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GENA NORRIS and CHUCK NORRIS,
also known as CARLOS RAY NORRIS

ENDORSED
FILED
San Francisco County Superior Court

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CLERK OF THE COURT
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Deputy Clerk

SUPERIOR COURT FOR THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

GENA NORRIS and CHUCK NORRIS, also known as CARLOS RAY NORRIS,

Plaintiffs,

vs.

McKESSON CORPORATION; McKESSON MEDICAL-SURGICAL, INC.; BRACCO DIAGNOSTICS, INC.; BRACCO RESEARCH USA, INC.; BIPSO GMBH; BRACCO IMAGING, S.P.A.; BRACCO GROUP; BRACCO IMAGING GROUP; TAKEDA GMBH; ACIST MEDICAL SYSTEMS, INC., dba ACIST SILICON VALLEY; MERRY X-RAY CHEMICAL CORPORATION; and DOES 1 through 50, inclusive,

Defendants.

Case No. CGC-17-562228

COMPLAINT FOR DAMAGES

1) STRICT LIABILITY: FAILURE TO WARN;
2) NEGLIGENCE;
3) FRAUD: MISREPRESENTATION;
4) FRAUD: CONCEALMENT, SUPPRESSION, OR OMISSION OF MATERIAL FACTS;
5) NEGLIGENT MISREPRESENTATION;
6) LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

COME NOW Plaintiffs, GENA NORRIS and CHUCK NORRIS, also known as CARLOS RAY NORRIS ("CHUCK NORRIS") (hereinafter "Plaintiffs"), and allege as follows:

BACKGROUND AND INVOLVED PARTIES

1. Gena Norris and Chuck Norris are a celebrity couple whose battle with Gena's Gadolinium Deposition Disease, and their concerns with the dangers of the gadolinium-based

contrast agents (commonly used during MRIs), has played out in the public eye. Chuck Norris is a world-famous actor, martial artist, and author, who many consider to be an international icon. Gena Norris was a model, actress, business owner, CEO, and former deputy sheriff of Chester, a small town in Northern California. Gena always lived an active and athletic lifestyle prior to being stricken with Gadolinium Deposition Disease. Both Gena Norris and Chuck Norris are noted philanthropists who spend much of their time and money doing charity work through their foundation, Kickstart Kids, and other charities to help children and those less fortunate. Gena and Chuck Norris have been married for 19 years, and have two children together, twins who are 16-years-old.

2. Gena Norris was poisoned by free gadolinium and sustained Gadolinium Deposition Disease following an otherwise routine MRI procedure. She was hospitalized numerous times when she suffered multiple, debilitating bouts of pain and burning throughout her body following the MRIs and resulting gadolinium poisoning. Some of Gena's long-term injuries include cognitive deficits; body pain and burning; kidney damage; loss of energy and mobility; and difficulty breathing due to rib damage. Now, almost five-years post-gadolinium poisoning, she continues to require regular stem cell therapies and other treatments to heal her central nervous system. While the Norris family has spent millions of dollars to save Gena's life, they have had to go outside of mainstream medicine to accomplish this. The FDA has still not approved the most common gadolinium removal treatment, chelation, which patients like Gena must pay for out-of-pocket.

3. Gena Norris and Chuck Norris have incurred out-of-pocket medical expenses close to $2 million to treat Gena's Gadolinium Deposition Disease, and they bring this suit seeking money damages from the drug companies in excess of $10 million.

4. Recently, the FDA announced that it will require additional warnings for gadolinium-based contrast agents to alert patients to gadolinium retention in the human body, including in organs and the brain. In Europe, the European Medicines Agency (EU's version of the FDA) has banned several of the most common linear gadolinium-based contrast agents.

5. Plaintiff Gena Norris is a resident of Chester, California. She spends time in other

locations as well. She was administered drugs called ProHance and MultiHance, which were sold, processed, and distributed by Defendants McKesson Corporation and McKesson Medical-Surgical Inc., both of San Francisco, California.

6. Plaintiff Chuck Norris is also a resident of Chester, California. He spends time in other locations as well. He has suffered a loss of consortium as a result of his wife's devastating illness.

7. Plaintiff Gena Norris suffers from Gadolinium Deposition Disease ("GDD"). GDD is an incurable, painful disease. Plaintiff Gena Norris contracted GDD as a result of receiving MRIs using intravenous injections of gadolinium-based contrast agents ("GBCAs") known as ProHance and MultiHance.

Manufacturing Defendants

8. Bracco Diagnostics Inc., Bracco Research USA Inc., BIPSO GmbH, Bracco Imaging S.P.A., Bracco Group, Bracco Imaging Group, Takeda GmbH, Acist Medical Systems, Inc., dba Acist Silicon Valley, and DOES 1 through 20, inclusive (collectively referred to as the "Manufacturing Defendants"), manufacture, market, and sell ProHance and MultiHance, gadolinium-based contrast agents ("GBCAs") that were injected into Plaintiff's body.

9. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. has elected to establish an agent for service of process in the State of California. Bracco Diagnostics, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing ProHance and MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of California's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of ProHance and MultiHance within California, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal.

June 27, 2017).

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

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

12. Defendant Bracco Imaging S.P.A. is a foreign company domiciled in Italy. Bracco Imaging S.P.A. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing ProHance and MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of California's state laws, and Plaintiff's claim arises

out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of ProHance and MultiHance within California, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.,* No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

13. Defendant Bracco Group is a foreign company domiciled in Italy. Bracco Group is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing ProHance and MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of California's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of ProHance and MultiHance within California, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.,* No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017). Defendant Bracco Group also conducted research and development activities in Silicon Valley, California.

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

15. Defendant Takeda GmbH is a foreign company domiciled in Germany. Takeda GmbH is engaged in the business of designing, licensing, manufacturing, distributing, selling,

marketing, and/or introducing ProHance and MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of California's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of ProHance and MultiHance within California, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.,* No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

16. Defendant Acist Medical Systems, Inc., dba Acist Silicon Valley is a Delaware corporation with its principal place of business in Minnesota. Acist Medical Systems, Inc., dba Acist Silicon Valley has elected to establish an agent for service of process in the State of California. Additionally, Defendant has an office at 47621 Westinghouse Drive, Fremont, California, in Alameda County, which is within the Northern District of California. Acist Medical Systems, Inc., dba Acist Silicon Valley is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing ProHance and MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of California's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant conducted clinical trials of ProHance and MultiHance within California, which became part of an unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.,* No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

17. At all times relevant to this complaint, the Manufacturing Defendants advertised, promoted, marketed, distributed, and sold ProHance and MultiHance in California and nationwide.

18. 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/or manufactured MRI

machines and products with which MRIs were performed on Plaintiff using gadolinium-based contrast agents. Plaintiff alleges on information and belief that each of these fictitiously named defendants bears some legal responsibility for the events set forth in this complaint.

19. Plaintiff alleges on information and belief that DOES 1-20 were and are companies authorized to do and doing business in the State of California and have regularly conducted business in the County of San Francisco, State of California.

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

21. The Manufacturing Defendants, along with DOES 1-20, are collectively referred to as the Manufacturing Defendants.

Distributor Defendants

22. Defendant McKesson Corporation ("McKesson") distributes ProHance and MultiHance and other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that McKesson distributed the ProHance and MultiHance and/or other gadolinium-based contrast agents that were injected into Plaintiff.

23. Defendant McKesson Corporation is a Delaware corporation with its principal place of business and headquarters at One Post Street, San Francisco, San Francisco County, California.

24. McKesson Corporation is duly authorized to conduct business in the State of California and does business in San Francisco County.

25. At all times relevant to this complaint, McKesson Corporation sold ProHance and MultiHance and/or other gadolinium-based contrast agents in San Francisco County and elsewhere.

26. Defendant McKesson Medical-Surgical, Inc. distributes ProHance and MultiHance and other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that McKesson Medical-Surgical, Inc. distributed the ProHance and MultiHance and/or other gadolinium-based contrast agents that were injected into Plaintiff.

27. Defendant McKesson Medical-Surgical, Inc. is a Virginia corporation with its

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

28. Defendant McKesson Medical-Surgical, Inc. is duly authorized to conduct business in the State of California and does business in San Francisco County.

29. At all times relevant to this complaint, Defendant McKesson Medical-Surgical, Inc. sold ProHance and MultiHance and/or other gadolinium-based contrast agents in San Francisco County and elsewhere.

30. Defendant Merry X-Ray Chemical Corporation ("Merry X-Ray") distributes ProHance and MultiHance, and/or other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that Merry X-Ray distributed the ProHance and MultiHance and/or other gadolinium-based contrast agents that were injected into Plaintiff.

31. Defendant Merry X-Ray Chemical Corporation is a California corporation with its principal place of business and headquarters at 4444 Viewridge Avenue, San Diego, California.

32. Merry X-Ray Chemical Corporation is duly authorized to conduct business in the State of California and does business in San Francisco County.

33. At all times relevant to this complaint, Merry X-Ray sold ProHance and MultiHance and/or other gadolinium-based contrast agents in San Francisco County.

34. The true names and capacities of those Defendants designated as DOES 21-30 are unknown to Plaintiff. Plaintiff alleges on information and belief that DOES 21-30 distributed gadolinium-based contrast agents that were injected into Plaintiff. Plaintiff alleges on information and belief that each of these fictitiously named Defendants bear some legal responsibility for the events and damages set forth in this Complaint.

35. Plaintiff alleges on information and belief that DOES 21-30 were and are companies authorized to do and doing business in the State of California and have regularly conducted business in the County of San Francisco, State of California.

36. Plaintiff will amend this Complaint if necessary to show the identity of each fictitiously named defendant when they have been ascertained.

37. McKesson Corporation, McKesson Medical-Surgical, Inc., Merry X-Ray Chemical Corporation, along with DOES 21-30, are collectively referred to as the Distributor Defendants.

38. The Manufacturing Defendants and the Distributor Defendants are collectively referred to as the Defendants.

JURISDICTION AND VENUE

39. Jurisdiction and venue are both proper in San Francisco County Superior Court, in the State of California.

40. This Court has personal jurisdiction over all parties named herein, as described above.

41. Plaintiffs are all residents of the State of California.

42. Many of the acts and omissions related to the liability of the Defendants occurred in California.

43. Diversity jurisdiction, as is required in federal district court for a case of this nature, does not exist here. Diversity jurisdiction requires "complete diversity," which does not exist if any plaintiff is from the same State as any defendant. 28 U.S.C. § 1332. Here, Plaintiffs are all California residents. Defendants McKesson Corporation, McKesson Medical-Surgical, Inc., and Merry X-Ray Chemical Corporation are also California residents. Therefore, there is not complete diversity of the parties and diversity jurisdiction does not apply.

44. Removal of this case to federal court would be improper due to the lack of diversity.

45. Furthermore, this venue (particularly the San Francisco Superior Court Complex Civil Litigation Department which handled the previous gadolinium litigation) is convenient to the parties and is an appropriate venue for a multiple party product liability action.

FACTS

46. Plaintiff Gena Norris had normal kidney function prior to developing Gadolinium Deposition Disease ("GDD"). Plaintiff Gena Norris was subjected to several MRIs. At the time of these procedures, Plaintiff was injected with the gadolinium-based contrast agents ProHance and MultiHance. Unbeknownst to her, she developed GDD soon thereafter. Plaintiff Gena Norris'

symptoms of GDD included, but were not limited to, the following: burning pain in abdomen and throughout her body; violent shaking; tremors; clouded mentation; confusion; weakness; fatigue; hypoglycemia; difficult, painful movement; low body temperature; inflammation, especially throughout her lymphatic system; fasciculation; muscle cramps; numbness; tingling sensation; aching joints; weight loss; hair loss; lumps and rashes on body; kidney damage; and osteoporosis.

47. Plaintiff Gena Norris was hospitalized numerous times when she suffered multiple, debilitating bouts of pain and burning throughout her body following the MRIs and resulting gadolinium poisoning. Long term effects of her GDD include cognitive deficits; body pain and burning; kidney damage; loss of energy and mobility; and difficulty breathing due to damage to her ribs.

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

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

50. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human

body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.

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

52. The gadolinium-based contrast agents (ProHance and MultiHance) injected into Plaintiff was manufactured by the Manufacturing Defendants and distributed by the Distributor Defendants.

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

54. As stated above, Plaintiff Gena Norris received MRIs utilizing gadolinium-based contrast agents (including ProHance and MultiHance).

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

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

57. As a direct and proximate result of receiving injections of gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants (including ProHance and

MultiHance), Plaintiff developed GDD.

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

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

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

61. As a direct and proximate result of being administered gadolinium-based contrast agents (including ProHance and MultiHance), 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.

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

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

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

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

65. In 1984 --prior to FDA approval-- the inventors of gadolinium-based contrast agents claimed that their product, Gd-DTPA, did not cross the blood-brain barrier, and that the bonds between the Toxic Gadolinium and its protective coating did not break inside the body. Additionally, they claimed that there would be no toxic gadolinium residue left behind to cause illness.

66. In 1986, The National Institutes of Health (NIH) published an article warning about a 10-20% release of free gadolinium from the linear agents, like Magnevist, and recommended instead the use of macrocyclic agents. (Source: Magerstadt, et al., "Gd(DOTA): An Alternative to Gd(DTPA) as a T 1,2 Relaxation Agent for NMR Imaging or Spectroscopy," *Magnetic Resonance in Medicine* 3, 1986).

67. Magnevist was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988. There are two basic types of contrast agents differentiated by their chemical structure which include linear agents and macrocyclic agents. The main difference is that the linear agents do not fully surround the gadolinium ion, whereas the macrocyclic agents form a complete ring around gadolinium ion which creates a much more difficult bond to break. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE Healthcare), Optimark (manufactured by Guerbet), and MultiHance (manufactured by the Manufacturing Defendants). Greater safety due to the stronger bonds of the macrocyclic contrast agents as compared to their linear contrast counterparts has been well established by scientists (Huckle, et al. 2016).

68. Then, coincidentally again in 1988, it was recognized that gadolinium was breaking free from the bonds in the linear-based contrast agents, and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron (Huckle, et al. 2016). Furthermore, emerging science showed that the bond between toxic

gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH conditions such as those found in many compartments of the human body, including extracellular fluid spaces.

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

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

71. 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.

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

73. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over one year after the approval of Magnevist. Authors Tien, et al.

reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)." Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue. After this report, however, there was no further mention of gadolinium retention in humans until 1998.

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

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

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

77. Although many patients with debilitating symptoms who had normal renal function that received injections with gadolinium-based contrast agents had already been reporting adverse

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

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

79. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents up to several years prior. They found that the brain had hyperintense signals in critical areas of the brain. These were very alarming findings.

80. 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.

81. As these new findings emerged, the entire radiology community was put on high

alert, with several large universities conducting research to further address this concern.

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

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

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

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

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

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

86. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injuries and the connection between their injuries and all Defendants' tortious conduct.

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

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

88. Defendants' gadolinium-based contrast agents (including ProHance and MultiHance), and MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

89. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents (including ProHance and MultiHance) which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents (including ProHance and MultiHance) 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.

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

SECOND CAUSE OF ACTION
(Against All Defendants)
NEGLIGENCE

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

92. Defendants had a duty to exercise reasonable care in the design, formulation, testing,

manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents (including ProHance and MultiHance) and the MRI machines and products designed to be used in conjunction with 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.

93. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of gadolinium-based contrast agents (including ProHance and MultiHance) and the MRI machines and products designed to be used in conjunction with gadolinium-based contrast agents in that they knew or should have known that the products could cause significant bodily harm or death and were not safe for use by certain types of consumers.

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

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

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

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

THIRD CAUSE OF ACTION
(Against the Manufacturing Defendants)
FRAUD: MISREPRESENTATION

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

99. The Manufacturing Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based contrast agents (including ProHance and MultiHance) were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

100. The Manufacturing Defendants' representations were in fact false. Gadolinium-based contrast agents (including ProHance and MultiHance) are not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

101. The Manufacturing Defendants had actual knowledge that gadolinium-based contrast agents (including ProHance and MultiHance) created an unreasonable risk of serious bodily injury to consumers.

102. The Manufacturing Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials, and instead, labeled, promoted, and marketed their products as safe for use in order to increase and sustain sales.

103. When the Manufacturing Defendants made representations that gadolinium-based contrast agents (including ProHance and MultiHance) were safe for use, they knowingly and intentionally concealed and withheld from Plaintiff Gena Norris, her physicians, and the public, the fact that their gadolinium-based contrast (including ProHance and MultiHance) agents are not safe for use.

104. The Manufacturing Defendants had a duty to disclose that gadolinium-based

contrast agents (including ProHance and MultiHance) are not safe for use. The Manufacturing Defendants had superior knowledge of these facts that were material to Plaintiff Gena Norris and her healthcare providers' decisions to use gadolinium-based contrast agents (including ProHance and MultiHance).

105. Plaintiff Gena Norris and her healthcare providers reasonably and justifiably relied on the Manufacturing Defendants' representations that gadolinium-based contrast agents (including ProHance and MultiHance) were safe for human use and that Manufacturing Defendants' labeling, marketing and promotional materials fully described all known risks associated with the products.

106. Plaintiff Gena Norris did not know, and could not have learned of the facts that the Defendants omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff Gena Norris and her healthcare providers known that gadolinium-based contrast agents (including ProHance and MultiHance) are not safe for use, Plaintiff would not have been injected with gadolinium-based contrast agents.

107. As a direct and proximate result of the Manufacturing Defendants' misrepresentations and concealment, Plaintiff Gena Norris was administered gadolinium-based contrast agents (including ProHance and MultiHance) and has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

108. The foregoing acts, conduct and omissions of Manufacturing 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 the Manufacturing Defendants' products, and for the primary purpose of increasing the Manufacturing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

FOURTH CAUSE OF ACTION
(Against the Manufacturing Defendants)
FRAUD: CONCEALMENT, SUPPRESSION, OR OMISSION OF MATERIAL FACTS

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

110. The Manufacturing Defendants omitted, suppressed, or concealed material facts

concerning the dangers and risk associated with the use of their gadolinium-based contrast agents (including ProHance and MultiHance), and the fact that safer alternatives were available. Further, the Manufacturing Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents (including ProHance and MultiHance) in order to increase and sustain sales.

111. As a direct and proximate result of the Manufacturing Defendants' concealment of material facts, Plaintiff Gena Norris was administered gadolinium-based contrast agents (including ProHance and MultiHance) and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

112. The foregoing acts, conduct and omissions of the Manufacturing 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 the Manufacturing Defendants' products, and for the primary purpose of increasing the Manufacturing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

FIFTH CAUSE OF ACTION
(Against the Manufacturing Defendants)
NEGLIGENT MISREPRESENTATION

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

114. The Manufacturing Defendants supplied the public and Plaintiff Gena Norris' healthcare providers with materially false and incomplete information with respect to the safety of their gadolinium-based contrast agents (including ProHance and MultiHance).

115. The false information supplied by the Manufacturing Defendants was that gadolinium-based contrast agents (including ProHance and MultiHance) were safe.

116. In supplying this false information, the Manufacturing Defendants failed to exercise reasonable care.

117. The false information communicated by Defendants to Plaintiff Gena Norris and her healthcare providers was material and Plaintiff justifiably relied in good faith on the information to her detriment.

118. As a direct and proximate result of Defendants' misrepresentations, Plaintiff Gena Norris was administered gadolinium-based contrast agents (including ProHance and MultiHance) and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION
(Plaintiff CHUCK NORRIS Against All Defendants)
LOSS OF CONSORTIUM

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

120. At all times herein mentioned, Plaintiffs Chuck Norris and Gena Norris were lawfully married and are husband and wife.

121. As a proximate result of the negligence of the Defendants, and each of them, and of Gena Norris' resulting injuries, Chuck Norris has been deprived of the services of his wife by reason of her inability to carry on her usual duties, and loss of consortium. Plaintiff, Chuck Norris, is informed and believes, and thereon alleges, that the said injuries to his wife are of a permanent nature, and that he will be deprived of her services, love, affection, comfort, care and society for a long period in the future, all to his general damage in an amount in excess of the minimum jurisdictional limits of this Court, together with prejudgment interest thereon from the date of the incident herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

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

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

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

d) Pre-judgment and post-judgment interest;

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

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

DEMAND FOR JURY TRIAL

In addition to the above, Plaintiffs Gena Norris and Chuck Norris hereby demand a trial by jury for all causes of action and issues that can be tried by a jury.

Dated: November 1, 2017

CUTTER LAW, P.C.

By: _____
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