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San Francisco County Superior Court

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CLERK OF THE COURT

BY:  Deputy Clerk

Attorneys for Plaintiffs
GENA NORRIS and CHUCK NORRIS,
also known as CARLOS RAY NORRIS

**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

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

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

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

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

27 5. Plaintiff Gena Norris is a resident of Chester, California. She spends time in other
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1 locations as well. She was administered drugs called ProHance and MultiHance, which were sold,
2 processed, and distributed by Defendants McKesson Corporation and McKesson Medical-Surgical
3 Inc., both of San Francisco, California.

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

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

11 ***Manufacturing Defendants***

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

17 9. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal
18 place of business in New Jersey. Bracco Diagnostics, Inc. has elected to establish an agent for
19 service of process in the State of California. Bracco Diagnostics, Inc. is engaged in the business of
20 designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing ProHance
21 and MultiHance into interstate commerce, either directly or indirectly through third parties or
22 related entities. This court has personal jurisdiction over said Defendant under the doctrine of
23 specific jurisdiction because said Defendant purposefully availed itself of the benefits and
24 protections of California's state laws, and Plaintiff's claim arises out of Defendant's forum-related
25 activities. Specifically, Defendant conducted clinical trials of ProHance and MultiHance within
26 California, which became part of an unbroken chain of events leading to Plaintiff's injury. See
27 *Dubose v. Bristol-Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal.
28

1 June 27, 2017).

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

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

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

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

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

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

9 16. Defendant Acist Medical Systems, Inc., dba Acist Silicon Valley is a Delaware
10 corporation with its principal place of business in Minnesota. Acist Medical Systems, Inc., dba
11 Acist Silicon Valley has elected to establish an agent for service of process in the State of
12 California. Additionally, Defendant has an office at 47621 Westinghouse Drive, Fremont,
13 California, in Alameda County, which is within the Northern District of California. Acist Medical
14 Systems, Inc., dba Acist Silicon Valley is engaged in the business of designing, licensing,
15 manufacturing, distributing, selling, marketing, and/or introducing ProHance and MultiHance into
16 interstate commerce, either directly or indirectly through third parties or related entities. This court
17 has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because
18 said Defendant purposefully availed itself of the benefits and protections of California's state laws,
19 and Plaintiff's claim arises out of Defendant's forum-related activities. Specifically, Defendant
20 conducted clinical trials of ProHance and MultiHance within California, which became part of an
21 unbroken chain of events leading to Plaintiff's injury. See *Dubose v. Bristol-Myers Squibb Co.*, No.
22 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

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

25 18. The true names and capacities of those Defendants designated as DOES 1-20 are
26 unknown to Plaintiff. Plaintiff alleges on information and belief that DOES 1-20 manufactured
27 gadolinium-based contrast agents that were injected into Plaintiff and/or manufactured MRI
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1 machines and products with which MRIs were performed on Plaintiff using gadolinium-based
2 contrast agents. Plaintiff alleges on information and belief that each of these fictitiously named
3 defendants bears some legal responsibility for the events set forth in this complaint.

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

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

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

11 ***Distributor Defendants***

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

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

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

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

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

27 27. Defendant McKesson Medical-Surgical, Inc. is a Virginia corporation with its
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1 principal place of business and headquarters at One Post Street, San Francisco, San Francisco
2 County, California.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 57. As a direct and proximate result of receiving injections of gadolinium-based contrast
27 agents manufactured, distributed, marketed, and/or sold by Defendants (including ProHance and
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1 MultiHance), Plaintiff developed GDD.

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

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

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

13 61. As a direct and proximate result of being administered gadolinium-based contrast
14 agents (including ProHance and MultiHance), Plaintiff suffered and continues to suffer significant
15 mental anguish and emotional distress and will continue to suffer significant mental anguish and
16 emotional distress in the future.

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

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

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

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

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

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

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

24 68. Then, coincidentally again in 1988, it was recognized that gadolinium was breaking
25 free from the bonds in the linear-based contrast agents, and this was in part due to the competition
26 for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron
27 (Huckle, et al. 2016). Furthermore, emerging science showed that the bond between toxic
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1 gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH
2 conditions such as those found in many compartments of the human body, including extracellular
3 fluid spaces.

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

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

18 71. Peer-reviewed articles on the deposition of gadolinium in animals with normal renal
19 function, some illustrating deleterious consequences, have been published as early as 1984.

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

26 73. The first report of toxic gadolinium retention in humans may have been presented
27 in September 1989, a little over one year after the approval of Magnevist. Authors Tien, et al.
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1 reported that intracerebral masses “remained enhanced on MRI images obtained 8 days after
2 injection of gadolinium DTPA dimeglumine (Magnevist).” Subsequent chemical analysis revealed
3 that a high concentration of gadolinium remained in the tissue. After this report, however, there
4 was no further mention of gadolinium retention in humans until 1998.

