UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JOHN M. CARNEY, Plaintiff, v. GUERBET, LLC, MALLINCKRODT, INC., MALLINCKRODT LLC, and LIEBEL-FLARSHEIM COMPANY LLC, Defendants.	)	Case No. **DEMAND FOR JURY TRIAL**

COMPLAINT FOR DAMAGES

Come now Plaintiff JOHN M. CARNEY ("Plaintiff") and alleges as follows:

PARTIES AND BACKGROUND

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. Plaintiff JOHN M. CARNEY resides in Dividing Creek, New Jersey. He was injected with a linear gadolinium-based contrast agent ("GBCAs") prior to receiving an MRI. Contrary to the Defendant's promotion of GBCAs as being benign contrast agents that harmlessly exit the body shortly after administration in patients with normal kidney function, Plaintiff continues to have retained gadolinium in his body, years after being administered the GBCAs.

3. Plaintiff's primary injuries alleged herein are related to gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, causes fibrosis in organs, bone, and skin, and crosses the blood-brain barrier and deposits in the neuronal nuclei of the brain.

4. Plaintiff was never warned about the risks of gadolinium retention because he had normal renal function and the GBCA manufacturers chose to only provide warnings to patients with reduced renal function.

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

6. Defendant Guerbet, LLC is a Delaware corporation with its principal place of business in Indiana. The sole officer of Guerbet, LLC, Mr. Massimo Carrara, resides in Indiana. Guerbet, LLC is wholly owned by Guerbet S.A., and Guerbet S.A. is the only member of Guerbet, LLC. Guerbet S.A. is a publicly traded company organized under the laws of France. Guerbet S.A.'s principal place of business is in Villepinte, France. Accordingly, Guerbet, LLC is a citizen of France for purposes of determining diversity under 28 U.S.C. § 1332. 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.

7. Defendant Mallinckrodt Inc. is a Delaware corporation with its principal place of business in St. Louis, 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.

8. Defendant Mallinckrodt LLC is a Delaware corporation with its principal place of business in St. Louis, Missouri. Mallinckrodt LLC and Mallinckrodt Inc. are indirect affiliates of Mallinckrodt plc, a publicly owned corporation. Mallinckrodt LLC operates as a subsidiary of Mallinckrodt Public Limited Company. Mallinckrodt Public Limited Company's principal place of business is in Staines-Upon-Thames, the United Kingdom. Accordingly, Mallinckrodt LLC is a citizen of the United Kingdom for purposes of determining diversity under 28 U.S.C. § 1332. 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.

9. Defendant Liebel-Flarsheim Company LLC is a Delaware corporation with its principal place of business in St. Louis, Missouri. Liebel-Flarsheim Company, LLC is a limited liability corporation organized under the laws of Delaware. The sole member of Liebel-Flarsheim Company, LLC is Liebel-Flarsheim Company Ireland, Limited, a privately-held company organized under the laws of Ireland. Liebel-Flarsheim Company Ireland, Limited's principal place of business is in Dublin, Ireland. Accordingly, Liebel-Flarsheim Company LLC is a citizen of Ireland for purposes of determining diversity under 28 U.S.C. § 1332. 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.

10. Defendants Guerbet, LLC, Mallinckrodt Inc., Mallinckrodt LLC, and Liebel-Flarsheim Company LLC shall hereinafter be collectively referred to as "Defendants."

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of New Jersey. As set forth more fully above, all Defendants are entities organized in states other than the State of New Jersey, all Defendants have their principal place of business in a state other than the State of New Jersey, and none of the Defendants is a citizen or resident of the State of New Jersey. Defendants Mallinckrodt Inc., Mallinckrodt LLC, and Liebel-Flarsheim Company LLC all have their principle places of business in St. Louis, Missouri.

12. This Court has personal jurisdiction over 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 GBCA's of the type received by Plaintiff, to the residents in this State.

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants marketed, advertised, and distributed the dangerous product in this District, Defendants do substantial business in this State and within this District, and Defendants

developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold the referenced GBCAs in interstate commerce.

FACTS COMMON TO ALL CAUSES OF ACTION

14. Plaintiff underwent an MRI during which he was injected with the linear GBCA OptiMark. Plaintiff had normal kidney function at the time he was injected with this GBCA. The gadolinium that Plaintiff was injected with was retained in his body and resulted in fibrosis in his organs, skin, and bones, retained gadolinium in the neuronal nuclei of his brain, and related injuries.

15. The type of gadolinium retention sustained by Plaintiff occurs in patients with normal or near-normal renal function that 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.

16. 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

17. Defendants failed to warn Plaintiff and his 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).

18. 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 his organs, skin, and bones, retained gadolinium in his brain, and related injuries.

19. Defendants have repeatedly and consistently failed to advise consumers and their healthcare providers of the causal relationship between linear gadolinium-based contrast agents and gadolinium retention resulting in fibrosis in the organs, skin, and bones, retained gadolinium in the brain, and related injuries. Defendants knew or should have known of the risks posed by linear gadolinium-based contrast agents to individuals with normal or near-normal kidney function.

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

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

22. 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.

23. 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.

24. The nature of Plaintiff's injuries and damages, and their relationship to linear gadolinium-based contrast agents, were not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than two years before the filing of this complaint.

25. 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.

26. 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]

27. 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 Defendants), and MultiHance (manufactured by Bracco).

[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.

28. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988.

29. In 1988 it was recognized that gadolinium was breaking free from the bonds in the linear-based contrast agents and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron.[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.

30. 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]

31. 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]

32. The lack of stability seen within the linear agents was dismissed as an issue by the defendants claiming that the GBCA's were excreted out of the body according to the drug's

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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.

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.

33. 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]

34. 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]

35. 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.

36. 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

[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.

the risks that linear gadolinium-based contrast agents pose to people with normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[8]

37. 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.

38. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their products, or anywhere that a patient or physician could be informed.

39. 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), prompting the Food and Drug Administration (FDA) to issue a black box warning 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) on all gadolinium-based contrast agents in 2007.

40. Defendants corrected their label to include contraindications for use in people with kidney disease and acute kidney injury.

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

[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.

non-reported. There was a prior MDL and other litigation involving NSF against the defendants in the current litigation. A trial in that litigation resulted in a verdict in favor of the plaintiff and against GE. The litigation resolved and the MDL was formally closed in 2015. Due to the new black box warning in the GBCA's labelling, doctors stopped using GBCAs in patients with abnormal kidney function. However, the warnings for patients with normal kidney function remained unchanged until May 21, 2018, and as a result the linear GBCAs continued to be widely used and marketed notwithstanding the Defendants' knowledge of the dangers of the product. This case and the others pending throughout the country involve widespread fibrosis and other symptoms in the bodies of patients with normal kidney function.

42. The vast majority of the medical community was not aware, until recently, of any disease that was associated with gadolinium other than NSF, which was defined as only occurring in patients with renal failure.

43. Gadolinium toxicity is, therefore, an underreported and underdiagnosed condition. Over the past several years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients with normal renal function have been forming advocacy groups and coming forward to create awareness for their condition. Symptomatic patients often have documentation of high levels of gadolinium in their blood and urine long after their exposure to gadolinium-based contrast agents. Many patients also have tissue biopsies of various parts of their body that show additional evidence of retained gadolinium years after their exposure.

44. Some patients sent several strongly worded letters with scientifically-supported research data to the FDA, warning about the occurrence of gadolinium toxicity in those with normal renal function following injections of gadolinium-based contrast agents. Correspondence was confirmed as early as 2012.

45. 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 up to several years prior. They found that the brain had hyperintense signals in critical areas of the brain.[10]

46. 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 gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.[11]

47. 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.

48. 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 normal kidney function.

49. On May 21, 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

[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.

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:

   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.

The Warning deliberately downplays the state of the evidence concerning the health effects of

gadolinium retention.

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

COUNT I – STRICT PRODUCT LIABILITY: FAILURE TO WARN

(Against All Defendants)

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

52. Defendants' linear gadolinium-based contrast agents were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

53. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers yet Defendants failed to adequately warn consumers and their healthcare providers of such risks.

54. As a result of Defendants' failure to provide adequate warnings for their products, Plaintiff was unknowingly injected with dangerous linear gadolinium-based contrast agents which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce.

55. The linear GBCAs injected into Plaintiff are the legal cause of Plaintiff's serious physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the future.

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

damages.

COUNT II - NEGLIGENCE

(Against All Defendants)

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

58. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and distribution of their linear gadolinium-based contrast agents. In particular, they had a duty to ensure that their products did not pose an unreasonable risk of bodily harm and adverse events.

59. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of their linear gadolinium-based contrast agents in that they knew or should have known that these products could cause significant bodily harm or death, and were not safe for use by consumers.

60. Defendants failed to exercise ordinary care in the labeling of their linear gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury due to the use of linear GBCAs.

61. Despite the fact that Defendants knew or should have known that their linear gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market linear gadolinium-based contrast agents and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

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

63. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered

physical injuries, emotional injuries, harm, non-economic and economic damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

a) Non-economic damages including pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

b) Economic damages including past and future medical expenses, past and future loss of income, loss of earning capacity, and other economic damages in an amount to be determined at trial of this action;

c) Punitive damages as allowed by law and in an amount to be determined at the time of trial of this action;

d) Pre-judgment and post-judgment interest;

e) Attorneys' fees, expenses, and costs; and

f) Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

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

Dated: September 6, 2018

BAILEY & GLASSER LLP

By: /s/ Jeffrey Baron

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

JOHN M. CARNEY

(b) County of Residence of First Listed Plaintiff 99999 - NJ
(EXCEPT IN U.S. PLAINTIFF CASES)

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

See Attachment A for complete list.

DEFENDANTS

Guerbet, LLC, Mallinckrodt,

County of Residence of First Listed Defendant St. Louis County
(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	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 7,500.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE 09/06/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Jeffrey R. Baron

FOR OFFICE USE ONLY

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

CIVIL COVER SHEET FOR JOHN M. CARNEY v. GUERBET, LLC

ATTACHMENT A

I.

(a) JOHN M CARNEY v. Guerbet, LLC, et al.

(b) Jeffrey R. Baron, Bar No. 54713
Benjamin L. Bailey (*Pro Hac Vice to be filed*)
P. Gregory Haddad (*Pro Hac Vice to be filed*)
Amy S. Rubin, (*Pro Hac Vice to be filed*)
David L. Selby, II (*Pro Hac Vice to be filed*)
8012 Bonhomme Avenue, Suite 300
Clayton, MO 63105
Tel: (314) 863-5446
Fax: (314) 863-5483
Email: *jbaron@baileyglasser.com*
Email: *bbailey@baileyglasser.com*
Email: *ghaddad@baileyglasser.com*
Email: *arubin@baileyglasser.com*
Email: *dselby@baileyglasser.com*

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

JOHN M. CARNEY,

,

Plaintiff,

v.

GUERBET, LLC, et al.

,

Defendant,

Case No.

ORIGINAL FILING FORM

THIS FORM MUST BE COMPLETED AND VERIFIED BY THE FILING PARTY WHEN INITIATING A NEW CASE.

☐ THIS SAME CAUSE, OR A SUBSTANTIALLY EQUIVALENT COMPLAINT, WAS PREVIOUSLY FILED IN THIS COURT AS CASE NUMBER _____ AND ASSIGNED TO THE HONORABLE JUDGE _____.

☐ THIS CAUSE IS RELATED, BUT IS NOT SUBSTANTIALLY EQUIVALENT TO ANY PREVIOUSLY FILED COMPLAINT. THE RELATED CASE NUMBER IS _____ AND THAT CASE WAS ASSIGNED TO THE HONORABLE _____. THIS CASE MAY, THEREFORE, BE OPENED AS AN ORIGINAL PROCEEDING.

☒ NEITHER THIS SAME CAUSE, NOR A SUBSTANTIALLY EQUIVALENT COMPLAINT, HAS BEEN PREVIOUSLY FILED IN THIS COURT, AND THEREFORE MAY BE OPENED AS AN ORIGINAL PROCEEDING.

The undersigned affirms that the information provided above is true and correct.

Date: 09/06/2018

/s/ Jeffrey R. Baron
Signature of Filing Party

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

JAMES M. CARNEY

Plaintiff

v.

GUERBET, LLC, MALLINCKRODT, INC., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

GUERBET, LLC
Serve Registered Agent:
C.T. CORPORATION SYSTEM
120 South Central Avenue
Clayton, Missouri 63105

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:

Jeffrey R. Baron
BAILEY & GLASSER LLP
8012 Bonhomme Avenue
Suite 300
Clayton, Missouri 63105
314-863-5446

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:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

JAMES M. CARNEY

Plaintiff

v.

GUERBERT, LLC, et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Mallinckrodt, Inc.
Serve Registered Agent
Secretary of State
State of Missouri
600 West Main
Jefferson City, Missouri 65102

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:

Jeffrey R. Baron
BAILEY & GLASSER LLP
8012 Bonhomme Avenue
Suite 300
Clayton, Missouri 63105
314-863-5446

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:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

JAMES M. CARNEY

Plaintiff

v.

GUERBET, LLC, MALLINCKRODT, INC., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

MALLINCKRODT LLC
Serve Registered Agent:
C.T. CORPORATION SYSTEM
120 South Central Avenue
Clayton, Missouri 63105

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:

Jeffrey R. Baron
BAILEY & GLASSER LLP
8012 Bonhomme Avenue
Suite 300
Clayton, Missouri 63105
314-863-5446

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:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

JAMES M. CARNEY

Plaintiff

v.

GUERBET, LLC, MALLINCKRODT, INC., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

LIEBEL-FLARSHEIM COMPANY LLC
Serve Registered Agent:
C.T. CORPORATION SYSTEM
120 South Central Avenue
Clayton, Missouri 63105

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:

Jeffrey R. Baron
BAILEY & GLASSER LLP
8012 Bonhomme Avenue
Suite 300
Clayton, Missouri 63105
314-863-5446

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: