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13
14 **UNITED STATES DISTRICT COURT**
15 **NORTHERN DISTRICT OF CALIFORNIA**

16 SRIHARI MUNNURU,

17 Plaintiff,

18 vs.

19 GUERBET, LLC; MALLINCKRODT INC.;
20 MALLINCKRODT LLC; LIEBEL-
21 FLARSHEIM COMPANY LLC; McKESSON
22 CORPORATION; McKESSON MEDICAL-
23 SURGICAL, INC.; MERRY X-RAY
24 CHEMICAL CORPORATION; and DOES 1
25 through 50, inclusive,

26 Defendants.

27 **Case No.**

28 **[Related to the Gadolinium Cases Assigned
to the Honorable James Donato]**

COMPLAINT FOR DAMAGES

- 1) STRICT PRODUCTS LIABILITY:
FAILURE TO WARN;
- 2) NEGLIGENCE

DEMAND FOR JURY TRIAL

29 COMES NOW Plaintiff, Srihari Munnuru (hereinafter “Plaintiff”), and allege as follows:

30 **PARTIES**

31 ***Plaintiff***

32 1. Plaintiff Srihari Munnuru is a resident of the City of Phoenix, in the State of Arizona. He
33 was administered the drug OptiMark, which was sold by McKesson Corporation and McKesson
34 Medical-Surgical Inc., both of San Francisco, California.

35 2. Plaintiff suffers from Gadolinium Deposition Disease (“GDD”). GDD is an incurable,
36 painful disease. Plaintiff contracted GDD because of receiving MRIs/MRAs using intravenous
37 injections of a gadolinium-based contrast agent known as OptiMark.
38

1 ***Manufacturing Defendants***

2 3. Guerbet, LLC; Mallinckrodt Inc.; Mallinckrodt LLC; and Liebel-Flarsheim Company
3 LLC (collectively referred to as “Manufacturing Defendants”) manufacture, market and sell Optimark,
4 a gadolinium-based contrast agent that was injected into Plaintiff’s body.

5 4. Defendant Guerbet, LLC is a Delaware corporation with its principal place of business
6 in Indiana. Defendant Guerbet, LLC is engaged in the business of designing, licensing, manufacturing,
7 distributing, selling, marketing, and/or introducing OptiMark into interstate commerce, either directly
8 or indirectly through third parties or related entities. This court has personal jurisdiction over said
9 Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself
10 of the 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 OptiMark within California,
12 which became part of an unbroken chain of events leading to Plaintiff’s injury. See *Dubose v. Bristol-*
13 *Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

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

24 6. Defendant Mallinckrodt LLC is a Delaware corporation with its principal place of
25 business in Missouri. Defendant Mallinckrodt LLC is engaged in the business of designing, licensing,
26 manufacturing, distributing, selling, marketing, and/or introducing OptiMark into interstate commerce,
27 either directly or indirectly through third parties or related entities. This court has personal jurisdiction
28 over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully

1 availed itself of the benefits and protections of California’s state laws, and Plaintiff’s claim arises out of
2 Defendant’s forum-related activities. Specifically, Defendant conducted clinical trials of OptiMark
3 within California, which became part of an unbroken chain of events leading to Plaintiff’s injury. See
4 *Dubose v. Bristol-Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June
5 27, 2017).

6 7. Defendant Liebel-Flarsheim Company LLC is a Delaware corporation with its principal
7 place of business in Missouri. Defendant Liebel-Flarsheim Company LLC is engaged in the business of
8 designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing OptiMark into
9 interstate commerce, either directly or indirectly through third parties or related entities. This court has
10 personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said
11 Defendant purposefully availed itself of the benefits and protections of California’s state laws, and
12 Plaintiff’s claim arises out of Defendant’s forum-related activities. Specifically, Defendant conducted
13 clinical trials of OptiMark within California, which became part of an unbroken chain of events leading
14 to Plaintiff’s injury. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS
15 99504 (N.D. Cal. June 27, 2017). Defendant Liebel-Flarsheim Company is duly authorized to conduct
16 business in the State of California and does business in San Francisco County. Said Defendant has
17 elected to establish an agent for service of process in the State of California.

18 8. At all times relevant to this complaint, the Manufacturing Defendants advertised,
19 promoted, marketed, distributed, and sold Optimark in California and nationwide.

20 9. The true names and capacities of those Defendants designated as DOES 1 through 10 are
21 unknown to Plaintiff. Plaintiff alleges on information and belief that DOES 1 through 10 manufactured
22 gadolinium-based contrast agents that were injected into Plaintiff. Plaintiff alleges on information and
23 belief that each of these fictitiously named defendants bears some legal responsibility for the events and
24 damages set forth in this complaint.

25 10. Plaintiff alleges on information and belief that DOES 1 through 10 were and are
26 companies authorized to do and doing business in the State of California and have regularly conducted
27 business in the County of San Francisco, State of California.
28

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

3 12. The Manufacturing Defendants, including DOES 1 through 20, are collectively referred
4 to as the Manufacturing Defendants.

5 ***Distributor Defendants***

6 13. Defendant McKesson Corporation (“McKesson”) distributes OptiMark and other
7 gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that McKesson
8 distributed the OptiMark and/or other gadolinium-based contrast agents that were injected into Plaintiff.

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

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

13 16. At all times relevant to this complaint, McKesson Corporation sold OptiMark and/or
14 other gadolinium-based contrast agents in San Francisco County and elsewhere.

15 17. Defendant McKesson Medical-Surgical, Inc. distributes OptiMark and other gadolinium-
16 based contrast agents in California and elsewhere. Plaintiff alleges that McKesson Medical-Surgical,
17 Inc. distributed the OptiMark and/or other gadolinium-based contrast agents that were injected into
18 Plaintiff.

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

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

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

25 21. Defendant Merry X-Ray Chemical Corporation (“Merry X-Ray”) distributes OptiMark
26 and/or other gadolinium-based contrast agents in California and elsewhere. Plaintiff alleges that Merry
27 X-Ray distributed the OptiMark and/or other gadolinium-based contrast agents that were injected into
28 Plaintiff.

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

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

5 24. At all times relevant to this complaint, Merry X-Ray sold OptiMark, and/or other
6 gadolinium-based contrast agents in San Francisco County.

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

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

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

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

19 29. The Manufacturing Defendants and the Distributor Defendants are collectively referred
20 to as the Defendants.

21 **JURISDICTION AND VENUE**

22 1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity
23 jurisdiction). The amount in controversy exceeds \$75,000 exclusive of interest and costs. There is
24 complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of
25 and is domiciled in the State of Arizona. As set forth more fully above, all Defendants are entities
26 organized in states other than the State of Arizona, all Defendants have their principal place of business
27 in a state other than the State of Arizona, and none of the Defendants is a citizen or resident of the State
28 of Arizona. Defendant McKesson Corporation is a Delaware corporation with its principal place of

1 business and headquarters at One Post Street, San Francisco, San Francisco County, California.
2 Defendant McKesson Medical-Surgical, Inc. is a Virginia corporation with its principal place of business
3 and headquarters at One Post Street, San Francisco, San Francisco County, California. Defendant Merry
4 X-Ray Chemical Corporation is a California corporation with its principal place of business in San
5 Diego, California. Additionally, the Manufacturing Defendants conducted clinical trials regarding the
6 safety and efficacy of OptiMark in the State of California.

7 2. This Court has personal jurisdiction over Defendants, each of which is licensed to
8 conduct and/or is systematically and continuously conducting business in the State of California,
9 including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of
10 drugs, including OptiMark, to the residents in this State.

11 3. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants
12 marketed, advertised, and distributed the dangerous product in this District; Defendants do substantial
13 business in the State of California and within this District; and at all times relevant hereto, Defendants
14 developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold
15 OptiMark in interstate commerce.

16 **FACTS**

17 4. Plaintiff Srihari Munnuru had normal kidney function prior to developing Gadolinium
18 Deposition Disease ("GDD"). Plaintiff Srihari Munnuru, was subjected to one or multiple MRIs/MRAs.
19 At the time of these procedures, Plaintiff was injected with the gadolinium-based contrast agent,
20 OptiMark. Unbeknownst to him, he developed GDD soon thereafter. Plaintiff Srihari Munnuru's
21 symptoms of GDD include but are not limited to the following: weight loss, immobility, kidney
22 impairment, stiffness, body aches, joint pain, and brain fog.

23 5. Gadolinium Deposition Disease ("GDD") is the name for a disease process observed in
24 people with normal or near-normal renal function who develop persistent symptoms that arise hours to
25 months after the administration of gadolinium-based contrast agents like OptiMark. In these cases, no
26 preexistent disease or subsequently developed disease of an alternate known process is present to
27 account for the symptoms. People suffering from GDD experience symptoms consistent with the known
28 toxic effects of retained gadolinium. Typical clinical features of GDD include persistent headaches,

1 bone and joint pain, and clouded mental activity. People with GDD often experience subcutaneous soft-
2 tissue thickening that clinically appears somewhat spongy or rubbery. Tendons and ligaments in a
3 comparable distribution may also be painful and have a thickened appearance. People with GDD often
4 experience excruciating pain, typically in a distal distribution, of the arms and legs but may also be in
5 the torso or generalized in location. This pain is often described as feeling like sharp pins and needles,
6 cutting, or burning. GDD often progresses to painful inhibition of the ability to use the arms, legs, hands,
7 feet and other joints. GDD is a progressive disease for which there is no known cure.

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

10 7. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body.
11 The only known route for gadolinium to enter the human body is injection of a gadolinium-based
12 contrast agent.

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

15 9. The gadolinium-based contrast agents (including OptiMark) injected into Plaintiff were
16 manufactured by the Manufacturing Defendants and distributed by the Distributor Defendants.

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

25 11. Plaintiff received MRIs/MRAs utilizing gadolinium-based contrast agents, including
26 Optimark.

27 12. During the time period when Plaintiff received injections of the Manufacturing
28 Defendants' gadolinium-based contrast agents, Defendants knew or should have known that the use of

1 gadolinium-based contrast agents created a risk of serious bodily injury in patients with normal or near-
2 normal kidney function.

3 13. Defendants failed to warn Plaintiff and his healthcare providers about the serious health
4 risks associated with gadolinium-based contrast agents, including OptiMark, and failed to disclose the
5 fact that there were safer alternatives.

6 14. As a direct and proximate result of receiving injections of gadolinium-based contrast
7 agents manufactured, distributed, marketed, and/or sold by Defendants, including OptiMark, Plaintiff
8 developed GDD.

9 15. Defendants have repeatedly and consistently failed to advise consumers and/or their
10 healthcare providers of the causal relationship between gadolinium-based contrast agents and GDD.
11 Defendants knew or should have known of the risk of GDD posed by gadolinium-based contrast agents,
12 including OptiMark, to individuals with normal or near-normal kidney function.

13 16. Had Plaintiff and/or his healthcare providers been warned about the risks associated with
14 gadolinium-based contrast agents, including OptiMark, he would not have been administered
15 gadolinium-based contrast agents and would not have been afflicted with GDD.

16 17. As a direct and proximate result of Plaintiff's being administered gadolinium-based
17 contrast agents, including OptiMark, he has suffered severe physical injury and pain and suffering,
18 including, but not limited to, the effects of GDD.

19 18. As a direct and proximate result of being administered gadolinium-based contrast agents,
20 including OptiMark, Plaintiff suffered and continues to suffer significant mental anguish and emotional
21 distress and will continue to suffer significant mental anguish and emotional distress in the future.