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

8 75. Over the next 18 years, more evidence was forthcoming and research began to
9 flourish regarding the release of toxic gadolinium from the linear contrast agents such as ProHance
10 and MultiHance, and its long-term retention in the bodies of animals and humans. Nephrologists
11 and other scientists connected the administration of linear gadolinium-based contrast agents
12 including ProHance and MultiHance, to a rapidly progressive debilitating and often fatal condition
13 called Gadolinium-induced Nephrogenic Systemic Fibrosis (NSF), prompting the Food and Drug
14 Administration (FDA) to issue a black box warning on all gadolinium based contrast agents in
15 2006. NSF is a horrible disease in which patients’ skin and vital organs would fibrose, becoming
16 wood-like. There were over 500 NSF cases reported and estimated to be well over a thousand non-
17 reported. Over 500 lawsuits were filed against gadolinium-based contrast manufacturers. All of
18 them settled before trial except *Decker vs. GE (Omniscan)*, which resulted in a five-million-dollar
19 verdict for Mr. Decker. Unfortunately, Mr. Decker passed away from his Gadolinium-triggered
20 disease before the verdict was reached.

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

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

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

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

22 80. These findings were confirmed by scientists at the Mayo Clinic in 2014 when
23 autopsy studies were performed on 13 deceased individuals, all of whom had normal or near normal
24 renal function and who had received six or more-injections of gadolinium-based contrast agents in
25 the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the
26 brains of these patients.

27 81. As these new findings emerged, the entire radiology community was put on high
28

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

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

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

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

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

25
26 ¹ Schumann-Giampieri G, Krestin G. Pharmacokinetics of Gd-DTPA in patients with chronic renal failure.
Invest Radiol., 1991; 26:975-979.

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

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

4
5 **FIRST CAUSE OF ACTION**
6 **(Against All Defendants)**
7 **STRICT LIABILITY: FAILURE TO WARN**

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

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

15 89. Because of Defendants' failure to provide adequate warnings with their products,
16 Plaintiff was injected with gadolinium-based contrast agents (including ProHance and MultiHance)
17 which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced
18 into the stream of commerce. Those gadolinium-based contrast agents (including ProHance and
19 MultiHance) are the legal cause of Plaintiff's serious physical injuries, harm, damages, and
20 economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the
21 future.

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

26 **SECOND CAUSE OF ACTION**
27 **(Against All Defendants)**
28 **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,

1 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents
2 (including ProHance and MultiHance) and the MRI machines and products designed to be used in
3 conjunction with gadolinium-based contrast agents. In particular, they had a duty to assure that
4 their products did not pose an unreasonable risk of bodily harm and adverse events.

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

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

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

26 96. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff
27 would suffer injury as a result of their failure to exercise ordinary care as described above.
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1 contrast agents (including ProHance and MultiHance) are not safe for use. The Manufacturing
2 Defendants had superior knowledge of these facts that were material to Plaintiff Gena Norris and
3 her healthcare providers' decisions to use gadolinium-based contrast agents (including ProHance
4 and MultiHance).

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

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

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

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

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

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

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

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

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

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

15 **FIFTH CAUSE OF ACTION**
16 **(Against the Manufacturing Defendants)**
17 **NEGLIGENT MISREPRESENTATION**

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

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

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

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

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

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

5
6 **SIXTH CAUSE OF ACTION**
7 **(Plaintiff CHUCK NORRIS Against All Defendants)**
8 **LOSS OF CONSORTIUM**

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

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

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

20 **PRAYER FOR RELIEF**

21 WHEREFORE, Plaintiffs pray for relief as follows:

- 22 a) Compensatory damages in excess of the jurisdictional amount, including, but not
23 limited to pain, suffering, emotional distress, loss of enjoyment of life, and other
24 non-economic damages in an amount to be determined at trial of this action;
25 b) Past and future medical expenses, loss of income, and other economic damages in
26 an amount to be determined at trial of this action;
27 c) Punitive damages in an amount to be determined at trial of this action (only
28 applicable to the Defendants and Causes of Action noted above);
 d) Pre-judgment and post-judgment interest;

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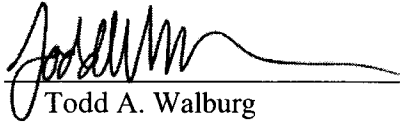
- e) Attorneys' fees, expenses, and costs; and
- f) Such further relief as this Court deems necessary, just, and proper.

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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