UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

JAMES TOUPS and EMILY TOUPS,

Plaintiffs,

vs.

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; and BAYER HEALTHCARE LLC;

Defendants.

Civil Action No.

ORIGINAL 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
8) LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

COMES NOW Plaintiffs, JAMES TOUPS and EMILY TOUPS, by and through undersigned counsel, and alleges as follows:

INTRODUCTION

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 drug Magnevist, gadolinium-based contrast agent used in MRIs.

3. Plaintiff maintains that Magnevist is 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 Magnevist does not wash out of the patient's body as readily as promised, and instead can be retained indefinitely or permanently in multiple organs and soft tissues (e.g., brain, heart, liver, kidney, bones, and skin) in patients with normal renal function. This gadolinium, a toxic heavy metal, causes fibrosis in organs, bone, and skin, other adverse reactions, and crosses the blood-brain barrier and deposits 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 the State of Louisiana. As set forth more fully below, all Defendants are entities organized in states other than the State of Louisiana, have their principal places of business in states other than Louisiana, and none of the Defendants is a citizen or resident of the State of Louisiana.

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

8. This Court has general jurisdiction over Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation and Bayer Healthcare, as these Defendants sell, advertise, market and/or distribute Magnevist within the Eastern District of Louisiana, and do substantial business in this state and within this District.

9. This Court has personal jurisdiction over all Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in this state, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including Magnevist, to the residents of this state.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the Defendants conduct business in the Eastern District of Louisiana and are subject to personal jurisdiction in this District. Defendants sell, advertise, market and/or distribute Magnevist within the Eastern

District of Louisiana, and do substantial business in this state and within this District.

11. Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold Magnevist in interstate commerce.

PARTIES

12. Plaintiff JAMES TOUPS is a natural person and at all relevant times a resident and citizen of the State of Louisiana.

13. Plaintiff EMILY TOUPS (hereafter referred to as "Spouse Plaintiff") is a natural person and at all relevant times a resident and citizen of the State of Louisiana,

14. Plaintiff JAMES TOUPS was injected with the linear gadolinium-based contrast agent ("GBCA") Magnevist prior to receiving a MRI on or around February 15, 2017.

15. Unbeknownst to him and contrary to the Defendant's 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, Mr. Toups continues to have retained gadolinium in his body years after being administered the GBCAs, resulting in permanent physical and emotional injuries. He did not realize the connection between his use of linear GBCAs and his injuries until in or around December 2018.

16. 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, causes fibrosis in organs, bone, and skin, other adverse reactions, and crosses the blood-brain barrier and deposits in the neuronal nuclei of the brain.

17. 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 his healthcare providers about the risks of gadolinium retention in patients with normal renal function.

18. Upon information and belief, Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation and Bayer Healthcare LLC manufacture, test, market, advertise, and sell the linear GBCA named Magnevist.

19. Upon information and belief, Defendant Bayer Healthcare Pharmaceuticals, Inc. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

20. Bayer Healthcare Pharmaceuticals, Inc. is, and at all relevant times was, engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities.

21. Upon information and belief, Bayer Healthcare Pharmaceuticals, Inc. is owned by Defendant Bayer Corporation.

22. Upon information and belief, Defendant Bayer Corporation is, and at all relevant times was, a corporation organized under the laws of the State of Indiana, with its principal place of business in the State of Pennsylvania.

23. Bayer Corporation is, and at all relevant times was, engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities.

24. Upon information and belief, Defendant Bayer Healthcare LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of

Delaware, with its principal place of business in the State of New Jersey.

a) Upon information and belief, from on or about the early January 1, 2003 until on or about late December, 2014, Bayer Healthcare LLC's sole member was Bayer Corporation, and is wholly owned by Bayer Corporation, which is an Indiana corporation with its principal place of business in Pennsylvania.

b) Upon information and belief, from on or about early January, 2015 to on or about June 30, 2015, Bayer Healthcare LLC's sole member was Bayer Medical Care, Inc., and is wholly owned by Bayer Medical Care, Inc., which is a Delaware Corporation, with its principal place of business in Pennsylvania.