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

25 **APPLICATION OF THE DISCOVERY RULE AND THE HISTORY OF**
26 **DEFENDANTS' CONCEALMENT OF INFORMATION**

27 20. The nature of Plaintiff's injuries and damages, and their relationship to gadolinium-based
28 contrast agents used in conjunction with MRIs and MRAs, including OptiMark, was not discovered, and

1 through reasonable care and due diligence could not have been discovered, by Plaintiff, until less than
2 two years before the filing of this Complaint. On or about January 28, 2016, Plaintiff became aware
3 that he had retained gadolinium from the OptiMark gadolinium-based contrast agent that was injected
4 into him.

5 21. Plaintiff became aware of the disease, GDD, in August 2016 upon publication of
6 “Gadolinium in Humans: A Family of Disorders,” in volume 207:2 of the American Journal of
7 Roentgenology.

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

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

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

27 25. Stability differences among gadolinium contrast agents have long been recognized in
28 laboratory (in vitro), and deposition of toxic gadolinium in tissues has been described in animal models

1 since at least 1984. The first major study that showed deposition in humans appeared in 1998 regarding
2 patients with renal failure and later in 2004 in patients with normal renal function. (Huckle, et al. 2016).

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

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

14 28. Three months after the FDA approval of Omniscan (a linear contrast agent with a similar
15 structure to OptiMark) the preclinical safety assessment and pharmacokinetic data were published
16 describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies demonstrated
17 that while toxic gadolinium was no longer detectable in the blood 7-days after administration,
18 quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone
19 cartilage.

20 29. The first report of toxic gadolinium retention in humans may have been presented in
21 September 1989, a little over 1 year after the approval of Magnevist. Authors Tien, et al. reported that
22 intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium
23 DTPA dimeglumine (Magnevist)." Subsequent chemical analysis revealed that a high concentration of
24 gadolinium remained in the tissue. After this report, however, there was no further mention of
25 gadolinium retention in humans until 1998.

26 30. Manufacturing Defendants knew that their product, OptiMark, did not have very stable
27 bonds and could come apart easily causing significant toxicity in humans.

28 31. Over the next 18 years, more evidence was forthcoming, and research began to flourish

1 regarding the release of toxic gadolinium from the linear contrast agents such as OptiMark, and its long-
2 term retention in the bodies of animals and humans. Nephrologists and other scientists connected the
3 administration of linear gadolinium-based contrast agents including OptiMark, to a rapidly progressive
4 debilitating and often fatal condition called gadolinium induced Nephrogenic Systemic Fibrosis (NSF),
5 prompting the Food and Drug Administration (FDA) to issue a black box warning on all gadolinium
6 based contrast agents in 2006. NSF is a horrible disease where patients' skin and vital organs fibrose,
7 becoming wood-like. There were over 500 NSF cases reported and estimated to be well over a thousand
8 non-reported. Over 500 lawsuits were filed against gadolinium-based contrast manufacturers. All of
9 them settled before trial except *Decker vs. GE (Omniscan)*, which resulted in a multi-million-dollar
10 verdict for Mr. Decker. Unfortunately, Mr. Decker passed away from his gadolinium-triggered disease
11 before the verdict was reached.

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

17 33. Although many patients with debilitating symptoms who had normal renal function that
18 received injections with gadolinium-based contrast agents had already been reporting adverse reactions
19 for years to the FDA, manufacturers, and poison control, no link between gadolinium and their
20 symptoms were ever officially made publicly. This is partially because blood and urine testing for
21 gadolinium only became available recently. Additionally, most doctors were not aware of any disease
22 that was associated with gadolinium other than NSF, which is said to only occur in patients with renal
23 failure. Gadolinium Toxicity is an underreported and underdiagnosed condition. Over the past several
24 years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients
25 with normal renal function have been forming advocacy groups and coming forward to create awareness
26 for their condition. Symptomatic patients often have documentation of high levels of gadolinium in
27 their blood and urine several days, weeks, months and even years after their exposure to gadolinium-
28 based contrast agents. Many patients even had tissue biopsies of various parts of their body that showed

1 additional evidence of retained gadolinium years after their exposure.

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

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

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

15 37. As these new findings emerged, the entire radiology community was put on high alert,
16 with several large universities conducting research to further address this concern.

17 38. In July of 2015, and in direct response to the Mayo Clinic study's findings, the FDA
18 issued a new public safety alert. The FDA is evaluating the risk of brain deposits from repeated use of
19 Gadolinium-based contrast agents use in MRI's and they now have their National Center for
20 Toxicological Research team working on determining the exact consequences of these new findings.

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

24 40. On December 19, 2017 the FDA announced that it is requiring a new class warning and
25 other safety measures for all gadolinium-based contrast agents for MRI concerning gadolinium
26 remaining in patients' bodies, including the brain, for months to years after receiving these drugs.

27 41. Defendants have known about the risks that gadolinium-based contrast agents, including
28 OptiMark, pose to people with normal kidney function for many years. Pharmacokinetic studies in 1991

1 indicated that gadolinium retention was occurring in people with normal renal function.¹ In 2004,
2 gadolinium was shown to be deposited in the resected femoral heads of people who had undergone
3 gadolinium-chelate enhanced MRI studies.² Since then, studies have continued to indicate that
4 gadolinium remains within people's bodies long after the suggested half-life.

5 42. Despite this well-documented evidence of gadolinium retention, Defendants have
6 continuously failed to warn consumers and their healthcare providers on the label of their product,
7 OptiMark. In 2012, Defendants corrected their label to include contraindications for use in people with
8 kidney disease and acute kidney injury. Yet, Defendants have failed to update their label to reflect the
9 extensive evidence of gadolinium retention in people with normal renal function.

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

13 44. Defendants are estopped from asserting a statute of limitations defense because all
14 Defendants concealed from Plaintiff the nature of Plaintiff's injuries and the connection between their
15 injuries and all Defendants' tortious conduct.

16 **FIRST CAUSE OF ACTION**

17 **(Against All Defendants)**

18 **STRICT PRODUCTS LIABILITY: FAILURE TO WARN**

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

20 46. Defendants' gadolinium-based contrast agents, including OptiMark, were defective due
21 to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants
22 knew or should have known that their products created significant risks of serious bodily harm to
23 consumers. Defendants failed to adequately warn consumers and their healthcare providers of such
24 risks.

25 47. Because of Defendants' failure to provide adequate warnings with their products,

26 ¹ Schumann-Giampieri G, Krestin G. Pharmacokinetics of Gd-DTPA in patients with chronic renal failure. *Invest Radiol.*,
27 1991; 26:975-979.

28 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.

1 Plaintiff was injected with gadolinium-based contrast agents, including OptiMark, which the Defendants
2 manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce.
3 Those gadolinium-based contrast agents, including OptiMark, are the legal cause of Plaintiff's serious
4 physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm,
5 damages, and economic loss in the future.

6 48. Defendants knew that their product was unsafe and would cause death or serious physical
7 injury to those who were exposed to the product yet failed to warn those who would be exposed to the
8 product of the serious safety risks of the product. This allegation is sufficient to show despicable conduct
9 carried on with a willful and conscious disregard of the rights and safety of others per California Civil
10 Code Section 3294(c)(1).

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

15 **SECOND CAUSE OF ACTION**

16 **(Against All Defendants)**

17 **NEGLIGENCE**

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

19 51. Defendants had a duty to exercise reasonable care in the design, formulation, testing,
20 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents,
21 including OptiMark. They had a duty to ensure that their products did not pose an unreasonable risk of
22 bodily harm and adverse events.

23 52. Defendants failed to exercise reasonable care in the design, formulation, manufacture,
24 sale, testing, marketing, or distribution of gadolinium-based contrast agents, including OptiMark, in that
25 they knew or should have known that the products could cause significant bodily harm or death and
26 were not safe for use by certain types of consumers.

27 53. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast
28 agents, including OptiMark, and failed to issue to consumers and their health care providers adequate

1 warnings concerning the risks of serious bodily injury due to the use of gadolinium-based contrast
2 agents, including OptiMark.

3 54. Even though Defendants knew or should have known that gadolinium-based contrast
4 agents, including OptiMark, posed a serious risk of bodily harm to consumers, Manufacturing and
5 Distributor Defendants unreasonably continued to manufacture and market gadolinium-based contrast
6 agents, including OptiMark, and failed to exercise reasonable care with respect to post-sale warnings
7 and instructions for safe use.

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

10 56. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
11 physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and
12 economic loss in the future.

13 **PRAYER FOR RELIEF**

14 WHEREFORE, Plaintiff prays for relief as follows:

15 1. Compensatory damages more than the jurisdictional amount, including, but not limited
16 to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an
17 amount to be determined at trial of this action;

18 2. Past and future medical expenses, income, and other economic damages in an amount to
19 be determined at trial of this action;

20 3. Punitive damages as to the First Cause of Action in an amount to be determined at trial
21 of this action;

22 4. Pre-judgment and post-judgment interest;

23 5. Attorneys' fees, if applicable, expenses, and costs; and

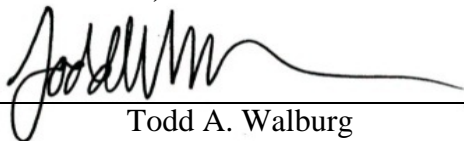
24 6. Such further relief as this Court deems necessary, just, and proper.

25 **DEMAND FOR JURY TRIAL**

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

1 Respectfully submitted this 26th day of January 2018.

2 **CUTTER LAW, P.C.**

3 By: 
4 _____
5 Todd A. Walburg

6 C. Brooks Cutter (SBN 121407)
7 Todd A. Walburg (SBN 213063)
8 Margot P. Cutter (SBN 306789)
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17 *Attorneys for the Plaintiff*

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CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

SRIHARI MUNNURU

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

(c) Attorneys (Firm Name, Address, and Telephone Number) C. Brooks Cutter (SBN 121407); Todd A. Walburg (SBN 213063); Margot P. Cutter (SBN 306789); CUTTER LAW, P.C., 401 Watt Ave., Sacramento, CA 95864, (916) 290-9400, Fax: (916) 588-9330

DEFENDANTS

GUERBET, LLC, et al.

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

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

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

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

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes categories like Personal Injury, Civil Rights, Prisoner Petitions, Habeas Corpus, and others.

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

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

VI. CAUSE OF ACTION

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

Brief description of cause: Strict Liability, Failure to Warn, Negligence

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P. DEMAND \$

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

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

JUDGE DOCKET NUMBER

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

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

DATE 01/26/2018

SIGNATURE OF ATTORNEY OF RECORD

Handwritten signature of Todd A. Walburg

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

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

- I. a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the “defendant” is the location of the tract of land involved.)
- c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section “(see attachment).”
- II. Jurisdiction.** The basis of jurisdiction is set forth under Federal Rule of Civil Procedure 8(a), which requires that jurisdictions be shown in pleadings. Place an “X” in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- (1) United States plaintiff. Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.
 - (2) United States defendant. When the plaintiff is suing the United States, its officers or agencies, place an “X” in this box.
 - (3) Federal question. This refers to suits under 28 USC § 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 - (4) Diversity of citizenship. This refers to suits under 28 USC § 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS-CAND 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an “X” in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an “X” in one of the six boxes.
- (1) Original Proceedings. Cases originating in the United States district courts.
 - (2) Removed from State Court. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.
 - (3) Remanded from Appellate Court. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 - (4) Reinstated or Reopened. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 - (5) Transferred from Another District. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 - (6) Multidistrict Litigation Transfer. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.
 - (8) Multidistrict Litigation Direct File. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket. Please note that there is no Origin Code 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC § 553. Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an “X” in this box if you are filing a class action under Federal Rule of Civil Procedure 23. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction. Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- IX. Divisional Assignment.** If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: “the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated.”
- Date and Attorney Signature.** Date and sign the civil cover sheet.