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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

REGINALD BROWN Plaintiff, v. BRACCO DIAGNOSTICS, INC. Defendant.	Civil Action No._____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Reginald Brown ("Plaintiff"), tenders the following as his Complaint and Jury Demand against Defendant, Bracco Diagnositcs, Inc. ("Defendant") for personal injuries suffered as a proximate result of Plaintiff being prescribed and administered Defendant's defective and unreasonably dangerous Gadolinium-Based Contrast Agent ("GBCA"), specifically Multihance.

INTRODUCTION

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. This is an action for damages suffered by Plaintiff as a direct and proximate

result of Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of their GBCA used in MRIs.

3. Plaintiff maintains that Defendant's GBCA is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

4. The gadolinium from Defendant's GBCA does not wash out of the patient's body as readily as promised, and instead can be retained indefinitely or permanently in multiple organs and soft tissues (e.g., brain, heart, liver, kidney, bones, and skin) in patients with normal renal function. This gadolinium, a toxic heavy metal, causes fibrosis in organs, bone, and skin, other adverse reactions, and crosses the blood-brain barrier and deposits in the neuronal nuclei of the brain.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business outside of the state in which the Plaintiff resides.

6. There is complete diversity of citizenship between Plaintiff and Defendant. Plaintiff is a resident and citizen of and is domiciled in the state of California. As set forth more fully below, Defendant is organized in states other than the state of California, has its principal places of business in states other than California, and is not a citizen or resident of the state of California.

7. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

8. This Court has personal jurisdiction over Defendant, which is licensed to conduct and is systematically and continuously conducting business in this state, including, but not limited to, marketing, advertising, selling, and distributing drugs, including its GBCA, to the residents of this state. Further, this Court has personal jurisdiction over Defendant because

Plaintiff's claims arise from the marketing, advertising, selling, and distributing its GBCA to Plaintiff in California.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the Plaintiff's cause of action occurred in this District. Defendant sells, advertises, markets and/or distributes its GBCA within this District and does substantial business in this state and within this District.

10. Defendant developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold its GBCA in interstate commerce.

PARTIES

11. Plaintiff Reginald Brown is a natural person and at all relevant times a resident and citizen of the State of California.

12. As used herein, "Defendant" includes Bracco Diagnostics, Inc.

13. Defendant Bracco Diagnostics Inc. manufactures, tests, markets, advertises, and sells the linear GBCA named MultiHance.

14. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. is duly authorized to conduct business in the state of California and does significant business in the Northern District of California. Bracco Diagnostics, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over Bracco Diagnostics, Inc. under the doctrine of specific jurisdiction because this 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.

15. Defendant Bracco Diagnostics, Inc. is the holder of the approved New Drug Application ("NDA") for MultiHance.

FACTS COMMON TO ALL CAUSES OF ACTION

16. The type of gadolinium retention sustained by Plaintiff occurs in patients without chronic/severe kidney disease or acute kidney injury who develop persistent symptoms that arise hours to months after the administration of a linear GBCA. Plaintiff had no preexisting disease or subsequently developed disease of an alternate known process to account for the symptoms he sustained. Gadolinium retention can be a progressive condition for which there is no known cure.

17. During the years that Defendant manufactured, marketed, distributed, sold, and administered linear GBCAs, 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 GBCAs.

18. Defendant failed to warn Plaintiff and his healthcare providers about the serious health risks associated with linear GBCAs, and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents).

19. As a direct and proximate result of receiving injections of linear GBCAs manufactured, distributed, marketed, and/or sold by Defendant, Plaintiff developed gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

20. 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 GBCAs and would not have been afflicted with gadolinium retention resulting in injuries.

21. As a direct and proximate result of Plaintiff being administered linear GBCAs, 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.

22. As a direct and proximate result of being administered linear GBCAs, 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.

23. As a direct and proximate result of being administered linear GBCAs, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

24. Meanwhile, unknown to Plaintiff, 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 about such retention have been misleading and false.

25. In 1984 – prior to FDA approval – the inventors of linear GBCAs 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]

26. 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. More specifically, linear GBCAs consist of gadolinium linked to a larger open-chained molecule (a ligand). Macrocyclic GBCAs consist of gadolinium linked to a cyclic ligand. The linear GBCAs are chemically less stable in terms of their tendency to release gadolinium ions; the macrocyclic GBCAs tend to stay intact. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured by Guerbet/ Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

[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.

27. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988, and in that same year, 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.

28. 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]

29. 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]

30. The lack of stability seen within the linear agents was dismissed as a cause of concern by the Defendant, who claimed 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,

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[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.*
[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.

a delayed elimination phase of the GBCAs would later be discovered.

31. 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]

32. 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]

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

34. Defendant knew that its linear GBCAs did not have very stable bonds and could come apart easily, causing significant toxicity in humans. Defendant has known about the risks that linear GBCAs pose to people with normal kidney function for years. In fact, pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[8]

35. In 2004, gadolinium was shown to be deposited in the resected femoral heads

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

(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.

36. Despite this well-documented evidence of gadolinium retention, Defendant has continuously failed to warn consumers and their healthcare providers in the package insert/ prescribing information or in any other way about the risks of gadolinium retention in patients with normal renal function.

37. Dermatologists, nephrologists, and other scientists connected the administration of linear GBCAs to a rapidly progressive, debilitating and often fatal condition called gadolinium-induced Nephrogenic Systemic Fibrosis (NSF). This, in turn, prompted the Food and Drug Administration (FDA) to issue a black box warning in 2007 for all GBCAs 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).

38. Accordingly, Defendant revised its label to include contraindications for use in people with kidney disease and acute kidney injury.

39. There were over 500 NSF cases reported and there were estimated to be well over a thousand non-reported cases. Due to the new black box warning in the GBCA's labelling, patients and medical providers were warned about the risks of using GBCAs in patients with chronic/severe kidney disease or acute kidney injury. However, the warnings for patients with normal kidney function remained unchanged until approximately May 2018. As a result, for years prior the linear GBCAs continued to be widely used and marketed in patients with normal renal function, notwithstanding the Defendant's knowledge of these risks. Indeed, the vast majority of the medical community was not aware, until recently, of any disease that was associated with gadolinium other than NSF, and even that disease was understood in the medical

[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.

community to only occur in patients with renal failure. Defendant knew otherwise.

40. 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 GBCAs. They found that the brain had hyperintense signals in critical areas of the brain.[10]

41. 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 GBCAs in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.[11]

42. 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 was evaluating the risk of brain deposits from repeated use of GBCAs used in MRIs.

43. 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.

44. On May 21, 2018, the GBCA manufacturers finally issued a joint warning (i.e. "Dear Health Care Provider" letter) to medical providers about the risks of GBCAs in 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;

[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.

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

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 reported in patients with normal kidney function;

i. Warning that certain patients are at higher risk, including:

   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.

45. This "Dear Health Care Provider" letter is the first time that Defendant made any effort to warn Plaintiff, his health care providers, the medical community, or the general public about the significant risks identified with the use of linear GBCAs.

46. Therefore, Defendant is estopped from relying on any statute of limitations because of its fraudulent concealment of the true character, quality, and nature of their linear GBCAs. Defendant was under a duty to disclose the true character, quality, and nature of their linear GBCAs because this was non-public information over which Defendant had and continues

to have exclusive control, and because Defendant knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. Defendant is estopped from relying on any statute of limitations because of its intentional concealment of those facts.

47. Plaintiff Reginald Brown was injected with the linear GBCAs prior to receiving MRIs on or around January 20, 2017 and February 28, 2018. These GBCAs included Defendant's Multihance.

48. Unbeknownst to Plaintiff and contrary to the Defendant's promotion of GBCAs as benign contrast agents that harmlessly exit the body shortly after administration in patients who did not have chronic/severe kidney disease or acute kidney injury, Plaintiff continues to have retained gadolinium in his body after being administered the GBCAs, resulting in permanent physical and emotional injuries.

49. Plaintiff has suffered gadolinium retention in multiple organs and soft tissues (e.g., brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, causes fibrosis in organs, bone, and skin, other adverse reactions, and crosses the blood-brain barrier and deposits in the neuronal nuclei of the brain.

50. At the time of Plaintiff's use of the linear GBCAs at issue, Plaintiff did not have chronic/severe kidney disease or acute kidney injury, and the GBCA manufacturers chose to only provide warnings to patients with these types of reduced renal function. Defendant failed to appropriately and adequately inform or warn Plaintiff and his healthcare providers about the risks of gadolinium retention in patients with normal renal function.

COUNT I
STRICT LIABILITY – INADEQUATE WARNING

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

52. Defendant's GBCA was manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendant and was defective at the time it left Defendant's control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of

linear GBCAs.

53. Defendant failed to provide adequate warnings to healthcare providers and users, including Plaintiff and his healthcare providers, of the increased risk of gadolinium retention and resulting injuries associated with linear GBCAs.

54. Prescribing physicians, healthcare providers and patients, including Plaintiff and his healthcare providers, neither knew, nor had reason to know at the time of their use of Defendant's GBCAs, of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which Defendant failed to include appropriate warnings, and which Defendant 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.

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

56. Defendant is strictly liable for failure to warn by virtue of its conduct of selling products that are unreasonably dangerous and for failing to provide an adequate warnings about their GBCAs.

57. Defendant is therefore strictly liable by virtue of the following acts and/or omissions:

(a) Failing to adequately and correctly warn the Plaintiff, the public, and the medical and healthcare communities of the dangers of their 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 patient with normal renal function;

(g) Failing to disclose their knowledge that certain patients are a 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.

58. Had Plaintiff and his medical providers been adequately warned of the risks associated with their GBCAs, Plaintiff would not have used the GBCAs or agreed to being administered with these drugs.

59. Had Plaintiff not taken Defendant's GBCAs, Plaintiff would not have suffered injuries and damages as set forth herein. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

COUNT II
STRICT LIABILITY – DEFECTIVE DESIGN

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

61. Defendant's GBCA was manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendant and was defective at the time it left Defendant's control in that, and not by way of limitation, the drug was defective in its design.

62. At all times alleged herein, the Defendant's GBCA was prescribed to and used by Plaintiff as intended by Defendant and in a manner reasonably foreseeable to Defendant. The

GBCAs injected into Plaintiff's body were neither misused nor materially altered.

63. Defendant's GBCA was unreasonably dangerous for the use for which it was intended, and its unreasonably dangerous condition existed when it left the control of Defendant.

64. Defendant's GBCA is defective because it failed to perform in a manner reasonably expected in light of its nature and intended function.

65. The foreseeable risks associated with the design or formulation of Defendant's GBCAs include, but are not limited to, the fact that the design or formulation of the GBCAs is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

66. The foreseeable risks associated with the design or formulation of 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.

67. The foreseeable risks associated with Defendant's GBCA's design, including the risks of retention of gadolinium in tissues and organs, outweigh its utility for the foreseeable uses for which it is prescribed to patients like the Plaintiff.

68. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

69. Defendant placed its GBCAs into the stream of commerce with wanton and reckless disregard for the public safety.

70. Defendant knew or should have known that physicians and other healthcare

providers began commonly prescribing this product despite its potential to cause serious permanent injuries.

71. Defendant knew or should have known that its GBCAs cause and/or contribute to the injuries described in this complaint.

72. 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.

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

74. These safer alternatives were both technologically and economically feasible when Defendant's GBCAs left the control of Defendant.

75. Had Plaintiff not taken Defendant's GBCAs, Plaintiff would not have suffered injuries and damages as set forth herein. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

COUNT III
NEGLIGENCE

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

77. At all times material hereto, Defendant had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of their GBCAs, and post-marketing vigilance regarding same. Defendant knew or should have known that injecting their GBCAs into the bodies of patients created an unreasonable risk of dangerous side effects, including gadolinium retention.

78. Defendant breached their duty of reasonable care to Plaintiff in that they

negligently designed, developed, promoted, marketed, distributed, and/or labeled their GBCAs.

79. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendant, including, but not limited to, one or more of the following particulars:

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

b) In failing to adequately and correctly warn the Plaintiff, the public, and the medical and healthcare communities of the dangerous and defective characteristics of their GBCAs;

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

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to their GBCA's defective and dangerous characteristics due to its propensity to cause irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin;

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 testing of their GBCAs;

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

h) In failing to perform appropriate post-marketing testing of their GBCAs; and

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

80. Defendant knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendant's failure to exercise reasonable

and ordinary care.

81. As a direct and proximate result of Defendant's carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, gadolinium retention in multiple organs (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. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

COUNT IV
BREACH OF IMPLIED WARRANTY
(including but not limited to Cal. U. Com. Code §§ 2314 and 2315)

82. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

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

84. Defendant knew the use for which their product was intended and impliedly warranted their GBCAs to be of merchantable quality, safe and fit for use.

85. Plaintiff and Plaintiff's physicians relied on the skill and judgment of the Defendant, and as such, their implied warranty, in using Defendant's GBCAs.

86. Plaintiff used Defendant's GBCAs for the ordinary purposes for which they were indicated for use, and Plaintiff's physician used the GBCAs pursuant to the Defendant's instructions.

87. Defendant's GBCAs were defective and not of merchantable quality or safe or fit

for its intended use because it is unreasonably dangerous and unfit for the ordinary purpose for which it is intended and was used. Specifically, they are unreasonably dangerous, unmerchantable, and unfit for the ordinary purpose for which they are intended and were used because they cause injury, which 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, foreseeable risks, which Defendant knew or should have known.

88. Defendant's GBCA does not meet the reasonable expectations of an ordinary consumer, including the Plaintiff, as to its safety and is not reasonably safe for its intended purpose and use because it is defectively designed and because Defendant inadequately warned of the risks of this drug.

89. Defendant had reason to know that Plaintiff would purchase their GBCAs for the purpose of diagnostic imaging.

90. Defendant had reason to know that Plaintiff would rely on Defendant's skill or judgment to furnish and produce GBCAs in a safe and appropriate manner.

91. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

92. Plaintiff demands judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT V
BREACH OF EXPRESS WARRANTY
(including but not limited to Cal. U. Com. Code § 2313)

93. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

94. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Defendant's GBCA were expressly warranted to be safe by Defendant for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendant had knowledge of the foreseeable purposes for which the GBCA was to be used and Defendant warranted the GBCA to be in all respects safe, effective and proper for such purposes.

95. Defendant expressly warranted their GBCA in its label, which was directly intended to benefit Plaintiff.

96. Defendant's express warranties in their GBCA label were intended for the product's consumers, including the Plaintiff.

97. Defendant expressly warranted their GBCA in its patient labeling, which was intended to benefit Plaintiff and intended to be provided directly to Plaintiff.

98. Defendant expressly warranted their GBCA in advertisements and/or brochures, which Plaintiff read and relied upon.

99. Defendant expressly represented to Plaintiff, his physician(s), healthcare providers, and/or the FDA that their GBCA was safe and fit for the uses in which it is intended.

100. Further, Defendant's promotional and marketing activities, including pamphlets, and brochures stated or implied that their GBCA is safe and fit for its intended uses, that it did not produce severe side effects.

101. Plaintiff read and relied upon Defendant's express warranties in its patient labeling and/or in other information, including marketing and promotional material, disseminated by

Defendant.

102. Plaintiff's physician(s) read and relied upon Defendant's express warranties in the the GBCA label and/or in other information, including marketing and promotional material, disseminated by Defendant.

103. Defendant's GBCA does not conform to these express warranties and representations because it is not safe and may produce serious side effects.

104. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

105. Plaintiff demands judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT VI
NEGLIGENT MISREPRESENTATION

106. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

107. Defendant has consistently represented that its GBCA is safe and that it does not produce serious side effects.

108. At the timeframes discussed herein, these misrepresentations were made in Defendant's GBCA's labeling, patient education, and marketing materials, which were produced and distributed by Defendant with the intent to defraud Plaintiff, his healthcare providers, the healthcare community, patients, the FDA, and the public.

109. Likewise, Defendant made these representations to Plaintiff in advertising, in the

patient labeling, and/or in other marketing intended for consumers, prior to Plaintiff's administration with GBCAs, when he received the patient labeling, and when he was administered with the GBCAs.

110. Defendant additionally used key opinion leaders, thought leaders and/or sales representatives to make these misrepresentations to physicians, including Plaintiff's physicians, throughout Defendant's GBCA's post-marketing period and prior to Plaintiff's administration with the GBCA.

111. Defendant had pecuniary interest in transaction in which Plaintiff purchased Multihance, because they earned money as a result of the transaction.

112. Defendant supplied the above false information for the guidance of others, including Plaintiff, his healthcare providers, the healthcare community, patients, the FDA, and the public, in the business transaction of purchasing Defendant's product GBCA.

113. Plaintiff's pecuniary losses were caused by his justifiable reliance upon Defendant's false information.

114. Defendant failed to exercise reasonable care or competence in obtaining or communicating the above false information.

115. Plaintiff and his healthcare practitioners reasonably relied and actually relied upon the above misrepresentations.

116. As a result of the above misrepresentations, Defendant has negligently misrepresented that their GBCA is safe and effective and does not cause serious side effects.

117. But for these misrepresentations, Plaintiff would not have purchased Defendant's GBCAs or agreed to being administered with these GBCAs.

118. Defendant, having undertaken the designing, manufacturing, marketing,

formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of their GBCA, owed a duty to provide accurate and complete information regarding this drug.

119. Defendant has made false statements of material facts, of which Defendant was careless and/or negligent in ascertaining the truth of, with an intention of inducing Plaintiff and/or his healthcare providers to act upon them.

120. Plaintiff and his healthcare providers did take action in prescribing and using Defendant's GBCA in reliance upon Defendant's false statements of material facts, which has caused damage and injuries to Plaintiff as described herein.

121. Defendant falsely represented to Plaintiff and Plaintiff's healthcare providers that their GBCA was a safe and effective drug. The representations by Defendant were in fact false, as their GBCA is not safe and is dangerous to the health of its users.

122. At the time the aforesaid representations were made, Defendant concealed from Plaintiff and his healthcare providers information about the propensity of their GBCA to cause serious side effects. Defendant negligently misrepresented claims regarding the safety and efficacy of their GBCA despite the lack of information regarding same.

123. These misrepresentations were made by Defendant with the intent to induce Plaintiff to use their GBCA and to induce Plaintiff's healthcare providers to prescribe the GBCA, which Plaintiff and his healthcare providers were induced and did act, and which caused injury.

124. At the time of Defendant's misrepresentations and omissions, Plaintiff was unaware of the falsity of these statements and reasonably believed them to be true.

125. Defendant breached its duties to Plaintiff by providing false, incomplete and/or misleading information regarding its product.

126. Plaintiff and his healthcare providers reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when using and prescribing Defendant's GBCA.

127. However, Defendant's GBCA is not safe and is dangerous to the health of its users because it has a propensity for causing severe injuries.

128. Defendant negligently misrepresented that their GBCA does not have the propensity to cause or contribute to severe injuries.

129. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

130. Plaintiff demands judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT VII
FRAUDULENT MISREPRESENTATION

131. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

132. Defendant has consistently represented that its GBCA is safe and that it does not produce serious side effects.

133. The above representations are in fact false.

134. Defendant knew of the falsity of these misrepresentations, or they were made with reckless disregard as to their truth or falsity.

135. At the timeframes discussed herein, these affirmative misrepresentations were

made in Defendant's GBCA's labeling, patient education, and marketing materials, which were produced and distributed by Defendant with the intent to defraud, Plaintiff, his healthcare providers, the healthcare community, patients, the FDA, and the public.

136. Likewise, Defendant made these representations to Plaintiff in advertising, in the patient labeling, or in other marketing materials intended for consumers prior to Plaintiff's use of Defendant's GBCAs, when he received the patient labeling, and when he had the GBCAs administered.

137. Defendant additionally used key opinion leaders, thought leaders and/or sales representatives to make these misrepresentations to physicians, including Plaintiff's physicians, throughout Defendant's GBCA's post-marketing period and prior to Plaintiff's administration.

138. Defendant made the above misrepresentations in order to induce Plaintiff, Plaintiff, his healthcare providers, the healthcare community, patients, the FDA, and the public to act upon them.

139. Plaintiff and his healthcare practitioners reasonably and actually relied upon the above affirmative misrepresentations.

140. As a result of these affirmative misrepresentations, Defendant has fraudulently misrepresented that its GBCA is safe and effective and does not cause side effects like PTC/IIH or other neurological conditions.

141. The above misrepresentations were material to the transaction; but for these affirmative misrepresentations, Plaintiff would not have purchased Defendant's GBCA.

142. Defendant, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of their GBCA described herein, owed a duty to provide accurate and

complete information regarding this GBCA.

143. Defendant has made false statements of material facts, of which Defendant knew or believed to be false, with an intention of inducing Plaintiff and/or his healthcare providers to act upon them.

144. Plaintiff and his healthcare providers did take action in prescribing and using Defendant's GBCA in reliance upon Defendant's false statements of material facts, which has caused damage and injuries to Plaintiff as described herein.

145. Defendant fraudulently misrepresented material facts and information regarding their GBCA including, but not limited to, its propensity to cause serious physical harm.

146. Defendant fraudulently misrepresented that their GBCA caused few, if any, adverse reactions and side effects.

147. However, Defendant's GBCA is not safe and is dangerous to the health of its users because it has a propensity for causing severe side effects, including retention in bone and organs.

148. Defendant made these misrepresentations to the FDA, the public, patients, physicians, and the healthcare community at large, throughout Defendant's pre- and post-marketing period and continuing to the present.

149. Defendant made these misrepresentations to Plaintiff and his healthcare providers, with the intent to induce Plaintiff and his healthcare providers to use and prescribe their GBCA, and with the intent to defraud Plaintiff and his healthcare providers.

150. Defendant made these misrepresentations prior to Plaintiff's physicians prescribing Plaintiff Defendant's GBCA.

151. Defendant made these misrepresentations in advertisements, marketing, commercials, promotional materials, reports, press releases, campaigns, and instructional material

and labeling.

152. Defendant made these misrepresentations in its patient labeling provided to Plaintiff.

153. Defendant made these misrepresentations through contact with Plaintiff's physicians in material provided to Plaintiff's physicians through Defendant's sales representatives, or through communication with Plaintiff's physicians by Defendant's sales representatives.

154. Defendant also made these misrepresentations through promotional and educational campaigns specifically targeting prescribing physicians, including, upon information and belief, Plaintiff's physicians.

155. Defendant intended to defraud prescribing physicians, patients, the public, and Plaintiff and Plaintiff's physicians in making these misrepresentations.

156. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiff was unaware of the falsity of the statements and reasonably believed them to be true.

157. Defendant knew this information to be false, incomplete and misleading and/or made fraudulent misrepresentations recklessly and without regard to its truth or falsity.

158. Defendant intended to deceive and mislead Plaintiff and his healthcare practitioners so that they might rely on these fraudulent misrepresentations.

159. Plaintiff and his healthcare practitioners had a right to rely on and did reasonably rely upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

160. Plaintiff and his healthcare practitioners were deceived by Defendant's fraudulent misrepresentations.

161. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff has been permanently injured and has incurred or will incur past and

future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

162. Plaintiff demands judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT VIII
FRAUD BY SUPPRESSION AND CONCEALMENT

163. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

164. Defendant has omitted or concealed the dangers of their GBCA in the following ways:

a. Concealing and suppressing information regarding the dangers of their GBCAs with respect to the risk of gadolinium retention;

b. Concealing their knowledge that gadolinium is retained for months to years in several organs;

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

d. Concealing their knowledge that Gadolinium retention is longest in bone and varies by organ;

e. Concealing their knowledge that linear GBCAs cause more retention than macrocyclic GBCAs;

f. Concealing their knowledge about adverse event reports involving multiple organ systems in patient with normal renal function;

g. Concealing their knowledge that certain patients are a higher risk of adverse effects from linear GBCAs; and

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

165. Defendant knew of the falsity or materiality of these omissions, or they were made with reckless disregard as to their truth or materiality.

166. Defendant has defrauded Plaintiffs and his healthcare providers into the reasonable belief that Defendant's GBCA is safe and effective and does not cause injuries by the omission, suppression, and concealment of these material facts.

167. Defendant omitted the above information in order to induce Plaintiff, Plaintiff, his healthcare providers, the healthcare community, patients, and the public to act by purchasing Defendant's GBCA.

168. The above omissions were material to the transaction; but for these omissions, Plaintiff would not have purchased Defendant's GBCA.

169. Defendant had a duty and obligation to disclose to Plaintiff and Plaintiff's healthcare providers that Defendant's GBCA was dangerous and likely to cause serious health consequences to users when used as prescribed.

170. Defendant had a duty to disclose to Plaintiff and Plaintiff's healthcare providers that their GBCA causes and/or contributes to serious injuries as described in this complaint.

171. Defendant intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff and Plaintiff's healthcare providers with the intent to defraud his as alleged herein.

172. Defendant induced Plaintiff and his healthcare providers to choose their GBCA by

inducing them to believe that this GBCA is safe in patients with normal renal function.

173. Neither Plaintiff nor his physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

174. Defendant's fraudulent suppression of the above facts induced Plaintiff to use their GBCA and induced Plaintiff's healthcare providers to prescribe the Plaintiff this GBCA.

175. Defendant fraudulently concealed this information from the public, patients, physicians, and the healthcare community at large, throughout Defendant's pre- and post-marketing period and continuing to the present.

176. Defendant fraudulently concealed this information when initially obtaining FDA approval, during their GBCA's entire post-marketing period, and continuing to the present.

177. Defendant fraudulently concealed this information in advertisements, marketing, commercials, promotional materials, reports, press releases, campaigns, billboards, and instructional material and labeling.

178. Defendant also fraudulently concealed this information in its patient labeling provided to Plaintiff.

179. Defendant additionally used key opinion leaders, thought leaders and/or sales representatives to conceal this information in representations to physicians, including Plaintiff's physicians, throughout Defendant's GBCA's post-marketing period and prior to Plaintiff's insertion.

180. Defendant intended to defraud prescribing physicians, patients, the public, and Plaintiff and Plaintiff's physicians by fraudulently concealing this information.

181. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

182. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

183. Plaintiff demands judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

PRESERVATION CLAIMS

184. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

185. Many States have recently enacted tort reform statutes with "exclusive remedy" provisions. Courts have yet to determine whether these exclusive remedy provisions eliminate or supersede, to any extent, state common law claims. If during the pendency of this action this court makes any such determination, Plaintiffs hereby specifically make claim to and preserve any State claim based upon any exclusive remedy provision, under any state law this court may apply, to the extent not already alleged above.

STATUTE OF LIMITATIONS ALLEGATIONS

186. To the extent that Defendant may claim that one or more of Plaintiff's claims are barred by the applicable statute of limitations, Plaintiff asserts that the statute of limitations has been tolled by Plaintiff's delayed discovery that his injuries were caused by Defendant's defective product and failure to properly and adequately warn of the product's risks, all as more fully set forth in this Complaint. Specifically, the Plaintiff could not reasonably have discovered, and in fact did not discover, that his injuries were caused by the Defendant's defective product and/or the

wrongful conduct of the Defendant until he learned that many other patients had also suffered similar injuries after being administered GBCAs.

187. Plaintiff had no way to know that his symptoms were caused by gadolinium retention, especially since Defendant claimed that gadolinium was not retained in the body after administration in patients with normal renal function.

188. Further, as alleged herein, Plaintiff could not have discovered that his injuries were caused by Defendant's defective product and/or the wrongful conduct of the Defendant due to the Defendant's fraudulent concealment of facts material to his cause of action.

PUNITIVE DAMAGES ALLEGATIONS

172. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

173. At all times relevant herein, Defendant:

a. knew that their GBCA was dangerous;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA and the public at large;

c. made misrepresentations to Plaintiff, his physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety of their GBCA; and

d. with full knowledge of the health risks associated with their GBCA and without adequate warnings of the same, manufactured, designed, formulated, testing, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold their GBCA for routine use.

174. Defendant, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct toward Plaintiff and the public, acted with willful and wanton and/or conscious and/or reckless disregard for the safety of Plaintiff and the general public.

175. Defendant consciously and deliberately engaged in wanton disregard of the rights and safety of the Plaintiff.

189. Defendant had actual knowledge of their GBCA's defective nature and capacity to cause injury including, but 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.

176. Plaintiff's injuries are a result of fraud, malice, and/or gross negligence on the part of the Defendant.

177. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff is entitled to a recovery of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendant as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For compensatory damages in excess of the jurisdictional minimum of this Court;

(e) For consequential damages in excess of the jurisdictional minimum of this Court;

(f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendant the seriousness of their conduct and to deter similar conduct in the future;

(g) For attorneys' fees, expenses, and costs of this action; and

(h) For such further relief as this Court deems necessary, just, and proper.

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: August 28, 2018

/s/ Trevor B. Rockstad
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(pending *pro hac vice* admission)

Attorneys for Plaintiff

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
Reginald Brown

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Davis & Crump, P.C., 2601 14th Street, Gulfport, MS 39501, (228) 863-6000

DEFENDANTS
Bracco Diagnostics, Inc.

County of Residence of First Listed Defendant Middlesex
(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
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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:
Product liability case involving use of Gadolinium

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. James Donato DOCKET NUMBER 3:17-cv-07026

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

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

DATE

SIGNATURE OF ATTORNEY OF RECORD /s/ Trevor B. Rockstad

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.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Reginald Brown

Plaintiff(s)

v.

Bracco Diagnostics, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bracco Diagnostics, Inc., 259 Prospect Plains Road, Building H, Monroe Township, NJ 08831

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Trevor B. Rockstad, Davis & Crump, P.C., 2601 14th Street, Gulfport, MS 39501

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: