GBCAs were safe for their intended use when, in fact, the drugs were unsafe for their intended use;

(f) In failing to perform appropriate pre-market and post-market testing of their linear GBCAs;

(g) In failing to perform appropriate post-market safety surveillance of their linear GBCAs;

(h) In failing to take post-market actions to protect and/or warn consumers about the risks of linear GBCAs; and

(i) In failing to disclose reports of gadolinium retention associated with their linear GBCAs to medical providers and consumers.

110. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

111. Defendants' negligence was a factual cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

COUNT IV—BREACH OF EXPRESS WARRANTY

(*all Defendants*)

112. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

113. Through their product labeling, marketing, advertising, promotion, and educational efforts, including but not limited to creation and control of various aspects of the

peer-reviewed medical and scientific literature, Defendants expressly warranted to Plaintiff and the healthcare community that linear GBCAs are safe and fit for their intended uses.

114. Plaintiff and Plaintiff's healthcare providers read and relied upon Defendants' express warranties.

115. Defendants breached said warranties by delivering to Plaintiff and Plaintiff's healthcare providers linear GBCAs that did not conform to said express warranties, insofar as they are not safe or fit for their intended uses and may produce serious side effects.

116. Defendants' breach of said express warranties was a factual cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

COUNT V—BREACH OF IMPLIED WARRANTY

(*all Defendants*)

117. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

118. Defendants developed, designed, formulated, tested, packaged, labeled, produced, created, marketed, advertised, distributed, and sold their linear GBCAs as safe for use by the public at large, including Plaintiff, who purchased these drugs.

119. Defendants knew the use for which their linear GBCAs were intended and impliedly warranted their linear GBCAs to be of merchantable quality, safe, and fit for a particular purpose.

120. Plaintiff and Plaintiff's healthcare providers relied on the skill and judgment of Defendants, and as such, their implied warranties, in using Defendants' linear GBCAs.

121. Plaintiff and Plaintiff's healthcare providers used Defendants' linear GBCAs for the ordinary purposes for which they were indicated for use and pursuant to Defendants'

instructions, labeling, and guidance.

122. Defendants' linear GBCAs were defective and not of merchantable quality or safe or fit for their intended use.

123. Specifically, Defendants' linear GBCAs are unreasonably dangerous, unmerchantable, and unfit for the ordinary purpose for which they are intended and were used because they cause injuries, including but not limited to, retention of gadolinium in organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), resulting in fibrosis in organs, bone, and skin, and gadolinium's tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, and foreseeable risks, which Defendants knew or should have known.

124. Defendants had reason to know that Plaintiff would purchase their linear GBCAs for the purpose of diagnostic imaging.

125. Defendants had reason to know that Plaintiff would rely on Defendants' skill or judgment to furnish and produce linear GBCAs in a safe and appropriate manner.

126. Defendants breached said implied warranties by delivering to Plaintiff and Plaintiff's healthcare providers linear GBCAs that did not conform to said implied warranties, insofar as they are not safe or fit for their intended uses and may produce serious side effects.

127. Defendants' breach of said implied warranties was a factual cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

COUNT VI—NEGLIGENT MISREPRESENTATION

(*all Defendants*)

128. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

129. Through their product labeling, marketing, advertising, promotion, and

educational efforts, including but not limited to creation and control of various aspects of the peer-reviewed medical and scientific literature, Defendants have consistently represented that their linear GBCAs are safe and that linear GBCAs do not pose health risks to patients with normal renal function.

130. At all times relevant hereto, said representations of material facts were false, and Defendants made said misrepresentations negligently and without any reasonable ground to believe in their truth.

131. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of these statements but reasonably believed them to be true.

132. At all times relevant hereto, Defendants made said misrepresentations with the intent to induce reliance on them.

133. Plaintiff and Plaintiff's healthcare providers relied on Defendants' misrepresentations in prescribing and using Defendants' linear GBCAs.

134. Defendants' negligent misrepresentations were a factual cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

COUNT VII—FRAUDULENT MISREPRESENTATION

(*all Defendants*)

135. Plaintiff re-alleges and incorporates by reference, as if fully set forth herein, each of the foregoing paragraphs and allegations.

136. Through their product labeling, marketing, advertising, promotion, and educational efforts, including but not limited to creation and control of various aspects of the peer-reviewed medical and scientific literature, Defendants have consistently represented that their linear GBCAs are safe and that linear GBCAs do not pose health risks to patients with

normal renal function.

137. At all times relevant hereto, said representations were of material facts and were false, and Defendants made said misrepresentations fraudulently and intentionally and with the intent of misleading Plaintiff, Plaintiff's healthcare providers, and the medical community.

138. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of these statements but reasonably believed them to be true.

139. At all times relevant hereto, Defendants made said misrepresentations with the intent to induce reliance on them.

140. Plaintiff and Plaintiff's healthcare providers relied on Defendants' misrepresentations in prescribing and using Defendants' linear GBCAs.

141. Defendants' fraudulent and intentional misrepresentations were a factual cause of Plaintiff's injuries and damages as set forth herein.

WHEREFORE, for the above reasons, Plaintiff demands judgment in Plaintiff's favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory and punitive damages, incidental and consequential damages, including pain and suffering and mental anguish, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

TOLLING: FRAUDULENT CONCEALMENT,

DISCOVERY RULE, AND EQUITABLE ESTOPPEL

Fraudulent Concealment

142. At all times relevant hereto, Defendants knew or should have known that linear GBCAs posed the risk of retention and harmful health effects outlined herein, that macrocyclic agents are more stable and thus safer, and that systemic fibrotic symptoms and injuries occur in GBCA-exposed patients irrespective of renal function.

143. At all times before Summer 2018, Defendants made misrepresentations and omissions that concealed from Plaintiff material facts that would have permitted Plaintiff to file this action for injuries sooner.

144. Plaintiff and Plaintiff's healthcare providers relied upon Defendants'

misrepresentations and omissions.

145. Said reliance prevented Plaintiff from learning or discovering facts that would lead a reasonably prudent person to make inquiry or assert available legal claims, including those set forth in the instant complaint, sooner than Plaintiff was in fact able.

146. As a result, any statute of limitations applicable to this action was tolled, and did not begin to run, until at least Summer 2018.

Discovery Rule

147. Plaintiff did not possess facts sufficient to put Plaintiff on notice that the wrongs, acts, and omissions set forth herein had been committed until at the very earliest, Summer 2018.

148. Plaintiff did not know of the claims, and their underlying facts, asserted in this complaint, nor could any reasonable prudent person have known of such claims, until at the very earliest, Summer 2018.

149. At all times relevant hereto, Plaintiff exercised reasonable diligence in investigating potential causes of Plaintiff's injuries, but no information gave Plaintiff a reason to suspect, or reasonably should have given Plaintiff a reason to suspect, that Defendants' products or tortious conduct were the cause of such injuries until at the very earliest, Summer 2018.

150. Regardless of the exercise of any reasonable diligence, Plaintiff did not know, nor reasonably should have known, that Plaintiff suffered injuries and that Plaintiff's injuries had been caused by Defendants' conduct until at the very earliest, Summer 2018.

151. Plaintiff neither suspected nor knew of Defendants' wrongdoings as alleged in this complaint until at the very earliest, Summer 2018.

152. In sum, Plaintiff was reasonably unaware, and had no reasonable way of knowing, that Plaintiff's injuries described herein were caused by Defendants' conduct until at the very earliest, Summer 2018.

153. As a result, any statute of limitations applicable to this action was tolled, and did not begin to run, until at least Summer 2018.

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Equitable Estoppel

154. Due to their concealment as set forth *supra*, Defendants are equitably estopped from invoking any statute of limitations as a time bar to Plaintiff's complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands judgment against all Defendants and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

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DEMAND FOR JURY TRIAL

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

DATED this 13th day of May, 2019.

GOMEZ TRIAL ATTORNEYS

By: /s/ Kristen K. Barton
John H. Gomez
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Attorney for Plaintiff Cheryl Mahnke

CIVIL COVER SHEET

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

CHERYL MAHNKE

(b) County of Residence of First Listed Plaintiff San Luis Obispo County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
John H. Gomez, Kristen K. Barton
Gomez Trial Attorneys 655 W Broadway, Suite 1700
San Diego, CA 92101 (619) 237-3490

DEFENDANTS

BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER HEALTHCARE PHARMACEUTICALS, INC.; MCKESSON CORPORATION; MCKESSON MEDICAL-SURGICAL, INC.; and DOES 1 through 20, inclusive,

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment Of Veteran's Benefits
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury – Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
- ☐ 448 Education

PRISONER PETITIONS

HABEAS CORPUS
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

OTHER
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee–Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC § 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent–Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 USC § 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation–Transfer ☐ 8 Multidistrict Litigation–Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:
Diversity Jurisdiction

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, Fed. R. Civ. P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S), IF ANY *(See instructions):*

JUDGE Hon. Judge Donato DOCKET NUMBER 3:18-cv-04146

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only) ☒ **SAN FRANCISCO/OAKLAND** ☐ **SAN JOSE** ☐ **EUREKA-MCKINLEYVILLE**

DATE 05/13/2019 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Kristen K. Barton

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-CAND 44

Authority For Civil Cover Sheet. The JS-CAND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)."

II. Jurisdiction. The basis of jurisdiction is set forth under Federal Rule of Civil Procedure 8(a), which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

(1) United States plaintiff. Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.

(2) United States defendant. When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

(3) Federal question. This refers to suits under 28 USC § 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

(4) Diversity of citizenship. This refers to suits under 28 USC § 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS-CAND 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.

(1) Original Proceedings. Cases originating in the United States district courts.

(2) Removed from State Court. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.

(3) Remanded from Appellate Court. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

(4) Reinstated or Reopened. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

(5) Transferred from Another District. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

(6) Multidistrict Litigation Transfer. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.

(8) Multidistrict Litigation Direct File. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

Please note that there is no Origin Code 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC § 553. Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Federal Rule of Civil Procedure 23.

Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

IX. Divisional Assignment. If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated."

Date and Attorney Signature. Date and sign the civil cover sheet.