

**BEFORE THE UNITED STATES JUDICIAL PANEL ON  
MULTIDISTRICT LITIGATION**

**IN RE: LINEAR GADOLINIUM-  
BASED CONTRAST AGENTS  
PRODUCTS LIABILITY  
LITIGATION**

**MDL NO. 2868**

**RESPONSE OF DEFENDANT BRACCO DIAGNOSTICS INC.  
TO THE MOTION FOR CONSOLIDATION AND TRANSFER**

Defendant Bracco Diagnostics Inc. (“BDI”) opposes Plaintiffs’ Motion for Transfer pursuant to 28 U.S.C. § 1407. BDI joins in and adopts by references the arguments made by Guerbet LLC and Liebel Flarsheim Company, LLC.

This Panel should not establish a global multidistrict procedure for all claims against the sponsors of four linear gadolinium-based contrast imaging agents available in the United States. The procedural tools otherwise available to the courts without MDL consolidation are more than sufficient to coordinate the small number of claims involving BDI. Moreover, given the significant questions as to each plaintiff’s highly variable (and changing) alleged symptoms and the unique formulation of each sponsor’s products, there are substantial individualized matters for discovery that weigh against centralization. BDI would be significantly prejudiced by the burden and expense of an MDL proceeding at this stage, given the few number of claims against BDI, the lack of evidence that any of these plaintiffs have been exposed to a BDI product, and the significantly more advanced state of discovery in the *Fischer* case pending in the District of Arizona on the critical issue of general causation.

## INTRODUCTION

The moving plaintiffs seek to transfer and consolidate for discovery purposes a small number of civil actions brought by plaintiffs who allege that they suffered personal injuries allegedly resulting from retention of gadolinium following magnetic resonance imaging (“MRI”) or magnetic resonance angiography (“MRA”) scans. A dosage of a gadolinium-based contrast agent (“GBCA”) permits enhanced diagnostic observation of bodily structures, organs, and tissues in these scans.

The U.S. Food and Drug Administration (“FDA”) has approved the marketing of four different linear gadolinium-based contrast agents. Critically, the FDA has repeatedly and consistently found that there is no scientific evidence that retention of gadolinium in the body following an MRI scan, if any, can cause adverse health effects in patients with normal kidney function, which is inconsistent with plaintiffs’ theories herein. The FDA’s most recent statement on the issue is that “Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and FDA has concluded that the benefit of all approved GBCAs continues to outweigh any potential risks.”<sup>1</sup> The FDA’s position is clear – linear GBCAs are safe and efficacious.

Moving plaintiffs must establish that any common questions of fact among the cases to be consolidated are sufficiently complex such that consolidation will actually promote more efficient discovery and the just administration of the consolidated matters. *See In re: Depo-Provera Products Liability Litigation*, 499 F. Supp. 2d 1348, 1349 (J.P.M.L. 2007). To the contrary, the

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<sup>1</sup> *Gadolinium-based Contrast Agents (GBCAs): Drug Safety Communication -Retained in Body; New Class Warnings*, issued Dec. 19, 2017 (available at <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm589580.htm>) (emphasis added).

question presented here is quite simple, and has already been answered in the negative by the FDA – there is no accepted scientific evidence that retention of gadolinium, if any, causes adverse health events in patients with normal kidney function.

Given that the FDA has expressly rejected the premise of any causal link between gadolinium deposition and any alleged resulting disease process, this Panel should afford particular scrutiny to Movants’ request to centralize cases that lack both scientific and legal foundation. Transfer and consolidation under 28 U.S.C. §1407 is designed to “provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to ensure the ‘just and efficient’ conduct of such actions.” *In re: New York City NUN Sec. Litig.*, 572 F.2d 49, 51 (2d Cir. 1970).

The Panel should be skeptical that the current request to centralize proceedings in a California federal court would result in a more just and efficient adjudication of these cases, because moving plaintiffs in fact seek to put a stop to the advanced proceedings of Judge Campbell in the U.S. District Court for the District of Arizona, who has set an expedited, phased discovery schedule geared toward a predicate determination of whether plaintiffs have sufficient support for their theory that gadolinium retention could cause any cluster of symptoms that they have described as “gadolinium deposition disease.” The parties in the three cases presently pending before Judge Campbell expect to be 45 days from the close of the initial phase of discovery in those cases by the time the Panel hears the motion to consolidate, and would face significant prejudice if the matters are taken from Judge Campbell after the product sponsors have incurred substantial costs and fees associated with with discovery in those actions. Plaintiffs’ motion should be denied because “centralization has the potential to delay resolution of the actions with little corresponding efficiency or convenience benefits.” *In re: Time Warner Cable, Inc.*, 247 F. Supp.

3d 1388, 1389 (J.P.M.L. 2016) (citing *In re: Caribbean Cruise Line, Inc., Tel. Consumer Prot. Act (TCPA) Litig.*, 89 F. Supp. 3d 1356, 1357 (J.P.M.L. 2015) (holding that “centralization could delay the proceedings in the more advanced action and result in additional expense to the parties and the courts in establishing an MDL with little or no benefit”).

**AN MDL PROCEEDING IS UNNECESSARY AND INAPPROPRIATE**

BDI agrees with the other sponsors that the nephrogenic systemic fibrosis (“NSF”) MDL, *In re: Gadolinium Based Contrast Dye Products Liability Action*, No. 1909, is not analogous to the claims presented here. NSF was a medically-recognized disease with established diagnostic criteria. Do the plaintiffs in these cases have any similar theory with a defined and recognized set of symptoms? No. Instead of relying on information that is widely accepted in the medical community, the moving plaintiffs have flailed about in a variety of unsuccessful attempts at pleading a theory of injury.

Initially, the plaintiffs’ Complaints pointed to a hodgepodge of non-specific symptoms that they broadly referred to as “gadolinium deposition disease,” even though the relevant medical community has not accepted the existence of any such thing. Recently, many of the plaintiffs experienced an apparent shift in symptoms and amended their Complaints to focus on “fibrosis” in what can only be described as a remarkable coincidence of shared symptomology. Even this abrupt shift in these plaintiffs’ symptoms (which have not been confirmed by medical records) cannot rescue the plaintiffs’ claims. As discussed above and more fully in the other sponsors’ briefing, plaintiffs’ causation theories are suspect (at best), and have been expressly rejected by the FDA. If anything, the recent changes to plaintiffs’ Complaints are a retreat from an undefined proposed disease process to an even less defined and completely subjective set of symptoms that are wholly untethered to scientific reality. Houses of cards are built of sterner stuff.

**I. BDI WOULD BE PREJUDICED BY CONSOLIDATION.**

This is not the first time BDI has opposed an MDL related to GBCAs. BDI opposed consolidation of claims against it within the NSF MDL, which was initiated in 2007. At that time, there were only two cases pending against BDI, and BDI disputed that there would be a sufficient number of claims against it to warrant the burden and expense of its participation in an MDL proceeding, largely because of the significant differences between the products. At the time that plaintiffs sought an NSF MDL, there was no evidence in the medical literature of any patient to have developed NSF following the sole administration of a BDI product.

Ultimately, BDI was correct in this position. Although, as GEHC notes in its brief, there were over 500 cases filed in the NSF MDL, not a single, unconfounded<sup>2</sup> case was ever confirmed against BDI, and BDI was voluntarily dismissed from the litigation without trial and without payment of any settlement funds. Before that happened, however, BDI was forced to participate in many years of MDL proceedings, at enormous cost and burden to the company.

Often, as in the NSF MDL, defendants with relatively few cases are required to proceed in document discovery and otherwise as if they were at the core of the controversy, when that is not the case. The formation of an MDL encourages the filing of doubtful claims that would not survive individualized scrutiny, resulting in a process that is expensive, burdensome, inefficient and completely antithetical to the purposes of MDL consolidation, which is what happened to BDI in the NSF MDL. The goal of Section 1407 is to achieve “significant savings of time, effort and expense as a result of pretrial centralization.” *See In re: Air Crash Disaster near Chicago*, 476 F. Supp. 445, 448 (J.P.M.L. 1979). That goal was not served for BDI in the NSF MDL, and would

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<sup>2</sup> That is, there was not a single case ever confirmed in which the plaintiff alleged exposure solely to one of BDI’s GBCAs without exposure to that of another sponsor’s.

not be served here. In light of the dubious nature of the claims here, the other sponsors in this proposed MDL would be in the same position as BDI was in the NSF MDL and would be similarly prejudiced. This is also true for the McKesson defendants, as there is as yet no evidence that they even distributed GBCAs that were allegedly administered to the plaintiffs, and they might have been named solely to manipulate the venue of these actions.

The Panel should be particularly cautious about consolidation with regard to a small number of cases resting upon an even more dubious foundation than the NSF litigation. The FDA at least recognized the existence of a disease called nephrogenic systemic fibrosis, and believed there to be an association<sup>3</sup> between NSF and the administration of certain GBCAs in patients with compromised renal function. By contrast, the FDA has had ample cause and opportunity to consider whether GBCAs are capable of causing “gadolinium deposition disease” or fibrosis in patients with normal kidney function, and has found that the scientific evidence does not support plaintiffs’ theories. The FDA has gone so far as to convene a multi-disciplinary, neutral advisory committee of experts in the field to advise it regarding the science and the health effects of GBCAs. The FDA has heard from GBCA sponsors, public health advocates, plaintiffs, plaintiffs’ attorneys and other medical professionals who have a particular interest in the ongoing use of GBCAs. After hearing all the evidence and presentations from every conceivable interested group, the FDA rejected any notion that there is a scientifically-proven causal link between gadolinium retention, if any, and any medical condition like “gadolinium deposition disease” in patients with normal kidney function.

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<sup>3</sup> “An association is not equivalent to causation.” See Michael D. Green et al., *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 552 (Fed. Judicial Ctr. 3rd ed. 2011). An association is used to describe the relationship between two events that occur “more frequently together than one would expect by chance.” *Id.* at 553. It “does not necessarily imply a causal effect.” *Id.* at 552.’

Finally, at this time BDI has received no discovery responses and no medical records from any plaintiff that would establish that he or she even received MultiHance, BDI's linear GBCA. After years of proceedings in the NSF MDL, BDI found that many of the plaintiffs who claimed to have been administered a BDI product, in fact, had not. BDI has received no cooperation to date from plaintiffs in any of its cases to produce any evidence that they were administered a BDI product. The Panel should balk at drawing BDI into another expensive, years-long MDL process without any threshold evidence that these plaintiffs even received a BDI product, let alone that there is any scientific support for the theory that linear GBCAs cause disease in patients with normal kidney function. Moving plaintiffs' application for consolidation is at best premature, and even under plaintiffs' best-case scenario, would require a substantial shift in the medical science to become a potentially viable claim.

## **II. THE CLAIMS AGAINST BDI DO NOT SHARE COMMON QUESTIONS OF FACT.**

BDI is a party in only six of the cases identified in the motion for consolidation,<sup>4</sup> one of which is part of the three cases currently pending before Judge Campbell in the District of Arizona involving several other of the sponsor defendants. As discussed more fully below, the parties have been engaged in substantial and cordial coordination of pretrial proceedings in these and the other pending cases, rendering centralization unnecessary. There are no "efficiencies" to be gained from

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<sup>4</sup> *Esserman v. Bracco Diagnostics Inc., et al.*, 1:18-cv-21396-KMM (S.D. Fla. Miami); *Fischer v. Bayer Healthcare Pharmaceuticals, Inc., et al.*, 2:18-CV-01778-DGC (D. Ariz. Phoenix); *Gerrity v. McKesson Corp., et al.*, 2:18-cv-2445-JWL-GLR (D. Kan.); *McGrath v. Bayer Healthcare Pharmaceuticals, Inc., et al.*, 1:18-cv-02134-RD-VMS (E.D.N.Y. Brooklyn); *Montani v. Bracco Diagnostics Inc.*, 4:18-cv-10054-KMM (S.D. Fla. Miami); and *Norris v. Bracco Diagnostics Inc.*, 4:18-cv-02762 (S.D. Tex. Houston). BDI has recently been served in *Welty v. Bracco Diagnostics Inc., et al.*, Case No. 3:18-cv-1460 (S.D. Illinois), but is not yet due to file a responsive pleading. It is BDI's understanding that an amended complaint adding BDI as a party was filed on August 10 in *Sabol v. Bayer Healthcare Pharmaceuticals Inc., et al.*, Case No. 8:18-cv-00850-CEH-AEP (M.D. Fla. Tampa), but BDI has not been served in that action.

the consolidation of the claims against BDI in an MDL proceeding.

Only four of the pending cases, in which plaintiffs allege administration of one of BDI's products, are allegedly unconfounded cases – that is, cases in which plaintiffs have allegedly been exposed only to BDI's product. In one of these, *Norris*, plaintiffs allege injuries resulting from both ProHance and MultiHance, which is inconsistent with the theory advanced before the Panel that the cases are unified by a theory that their symptoms are caused by linear GBCAs, as ProHance is a macrocyclic GBCA.

**A. Plaintiffs' claims do not share sufficient common questions of fact.**

Each of the plaintiffs allege unique injuries that will require highly individualized discovery, rendering their claims inappropriate for centralized discovery. Even the supposed disease or disorder allegedly experienced by plaintiffs has been a moving target over the course of what is now nearly two years' worth of litigation for some of the defendants. As set forth more fully in the Bayer Defendants' Brief, the alleged symptoms of "gadolinium deposition disease," which the plaintiffs originally claimed to have suffered, were a disunified collection of non-specific symptoms not associated with any medically-recognized disease. Indeed, beginning in June 2018, plaintiffs abandoned the "gadolinium deposition disease" theory, and have only recently contended that they are experiencing a "fibrosis"-like disorder that was not alleged in their original complaints.



The following is the status of allegations in the cases in which BDI has been served:

Case / Jurisdiction	Originally alleged injury	Alleged injury per amended complaint
<i>Esserman</i> - (S.D. Fla. Miami)	Severe pain, skin hardening, burning sensation, immobility and difficulty walking, cognitive issues, loss of balance, clenching/curling of toes and fingers, and sensation of tightness in skin.	Plaintiff amended the complaint prior to transfer to her home state, but did not make new injury allegations. BDI's motion to dismiss pending.
<i>Fischer</i> (D. Ariz. Phoenix)	Burning sensation; violent shaking; tremors; clouded mentation; confusion; weakness; fatigue; hypoglycemia; difficult, painful movement; low body temperature; inflammation, especially throughout her lymphatic system; muscle cramps; numbness; tingling sensation; aching joints; weight loss; hair loss; lumps and rashes on body, kidney damage; and osteoporosis.	Fibrosis in her organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, and related injuries.
<i>Gerrity</i> (D. Kansas)	Immobility, weakness, difficulty speaking, impaired cognition, and impaired muscle and voluntary movement control.	Fibrosis in his organs, skin, and bones, retained gadolinium in his brain, and related injuries
<i>McGrath</i> (E.D.N.Y. Brooklyn)	Severe nausea, burning sensation on her skin, elevated heart rate, loss of appetite, feeling of dehydration, anxiousness, digestive disturbances, food intolerance, and sensitivity to other medications and supplements.	Fibrosis in her organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, and related injuries.

Case / Jurisdiction	Originally alleged injury	Alleged injury per amended complaint
<i>Montani</i> (S.D. Fla. Miami)	Burning sensation, metallic taste in her mouth, rashes and patches on her skin, swelling, hair loss, vision loss, extreme pain, joint pain and tightness, and memory loss.	Fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.
<i>Norris</i> (S.D. Tex. Houston);	Burning pain in abdomen and throughout her body; violent shaking; tremors; clouded mentation; confusion; weakness; fatigue; hypoglycemia; difficult, painful movement; low body temperature; inflammation, especially throughout her lymphatic system; fasciculation; muscle cramps; numbness; tingling sensation; aching joints; weight loss; hair loss; lumps and rashes on body; kidney damage; and osteoporosis.	Plaintiffs have not filed an amended complaint.

The tremendous variety in symptoms that have been alleged by these plaintiffs will require substantial individualized discovery. Centralization is inappropriate where “[i]ndividualized issues of causation concerning each plaintiff’s injuries appear to predominate among the actions.” *In re: Ne. Contaminated Beef Prods. Liab. Litig.*, 856 F. Supp. 2d 1354, 1354-55 (J.P.M.L. 2012).

Furthermore, it reasonably appears that many, if not all, of the claims asserted against BDI will be time-barred and subject to disposition upon summary judgment following minimal discovery of the plaintiffs. In many of these cases, the plaintiffs’ social media activity, internet forum postings, and even public statements reflect that they had formed a belief that they had experienced adverse health effects that they linked to gadolinium outside the relevant limitations

period, which would bar their claims even in jurisdictions that recognize a “discovery rule.” For example, in the *Norris* case, Gena Norris and her husband, Chuck Norris, have made a wealth of public statements admitting that they linked Mrs. Norris’s alleged symptoms to GBCAs “within hours” after she received an MRI in 2013.<sup>5</sup> Having filed their suit in October 2017, their claims appear to be time-barred by the two-year statute of limitations under Texas law, and not saved by any potential “discovery rule.” *See* Tex. Civ. Prac. & Rem. Code Ann. § 16.003(a); *Upjohn Co v Freeman*, 885 S.W.2d 538, 541 (Tex. App. 5th Dist. 1994). The statute of limitations issue should be determined promptly in the individual courts in which these cases are pending, or it will be subsumed in the MDL and time-barred cases will languish. This further weighs against centralization.

