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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Candice Drescher, Plaintiff, vs. Bracco Diagnostics, Inc.; Guerbet LLC; Mallinckrodt Inc.; Mallinckrodt LLC; and Liebel-Flarsheim Company LLC, Defendants.	No. **COMPLAINT AND DEMAND FOR JURY TRIAL**

Comes now Plaintiff Candice Drescher ("Plaintiff") and alleges as follows:

1. Gadolinium is a highly toxic heavy metal and rare earth element. It does not occur naturally in the human body. The only known route for gadolinium to enter the

human body is by injection of a gadolinium-based contrast agent.

2. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drugs Multihance and Optimark, linear gadolinium-based contrast agents used in MRIs.

3. Plaintiff maintains that Multihance and Optimark are defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

4. The gadolinium from Multihance and Optimark did not leave the Plaintiff's body as readily promised, and instead it was retained permanently or indefinitely in multiple organs and soft tissues (e.g., brain, heart, liver, kidney, bones, and skin). This gadolinium, a toxic heavy metal, caused fibrosis in Plaintiff's organs, bone, and skin, and crossed the blood-brain barrier and deposited in the neuronal nuclei of the brain.

JURISDICTION AND VENUE

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

6. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in Tucson in the State of Arizona. As set forth more fully below, all Defendants are entities organized in states other than the

state of Arizona, have their principal places of business in states other than Arizona, and none of the Defendants is a citizen or resident of the state of Arizona.

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

8. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and is systematically and continuously conducting business in this state, including, but not limited to, marketing, researching, testing, advertising, selling, and distributing of drugs, including Multihance and Optimark, to Plaintiff in Arizona.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the Plaintiff's cause of action occurred in this District. Defendants sell, advertise, market, and/or distribute their GBCAs within this district and do substantial business in this state and within this District.

10. Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold Multihance and Optimark in interstate commerce.

PARTIES

11. Plaintiff Candice Drescher is a natural person and at all relevant times a resident and citizen of Tucson, Arizona. Ms. Drescher was injected with linear gadolinium-based contrast agents ("GBCAs") in Arizona. Unbeknownst to her and contrary to the Defendants' promotion of GBCAs as being benign contrast agents that harmlessly exit the body shortly after administration in patients who did not have chronic/severe kidney disease or acute kidney injury, Ms. Drescher continues to have retained gadolinium in her body, years after being administered the GBCA.

12. Plaintiff's primary injury alleged herein is gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, caused fibrosis in her organs, bone, and skin, and crossed the blood-brain barrier and deposited in the neuronal nuclei of the brain.

13. Plaintiff was never warned about the risks of gadolinium retention because she did not have chronic/severe kidney disease or acute kidney injury, and the GBCA manufacturers chose to only provide warnings to patients with these types of reduced renal function.

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

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

16. Defendants Guerbet LLC, Mallinckrodt Inc., Mallinckrodt LLC, and Liebel-Flarsheim Company LLC manufacture, test, market, advertise, and sell the linear GBCA named OptiMark.

17. Defendant Guerbet, LLC is a Delaware corporation with its principal place of

business in Indiana. Defendant Guerbet, LLC engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing OptiMark 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 this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

18. Defendant Mallinckrodt Inc. is a Delaware corporation with its principal place of business in Missouri. Defendant Mallinckrodt Inc. engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing OptiMark 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 this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

19. Defendant Mallinckrodt LLC is a Delaware corporation with its principal place of business in Missouri. Defendant Mallinckrodt LLC engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing OptiMark 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 this state's laws, and Plaintiff's claim arises out of Defendant's forum-

related activities.

20. Defendant Liebel-Flarsheim Company LLC is a Delaware corporation with its principal place of business in Missouri. Defendant Liebel-Flarsheim Company LLC engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing OptiMark 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 this state laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

21. As used herein, "Defendants" includes Bracco Diagnostics, Inc.; Guerbet LLC; Mallinckrodt Inc.; Mallinckrodt LLC; and Liebel-Flarsheim Company LLC.

22. Defendants are authorized to do business in Arizona and derive substantial income from doing business in this state.

23. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities in Arizona, thus invoking the benefits and protections of its laws.

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

FACTS COMMON TO ALL CAUSES OF ACTION

25. The type of gadolinium retention sustained by Plaintiff occurs in patients without chronic/severe kidney disease or acute kidney injury who develop persistent

symptoms that arise hours to months after the administration of a linear gadolinium-based contrast agent. Plaintiff had no preexisting disease or subsequently developed disease of an alternate known process to account for the symptoms. This is a progressive condition for which there is no known cure.

26. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use of linear gadolinium-based contrast agents.

27. Defendants discovered newly acquired information after the FDA's initial approval of their drugs' labels regarding the risks and dangers of retention and physical injuries associated therefrom of linear gadolinium-based contrast agents. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents). Therefore, it was reasonably foreseeable that that Defendants' drugs would cause gadolinium retention, fibrosis, and related injuries.

28. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with linear GBCAs, and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents). Had Plaintiff and her healthcare providers known about the serious risks related to retention in linear GBCAs and the fact that there were safer alternatives, Plaintiff would have either elected to have

the scan without contrast agent or chosen a safer alternative.

29. As a direct and proximate result of receiving injections of linear gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, Plaintiff developed gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

30. Had Plaintiff and/or her healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, she would not have been administered linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

31. As a direct and proximate result of Plaintiff being administered linear gadolinium-based contrast agents, she has suffered severe physical injury and pain and suffering, including, but not limited to, gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

32. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

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

34. Meanwhile, unbeknownst to Plaintiff, the manufacturers of the linear GBCAs

have known since the 1980s that their drugs could cause retention of toxic gadolinium. But their claims to the public and healthcare providers have been misleading and false.

35. In 1984 – prior to FDA approval – the inventors of linear gadolinium-based contrast agents claimed that their product, Gd-DTPA, did not cross the blood-brain barrier, and that the bonds between the toxic gadolinium and its protective coating did not break inside the body. Additionally, they claimed that there would be no toxic gadolinium residue left behind to cause illness.[1]

36. There are two basic types of contrast agents differentiated by their chemical structure – linear agents and macrocyclic agents. The main difference is that the linear agents do not fully surround the gadolinium ion, whereas the macrocyclic agents form a more complete ring around the gadolinium ion which creates a stronger bond. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured by Guerbet/ Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

37. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988, and in that same year, it was recognized that gadolinium was breaking free from the bonds in the linear-based contrast agents and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron.[2] Furthermore, emerging science

[1] Brasch RC. Inherent contrast in magnetic resonance imaging and the potential for contrast enhancement – the 1984 Henry Garland lecture. *West J Med.* 1985 Jun; 142:847-853.

[2] Huckle JE, Altun E, Jay M, et al. Gadolinium deposition in humans: when did we learn that gadolinium was deposited in vivo? *Invest. Radiol*. 2016; 51:236-240.

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

38. Stability differences among gadolinium contrast agents have long been recognized in laboratory (in vitro), and deposition of toxic gadolinium in tissues has been described in animal models since at least 1984. The first major study that showed deposition in humans appeared in 1998 regarding patients with renal failure and later in 2004 in patients with normal renal function.[3]

39. Laboratory (in vitro) studies assessing the stability of each gadolinium-based contrast agent in human blood were performed and demonstrated that, over time, greater percentages of gadolinium were released from linear agents as compared to the macrocyclic agents.[4]

40. The lack of stability seen within the linear agents was dismissed as a cause of concern by the Defendants claiming that the GBCA's were excreted out of the body according to the drug's claimed half-life, before the chelate could release the toxic gadolinium. However, it was later noted that some conditions could cause prolonged retention of the contrast agents, thus allowing more toxic gadolinium to be released in the bodies of patients. In addition, a delayed elimination phase of the gadolinium-based contrast agents would later be discovered.

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[3] *Id.*

[4] Tweedle MF, Eaton SM, Eckelman WC, et al. Comparative chemical structure and pharmacokinetics of MRI contrast agents. *Invest. Radiol*. 1988; 23 (suppl 1): S236-S239; *see also* Frenzel T, Lengsfeld P, Schimer H, et al. Stability of gadolinium-based magnetic resonance imaging contrast agents in serum at 37 degrees C. *Invest. Radiol*. 2008; 43:817-828.

41. Peer-reviewed articles on the deposition of gadolinium in animals with normal renal function, some illustrating deleterious consequences, have been published as early as 1984.[5]

42. Three months after the FDA approval of GE's Omniscan (a linear contrast agent) in 1993 the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies noted that while toxic gadolinium was no longer detectable in the blood 7-days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.[6]

43. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over 1 year after the approval of Magnevist. Authors *Tien et al.* reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)."[7] Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue.

44. Defendants knew that their linear GBCAs did not have very stable bonds and could come apart easily causing significant toxicity in humans. Defendants have known about the risks that linear gadolinium-based contrast agents pose to people with normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium

[5] Weinman HJ, Brasch RC, Press WR, et al. Characteristics of gadolinium-DTPA complex: a potential NMR contrast agent. *AJR Am J Roentgenol*. 1984; 142: 619-624.
[6] Harpur ES, Worah D, Hals PA, et al. Preclinical safety assessment and pharmaco-kinetics of gadodiamide injection, a new magnetic resonance imaging contrast agent. *Invest Radiol.* 1993; 28 (suppl 1): S28-S43.
[7] Tien RD, Brasch RC, Jackson DE, et al. Cerebral Erdheim-Chester disease: persistent enhancement with Gd-DTPA on MR images. *Radiology*. 1989; 172:791-792.

retention was occurring in people with normal renal function.[8]

45. In 2004, gadolinium was shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies.[9] Since then, studies have continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.

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

47. Dermatologists, nephrologists, and other scientists connected the administration of linear gadolinium-based contrast agents to a rapidly progressive, debilitating and often fatal condition called gadolinium-induced Nephrogenic Systemic Fibrosis (NSF). This, in turn, prompted the Food and Drug Administration (FDA) to issue a black box warning in 2007 for all GBCAs regarding the release of toxic gadolinium from the linear contrast agents, and its long-term retention in the bodies of animals and humans (for patients with abnormal kidney function).

48. Accordingly, Defendants revised their labels to include contraindications for use in people with kidney disease and acute kidney injury.

49. There were over 500 NSF cases reported and estimated to be well over a

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

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

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

50. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents. They found that the brain had hyperintense signals in critical areas of the brain.[10]

51. These findings were confirmed by scientists at the Mayo Clinic in 2014 when autopsy studies were performed on thirteen deceased individuals, all of whom had normal or near normal renal function and who had received six or more injections of gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated

[10] Kanda T, Ishii K, Kawaguchi H, et al. High signal intensity in the dentate nucleus and globus pallidus on unenhanced T1-weighted MR images: relationship with increasing cumulative dose of a gadolinium-based contrast material. *Radiology*. 2014; 270: 834-841.

tissue were found within the brains of these patients.[11]

52. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents used in MRIs.

53. In September 2017, the FDA's medical advisory committee voted thirteen to one 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.

54. In December 2017, the FDA required a new class warning and other safety measures for all gadolinium-based contrast agents for MRIs concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. The FDA required manufacturers to issue a patient medication guide, providing educational information that every patient must be asked to read before receiving a GBCA. The FDA also required manufacturers of GBCAs to conduct human and animal studies to further assess their safety.

55. In May 2018, the GBCA manufacturers finally issued a joint warning to patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

a. "Subject: Gadolinium from GBCAs may remain in the body for months to years after injection;"

b. A new class warning, patient counseling, and a medication guide;

c. Warning that gadolinium is retained for months to years in several

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

organs;

d. Warning that the highest concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);

e. Warning that the duration of gadolinium retention is longest in bone and varies by organ;

f. Warning that linear GBCAs cause more retention than macrocyclic GBCAs;

g. Warning about reports of pathological skin changes in patients with normal renal function;

h. Warning that adverse events involving multiple organ systems have been reported in patients with normal kidney function;

i. Warning that certain patients are at higher risk:

   i. patients with multiple lifetime doses;

   ii. pregnant patients;

   iii. pediatric patients;

   iv. patients with inflammatory process;

j. Instructions for health care providers to advise patients that:

   i. Gadolinium is retained for months or years in brain, bone, skin, and other organs in patients with normal renal function;

   ii. Retention is greater following administration of linear GBCAs than following administration of macrocyclic GBCAs.

This also warning deliberately downplays the state of the evidence concerning the health

effects of gadolinium retention.

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

57. Therefore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality, and nature of their linear GBCAs. Defendants were under a duty to disclose the true character, quality, and nature of the linear GBCAs because this was non-public information over which Defendants had and continue to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers, and/or to their facilities. Defendants are estopped from relying on any statute of limitations defense because of their intentional concealment of those facts.

58. Plaintiff Candice Drescher was injected with the linear GBCA Optimark prior to receiving MRIs on or around January 19, 2013. Plaintiff Candice Drescher was injected with the linear GBCA Multihance prior to receiving MRIs on or around August 11, 2015; and November 8, 2016.

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

60. Plaintiff has suffered gadolinium retention in multiple organs and soft tissues

(e.g., brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, caused fibrosis in organs, bone, and skin, other adverse reactions, and crossed the blood-brain barrier and deposited in the neuronal nuclei of her brain.

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

FIRST CAUSE OF ACTION
(Against All Defendants)
STRICT LIABILITY: INADEQUATE WARNING

62. Plaintiff incorporates by reference and realleges each paragraph set forth herein.

63. Defendants' linear gadolinium-based contrast agents were manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants and were defective at the time they left Defendants' control in that, and not by way of limitation, the drugs failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of linear GBCAs.

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

65. Prescribing physicians, healthcare providers and patients, including Plaintiff

and her healthcare providers, neither knew, nor had reason to know at the time of their use of Defendants' GBCAs, of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which Defendants failed to include appropriate warnings, and which Defendants concealed, including the risk of gadolinium retention in multiple organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

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

67. Defendants are strictly liable for failure to warn by virtue of their conduct of selling products that are unreasonably dangerous and for failing to provide adequate warnings about their GBCAs.

68. Defendants are therefore strictly liable by virtue of the following acts and/or omissions:

a) Failing to adequately and correctly warn the Plaintiff, the public, and the medical and healthcare communities of the dangers of their GBCAs with respect to the risk of gadolinium retention;

b) Failing to disclose their knowledge that gadolinium is retained for months to years in several organs;

c) Failing to disclose their knowledge that higher concentrations of

retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);

d) Failing to disclose their knowledge that gadolinium retention is longest in bone and varies by organ;

e) Failing to disclose their knowledge that linear GBCAs cause more retention than macrocyclic GBCAs;

f) Failing to disclose their knowledge about adverse event reports involving multiple organ systems in patients with normal renal function;

g) Failing to disclose their knowledge that certain patients are at higher risk of adverse effects from linear GBCAs; and

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

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

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

SECOND CAUSE OF ACTION
(Against All Defendants)
STRICT LIABILITY: DEFECTIVE DESIGN

71. Plaintiff incorporates by reference and realleges each paragraph set forth herein.

72. Defendants' GBCAs were manufactured, sold, marketed, distributed, supplied, and/or placed into the stream of commerce by Defendants and were defective at the time they left Defendants' control in that, and not by way of limitation, the drugs were defective in their design.

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

74. Defendants' GBCAs were unreasonably dangerous for the use for which they were intended, and their unreasonably dangerous condition existed when they left the control of Defendants.

75. Defendants' GBCAs are defective because they failed to perform in a manner reasonably expected in light of their nature and intended function.

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

77. The foreseeable risks associated with the design or formulation of GBCAs

include, but are not limited to, retention of gadolinium in organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), resulting fibrosis in organs, bone, and skin, and gadolinium's tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

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

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

80. Defendants placed their GBCAs into the stream of commerce with wanton and reckless disregard for the public safety.

81. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product despite its potential to cause serious permanent injuries.

82. Defendants knew or should have known that their GBCAs cause and/or contribute to the injuries described in this complaint.

83. There are GBCAs on the market, including macrocyclic GBCAs, with safer alternative designs in that they provide equal or greater efficacy and far less risk.

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

85. These safer alternatives were both technologically and economically feasible when Defendants' GBCAs left the control of Defendants.

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

THIRD CAUSE OF ACTION
(Against All Defendants)
NEGLIGENCE

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

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

89. Defendants breached their duty of reasonable care to Plaintiff in that they negligently designed, developed, promoted, marketed, distributed, continued to sell, and/or labeled their GBCAs.

90. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not

limited to, one or more of the following particulars:

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

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

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

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

e) In representing that linear GBCAs were safe for their intended use when, in fact, the drugs were unsafe for their intended use;

f) In failing to perform appropriate pre-market testing of their GBCAs;

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

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

GBCAs;

i) In failing to take post-market actions to protect and/or warn consumers in light of what Defendants knew or should have known about their GBCAs; and

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

91. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

92. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its deposition in the neuronal nuclei of her brain. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

FOURTH CAUSE OF ACTION
(Against All Defendants)
BREACH OF EXPRESS WARRANTY
(including but not limited to A.R.S. §§ 47-2313)

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

94. Defendants developed, designed, formulated, tested, packaged, labeled,

produced, created, marketed, advertised, distributed, and sold their GBCAs as safe for use by the public at large, including Plaintiff, who purchased these drugs.

95. Defendants knew the use for which their product was intended and expressly warranted their GBCAs to be of merchantable quality, safe, and fit for use. Specifically, Defendants warranted that gadolinium was not retained in people with normal renal function.

96. Defendants made written warranties that their GBCAs were not retained in people with normal or near normal renal function. Defendants also warranted that people with normal renal function were not at risk of fibrosis or other medical conditions. These written warranties were located in brochures, websites, speeches, pamphlets, articles, and other marketing materials.

97. Plaintiff and Plaintiff's physician relied on the skill and judgment of the Defendants, and as such, their express warranty, in using Defendants' GBCAs.

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

99. Plaintiff took steps to notify Defendants that their GBCAS were not as represented.

100. The GBCAs did not meet the descriptions provided as they are retained in people, including Plaintiff, who has normal renal function. Plaintiff was harmed as a result of this. She suffers from severe physical, mental, and economic injury.

101. The failure of the GBCAs to be as represented was a substantial factor in

causing Plaintiff's harm.

102. Defendants' GBCAs were defective and not of merchantable quality or safe or fit for its intended use because it is unreasonably dangerous and unfit for the ordinary purpose for which it is intended and was used. Specifically, they are unreasonably dangerous, unmerchantable, and unfit for the ordinary purpose for which they are intended and were used because they cause injury, which include but are not limited to, retention of gadolinium in organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), resulting in fibrosis in organs, bone, and skin, and gadolinium's tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, foreseeable risks, which Defendants knew or should have known.

103. Defendants' GBCAs do not meet the reasonable expectations of an ordinary consumer, including the Plaintiff, as to their safety and are not reasonably safe for their intended purpose and use because they're defective designed and because Defendants inadequately warned of the risks of these drugs.

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

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

106. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Defendants' GBCAs were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally because they claimed

gadolinium was not retained in people with normal renal function. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which the GBCA was to be used and Defendants warranted the GBCA to be in all respects safe, effective, and proper for such purposes.

107. Defendants expressly warranted their GBCAs in their labels, which were directly intended to benefit Plaintiff.

108. Defendants' express warranties in their GBCA labels were intended for the products' consumers, including the Plaintiff.

109. Defendants expressly warranted their GBCAs in their patient labeling, which were intended to benefit Plaintiff and intended to be provided directly to Plaintiff.

110. Defendants expressly warranted their GBCAs in advertisements and/or brochures, which Plaintiff read and relied upon.

111. Defendants expressly represented to Plaintiff, her physician(s), healthcare providers, and/or the FDA that their GBCAs were safe and fit for the uses in which they are intended.

112. Further, Defendants' promotional and marketing activities, including pamphlets and brochures, stated or implied that their GBCAs were safe and fit for their intended uses, that they did not produce severe side effects, and that the gadolinium was only retained in people with impaired renal function.

113. Plaintiff read and relied upon Defendants' express warranties in their patient labeling and/or in other information, including marketing and promotional material, disseminated by Defendants.

114. Plaintiff's physician(s) read and relied upon Defendants' express warranties in the GBCA labels and/or in other information, including marketing and promotional materials, disseminated by Defendants.

115. Defendants' GBCAs do not conform to these express warranties and representations because they are not safe and may produce serious side effects, including but not limited to, gadolinium retaining in people with normal renal function and causing related physical side effects.

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

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

FIFTH CAUSE OF ACTION
(Against All Defendants)
NEGLIGENT MISREPRESENTATION

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

119. Defendants have consistently represented that their GBCAs are safe and that they do not produce serious side effects.

120. At the timeframes discussed herein, these misrepresentations were made in

Defendants' GBCAs' labeling, patient education, and marketing materials, which were produced and distributed by Defendants with the intent to defraud Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public.

121. Likewise, Defendants made these representations to Plaintiff in advertising, in the Patient Information Booklet, and/or in other marketing intended for consumers, prior to Plaintiff's administration with GBCAs, when she received the patient labeling, and when she was administered with the GBCAs.

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

123. Defendants had pecuniary interest in the transactions in which Plaintiff purchased Multihance and Optimark, because they earned money as a result of the transaction.

124. Defendants supplied the above false information for the guidance of others, including Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public, in the business transaction of purchasing Defendants' GBCAs.

125. Plaintiff's pecuniary losses were caused by her justifiable reliance upon Defendants' false information.

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

127. Plaintiff and her healthcare practitioners reasonably relied and actually relied

upon the above misrepresentations.

128. As a result of the above misrepresentations, Defendants have negligently misrepresented that their GBCAs are safe and effective and do not cause serious side effects.

129. But for these misrepresentations, Plaintiff would not have purchased Defendants' GBCAs or agreed to being administered with these GBCAs.

130. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of their GBCAs, owed a duty to provide accurate and complete information regarding these drugs.

131. Defendants have made false statements of material facts, of which Defendants were careless and/or negligent in ascertaining the truth of, with an intention of inducing Plaintiff and/or her healthcare providers to act upon them.

132. Plaintiff and her healthcare providers did take action in prescribing and using Defendants' GBCAs in reliance upon Defendants' false statements of material facts, which has caused damage and injuries to Plaintiff as described herein.

133. Defendants falsely represented to Plaintiff and Plaintiff's healthcare providers that their GBCAs were safe and effective drugs. The representations by Defendants were in fact false, as their GBCAs are not safe and are dangerous to the health of their users because the heavy metal gadolinium remains in users bodies and causes associated side effects. This occurred in Plaintiff's body.

134. At the time the aforesaid representations were made, Defendants concealed

from Plaintiff and her healthcare providers information about the propensity of their GBCAs to cause serious side effects. Defendants negligently misrepresented claims regarding the safety and efficacy of their GBCAs despite the lack of information regarding same.

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

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

137. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding its product.

138. Plaintiff and her healthcare providers reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when using and prescribing Defendants' GBCAs.

139. However, Defendants' GBCAs are not safe and are dangerous to the health of their users because they have a propensity for causing severe injuries.

140. Defendants negligently misrepresented that their GBCAs do not have the propensity to cause or contribute to severe injuries.

141. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and

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

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

SIXTH CAUSE OF ACTION
(Against All Defendants)
VIOLATION OF CONSUMER PROTECTION LAWS
(including but not limited to A.R.S. §§ 44-1521 through 44-1534)

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

144. Defendants have consistently represented that their GBCAs are safe and that they do not produce serious side effects.

145. The above representations are in fact false.

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

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

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

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

150. Defendants advertised to GBCAs to Plaintiff directly as a consumer.

151. Defendant made these misrepresentations in order to induce Plaintiff, Plaintiff's healthcare providers, the healthcare community, patients, the FDA, and the public to act upon them.

152. Plaintiff and her healthcare practitioners reasonably and actually relied upon the above affirmative misrepresentations.

153. As a result of these affirmative misrepresentations, Defendants have misrepresented that their GBCAs are safe and effective and do not cause side effects like retention, fibrosis, or other related conditions.

154. The above misrepresentations were material to the transaction; but for these affirmative misrepresentations, Plaintiff would not have purchased Defendants' GBCAs.

155. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of their GBCAs described herein, owed a duty to provide accurate and complete information regarding these GBCAs.

156. Defendants have made false statements of material facts, of which Defendants knew or believed to be false, with an intention of inducing Plaintiff and/or her healthcare providers to act upon them.

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

158. Defendants misrepresented material facts and information regarding their GBCAs including, but not limited to, their propensity to cause serious physical harm.

159. Defendants misrepresented that their GBCAs caused few, if any, adverse reactions and side effects.

160. However, Defendants' GBCAs are not safe and are dangerous to the health of their users because they have a propensity for causing severe side effects, including retention in bone and organs and fibrosis.

161. Defendants made these misrepresentations to the FDA, the public, patients, physicians, and the healthcare community at large, throughout Defendants' pre- and postmarketing period and continuing to the present.

162. Defendants made these misrepresentations to Plaintiff and her healthcare providers, with the intent to induce Plaintiff and her healthcare providers to use and prescribe their GBCAs, and with the intent to defraud Plaintiff and her healthcare providers.

163. Defendants made these misrepresentations prior to Plaintiff's physicians prescribing Plaintiff Defendants' GBCA.

164. Defendants made these misrepresentations in advertisements, marketing, commercials, promotional materials, reports, press releases, campaigns, and instructional material and labeling.

165. Defendants made these misrepresentations in their patient labeling provided

to Plaintiff.

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

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

168. Defendants defrauded prescribing physicians, patients, the public, Plaintiff, and Plaintiff's physicians in making these misrepresentations.

169. At the time of Defendants' misrepresentations and omissions, Plaintiff was unaware of the falsity of the statements and reasonably believed them to be true.

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

171. Plaintiff and her healthcare practitioners had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate misrepresentations.

172. Plaintiff and her healthcare practitioners were deceived by Defendants' misrepresentations.

173. Plaintiff and her healthcare providers relied on the aforesaid misrepresentations in selecting and using Defendants' GBCA.

174. Upon information and belief, Defendants have omitted or concealed the dangers of their GBCAs in the

following ways:

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

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

c) Concealing their knowledge that gadolinium is retained in bones, skin, and other organs in people with normal renal function;

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

e) Concealing their knowledge that Gadolinium retention is longest in bone and varies by organ;

f) Concealing their knowledge that linear GBCAs cause more retention than macrocyclic GBCAs;

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

h) Concealing their knowledge that certain patients are a higher risk of adverse effects from linear GBCAs;

i) Concealing their knowledge that gadolinium retention causes adverse health effects;

j) Concealing their knowledge the gadolinium retention causes pain, fibrosis, loss of mobility, among other things; and

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

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

176. Defendants have defrauded Plaintiff and her healthcare providers into the reasonable belief that Defendants' GBCA is safe and effective and does not cause injuries by the omission, suppression, and concealment of these material facts.

177. Defendant omitted the above information in order to induce Plaintiff, her healthcare providers, the healthcare community, patients, and the public to act by purchasing Defendants' GBCA.

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

179. Defendants had a duty and obligation to disclose to Plaintiff and Plaintiff's healthcare providers that Defendants' GBCAs were dangerous and likely to cause serious health consequences to users when used as prescribed.

180. Defendants had a duty to disclose to Plaintiff and Plaintiff's healthcare providers that their GBCAs cause and/or contribute to serious injuries as described in this complaint.

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

182. Defendants induced Plaintiff and her healthcare providers to choose their GBCAs by inducing them to believe that this GBCA is safe in patients with normal renal function.

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

184. These misrepresentations as to Optimark were made prior to, on or around January 19, 2013. These misrepresentations as to Multihance were made prior to, on or around August 11, 2015 and November 8, 2016.

185. As a direct and proximate result of said Defendants' violation of A.S.R. §§ 4-1521 through 44-1534, Plaintiff has suffered damages as aforesaid and is entitled to all remedies available under these statutory provisions.

PRESERVATION CLAIMS

186. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

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

STATUTE OF LIMITATIONS ALLEGATIONS

188. Plaintiff incorporates by reference all other paragraphs of this Complaint as

if fully set forth herein.

189. To the extent that Defendants may claim that one or more of Plaintiff's claims are barred by the applicable statute of limitations, Plaintiff asserts that the statute of limitations has been tolled by Plaintiff's delayed discovery that her injuries were caused by Defendants' defective product and failure to properly and adequately warn of the product's risks, all as more fully set forth in this Complaint. Specifically, the Plaintiff could not reasonably have discovered, and in fact did not discover, that her injuries were caused by the Defendants' defective product and/or the wrongful conduct of the Defendants until she learned that many other patients had also suffered similar injuries after being administered GBCAs.

190. Plaintiff first learned of her gadolinium retention in May 2017 as a result of a heavy metal urine test result and prior to that date did not know nor have reason to suspect that gadolinium caused her symptoms.

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

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

PUNITIVE DAMAGES ALLEGATIONS

193. Plaintiff incorporates by reference all other paragraphs of this Complaint as

if fully set forth herein.

194. At all times relevant herein, Defendants:

a) knew that their GBCA was dangerous;

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

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

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

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

196. Defendants consciously and deliberately engaged in wanton disregard of the rights and safety of the Plaintiff.

197. Defendants had actual knowledge of their GBCA's defective nature and capacity to cause injury including, but not limited to, retention of gadolinium in organs and

tissues (e.g., brain, heart, liver, kidney, bones, and skin), resulting fibrosis in organs, bone, and skin, and gadolinium's tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

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

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

PRAYER FOR RELIEF

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

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

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

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

(d) For compensatory damages in excess of the jurisdictional minimum of this Court according to the proof at trial;

(e) For consequential damages in excess of the jurisdictional minimum of this Court according to proof at trial;

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

conduct in the future according to the proof at trial;

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

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

DEMAND FOR JURY TRIAL

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

Dated: February 22, 2019.

CLAUSEN & WILLIAMSON, PLLC and CUTTER LAW, PC

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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): **Candice Drescher**

Defendant(s): **Bracco Diagnostics, Inc ; Guerbet LLC ; Mallinckrodt Inc. ; Mallinckrodt LLC ; Liebel-Flarsheim Company LLC**

County of Residence: Pima

County of Residence: Outside the State of Arizona

County Where Claim For Relief Arose: Outside the State of Arizona

Plaintiff's Atty(s):

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9162909400

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Arizona 85018

Defendant's Atty(s):

II. Basis of Jurisdiction: **4. Diversity (complete item III)**

III. Citizenship of Principal Parties **(Diversity Cases Only)**

Plaintiff:- **1 Citizen of This State**
Defendant:- **2 Citizen of Another State**

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **365 Personal Injury - Product Liability**

VI.Cause of Action: **Inadequate warning, defective design, negligence, breach of express warranty, negligence misrepresentation, violation of consumer protection**

laws.

VII. Requested in Complaint

Class Action: **No**

Dollar Demand:

Jury Demand: **Yes**

VIII. This case **IS RELATED** to Case Number **2:18-cv-01157-DGC, 2:18-cv-01778-DGC, 2:18-cv-01159-DGC** assigned to Judge **David G. Campbell.**

Signature: C. Brooks Cutter

Date: 2/21/2019

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014