c) Upon information and belief, from on or about July 1, 2015 to the present, Bayer Healthcare LLC's members are:

i) Bayer Medical Care Inc., a Delaware corporation with its principal place of business in Pennsylvania;

ii) NippoNex Inc., a Delaware corporation with its principal place of business in New York;

iii) Bayer West Coast Corporation, a Delaware Corporation with its principal place of business in California;

iv) Bayer Essure Inc., a Delaware corporation with its principal place of business in California;

v) Bayer Consumer Care Holdings, LLC, a limited liability company formed in Delaware with its principal place of business in New Jersey;

vi) Dr. Scholl's LLC, a limited liability company, formed in Delaware with its principal place of business in California;

vii) Coppertone LLC, a limited liability company, formed in Delaware with its principal place of business in California;

viii) MiraLAX LLC, a limited liability company, formed in Delaware with its principal place of business in California; and,

ix) Bayer HealthCare U.S Funding LLC, a limited liability company a limited liability company, formed in Delaware with its principal place of business in Pennsylvania.

25. Accordingly, Bayer Healthcare LLC is a citizen of Delaware, New Jersey, New York, Indiana, Pennsylvania, and California for purposes of determining diversity under 28 U.S.C. § 1332.

26. Upon information and belief, Defendant Bayer Healthcare LLC is, and at all relevant times was, engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities.

27. As used herein, "Defendants" includes Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation and Bayer Healthcare LLC.

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

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

30. Upon information and belief, Defendants did act together to design, sell, advertise,

manufacture, promote and/or distribute Magnevist, with full knowledge of its dangerous and defective nature.

FACTS COMMON TO ALL CAUSES OF ACTION

31. 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 GBCA. Plaintiff had no preexisting disease or subsequently developed disease of an alternate known process to account for the symptoms he sustained. Gadolinium retention can be a progressive condition for which there is no known cure.

32. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear GBCAs, 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 GBCAs.

33. Defendants failed to warn Plaintiff and his 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).

34. As a direct and proximate result of receiving injections of linear GBCAs manufactured, distributed, marketed, and/or sold by Defendants, Plaintiff developed gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

35. Had Plaintiff and/or him healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, he would not have been administered linear GBCAs and would not have been afflicted with gadolinium retention resulting in injuries.

36. As a direct and proximate result of Plaintiff being administered linear GBCAs, he has suffered severe physical injury and pain, including, but not limited to, gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

37. As a direct and proximate result of being administered linear GBCAs, 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.

38. As a direct and proximate result of being administered linear GBCAs, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

39. The nature of Plaintiff's injuries and damages, and their relationship to linear GBCAs, were not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff prior to December 2018 when he became aware of the connection between his condition and linear GBCAs.

40. Accordingly, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through reasonable care and diligence should have known, of his claims against Defendants, and in any event such tolling should continue until at least December 2018.

41. Meanwhile, unknown 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 about such retention have been misleading and false.

42. In 1984 – prior to FDA approval – the inventors of linear GBCAs 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]

43. 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. More specifically, linear GBCAs consist gadolinium linked to a larger open-chained molecule (a ligand). Macrocyclic GBCAs

[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.

consist of gadolinium linked to a cyclic ligand. The linear GBCAs are chemically less stable in terms of their tendency to release gadolinium ions; the macrocyclic GBCAs tend to stay intact. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured by Guerbet/ Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

44. Magnevist, the linear agent manufactured by Defendants, 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 in a paper 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 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.

45. 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]

46. 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]

47. The lack of stability seen within the linear agents was dismissed as a cause of

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[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.

[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.

concern by the Defendants, who 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 GBCAs would later be discovered.

48. 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]

49. 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]

50. 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.

51. 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 GBCAs pose to people with normal kidney function for years. In fact, pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal

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[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.

function.[8]

52. 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.

53. 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.

54. Dermatologists, nephrologists, and other scientists connected the administration of linear GBCAs to a rapidly progressive, debilitating and often fatal condition called gadolinium-induced Nephrogenic Systemic Fibrosis (NSF). This, in turn, prompting 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).

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

56. There were over 500 NSF cases reported and it was estimated to be well over a 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

[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.

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.

57. 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. They found that the brain had hyper intense signals in critical areas of the brain.[10]

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

59. 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 was evaluating the risk of brain deposits from repeated use of GBCAs used in MRIs.

60. 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.

61. On May 21, 2018, the GBCA manufacturers finally issued a joint warning (i.e. "Dear Health Care Provider" letter) to medical providers about the risks of GBCAs in patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

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[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.

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

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 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, including:
    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 to 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.

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

63. 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 their 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 because of their intentional concealment of those facts.

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

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

65. Magnevist was manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants and was defective at the time it left Defendants' control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of linear GBCAs.

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

67. Prescribing physicians, healthcare providers and patients, including Plaintiff and his healthcare providers, neither knew, nor had reason to know at the time of their use of Magnevist, 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.

68. At all times alleged herein, the Magnevist were prescribed to and used by Plaintiff

as intended by Defendants and in a manner reasonably foreseeable to Defendants. The Magnevist injected into Plaintiff's body was neither misused nor materially altered.

69. Defendants are strictly liable for failure to warn by virtue of its conduct of selling products that are unreasonably dangerous and for failing to provide an adequate warnings about Magnevist.

70. 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 Magnevist 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 Magnevist 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 patient with normal renal function;

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

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

(i) Failing to disclose to patients that Magnevist increased the risk of fibrosis in patients with normal renal function.

71. Had Plaintiff and his medical providers been adequately warned of the risks associated with Magnevist, Plaintiff would not have used Magnevist.

72. Had Plaintiff not taken Magnevist, Plaintiff would not have suffered injuries and damages as set forth herein.

73. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered 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)
NEGLIGENCE

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

75. 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 Magnevist, and post-marketing vigilance regarding same. Defendants knew or should have known that injecting Magnevist into the bodies of patients created an unreasonable risk of dangerous side effects, including gadolinium retention.

76. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled Magnevist

77. 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 Magnevist;

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

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

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to Magnevist'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;

e) Defendants represented in Magnevist's package insert/prescribing information that "Gadopentetate dimeglumine does not cross the intact blood-brain barrier and, therefore, does not accumulate in normal brain or in lesions that do not have an abnormal blood-brain barrier, e.g., cysts, mature postoperative scars, etc." when, in fact, Defendants knew or should have known that Magnevist can cross the blood-brain barrier in patients that no not have abnormal blood-brain barrier and deposit in the neuronal nuclei of the brain;

f) Defendants represented in Magnevist's package insert/prescribing information that "Gadopentetate is eliminated" from the body when Defendants knew or should have known that gadolinium deposits may be present for months to years in bone, liver, skin, brain, and other organs;

g) In representing that Magnevist was safe for its intended use when, in fact, the drug was unsafe for its intended use;

h) In failing to perform appropriate pre-market testing of Magnevist;

i) In failing to perform appropriate post-market surveillance of Magnevist;

j) In failing to perform appropriate post-marketing testing of Magnevist; and

k) In failing to disclose that Magnevist increased the risk of fibrosis in patients with normal renal function; and

l) In failing to disclose adverse event reports with Magnevist involving

multiple organ systems in patients with normal renal function.

78. Because of the adverse effects gadolinium retention can have on patients with normal renal function, Defendants should have promptly disclosed any increase in gadolinium retention risk to patients with normal renal function arising from exposure to GBCAs. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care.

79. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries and economic loss, including, but not limited to, gadolinium retention in multiple organs and tissues, which Plaintiff will continue to suffer. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

80. Had Plaintiff not been injected with Magnevist, Plaintiff would not have suffered those injuries and damages as described hereon. Had Defendants marketed Magnevist in a truthful and non-misleading manner and/or had Defendants corrected the misrepresentations and adequately warned, Plaintiff would not have been injected with Magnevist.

81. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has suffered severe and permanent physical and emotional injuries and economic loss, and will require lifelong medical treatment, monitoring and/or medications.

82. WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

THIRD CAUSE OF ACTION
(Against All Defendants)
NEGLIGENT MISREPRESENTATION

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

84. Defendants falsely and negligently misrepresented material facts on which Plaintiff and his healthcare providers acted.

85. Defendants failed to disclose material facts regarding the safety and efficacy of Magnevist with respect to patients with normal renal function.

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

87. In violation of existing standards and duties of care, Defendants 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.

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

(a) "Magnevist does not cross the intact blood-brain barrier" when Defendants knew or should have known that Magnevist can cross the intact blood-brain barrier;

(b) "Gadopentetate is eliminated" from the body when Defendants knew or should have known that gadolinium deposits may be present for months to years in bone, liver, skin, brain, and other organs;

(c) Gadolinium was safe and effective for patients with normal renal function;

(d) Gadolinium had been adequately tested and studied in patients; and

(e) Gadolinium did not increase the risk fibrosis in patients with normal renal function.

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

90. When Plaintiff used Magnevist, Plaintiff was unaware of the falsity of Defendants' said representations and reasonably believed them to be true.

91. In reasonable reliance upon said representations, Plaintiff's prescribers were induced to prescribe Magnevist and recommend the drug as safe for use in conjunction with MRI,

and Plaintiff was induced to and did use Magnevist when undergoing MRI. Had Defendants not made the foregoing express and implied false statements about Magnevist, Plaintiff would not have used the GBCAs and his medical providers would not have administered it and recommended it as safe.

92. Defendants' labeling of Magnevist was also rendered misleading by the omission of the material risk information listed in the preceding count.

93. Plaintiff and his healthcare providers justifiably relied on Defendants' representations and non-disclosures when using Magnevist.

94. At the time Plaintiff received injection of Magnevist, Defendants knew that Magnevist had not been sufficiently tested for gadolinium retention and lacked adequate warnings.

95. At the time Plaintiff received injection of Magnevist, Defendants knew or should have known that the use of Magnevist by patients with normal renal function increases the risk of gadolinium retention and resulting injuries

96. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably use Magnevist and that they and their prescribing healthcare providers would rely upon the representations and omissions.

97. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

FOURTH CAUSE OF ACTION
(Against All Defendants)
NEGLIGENCE PER SE

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

99. Defendants 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 Magnevist, and post-market vigilance regarding same.

100. Defendants 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 Magnevist, and post-market vigilance regarding same.

101. At all times material hereto, under federal law governing labeling for of Magnevist, Defendants were 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.

102. Prior to 2006, federal law also required Defendants to revise Magnevist'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. Breach of this duty is an independent breach of state law.

103. Defendants 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, in particular. The violations constitute independent violations of state negligence law.

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

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

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

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

108. Had Plaintiff not taken Magnevist, he would not have suffered injuries and damages.

109. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

FIFTH CAUSE OF ACTION
(Against All Defendants)
BREACH OF EXPRESS WARRANTY

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

111. Drug manufacturers, such as Defendants, 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)

112. At the time Plaintiff's medical providers prescribed Magnevist to him, and at the time Plaintiff was infused with the drug, the "Pharmacokinetics" section of the Magnevist label represented that "Gadopentetate is eliminated" from the body. This statement is specific and unequivocal in asserting that gadolinium is eliminated from the body.

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

114. At the time of the making of these express warranties, Defendants 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.

115. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff, relied upon the representations and warranties of Defendants for use of Magnevist in recommending, prescribing, and/or using the drug.

116. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

SIXTH CAUSE OF ACTION
(Against All Defendants)
BREACH OF IMPLIED WARRANTIES

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

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

119. Defendants breached the implied warranties, as Magnevist were not safe and fit for use by patients with normal renal function.

120. Defendants were aware that consumers, including Plaintiff, would use Magnevist for the purpose intended and warranted by Defendants.

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

122. Plaintiff and him physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Magnevist were of merchantable quality and safe and fit for their intended use.

123. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

SEVENTH CAUSE OF ACTION
(Against All Defendants)
FRAUDULENT MISREPRESENTATION AND CONCEALMENT

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

125. Defendants fraudulently represented to consumers and the medical and healthcare community, including Plaintiff and their providers, that:

(a) Magnevist was safe and effective for patients with normal renal function;

(b) the use of Magnevist in patients with normal renal function did not increase the risk of gadolinium retention;

(c) Magnevist had been adequately tested and studied in patients with normal renal function;

(d) "Gadopentetate is eliminated" from the body.

(e) "Magnevist does not cross the intact blood-brain barrier."

152. At the time Defendants made these representations, Defendants knew the representations were false and misleading.

153. Defendants' representations regarding Magnevist were material, false, misleading and made with actual or constructive knowledge that they were false.

154. Defendants made these representations with the intent of defrauding and deceiving healthcare providers and Plaintiff to recommend, prescribe, dispense and/or purchase Magnevist to treat patients with normal renal function.

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

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

159. Had Defendants not made the false statements about Magnevist, Plaintiff would not have used the product and his medical providers would not have administered it and recommended it as safe.

160. Defendants are and were under a continuing duty to monitor and disclose the risks of Magnevist for use with MRIs. They have fraudulently concealed the risks and their knowledge of them. Defendants' 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 Magnevist use with MRIs. Their fraudulent concealment also prevented Plaintiff from discovering, and/or with reasonable diligence being able to discover his cause of action.

161. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

EIGHTH CAUSE OF ACTION
(Against All Defendants)
LOSS OF CONSORTIUM

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

163. At all relevant times hereto, Plaintiff had a Spouse Plaintiff, EMILY TOUPS, who has suffered injuries and losses as a result of the Plaintiff's injuries from Defendants' GBCAs.

164. For the reasons set forth herein, Spouse Plaintiff has necessarily paid and has become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

165. For the reasons set forth herein, Spouse Plaintiff has suffered and will continue to suffer the loss of her loved one's support, companionship, services, society, love and affection.

166. For Spouse Plaintiff, Plaintiffs' allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

167. Spouse Plaintiff has suffered great emotional pain and mental anguish.

168. As a direct and proximate result of the foregoing acts and omissions, Spouse Plaintiff has sustained and will continue to sustain severe emotional pain and mental anguish,

economic losses and other damages for which she is entitled to compensatory and equitable damages in an amount to be proven at trial.

PUNITIVE DAMAGES

169. At all times material hereto, Defendants knew or should have known that their GBCAs, including Magnevist, were inherently dangerous to patients with normal renal function, including Plaintiff.

170. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their GBCAs, including Magnevist.

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

172. At all times material hereto, Defendants 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.

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

174. Defendants knew that their 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 Magnevist, 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.

175. Defendants' 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.

176. Defendants' 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 Defendants and deter them from similar conduct in the future.

177. As a direct and proximate result of the foregoing acts, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

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;

(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 Magnevist;

(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 Defendants 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.

Dated: April 26, 2019

THE CHEEK LAW FIRM LLC

By: /S/ Lindsey Cheek

THE CHEEK LAW FIRM LLC
Lindsey Cheek, LA Bar No. 34484
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-AND-

NAPOLI SHKOLNIK PLLC
Christopher L. Schnieders
(Pro Hac Vice to be filed)
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Attorneys for Plaintiffs

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

JAMES TOUPS and EMILY TOUPS,

(b) County of Residence of First Listed Plaintiff St. John the Baptist, LA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

DEFENDANTS

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; and BAYER HEALTHCARE LLC

County of Residence of First Listed Defendant Morris 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

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

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

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

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

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

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

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

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

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

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

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 USC 1332, 28 USC 1367, 28 USC 1391

Brief description of cause:
Personal injury due to health care product liability

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
04/26/2019

SIGNATURE OF ATTORNEY OF RECORD
/s/ Lindsey Cheek

FOR OFFICE USE ONLY

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

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.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JAMES TOUPS AND EMILY TOUPS

Plaintiff(s)

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; AND BAYER HEALTHCARE LLC

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BAYER CORPORATION
CORPORATION SERVICE COMPANY
501 LOUISIANA AVENUE
BATON ROUGE, LA 70802

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JAMES TOUPS AND EMILY TOUPS

Plaintiff(s)

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; AND BAYER HEALTHCARE LLC

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

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CORPORATION SERVICE COMPANY
501 LOUISIANA AVENUE
BATON ROUGE, LA 70802

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JAMES TOUPS AND EMILY TOUPS

Plaintiff(s)

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; AND BAYER HEALTHCARE LLC

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BAYER HEALTHCARE LLC.
CORPORATION SERVICE COMPANY
501 LOUISIANA AVENUE
BATON ROUGE, LA 70802

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset