UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

JAY THOMAS
Plaintiff,

v.

BRACCO DIAGNOSTICS, INC.;

Defendant.

Civil Action No.

COMPLAINT FOR DAMAGES

1) STRICT LIABILITY: FAILURE TO WARN;
2) NEGLIGENCE;
3) NEGLIGENT MISREPRESENTATION;
4) NEGLIGENCE PER SE;
5) BREACH OF EXPRESS WARRANTY;
6) BREACH OF IMPLIED WARRANTY;
7) FRAUDULENT MISREPRESENTATION AND CONCEALMENT; AND
8) CIVIL BATTERY

DEMAND FOR JURY TRIAL

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW Plaintiff, JAY THOMAS (hereinafter "Plaintiff"), and alleges as follows:

PARTIES

1. Plaintiff is a resident of West Monroe, Louisiana. He was administered the Gadolinium-Based Contrast Agent ("GBCA") MultiHance.

2. Plaintiff suffers from Gadolinium Deposition Disease ("GDD"). GDD is an incurable and painful disease. Plaintiff contracted GDD as a result of receiving MRIs and MRAs that required intravenous injections of MultiHance.

3. Defendant Bracco Diagnostics, Inc., manufacture, market, and sell MultiHance gadolinium-based contrast agents ("GBCA") that were injected into Plaintiff's body.

4. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. has elected to establish an agent for

service of process in the State of California. Bracco Diagnostics, Inc. may be served with process through its registered agent: The Corporation Trust Company located at the Corporation Trust Center at 1209 Orange St, Wilmington, DE 19801, or any other place it may be found.

5. Bracco Diagnostics, Inc. is engaged in the business of manufacturing, distributing, designing, selling, marketing, licensing and/or introducing MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of Louisiana's state laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

6. At all times relevant to this Complaint, the Manufacturing Defendants advertised, promoted, marketed, distributed, and sold Multihance, in Louisiana and nationwide.

7. Defendants are authorized to do business in the District of Louisiana and derive substantial income from doing business in this state.

8. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities within the District of Louisiana, thus invoking the benefits and protections of its laws.

9. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture, promote and/or distribute Multihance, with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendant. Plaintiff is a resident and citizen of and is domiciled in the State of Louisiana. As set forth more fully above, Defendant entity is organized in a state other than the State of Louisiana, and none of the Defendant are citizens or residents of the State of Louisiana.

11. This Court has personal jurisdiction over Defendant, which is licensed and/or is systematically and continuously conduction business in the State Louisiana, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including MultiHance, to the residents in this State. Specifically, Bracco Diagnostics, Inc. manufactured, distributed, designed, marketed and/or sold MutliHance either directly or indirectly through third parties or related entities to residents in this State. Plaintiff paid for, received intravenous MultiHance and was injured and treated for his injuries in Louisiana.

12. Venue is proper in this District pursuant to 28 U.S.C § 1391(a), because Defendant marketed, advertised, and distributed the dangerous product in this District; Defendant does substantial business in the State of Louisiana and within this District; and at all times relevant hereto, Defendant developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold MultiHance in interstate commerce.

FACTS

13. Plaintiff had normal kidney function prior to developing GDD. Plaintiff was subjected to several MRIs. At the time of the MRI's, Plaintiff was injected with the GBCA MultiHance. Unbeknownst to him, he developed GDD soon thereafter. Plaintiff's symptoms included but were not limited to the following: burning sensation; clouded

mentation; confusion; weakness; fatigue; difficult, painful movement; inflammation; muscle cramps; numbness; tingling sensation; aching joints; lumps and rashes on body.

14. GDD is a disease process seen in people with normal or near-normal kidney function who develop life-long symptoms that can be seen hours or months after the administration of the GBCA's. In these cases, no preexisting disease or subsequently developed disease of another origin is present to explain the individual's symptoms. These symptoms are consistent with the known toxic effects of retained gadolinium. Typical clinical features of GDD include persistent headaches, bone and joint pain, and clouded mental activity. People with GDD often experience thickening of the skin that appears somewhat spongy or rubbery. Tendons and ligaments are also found to be painful and have a thickened appearance. Additionally, people with GDD often experience excruciating pain, frequently in their extremities, but may also be in the torso or generalized in location. This debilitating pain is often described as feeling like sharp pins and needles, cutting, or burning. GDD frequently results in an inhibition of the ability to use the arms, legs, hands, feet, and other joints. There is no known cure for GDD.

15. GDD is man-made and occurs in patients who have received a GBCA.

16. Gadolinium is a highly toxic heavy metal. It is not found naturally in the human body. The only known route for gadolinium to enter the human body is injection of a GBCA.

17. Because gadolinium is toxic, it must be coated to keep it from coming into contact with human tissue. This coating process is called chelation.

18. The GBCA (MultiHance) injected into Plaintiff was manufactured by the Defendant.

19. During the years that Defendant manufactured, marketed, distributed, sold, and administered GBCAs, there have been numerous case reports, studies, assessments,

papers, peer-reviewed literature, and other clinical data that have described and/or demonstrated GDD in connection with the use of GBCAs.

20. During those same years, there has been a significant number of publicized complaints from those afflicted with GDD and others seeking to help these victims. Defendant has had this information available to it for several years and have been put on notice of these issues giving rise to Plaintiff's cause of action alleged herein.

21. Plaintiff received MRIs utilizing the GBCA MultiHance.

22. During the time period when Plaintiff received injections of Defendant's GBCAs, Defendant knew or should have known that the use of GBCAs created a risk of serious bodily injury, even in patients with normal or near-normal kidney function.

23. Defendant failed to warn Plaintiff and his healthcare providers about the serious health risks associated with GBCAs (including MultiHance) and failed to disclose the fact that there were safer alternatives.

24. As a direct and proximate result of receiving injections of GBCAs manufactured, distributed, marketed, and/or sold by Defendant (including MultiHance), Plaintiff developed GDD.

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

26. Had Plaintiff and/or his healthcare providers been warned about the risks associated with GBCAs (including MultiHance) he would not have been administered GBCAs and would not have been afflicted with GDD.

27. As a direct and proximate result of being administered GBCAs (including MultiHance), Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

THE DEFENDANT'S COVER-UP AND APPLICATION OF THE DISCOVERY RULE

28. Plaintiff only recently became aware of the dangers of GBCA's and the potential for GDD.

29. In late April of 2018, the FDA published a revised Product Labeling with the Medication Guide for all gadolinium-based contrast agents to its website.

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

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

became very weak and separates easily in low pH conditions such as those found in many compartments of the human body, including extracellular fluid spaces.

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

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

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

35. Three months after the FDA approval of Omniscan (a linear contrast agent with a similar structure to MultiHance) the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies demonstrated that while toxic gadolinium was no longer

detectable in the blood seven days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.

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

37. The Defendant knew that their product, MultiHance, did not have very stable bonds and could come apart easily causing significant toxicity in humans.

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

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

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

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

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

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

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

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

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

47. In May 2018, Defendant along with several other Manufacturers of GBCA's jointly issued a new drug warning admitting that:

a. "Gadolinium is retained for months or years in several organs."

b. "Linear GBCAs cause more retention than macrocyclic GBAs."

c. "There are rare reports of pathologic skin changes in patients with normal renal function. Adverse events involving multiple organ systems have been reported in patients with normal renal function…"

48. "While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at a higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions."

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

50. Despite this well-documented evidence of gadolinium retention, Defendant has continuously failed to warn consumers and their healthcare providers on the labels of their products. In 2012, Defendant corrected their label to include contraindications for use in people with kidney disease and acute kidney injury. Yet, Defendant has failed to

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

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

update their label to reflect the extensive evidence of gadolinium retention in people with normal renal function.

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

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

STRICT LIABILITY: FAILURE TO WARN

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

54. Defendant's GBCA (including MultiHance) was defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendant knew or should have known that their products created significant risks of serious bodily harm to consumers. Defendant failed to adequately warn consumers and their healthcare providers of such risks.

55. Because of Defendant's failure to provide adequate warnings, Plaintiff was injected with GBCAs (including MultiHance) which Defendant manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce. Those GBCAs (including MultiHance) are the legal cause of the following: Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

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

NEGLIGENCE

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

58. Defendant had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of GBCAs (including MultiHance) and the MRI machines and products designed to be used in conjunction with GBCAs. In particular, they had a duty to ensure that their products did not pose an unreasonable risk of bodily harm and adverse events.

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

60. Defendant failed to exercise ordinary care in the labeling of GBCAs (including MultiHance) and the labeling of MRI machines and products designed to be used in conjunction with GBCAs and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury due to the use of GBCAs (including MultiHance) and the MRI machines and products designed to be used in conjunction with GBCAs.

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

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

63. As a direct and proximate result of Defendant's negligence, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

NEGLIGENT MISREPRESENTATION

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

65. Defendant falsely and negligently misrepresented material facts on which Plaintiff and his healthcare providers acted.

66. Defendant Bracco Diagnostic, Inc. failed to disclose material facts regarding the safety and efficacy of MultiHance with respect to patients with normal renal function.

67. Defendant had a duty to exercise reasonable care to those whom they provided product information about MultiHance and to all those relying on the information provided, including Plaintiff and his healthcare providers.

68. In violation of existing standards and duties of care, Defendant made misrepresentations through their advertisements, labeling, marketing, marketing persons, notices, package

insert/prescribing information, and written and oral information provided to patients and medical providers.

69. Defendant negligently represented to patients and the medical and healthcare communities, including Plaintiff and his healthcare providers, that:

a. on or around September 4, 2007, included on the MultiHance injection label, "MultiHance does not cross the intact blood-brain barrier"[3] when such Defendant knew or should have known that MultiHance can cross the intact blood-brain barrier;

b. on or around May 1, 2005, Bracco Diagnostics, Inc.'s President and Chief Executive Officer Carlo Medici, publicly announced MultiHance "can have an immediate positive impact for patients and practitioners in the context of MRI" when he knew or should have known that MultiHance creates an unreasonable risk of dangerous side effects, including gadolinium retention in patients;[4]

c. "Gadobenate ion is eliminated" from the body when such Defendant knew or should have known that gadobenate deposits may be present for months to years in bone, liver, skin, brain, and other organs;[5]

70. The representations were material, false, misleading, and made with actual or constructive knowledge that they were false.

[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021357s003,021358s003lbl.pdf
[4] *See* Broadline to Offer Bracco Diagnostics' Multihance injection, 529 mg/mL, *available at* https://imaging.bracco.com/us-en/broadlane-offer-bracco-diagnostics-multihance-injection-529-mgml.
[5] *See* Bracco Diagnostics Receives FDA Approvable Letter for Multihance Injection, 529 mg/mL (Nov. 11, 2002), *available at* https://imaging.bracco.com/us-en/bracco-diagnostics-receives-fda-approvable-letter-multihance-injection-529-mgml (representing that MultiHance has a "slight hepatobiliary elimination" which "makes MultiHance truly exciting.").

71. When Plaintiff used MultiHance, Plaintiff was unaware of the falsity of Defendant Bracco Diagnostics, Inc.'s said representations and reasonably believed them to be true.

72. In reasonable reliance upon said representations, Plaintiff's prescribers were induced to prescribe MultiHance and recommend the drug as safe for use in conjunction with MRIs, and Plaintiff was induced to and did use MultiHance when undergoing MRIs. Had Defendant Bracco Diagnostics, Inc. not made the foregoing express and implied false statements about MultiHance, Plaintiff would not have used the GBCAs and his medical providers would not have administered it and recommended it as safe.

73. Defendant Bracco Diagnostics, Inc.'s labeling of MultiHance was also rendered misleading by the omission of the material risk information listed in the preceding count.

74. Plaintiff and his healthcare providers justifiably relied on Defendant Bracco Diagnostics, Inc.'s representations and non-disclosures when using MultiHance.

75. At the times Plaintiff received injections of MultiHance, Defendant Bracco Diagnostics, Inc. knew that MultiHance had not been sufficiently tested for gadolinium retention and that it lacked adequate warnings.

76. At the times Plaintiff received injections of MultiHance, Defendant Bracco Diagnostics, Inc. knew or should have known that the use of MultiHance by patients with normal renal function increases the risk of gadolinium retention and resulting injuries

77. Defendant Bracco Diagnostic, Inc. knew or should have known that consumers, such as Plaintiff, would foreseeably use MultiHance and that they and their prescribing healthcare providers would rely upon the representations and omissions.

78. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm,

damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

NEGLIGENCE PER SE

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

80. Defendant had a duty to exercise reasonable care and comply with existing standards in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of MultiHance, and post-market vigilance regarding same.

81. Defendant failed to exercise reasonable care and failed to comply with existing laws in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of MultiHance, and post-market vigilance regarding same.

82. At all times material hereto, under federal law governing labeling for MultiHance, Defendant was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e). Breaches of these duties constitute independent acts of negligence under state law.

83. Prior to 2006, federal law also required Defendant to revise MultiHance's labeling "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved . . .." 21 C.F.R. § 201.57(e). Under 21 C.F.R. §314.70(c)(6)(iii), pharmaceutical companies were (and are) free to add or strengthen – without prior approval from the FDA – a contraindication, warning, precaution, or adverse reaction, as soon as there was reasonable evidence of an association of a serious hazard with the drug, id. §201.57(e)), and to delete false,

misleading, or unsupported indications for use or claims for effectiveness. Defendant failed to exercise reasonable care and violated 21 U.S.C. §§ 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.80, and 201.128. The violations constitute independent violations of state negligence law.

84. The laws violated by Defendant were designed to protect Plaintiff and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, Defendant's conduct constitutes negligence per se.

85. Despite the fact that Defendant knew or should have known that MultiHance significantly increased the risk of gadolinium retention in patients with normal renal function, Defendant continued to negligently market and label MultiHance.

86. Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendant's failures to exercise reasonable care, as set forth above.

87. Defendant's negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss, which Plaintiff will continue to suffer.

88. Had Plaintiff not taken MultiHance, he would not have suffered injuries and damages.

89. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

BREACH OF EXPRESS WARRANTY

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

91. "Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation of promise." G.L.c. 106, § 2-213.

92. "Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." G.L.c. 106, § 2-213.

93. Drug manufacturers, such as Defendant, bear responsibility for the content of their label at all times. 21 C.F.R. § 201.80(e). Drug manufacturers are also charged "with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Wyeth v. Levine, 555 U.S. 555, 570-71 (2009)

94. At the time Plaintiff's medical providers prescribed MultiHance to him, and at the time Plaintiff was infused with the drug, the "Pharmacokinetics" section of the MultiHance label represented that that "Gadobenate ion is eliminated" from the body. These statements are specific and unequivocal in asserting that gadolinium is eliminated from the body.

95. MultiHance did not confirm to these express material representations because Defendant knew prior to these representations being made, and prior to Plaintiff's use of MultiHance, that MultiHance was not completely eliminated from the body, even in patients with normal renal function.

96. At the time of the making of these express warranties, Defendant knew or should have known that, in fact, these representations and warranties were false, misleading, and untrue in that gadolinium was not safe and fit for its warranted use.

97. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff, relied upon the representations and warranties of

Defendant for use of MultiHance in recommending, prescribing, and/or using these drugs.

98. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

BREACH OF IMPLIED WARRANTIES

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

100. Defendant impliedly warranted to the users of MultiHance and their healthcare providers that MultiHance would be eliminated from the body and were safe and fit for use in patients with normal renal function.

101. Defendant breached the implied warranties, as MultiHance was not safe and fit for use by patients with normal renal function.

102. Defendant was aware that consumers, including Plaintiff, would use MultiHance for the purpose intended and warranted by Defendant.

103. MultiHance reached consumers, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendant, and the MultiHance was neither misused nor materially altered.

104. Plaintiff and his physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether MultiHance was of merchantable quality and safe and fit for their intended use.

105. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm,

damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

FRAUDULENT MISREPRESENTATION AND CONCEALMENT

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

107. Defendant Bracco Diagnostics, Inc. fraudulently represented to consumers and the medical and healthcare community, including Plaintiff and their providers, that:

a. MultiHance was safe and effective for patients with normal renal function;

b. the use of MultiHance in patients with normal renal function did not increase the risk of gadolinium retention;

c. MultiHance had been adequately tested and studied in patients with normal renal function;

d. "Gadobenate ion is eliminated" from the body.

e. "MultiHance does not cross the intact blood-brain barrier."

108. At the time Defendant Bracco Diagnostics, Inc. made these representations, Defendant Bracco Diagnostics, Inc. knew the representations were false and misleading.

109. Defendant Bracco Diagnostics, Inc.'s representations regarding MultiHance were material, false, misleading and made with actual or constructive knowledge that they were false.

110. Defendant Bracco Diagnostics, Inc. made these representations with the intent of defrauding and deceiving healthcare providers and Plaintiff to recommend, prescribe, dispense and/or purchase MultiHance to treat patients with normal renal function.

111. When Plaintiff used MultiHance, he and his healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

112. In reasonable reliance upon said representations, Plaintiff's providers were induced to prescribe MultiHance to Plaintiff and recommend the drug as safe for use with MRIs, and Plaintiff was induced to and did use MultiHance prior to his MRIs.

113. Had Defendant Bracco Diagnostics, Inc. not made the false statements about MultiHance, Plaintiff would not have used the product and his medical providers would not have administered it and recommended it as safe.

114. Defendant is and was under a continuing duty to monitor and disclose the risks of MultiHance for use with MRIs. They have fraudulently concealed the risks and their knowledge of them. Defendant's fraudulent concealment was designed to prevent, and did prevent, the public and the medical community at large from discovering the risks and dangers associated with MultiHance use with MRIs. Their fraudulent concealment also prevented Plaintiff from discovering, and/or with reasonable diligence being able to discover his cause of action.

115. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

CIVIL BATTERY

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

117. In manufacturing and distributing MultiHance for use in MRIs, Defendant intended that gadolinium be injected into patient's bodies, including Plaintiff's.

118. Defendant intended to cause Plaintiff to be physically touched in an offensive and harmful manner.

119. Plaintiff was physically touched in an offensive and harmful manner.

120. Plaintiff did not consent to having MultiHance be retained inside his body for months to years.

121. As a direct and proximate result of the foregoing acts, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

PUNITIVE DAMAGES

122. At all times material hereto, Defendant knew or should have known that its GBCAs, including MultiHance, were inherently dangerous to patients with normal renal function, including Plaintiff.

123. At all times material hereto, Defendant attempted to misrepresent and did misrepresent facts concerning the safety of their GBCAs, including MultiHance.

124. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the GBCA drug at issue.

125. At all times material hereto, Defendant knew and recklessly disregarded the fact that their GBCAs could be retained in the body for months to years, resulting in fibrosis in the organs, skin, bones, and brain in patients with normal renal function.

126. Notwithstanding the foregoing, Defendant continued to aggressively market their GBCAs to consumers, including Plaintiff, without disclosing the aforesaid side effects.

127. Defendant knew that its GBCAs lacked adequate warnings regarding the risk of gadolinium retention and resulting injuries in patients with normal renal function, but they intentionally concealed and/or recklessly failed to disclose those risks and continued to market, distribute, and sell their GBCAs, including MultiHance, without

said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by their GBCAs.

128. Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable him to weigh the true risks of using GBCAs against their benefits.

129. Defendant's aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendant and deter them from similar conduct in the future.

130. As a direct and proximate result of the foregoing acts, Plaintiff has suffered and will continue to suffer from mental anguish, physical injuries, harm, damages, and economic loss. Additionally, Plaintiff will require lifelong medical treatment, monitoring and/or medications.

PRAYER FOR RELIEF

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

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

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

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

(d) For full refund of all purchase costs Plaintiff paid for MultiHance;

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

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

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

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

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

DEMAND FOR JURY TRIAL

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

Respectfully submitted,

S/Amanda L. Washington
AMANDA L. WASHINGTON
Louisiana State Bar No. 34811
DANIEL J. MCGLYNN
Louisiana State Bar No. 17051
MCGLYNN, GLISSON & MOUTON
340 Florida Street
Baton Rouge, LA 70801
Telephone (225) 344-3555
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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 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 by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

THOMAS, JAY

(b) County of Residence of First Listed Plaintiff Ouachita Parish, LA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Amanda L. Washington and Daniel J. McGlynn
340 Florida Street, Baton Rouge, LA 70801
225-344-3555

DEFENDANTS

BRACCO DIAGNOSTICS, INC.;

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Failure to Warn; Negligence; Negligent Misrepresentation; Negligence Per Se; etc.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
04/17/2019

SIGNATURE OF ATTORNEY OF RECORD
/s/ Amanda L. Washington

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 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 by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating 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 Rule 8(a), F.R.Cv.P., 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.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 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.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 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 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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

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 Rule 23, F.R.Cv.P.
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 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.