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Attorneys for Plaintiff JOSEPH LEWIS

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOSEPH LEWIS, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER CORPORATION; BAYER HEALTHCARE LLC; and DOES 1 through 20, inclusive, Defendants.	Case No. **COMPLAINT FOR DAMAGES** 1) STRICT LIABILITY: FAILURE TO WARN; 2) NEGLIGENCE **DEMAND FOR JURY TRIAL**

COMES NOW Plaintiff JOSEPH LEWIS ("Plaintiff") and alleges as follows:

PARTIES AND BACKGROUND

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

2. Plaintiff JOSEPH LEWIS, at all relevant times, was a resident and citizen of the State of California; residing in Petaluma, Califorina.

3. Plaintiff JOSEPH LEWIS was injected with a linear gadolinium-based contrast agent ("GBCA") prior to receiving an MRI. Contrary to the defendant's promotion of GBCAs as being benign contrast agents that harmlessly exit the body shortly after administration in patients with normal kidney function, he continues to have retained gadolinium in his body long after being administered the GBCA. Plaintiff's primary injuries alleged herein are serious, disabling symptoms caused by his gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin). Gadolinium is a toxic heavy metal that causes fibrosis in organs, bone, and skin.

4. Plaintiff was never warned about the risks of gadolinium retention because he had normal renal function and the GBCA manufacturers chose to only provide warnings to patients with reduced renal function.

5. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that was injected into Plaintiff's body.

6. 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.

7. 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 this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

8. Defendant Bayer Corporation is an Indiana corporation with its headquarters located in Pennsylvania.

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9. 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 this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

10. Defendant Bayer Healthcare LLC is a limited liability company duly formed and existing under and by the virtue of the laws of Delaware, with its principal place of business located in the State of New Jersey. Bayer Healthcare LLC's sole member is Bayer Corporation, and is wholly owned by Bayer Corporation, which is an Indiana corporation with its principal place of business in Pittsburgh, Pennsylvania. Accordingly, Bayer Healthcare LLC is a citizen of Delaware, New York, Indiana, and Pennsylvania for purposes of determining diversity under 28 U.S.C. § 1332.

11. 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 this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

12. 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 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. Plaintiff will amend this complaint if necessary to show the identity of each fictitiously named Defendant when they have been ascertained.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000 exclusive of interest and costs. There

is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of 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.

14. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in this state, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including GBCA's of the type received by Plaintiff JOSEPH LEWIS, to the residents in this state.

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

FACTS COMMON TO ALL CAUSES OF ACTION

16. Plaintiff JOSEPH LEWIS underwent an MRI during which he was injected with the linear gadolinium-based contrast agent, Magnevist.

17. Plaintiff JOSEPH LEWIS had normal kidney function at the time he was injected with Magnevist.

18. The gadolinium in the Magnevist that JOSEPH LEWIS was injected with was retained in his body and resulted in fibrosis in his organs, skin, and bones, and was retained in the neurons of his brain.

19. Plaintiff JOSEPH LEWIS's symptoms and injuries from Magnevist include, but are not limited to the following: significant burning sensations with red blotches and swelling; severe pain, weakness, stiffness, tingling and muscle spasms involving the left hand, bilateral shoulders, hips, knees, legs, and low back area; popping sounds of his joints; difficulty walking and immobility; nausea and vomiting; cognitive issues, headaches, insomnia, generalized malaise and sensations of tightness in his skin; silvery plaque patches and gray scaling and redness on the

knees, hands and feet; skin discoloration; and thrombophlebitis.

20. The type of gadolinium retention sustained by Plaintiff JOSEPH LEWIS occurs in patients with normal or near-normal renal function that develop persistent symptoms that arise hours to months after the administration of a linear gadolinium-based contrast agent.

21. Plaintiff JOSEPH LEWIS had no preexisting disease or subsequently developed disease of an alternate known process to account for the symptoms. People suffering from gadolinium retention experience symptoms consistent with the known toxic effects of retained gadolinium. Typical clinical features include persistent headaches, bone and joint pain, and clouded mental activity. People with gadolinium retention sometimes experience subcutaneous soft-tissue thickening that clinically appears somewhat spongy or rubbery. Tendons and ligaments may also be painful and have a thickened appearance. People with gadolinium retention often experience excruciating pain, typically in a distal distribution, of the arms and legs, but it may also manifest in the torso or other locations. This pain is often described as feeling like sharp pins and needles, cutting, or burning. Gadolinium retention often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. This is a progressive condition for which there is no known cure.

22. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear 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 gadolinium retention in connection with the use of linear gadolinium-based contrast agents

23. Defendants failed to warn Plaintiff and his healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives (*e.g.*, macrocyclic agents instead of linear agents).

24. As a direct and proximate result of receiving injections of linear gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, Plaintiff developed gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

25. Defendants have repeatedly and consistently failed to advise consumers and their healthcare providers of the causal relationship between linear gadolinium-based contrast agents and gadolinium retention resulting in fibrosis in the organs, skin, and bones, retained gadolinium in the brain, and related injuries. Defendants knew or should have known of the risks posed by linear gadolinium-based contrast agents to individuals with normal or near-normal kidney function.

26. Had Plaintiff and/or his healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, he would not have been administered linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

27. As a direct and proximate result of Plaintiff being administered linear gadolinium-based contrast agents, he has suffered severe physical injury and pain and suffering, including, but not limited to, gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

28. As a direct and proximate result of being administered linear gadolinium-based contrast agents, 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.

29. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

30. The nature of Plaintiff's injuries and damages, and their relationship to linear gadolinium-based contrast agents, were not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than two years before the filing of this complaint.

31. The manufacturers of the linear GBCAs have known since the 1980s that their drugs could cause retention of toxic gadolinium. But their claims to the public and healthcare

providers have been misleading and false.

32. In 1984 – prior to FDA approval – the inventors of linear 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.[1]

33. There are two basic types of contrast agents differentiated by their chemical structure – 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 more complete ring around the gadolinium ion which creates a stronger bond. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured by Guerbet/ Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

34. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988.

35. In 1988 it was recognized in a paper 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.[2] Furthermore, emerging science showed that the bond between toxic gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH conditions such as those found in many compartments of the human body including extracellular fluid spaces.

36. Stability differences among gadolinium 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.[3]

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[1] Brasch RC. Inherent contrast in magnetic resonance imaging and the potential for contrast enhancement – the 1984 Henry Garland lecture. *West J Med.* 1985 Jun; 142:847-853.

[2] Huckle JE, Altun E, Jay M, et al. Gadolinium deposition in humans: when did we learn that gadolinium was deposited in vivo? *Invest. Radiol.* 2016; 51:236-240.

[3] *Id.*

37. 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.[4]

38. The lack of stability seen within the linear agents was dismissed as an issue by the defendants claiming that the GBCA's were excreted out of the body according to the drug's claimed half-life, before the chelate could release the toxic gadolinium. However, it was later noted that some 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.

39. 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.[5]

40. Three months after the FDA approval of GE's Omniscan (a linear contrast agent) in 1993 the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies noted 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.[6]

41. 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)."[7] Subsequent chemical analysis

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[4] Tweedle MF, Eaton SM, Eckelman WC, et al. Comparative chemical structure and pharmacokinetics of MRI contrast agents. *Invest. Radiol*. 1988; 23 (suppl 1): S236-S239; *see also* Frenzel T, Lengsfeld P, Schimer H, et al. Stability of gadolinium-based magnetic resonance imaging contrast agents in serum at 37 degrees C. *Invest. Radiol*. 2008; 43:817-828.

[5] Weinman HJ, Brasch RC, Press WR, et al. Characteristics of gadolinium-DTPA complex: a potential NMR contrast agent. *AJR Am J Roentgenol*. 1984; 142: 619-624.

[6] Harpur ES, Worah D, Hals PA, et al. Preclinical safety assessment and pharmaco-kinetics of gadodiamide injection, a new magnetic resonance imaging contrast agent. *Invest Radiol.* 1993; 28 (suppl 1): S28-S43.

[7] Tien RD, Brasch RC, Jackson DE, et al. Cerebral Erdheim-Chester disease: persistent enhancement with Gd-DTPA on MR images. *Radiology*. 1989; 172:791-792.

revealed that a high concentration of gadolinium remained in the tissue.

42. Defendants knew that their linear GBCAs did not have very stable bonds and could come apart easily causing significant toxicity in humans. Defendants have known about the risks that linear gadolinium-based contrast agents pose to people with normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[8]

43. In 2004, gadolinium was shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies.[9] Since then, studies have continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.

44. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their products, or anywhere that a patient or physician could be informed.

45. Dermatologists, nephrologists, and other scientists connected the administration of linear gadolinium-based contrast agents 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 regarding the release of toxic gadolinium from the linear contrast agents, and its long-term retention in the bodies of animals and humans (for patients with abnormal kidney function) on all gadolinium-based contrast agents in 2007.

46. Defendants corrected their label to include contraindications for use in people with kidney disease and acute kidney injury.

47. There were over 500 NSF cases reported and estimated to be well over a thousand non-reported. There was a prior MDL and other litigation involving NSF against the defendants in the current litigation. A trial in that litigation resulted in a verdict in favor of the plaintiff and

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

[9] 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.

against GE. The litigation resolved and the MDL was formally closed in 2015. Due to the new black box warning in the GBCA's labelling, doctors stopped using GBCAs in patients with abnormal kidney function. However, the warnings for patients with normal kidney function remained unchanged until May 21, 2018, and as a result, the linear GBCAs continued to be widely used and marketed notwithstanding the Defendants' knowledge of the dangers of the product. This case and the others pending throughout the country involve widespread fibrosis and other symptoms in the bodies of patients with normal kidney function.

48. The vast majority of the medical community were not aware, until recently, of any disease that was associated with gadolinium other than NSF, which was defined as only occurring in patients with renal failure.

49. Gadolinium toxicity is, therefore, 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 long after their exposure to gadolinium-based contrast agents. Many patients also have tissue biopsies of various parts of their body that show additional evidence of retained gadolinium years after their exposure.

50. Some 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 as early as 2012.

51. 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.[10]

[10] Kanda T, Ishii K, Kawaguchi H, et al. High signal intensity in the dentate nucleus and globus pallidus on unenhanced T1-weighted MR images: relationship with increasing cumulative dose of a gadolinium-based contrast material. *Radiology*. 2014; 270: 834-841.

52. 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.[11]

53. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents used in MRIs.

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

55. On May 21, 2018, the GBCA manufacturers finally issued a joint warning to patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

a. "Subject: Gadolinium from GBCAs may remain in the body for months to years after injection;"

b. A new class warning, patient counseling, and a medication guide;

c. Warning that gadolinium is retained for months to years in several organs;

d. Warning that the highest concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);

e. Warning that the duration of gadolinium retention is longest in bone and varies by organ;

f. Warning that linear GBCAs cause more retention than macrocyclic GBCAs;

g. Warning about reports of pathological skin changes in patients with normal renal function;

h. Warning that adverse events involving multiple organ systems have been

[11] McDonald RJ, McDonald JS, Kallmes DF, et al. Intracranial gadolinium deposition after contrast-enhanced MR imaging. *Radiology.* 2015; 275:772-782.

reported in patients with normal kidney function;

i. Warning that certain patients are at higher risk:

i. patients with multiple lifetime doses;

ii. pregnant patients;

iii. pediatric patients;

iv. patients with inflammatory process;

j. Instructions for health care providers to advise patients that:

i. Gadolinium is retained for months or years in brain, bone, skin, and other organs in patients with normal renal function;

ii. Retention is greater following administration of linear GBCAs than following administration of macrocyclic GBCAs.

The Warning deliberately downplays the state of the evidence concerning the health effects of gadolinium retention.

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

FIRST CAUSE OF ACTION
(Against All Defendants)

STRICT PRODUCT LIABILITY: FAILURE TO WARN

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

58. Defendants' linear gadolinium-based contrast agent was defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

59. 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.

60. As a result of Defendants' failure to provide adequate warnings for their product, Plaintiff was unknowingly injected with dangerous linear gadolinium-based contrast agent which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced into

the stream of commerce.

61. The linear GBCA injected into Plaintiff are the legal cause of Plaintiff's serious physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the future.

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

SECOND CAUSE OF ACTION
(Against All Defendants)

NEGLIGENCE

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

64. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and distribution of their linear gadolinium-based contrast agents. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

65. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of their linear gadolinium-based contrast agents in that they knew or should have known that these products could cause significant bodily harm or death, and were not safe for use by consumers.

66. Defendants failed to exercise ordinary care in the labeling of their linear gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury due to the use of linear GBCAs.

67. Despite the fact that Defendants knew or should have known that their linear gadolinium-based contrast agent posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market linear gadolinium-based contrast agents and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

a) Non-economic damages including pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

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

c) Punitive damages (as to First Cause of Action) in an amount to be determined at the time of trial of this action;

d) Pre-judgment and post-judgment interest;

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

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

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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: July 11, 2018

GOMEZ TRIAL ATTORNEYS

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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

JOSEPH LEWIS

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
John H. Gomez, Kristen K. Barton
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DEFENDANTS

BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER CORPORATION; BAYER HEALTHCARE LLC; 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 3:17-cv-07026, 3:18-cv-03077, 3:18-cv-00811, 5:18-cv-03830

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

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

DATE 07/11/2018

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.