**B. Defenses to the claims do not share common questions of fact.**

Each of the gadolinium-based contrast agents at issue utilizes different active and inactive chemical components. Plaintiffs’ theories of product defect are presently entirely unknown to BDI. However, the differences in formulation of each product are likely to be substantially relevant to questions of alleged defective design and both general and specific causation. *See, e.g., Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp.2d 1347, 1365 (N.D. Ga. 2001) (it cannot be assumed that a drug will cause the same effects as the class of drugs of which it is member). “[S]mall differences in molecular structure often have significant consequences.” *Schudel v. General Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997).

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<sup>5</sup> *See, e.g.*, “Chuck Norris on why he believes his wife was poisoned by an MRI scan,” HELLO MAGAZINE (Nov. 7, 2017), available at: <https://www.hellomagazine.com/celebrities/2017110743785/chuck-norris-wife-gena-poisoned-mri-scan/> [Accessed Aug. 19, 2018].

Significant questions of fact that may go to the defenses to plaintiffs' claims, which will not be shared in common by all defendants, will likely include:

- the physico-chemical and pharmacologic properties of the particular contrast agents sponsored by each of the defendants,
- the pre-clinical testing of each product,
- the parameters and results of human clinical trials related to each product,
- the process by which defendant sought and obtained FDA approval, the content of their INDs (Investigational New Drug Application) and NDAs (New Drug Application) for each contrast agent,
- the warnings provided by each defendant,
- the Adverse Experience Reports, their dates and information provided to the sponsor, and
- the notice each defendant might have had regarding the alleged harmful properties of the contrast agent each sponsored.

Discovery regarding the claimed liability of each sponsor will thus involve individualized inquiries that are completely unrelated to the other defendant sponsors. Each of the sponsors will have individual and separate defenses to the claims related to their various products. Even the relevant scientific evidence will be materially different, because each sponsor's product has unique chemical, biochemical, structural, and pharmacologic properties. Details as to how each sponsor designed, tested, and marketed its own proprietary formulation of contrast imaging agent(s) will be sought.

An MDL proceeding does not lend itself to defenses based upon product differentiation. A global MDL encompassing all linear gadolinium-based contrast agents would deprive BDI of the substantive and procedural due process protections to which it is entitled. As it experienced in the NSF MDL, BDI is at risk of being subjected to significant delay, burden, and expense related

to discovery that does not pertain to its unique product. For these reasons, centralization would not result in a more just and efficient administration of the claims against BDI.

### **III. THE PANEL SHOULD NOT DISRUPT PROCEEDINGS IN ARIZONA.**

This Panel does not disrupt pending cases without good reason. *In re: Chiropractic Antitrust Litigation*, 483 F. Supp. 811, 813 (J.P.M.L. 1980) (no MDL transfer for a small number of cases capable of efficient handling without Panel intervention); *see also In re: G.D. Searle & Co.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980); *In re: Dow Chem. Co., “Polystyrene Foam” Prod. Liab. Litig.*, 429 F. Supp. 1035, 1036 (J.P.M.L. 1977) (transfer denied where parties could have entered into stipulation for discovery to apply to all pending actions). This is particularly true where pretrial proceedings are already far along in one or more of the cases sought to be consolidated.

There is no good reason to disrupt the proceedings in the District of Arizona. BDI adopts the position of the Guerbet Defendants that the Panel should defer any action pending Judge Campbell’s rulings on whether plaintiffs can muster sufficient scientific evidence for general causation (establishing that linear GBCAs can cause “gadolinium deposition disease” or any other medically-recognized disease process in patients with normal renal function).

Judge Campbell in the District of Arizona is appropriately focused upon the determination, as a predicate issue, of whether there is any medically-accepted cluster of symptoms comprising “gadolinium deposition disease” or any accepted scientific evidence establishing a causal link between gadolinium retention, if any, and disease process in patients with normal kidney function. Movants’ request to centralize cases away from the District of Arizona is an attempt to misuse the centralization process, and should be rejected by the Panel.

Although BDI believes that none of these cases will survive scientific scrutiny, one court has already substantially advanced the prioritization of its gate-keeper function in seeking to

determine if there is any accepted scientific evidence for plaintiffs' claims, and that is before Judge Campbell in the District of Arizona. The transferee court proposed by moving plaintiffs has not developed a road map to subject these doubtful claims to close scientific scrutiny the way that Judge Campbell has. Rather than promoting the just and efficient administration of the few claims against BDI, centralization of these dubious claims would subject BDI to unnecessary expense and burden, and would in fact delay adjudication of the predicate general causation question set to be determined in short order by Judge Campbell in the District of Arizona.

#### **IV. CENTRALIZATION IS UNNECESSARY.**

##### **A. Alternatives to centralization are preferable, as the number of cases and involved attorneys are not sufficient numerous to warrant consolidation.**

Where only a minimal number of actions are involved, the proponent of centralization bears a heavier burden to demonstrate that centralization is appropriate. *See In re: Transocean Ltd. Sec. Litig. (No. II)*, 753 F. Supp. 2d 1373, 1374 (J.P.M.L. 2010). Moving plaintiffs have not met that burden here. These cases already are being managed in an orderly and efficient manner, and the issues presented are not unusually complex – there is a threshold question of general causation, and no scientific evidence to support plaintiffs' allegations. Given the small number of plaintiffs' counsel and the limited number of actions, informal cooperation among the involved attorneys and courts is both practicable and preferable to centralization. *See In re: Caribbean Cruise Line, Inc.*, 89 F. Supp. 3d 1356, 1357 (J.P.M.L. 2015); *In re: Hangtime, Inc., Tel. Consumer Prot. Act (TCPA) Litig.*, MDL No. 2563, 52 F. Supp. 3d 1375, 2014 U.S. Dist. LEXIS 145743, 2014 WL 5100236, at \*1 (J.P.M.L. Oct. 9, 2014).

When only a minimal number of actions are under consideration for transfer under Section 1407, the moving party bears a strong burden to show that the common questions of fact are so complex and the accompanying discovery so time-consuming as to serve the overall

convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. *In re: Commercial Lighting Products, Inc. Contract Litigation*, 415 F. Supp. 392, 393 (J.P.M.L. 1976). As this Panel has repeatedly found, voluntary coordination of actions is a practicable and preferable alternative to centralization, and consolidation should be denied when this can be achieved. *See In re: G.D. Searle & Co.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980) (where “suitable alternatives” such as voluntary coordination of discovery efforts were available to avoid duplicative discovery, consolidation was improper under Section 1407); *In re: Dow Chem. Co., Polystyrene Foam*, 429 F. Supp. at 1036 (transfer denied where parties entered into stipulation for discovery to apply to all pending actions).

Here, the number of cases sought to be consolidated is small. Moving plaintiffs identified only 21 cases in their motion for consolidation. Compared to the number of cases at issue in many proposed consolidations, this number is miniscule. As discussed *infra*, discovery need not be complicated, can be coordinated, and in fact has been coordinated by the parties without issue to date. Consequently, moving plaintiffs cannot meet their high burden to prove the need for centralization.

Moving Plaintiffs are represented almost exclusively by a single law firm, Cutter Law, P.C., which represents plaintiffs in 18 of the 21 cases identified in the motion. Of the remaining three cases in which Cutter Law is not plaintiffs’ counsel of record, two have only been filed in the past 30 days,<sup>6</sup> and one involves a *pro se* plaintiff who, as set forth more fully in the Bayer Defendants’ briefing, has NSF and renal failure, and thus is not similarly-situated to the movants.<sup>7</sup> Although there is not complete identity of defendants across each of the actions sought to be

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<sup>6</sup> *Lewis v. Bayer Healthcare Pharmaceuticals Inc., et al.*, 3:18-04146 (N.D. Cal.); *Viruet v. Bayer Healthcare Pharmaceuticals Inc., et al.*, 1:18-11611 (D. Mass.).

<sup>7</sup> *White v. GE Healthcare Inc., et al.*, 1:17-00212 (S.D. Ohio).

centralized, the defendants have been coordinating with each other and with Mr. Walburg of Cutter Law with respect to the 18 actions that he has filed, and expect to cooperate with counsel in newly-filed actions as necessary. Additionally, all but the Arizona actions are at an early stage, which will allow for coordinated pretrial proceedings.

The small number of cases and common counsel will allow pretrial matters such as discovery to be effectively managed without formal centralization. Deposition notices can be cross-filed in multiple actions. *See In re: Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litigation*, 446 F. Supp. 242, 244 (J.P.M.L. 1978). With respect to document production, the parties may be able to agree to an electronic repository for documents to be available in any cases. Certainly, “the parties could seek to agree upon a stipulation that any discovery relevant to more than one action may be used in all those actions; and any party could seek orders from the three courts directing the parties to coordinate their pretrial efforts.” *Id.* BDI will take reasonable and appropriate actions to coordinate all discovery pertaining to the cases against it. Such informal coordination satisfies the concerns that underlie consolidation under Section 1407, making centralization unnecessary here.

**B. Plaintiffs’ speculation regarding the number of cases that might be filed should not be considered in determining whether to centralize the cases.**

Although plaintiffs allege that the number of actions is likely to expand, the mere possibility of additional actions does not warrant centralization. *See In re: Intuitive Surgical, Inc., Da Vinci Robotic Surgical Sys. Prods. Liab. Litig.*, 883 F. Supp.2d 1339, 1340 (J.P.M.L. 2012) (denying centralization, noting that “[w]hile proponents maintain that this litigation may encompass ‘hundreds’ of cases or ‘over a thousand’ cases, we are presented with, at most, five actions.”). Moreover, given the doubtful nature of the science behind the claims, and the FDA’s repeated statements that it finds no merit in the theory that gadolinium retention, if any, causes



injury in patients with normal kidney function, there is no reason to believe that the floodgates will open to this kind of claim.

### **PLACEMENT OF THE MDL PROCEEDING**

Alternatively, if the Panel believes that centralization is appropriate, BDI wishes to be heard on the location of any individualized or centralized MDL proceeding. Movants have suggested that a global MDL for all products be centered in the Northern District of California. BDI does not believe that centralization would be appropriate in California. Centralization for the convenience of the one plaintiff's attorney who was the first to file a number of claims is not appropriate. None of the actions currently pending against BDI is located in the Northern District of California, where centralization is requested by the movants.

Mere hours before the sponsors were due to file their response to the motion for centralization, plaintiff in *Welty v. Bracco Diagnostics Inc., et al.*, Case No. 3:18-cv-1460 (S.D. Illinois) filed, but did not serve on BDI, a "response" brief seeking consolidation in the Southern District of Illinois. BDI is the only sponsor defendant in that action, which is in its infancy – it was filed after the motion for centralization was filed, and BDI is not yet due to file a responsive pleading in *Welty*. Though the *Welty* plaintiff advocates for centralization in the Southern District of Illinois, BDI, the only sponsor defendant in the only case in that jurisdiction, has its headquarters in New Jersey and objects to centralization in that district. None of the other sponsor defendants have any cases pending in that jurisdiction.

*Welty* is a case filed by the Cutter Law firm, and is another example of plaintiffs' counsel attempting to centralize for their convenience in their own backyards. Moreover, *Welty* has been assigned to the Benton Division, not East St. Louis as suggested, which is not readily accessible by air travel and which does not appear to have ever hosted an MDL before. The Panel has

traditionally sought to maximize accessibility and convenience of all parties and their counsel. *See, e.g., In re: Medtronic, Inc., Implantable Defibrillators Prods. Liab. Litig.*, 408 F. Supp. 2d 1351, 1352 (J.P.M.L. 2005).

If the Panel is inclined to establish an MDL, BDI proposes centralization with Judge Campbell in the U.S. District Court for the District of Arizona, Phoenix, where Judge Campbell is presiding over three pending cases and has entered phased discovery orders consistent with the parties' proposed plan for discovery. As discussed above, Judge Campbell has adopted an efficient scheduling order focused upon general causation, and has already done the work of understanding and planning a road map for the progress of discovery in his cases. Phoenix is easily accessible by plane, close to plaintiffs' counsel Mr. Walburg, and reasonably centrally located geographically.

The Panel usually favors transfer to a district in which the court has experience with the action and at least one case that has been pending for months longer than the other courts—in this instance, that would be before Judge Campbell in the District of Arizona. *See, e.g., In re: Skechers Toning Shoe Products Liability Litigation*, 831 F. Supp. 2d 1367 (J.P.M.L. 2011) (Western District of Kentucky was appropriate transferee forum for centralized pretrial proceedings in 12 actions and eight potential tag-along actions where action pending there was filed several months before other such actions.); *In re: Ocean Financial Corp. Prescreening Litigation*, 435 F. Supp. 2d 1350 (J.P.M.L. 2006) (Northern District of Illinois was appropriate transferee forum for three purported class actions pending in three districts where the action pending in that district had been proceeding for months longer than the other actions.); *In re: H & R Block Mortg. Corp. Prescreening Litigation*, 435 F. Supp. 2d 1347 (J.P.M.L. 2006) (Northern District of Indiana was appropriate transferee forum for three actions pending in three districts where the action in that district had

been pending for months longer than the other actions.); *In re: Ford Motor Co. E-350 Van Products Liability*, 374 F. Supp. 2d 1353 (J.P.M.L. 2005) (District of New Jersey was proper transferee forum for centralization for coordinated or consolidated pretrial proceedings in five actions against automobile manufacturer where action in that district had been pending for over one year, and discovery had commenced in that action, while other actions had been pending only a few months.). The three cases pending before Judge Campbell in the District of Arizona are the most advanced of any, and this is a preferable location for centralization, if any.

## V. CONCLUSION

Centralization is not warranted here. The parties have considerable experience in working together, formally and informally, to coordinate the litigation, which is driven largely by a single law firm. Movants' request for centralization is a transparent attempt to preempt the efficient schedule established by Judge Campbell in the District of Arizona to reach an expeditious determination of whether there is any scientific evidence to support plaintiffs' theory that gadolinium retention, if any, could cause any medically-recognized syndrome or disease in patients with normal renal function, which the FDA denies. However, if the Panel determines it will consolidate proceedings, either globally or on a product-specific basis, BDI proposes Judge Campbell in the District of Arizona.

Respectfully submitted,

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Dated: August 23, 2018

**BEFORE THE UNITED STATES JUDICIAL PANEL  
ON MULTIDISTRICT LITIGATION**

**IN Re: Linear Gadolinium Based Contrast Agents  
Products Liability Litigation**

**MDL No. 2868**

**PROOF OF SERVICE**

I hereby certify that on August 23, 2018, the Response of Defendant Bracco Diagnostics Inc. to the Motion for Consolidation and Transfer was electronically filed with the Clerk of the Court using the Judicial Panel on Multidistrict Litigation's CM/ECF system, which will serve all counsel of record in the related cases via electronic notification, unless otherwise indicated below.

A courtesy copy has also been served via overnight mail to the following:

Clerk of the Panel  
United States Judicial Panel on Multidistrict Litigation  
Thurgood Marshall Federal Judiciary Building  
One Columbus Circle, NE  
Room G-255, North Lobby  
Washington, DC 20544-0005

No.	Case Captions	Plaintiff Counsel	Defense Counsel
1	Nikki Esserman v. Bracco Diagnostics, Inc.; Guerbet LLC; Mallinckrodt Inc.; Mallinckrodt LLC; Enterprise Holdings, Inc. dba Mallinckrodt Pharmaceuticals; Mallinckrodt Manufacturing LLC; Liebel-Flarsheim Company LLC; McKesson Corporation; McKesson Medical- Surgical, Inc.; Merry XRay Chemical	<b>C. Brooks Cutter</b> <b>Margot P. Cutter</b> <b>Todd A. Walburg</b> Cutter Law, P.C. 401 Watt Avenue Sacramento, CA 95864 (916) 290-9400 Fax: (916) 588-9330 bcutter@cutterlaw.com mcutter@cutterlaw.com twalburg@cutterlaw.com  <b>R. Jason Richards</b> Aylstock, Witkin, Kreis & Overholtz, PLLC 17 E Main St Ste 200 Pensacola, FL 32502-5998 850/916-7450	<b>Jordon Scott Cohen</b> Wicker Smith Tutan O'Hara McCoy Graham & Ford 515 E Las Olas Blvd Suite 1400 Suntrust Bank Fort Lauderdale, FL 33301 954-467-6405 Fax 760-93533 jcohen@wickersmith.com <i>Representing Bracco Diagnostics, Inc</i>  <b>Kevin Michael Benedicto</b> Morgan, Lewis and Bockius LLP One Market, Spear Street Tower San Francisco, CA 94108 <i>Representing Guerbet, LLC, Liebel-Flarsheim Company LLC</i>

No.	Case Captions	Plaintiff Counsel	Defense Counsel
	<p>Corporation; and Does 1 through 50, inclusive  <b>S.D. Florida No. 1:18-21396</b></p>	<p>Fax: 850-916-7449  jrichards@awkolaw.com</p>	<p><b>Michael A. De Giovanni</b>  Morgan, Lewis and Bockius LLP  200 S Biscayne Blvd, Suite 5300  Miami, FL 33131  Michael.degiovanni@morganlewis.com  <i>Representing Guerbet, LLC, Liebel-Flarsheim Company LLC</i></p> <p><b>Brian W. Shaffer</b>  Morgan, Lewis and Bockius LLP  1701 Market Street  Philadelphia, PA 19103  215-963-5000  Brian.shaffer@morganlewis.com  <i>Representing Guerbet, LLC, Liebel-Flarsheim Company LLC</i></p> <p><b>Jamie Kendall</b>  Kendall Law Firm PC  1201 County Line Rd., Ste. G  Brun Mawr, PA 19010  610-756-0200  Fax: 610-756-0202  jkendall@tkfirm.com  <i>Representing Guerbet, LLC, Liebel-Flarsheim Company LLC</i></p> <p><b>Devin Kyle Ross</b>  <b>Devin Arnold Moss</b>  Shook Hardy &amp; Bacon LLP –  Kansas City, MO  2555 Grand Blvd.  Kansas City, MO 64108  816-559-2688  Fax: 816-421-5547  dkross@shb.com  dmoss@shb.com  <i>Representing Malinckrodt Inc., Malinckrodt LLC,</i></p>

No.	Case Captions	Plaintiff Counsel	Defense Counsel
			<p><b>Robert T. Adams</b>  Shook, Hardy &amp; Bacon LLP  2555 Grand Blvd.  Kansas City, MO 64108  816-559-2230  Fax: 816-421-5547  rtadams@shb.com  <i>Representing Mallinckrodt Inc.  and Mallinckrodt LLC</i></p> <p><i>Service by U.S. Mail to the  following:</i></p> <p><b>McKesson Corporation</b>  McKesson Medical-Surgical, Inc.  CSC lawyers, Inc.  2710 Gateway Oaks Drive, 150N  Sacramento, CA 95833</p> <p><b>Merry X-Ray Chemical Corporation</b>  4444 Viewridge Ave  San Diego, CA 92123</p> <p><b>Takeda GMBH</b>  259 Prospect Plains Road, Bdl H  Monroe Township, NJ 08831</p> <p><b>Bracco Research USA, Inc.</b>  259 Prospect Plains Road, Bdl H  Monroe Township, NJ 08831</p> <p><b>Bipso GMBH</b>  259 Prospect Plains Road, Bdl H  Monroe Township, NJ 08831</p> <p><b>Bracco Imaging, S.P. A</b>  259 Prospect Plains Road, Bdl H  Monroe Township, NJ 08831</p> <p><b>Bracco Group</b>  259 Prospect Plains Road, Bdl H  Monroe Township, NJ 08831</p> <p><b>Bracco Imaging Group</b>  259 Prospect Plains Road, Bdl H  Monroe Township, NJ 08831</p>

No.	Case Captions	Plaintiff Counsel	Defense Counsel
			<b>Acist Medical Systems, Inc.</b> CT Corporation 818 W. 7 <sup>th</sup> St, Suite 930 Los Angeles, CA 90007
2	Susan Fischer v. Bayer Healthcare Pharmaceuticals Inc.; Bayer Corporation; Bayer Healthcare LLC; Bracco Diagnostics, Inc.; Guerbet LLC; Mallinckrodt Inc.; Mallinckrodt LLC; and Liebel-Flarsheim Company LLC <b>D. Arizona 2:18-01778</b>	<b>Curt William Clausen</b> Clausen & Williamson PLLC 2999 N 44 <sup>th</sup> St., Ste. 318 Phoenix, AZ 85018-7520 602-285-4450 Fax: 602-285-4483 Email: curt@cwazlw.com <b>Todd A. Walburg</b> Cutter Law, P.C. 401 Watt Avenue Sacramento, CA 95864 (916) 290-9400 Fax: (916) 588-9330 twalburg@cutterlaw.com	<b>Jennifer L. Greenblatt</b> Goldman Ismail Tomaselli Brennan & Baum LLP 564 W. Randolph St., Ste. 400 Chicago, IL 60661 312-681-6000 Fax: 312-881-5191 jgreenblatt@goldmanismail.com <i>Representing Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation and Bayer HealthCare LLC</i>  <b>Christina M. Vitale</b> Morgan, Lewis & Bockius LLP 1000 Louisiana St., Ste. 4000 Houston, TX 77002 713-890-5764 Fax: 713-890-5000 christina.vitale@morganlewis.com <i>Representing Guerbet, LLC and Liebel-Flarsheim LLC</i>  <b>Robert T. Adams</b> Shook, Hardy & Bacon LLP 2555 Grand Blvd. Kansas City, MO 64108 816-559-2230 Fax: 816-421-5547 rtadams@shb.com <i>Representing Mallinckrodt Inc. and Mallinckrodt LLC</i> <i>Served by U.S. Mail:</i>

3	<p>Michael Gerrity and Judy Gerrity v. McKesson Corporation; McKesson Medical-Surgical, Inc.; Bracco Diagnostics, Inc.; Merry X-Ray Chemical Corporation; and Does 1 through 50, inclusive  <b>D. Kansas No. 2:18-02245</b></p>	<p><b>R. Douglas Gentile</b>  <b>Rachel Nelson Boden</b>  <b>Randall L. Rhodes</b>  Rouse Frets Gentile Rhodes LLC  5250 W. 116th Place, Ste. 400  Leawood, KS 66211  913-387-1609  Fax: 913-928-6739  dgentile@rousefrets.com  rboden@rousefrets.com  rrhodes@rousefrets.com</p> <p><b>Todd A. Walburg</b>  Cutter Law, P.C. 401  Watt Avenue  Sacramento, CA 95864  (916) 290-9400 Fax:  (916) 588-9330  twalburg@cutterlaw.com</p>	<p><b>Craig R. May</b>  Wheeler Trigg O'Donnell LLP 370 17th Street, Ste. 4500  Denver, CO 80202  303-244-1800  Fax: 303-244-1879  may@wtotrial.com  <i>Counsel for McKesson Corporation</i></p> <p><b>Habib Nasrullah</b>  Wheeler Trigg O'Donnell LLP 370 17th Street, Ste. 4500  Denver, CO 80202  303-244-1800  Fax: 303-244-1879  nasrullah@wtotrial.com  <i>Counsel for McKesson Corporation and McKesson Medical-Surgical Inc.</i></p>
4	<p>Gail Montani v. Bracco Diagnostics, Inc.; McKesson Corporation; McKesson Medical-Surgical, Inc.; Merry XRay Chemical Corporation; and Does 1 through 50, inclusive  <b>S.D. Florida No. 4:18-10054</b></p>	<p><b>C. Brooks Cutter</b>  <b>Margot P. Cutter</b>  <b>Todd A. Walburg</b>  Cutter Law, P.C.  401 Watt Avenue  Sacramento, CA 95864  (916) 290-9400  Fax: (916) 588-9330  bcutter@cutterlaw.com  mcutter@cutterlaw.com  twalburg@cutterlaw.com</p> <p><b>Robert Jason Richards</b>  Aylstock Witkin Kreis &amp; Overholtz PLLC  803 N Palafox Street  Pensacola, FL 32501  850-202-1010  Fax: 850-916-7449  jrichards@awkolaw.com</p>	<p><i>Served by U.S. Mail:</i>  <b>McKesson Corporation</b>  McKesson Medical-Surgical, Inc.  CSC lawyers, Inc.  2710 Gateway Oaks Drive, 150N  Sacramento, CA 95833</p>



5	<p>Denise McGrath v. Bayer Healthcare Pharmaceuticals Inc.; Bayer Pharma AG, formerly known as Bayer Schering Pharma AG; Bayer Corporation; Bayer Healthcare LLC; Bracco Diagnostics, Inc.; McKesson Corporation; McKesson Medical- Surgical, Inc.; Merry XRay Chemical Corporation; and Does 1 through 50, inclusive <b>E.D. New York No. 1:18-02134</b></p>	<p><b>C. Brooks Cutter</b> <b>Margot P. Cutter</b> <b>Todd A. Walburg</b> Cutter Law, P.C. 401 Watt Avenue Sacramento, CA 95864 (916) 290-9400 Fax: (916) 588-9330 bcutter@cutterlaw.com mcutter@cutterlaw.com twalburg@cutterlaw.com</p>	<p><b>Rodney Michael Hudson</b> Drinker Biddle &amp; Reath LLP 50 Freemont Street, 20th Floor San Francisco, CA 94105 415-591-7500 Fax: 415-591-7510 Rodney.hudson@dbr.com <i>Counsel for Bayer Healthcare Pharmaceuticals Inc.; Bayer Pharma AG; Bayer Corporation; Bayer Healthcare LLC</i></p> <p><b>Allyson M. Julien</b> <b>Andrew L. Goldman</b> <b>Edward Dumoulin</b> <b>Jennifer L. Greenblatt</b> Goldman Ismail Tomaselli Brennan &amp; Baum 564 West Randolph Street Chicago, IL 60661 312-681-6000 Fax: 312-629-8107 ajulien@goldmanismail.com agoldman@goldmanismail.com edumoulin@goldmanismail.com jgreenblatt@goldmanismail.com <i>Counsel for Bayer Healthcare Pharmaceuticals Inc.; Bayer Corporation; Bayer Healthcare LLC</i></p> <p><b>Andrew Bouriat</b> <b>Robb William Patryk</b> Hughes Hubbard &amp; Reed LLP One Battery Park Plaza New York, NY 10004 347-901-0438 Andrew.bouriat@hugheshubbard.com robb.patryk@hugheshubbard.com <i>Representing Bayer Healthcare Pharmaceuticals Inc.; Bayer Corporation; Bayer Healthcare LLC</i></p>
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6	Gena Norris and Chuck Norris, also known as Carlos Ray Norris v. McKesson Corporation; McKesson Medical-Surgical, Inc.; Bracco Diagnostics, Inc.; Merry X-Ray Chemical Corporation; and Does 1 through 50, inclusive <b>S.D. Texas</b> <b>No. 4:18-02762</b>	<p><b>C. Brooks Cutter</b>  <b>Margot P. Cutter</b>  <b>Todd A. Walburg</b>                  Cutter Law, P.C.                  401 Watt Avenue                  Sacramento, CA 95864                  (916) 290-9400                  Fax: (916) 588-9330                  bcutter@cutterlaw.com                  mcutter@cutterlaw.com                  twalburg@cutterlaw.com</p>	<p><b>Emma Elizabeth Garrison</b>                  Wheeler Trigg O'Donnell LLP 370 17<sup>th</sup> Street, Ste. 4500                  Denver, CO 80202 303-244-1800                  Fax: 303-244-1879                  garrison@wtotrial.com  <i>Counsel for McKesson Corporation; McKesson Medical-Surgical, Inc.</i></p>

Dated: August 23, 2018

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