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OF COUNSEL
RACHAEL NASS••○

February 3, 2009

Hon. Glenn A. Grant, JAD
Acting Administrative Director of the Courts
POB 037
Trenton, NJ 08625-0037

Re: Mass Tort Designation of Stryker Trident Hip Implants

Dear Judge Grant:

We represent several clients who have suffered significant injuries from problems with Stryker Trident hip prostheses. Two of our clients have ongoing cases in the U.S. District Court for the District of New Jersey. We represent several other New Jersey residents for whom we have not yet started lawsuits against Howmedica Osteonics Corp., the actual manufacturer of the Trident devices.

We join in the application for mass tort designation for this litigation. Based on our experience in other mass torts, we believe centralized case management is both effective and efficient. Our experience with Judge Higbee in the Vioxx litigation has also convinced us that she would be an excellent manager, as her results with Vioxx must attest.

We do not believe that New Jersey jurists lacks the competence to decide legal issues that involve Federal law, as the Defendant has implied in our two Federal cases. In essence, it is the Defendant's position that no New Jersey state court has the capability to consider and rule on matters involving the Federal Food, Drug & Cosmetic Act and its amendments. Obviously, Judge Higbee, as well as the Middlesex and Bergen mass tort judges, have proved that contention incorrect.

On behalf of our clients, we welcome the change to resolve these matters fairly and expeditiously. Mass tort designation is the best method to accomplish those goals.

Respectfully submitted,

Terrence Smith
For the firm

MVP

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February 27, 2009

VIA LAWYER'S SERVICE

The Honorable Glenn A. Grant
Acting Administrative Director of the Courts
P.O. Box 037
Trenton, New Jersey 08625-0037

RE: Request for Mass Tort Designation of Cases Involving the Trident Stryker Hip Implant

Dear Judge Grant:

As you are aware, Ellen Relkin, Esq. of the law firm Weitz & Luxenberg recently submitted an application on behalf more than thirty plaintiffs seeking a mass tort designation of the Trident (Stryker) Hip Implant cases. I briefly write to lend my support of same and to join Ms. Relkin's request that the Supreme Court designate the Trident cases for mass tort treatment and centralize management of such matters in the Atlantic County Superior Court.

This law firm currently represents Plaintiffs Donald and Traci Titus in Middlesex County Superior Court against the Stryker Corporation and Howmedica Osteonics Corporation. (A copy of Plaintiffs' Second Amended Complaint is attached hereto for your immediate reference). As Ms. Relkin indicated in her December 30, 2008 correspondence, each of the previously filed cases, including the one filed by this law firm, will doubtless involve the same, recurrent and overlapping factual and legal issues. It would therefore seem inefficient and (frankly) unnecessarily burdensome upon all parties if the application is denied and counsel is ultimately forced to tie up courts in multiple counties with motions practice and endless briefing of the same legal issues.

Similarly, it would seem counterproductive for counsel in each of these matters to propound and respond to redundant discovery in multiple counties. As the number of filings and plaintiffs increase, these issues of

redundancy and inefficiency will only become exacerbated. Clearly, a coordinated effort under a mass tort designation would promote judicial economy and eliminate such duplicity. Since virtually all of the Trident cases filed in this State are already before the Honorable Carol E. Higbee in Atlantic County, and since it would follow that Judge Higbee is already quite familiar with this litigation, it would seem both fair and logical that Atlantic County be designated the appropriate venue for the Trident cases.

Therefore, on behalf of Plaintiffs Donald and Traci Titus, I respectfully request Ms. Relkin's application pursuant to R. 4:38A and the Revised Mass Tort Guidelines (Directive No. 10-07) be granted and that the Trident cases be given mass tort status and centralized in Atlantic County.

Respectfully submitted,

Todd Drayton, Esq.

Enclosure

cc: The Honorable Edward J. Ryan
The Honorable Carol E. Higbee
James D. Martin, Esq.
Kim M. Catullo, Esq.
Ellen Relkin, Esq.

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March 2, 2009

VIA HAND DELIVERY

Hon. Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts
Richard J. Hughes Justice Complex
25 W. Market Street
Trenton, New Jersey 08625-0037

Re: Opposition to Plaintiffs' Application for Mass Tort Designation and Centralized Management of Litigation Involving Stryker Trident Hip Implants and Assignment to Atlantic County

Dear Judge Grant:

Gibbons P.C. represents Howmedica Osteonics Corp. ("HOC") in twenty-five individual cases pending in New Jersey Superior Court alleging injuries from the implantation of a component, or some combination of components, of the Trident Ceramic on Ceramic Acetabular System (collectively, "Trident™").[1] Plaintiffs assert products liability claims, and seek compensatory and punitive damages for injuries ranging from the minor and infrequent "squeaking" of the Trident™ to alleged complete shattering or fracturing of the Trident™. By this letter, HOC opposes mass tort designation in these cases.

First, designating this litigation a mass tort would be improper as (1) the cases alleging injury due to the Trident™ are not a mass tort by definition and (2) the cases do not meet the criteria for designating actions as a mass tort. Second, certain of Plaintiffs' claims are subject to preemption and dismissal with prejudice pursuant to the United States Supreme Court's decision in Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008), thereby making mass tort designation moot. Third, only eight of the twenty-five actions involve Plaintiffs who are New Jersey residents, and

[1] Plaintiffs have also named Stryker Corporation ("Stryker") in four of the twenty-five cases, but have served Stryker in only three of these four cases. Similarly, Plaintiffs have named Stryker Sales Corporation ("Stryker Sales") as a defendant in two cases, but have served Stryker Sales in only one case.

the other seventeen cases are therefore subject to dismissal on *forum non conveniens* grounds -- a total of eight actions hardly warrants mass tort designation. Finally, despite counsel's representation in Plaintiffs' application for mass tort designation that dozens of additional cases are destined for New Jersey, only two cases have been served in the two months since Plaintiffs applied for mass tort designation.

Should this Court determine that the actions alleging injuries as a result of the Trident™ warrant mass tort designation, despite HOC's strenuous objections, assignment to Bergen County would be eminently sensible in the interests of fairness, given the geographical location of the parties and attorneys, given the existing caseload in Bergen County versus Plaintiffs' desired Atlantic County, and due to Plaintiffs' blatant, improper, and admitted attempt at forum shopping.

I. Background

HOC -- the *only* New Jersey resident party in the vast majority of cases alleging damages as a result of the implantation of the Trident™ -- maintains its principal place of business in Mahwah, Bergen County, New Jersey. HOC developed, marketed and introduced into the United States certain components of the Trident™ via HOC's headquarters in Bergen County, New Jersey.[2]

Stryker and Stryker Sales are Michigan corporations, and maintain their principal place of business in Kalamazoo, Michigan. Stryker and Stryker Sales do not design, manufacture,

[2] In an obvious ploy to smear HOC, Plaintiffs unceremoniously insert allegations into approximately two-thirds of their "Background" section regarding alleged violations of FDA regulations, alleged recalls, and alleged kickbacks, which have nothing to do with the device at issue. (See Request for Mass Tort Designation of Cases Involving the Trident Stryker Hip Implants, dated December 30, 2008 ("Mass Tort App."), at 2.) The "Background" section also contains various misstatements. (See id.) HOC submits that these allegations are improper and bear no relation whatsoever to Plaintiffs' application for mass tort designation. Accordingly, HOC requests that the Court ignore this section of Plaintiffs' application in ruling on the propriety of mass tort designation.

assemble, equip, test, inspect, service, maintain, repair, advertise or market the Trident™ or any components thereof; nor do Stryker or Stryker Sales design, manufacture, assemble, equip, test, inspect, service, maintain, repair, advertise or market medical devices of this type. These Stryker parties have been improperly named in four of the cases at issue. The remaining cases properly do not name the Stryker entities.

The Trident™ is indicated for patients requiring primary total hip arthroplasty or replacement. This state-of-the-art device is intended to allow patients to walk and move in ways that they were unable before implantation of the device. The United States Food and Drug Administration ("FDA") has classified the Trident™ device a Class III medical device, and evaluated it under the most rigorous FDA approval process -- the premarket approval ("PMA") process. Very few Class III medical devices -- only about 1% -- undergo this process, which is limited to the most complex and technologically advanced devices that present true innovation, but also present risk of injury or illness and are important to sustaining life or health. See id. at 1003.

Twenty-five cases alleging injuries as a result of a component or combination of components of the Trident™ are now pending in the Superior Court of New Jersey: two in Bergen County, one in Middlesex County, and twenty-two in Atlantic County. There is no pending, federal multi-district litigation ("MDL") for the Trident™.

II. Mass Tort Designation is Improper

This Court should exercise its discretion, and refrain from designating the actions alleging injuries as a result of the implantation of a component or combination of components of the Trident™ as a mass tort. As evidenced below, these cases do not rise to the definition of a mass tort, nor do they come close to meeting the guidelines established for the designation of a

mass tort. Tellingly, Plaintiffs' own four-page application for mass tort designation includes a mere five sentences as to why these actions should comprise a mass tort -- and those five sentences are simply comprised of bare allegations that lack any support. (See Mass Tort App. at 2-3 ("This litigation meets all of the above enunciated criteria. There are already 22 filed cases.... All cases will involve the recurrent legal issues under the Product Liability Act.... Moreover, there are significant overlapping factual liability issues....") After considering the true and accurate substance of these cases, as articulated below, the Court must conclude that mass tort designation is improper.

A. By Definition, These Cases Are Not a Mass Tort

1. The Number of Cases Does Not Rise to the Level of a Mass Tort

Rule 4:38A, entitled "Centralized Management of Mass Torts", was adopted on October 23, 2003 in response to large-scale litigations involving a significant number of claims arising out of exposure to the same product, a mass disaster, or a common event. Designation of cases as a "mass tort" is and always has been discretionary, not mandatory. The Mass Tort Guidelines, promulgated by Directive # 11-03 and subsequently superceded by Directive #10-07, were later accompanied by the Mass Tort (Non-Asbestos) Resource Book, issued in November 2007 ("Resource Book"). According to the Resource Book, by definition, there must be "large numbers of claims" for litigation involving a single product to be designated a mass tort. Resource Book 1 (3d ed. Nov. 2007). The examples provided in the Resource Book -- tobacco, Rezulin and others -- illustrate the magnitude of the litigation contemplated by this designation. See id. Plaintiffs even admit that the Vioxx, Bextra and Celebrex mass torts involved "thousands

of cases". (See Mass Tort App. at 3.) These litigations dwarf the actions asserting claims for injuries allegedly resulting from the implantation of the Trident™ by several multiples.[3]

As of the dates of Plaintiffs' application for mass tort designation and supplemental letter, December 30, 2008 and January 6, 2009, respectively, Plaintiffs had served HOC with complaints in twenty-three cases in the Superior Court of New Jersey involving allegations relating to a component or combination of components of the Trident™. In an obvious attempt to persuade the Court that more cases regarding the Trident™ were pending in the Superior Court of New Jersey than actually were, Plaintiffs misrepresented to the Court that there were twenty-five pending New Jersey state court actions involving the Trident™ when, in fact, at least two of the cases included on Plaintiffs' list do not even involve the Trident™: Richter v. Palmieri et al., Docket No. OCN-L-3466-08, is an action involving a prosthetic *knee* device; and Sachs v. Howmedica Osteonics Corp, Docket No. MID-L-5423-07, is an action involving a non-Trident™ hip system.

Plaintiffs also attempt to create the appearance that the number of cases pending is large by stating that the cases involve "at least 34 plaintiffs." (Mass Tort App. at 2.) This statement is misleading because the only reason the number of Plaintiffs exceeds the number of pending cases is that various spouses have elected to assert loss of consortium claims. The inclusion of these claimants may add to the number of Plaintiffs that counsel can cite to support the mass tort application, but does not affect the number of actions pending. Indeed, the inclusion of *per quod* claimants should in no way influence this Court's decision regarding mass tort designation.

As of today's date, there are a mere twenty-five cases alleging injuries relating to a component or combination of components of the Trident™ pending in New Jersey state court.

[3] Even the "smaller" Bristol-Myers Squibb environmental mass tort cited by Plaintiffs in their mass tort application is comprised of four times as many cases as those alleging injuries as a result of the Trident™. (See id. at 4.)

Despite counsel's bald statement that her "firm has more than seventy additional cases we are reviewing and contemplate filing in New Jersey" (Mass Tort App. at 2), only *two* cases have been served since January 6, 2009, and only *one* of those cases was filed by the Weitz & Luxenberg firm.

2. The Various Injuries Alleged Do Not Permit These Actions to Be Designated as a Mass Tort

By definition, a mass tort involves actions alleging common injuries or damages. Resource Book at 1. Neither of these factors exist in the cases alleging injuries as a result of the implantation of the Trident™ due to the wide variety of problems that these Plaintiffs have allegedly encountered. This overall variety of alleged injuries prevents these actions from being designated as a mass tort.

By way of illustration of the scope of alleged "injuries," some Plaintiffs allege "injuries" as minor as "squeaking," "audible noise," "instability," and/or "irritation and discomfort" with a functioning device, while other Plaintiffs' injuries rise to the level of "fractured" or "shattered" devices that are no longer functioning. Still others allege such injuries as tenderness, decreased range of motion, neuroma, abnormal bone growth, infection, bone loss, hardware loosening, device failure, stripe wear, and/or posterior impingement. (See Mass Tort App. at 1 (Plaintiffs admit that a wide variety of injuries have been reported, such as "fractures and bone chipping; uneven wear; pain and loss of function; loud squeaking or clicking noises and difficulty walking").) Even Plaintiffs who allege "squeaking" as an injury are experiencing vastly different magnitudes of "squeaking" -- one Plaintiff might hear "squeaking" in the area of the device once every few months, while another Plaintiff may hear "squeaking" each and every time he/she walks, sits, or otherwise moves. In addition, the level of "squeaking" will most certainly vary

from Plaintiff to Plaintiff, ranging from "squeaking" that is barely audible to Plaintiff himself/herself to "squeaking" audible to third persons.

Also, some Plaintiffs have allegedly undergone revision surgeries to replace the Trident™ as a result of their alleged injuries, while others have functioning Trident™ devices that do not require premature revision.[4] Obviously, a Plaintiff who has had revision surgery will likely seek compensatory damages that exceed one who has not had such surgery.

In light of these examples of the vast differences in injuries and damages, one cannot find that a commonality of injuries and damages exists.

3. The Lack of Commonality Regarding Legal and Factual Issues Precludes These Actions From Being Designated as a Mass Tort

Given the nature of the various claims and injuries asserted, each action will, by necessity, focus primarily on claimant-specific issues, including device-specific issues (such as the Trident™ model and size, the component at issue, the other system components used with the Trident™, the production year of the component, any applicable recall history of that specific component, and warnings related to the specific component) and specific medical causation (such as medical history, anatomy, and activity level).

There will be differences with regard to each Plaintiff's device. As discovery has not yet commenced in the majority of cases pending in New Jersey state court, Plaintiffs have not yet identified which component or combination of components of the Trident™ they allegedly received. The components of the Trident™ differ from patient to patient based upon the size needed and the actual component(s) needed.

[4] The Trident™ devices, like *any* hip replacement device, will require revision as a matter of course at some point in time given the nature of these devices. This further complicates each Plaintiff's claims because certain risk factors inherent in each Plaintiff affect the life of the device.

With regard to the alleged recalls set forth in Plaintiffs' complaint, it is likely that discovery will show that the alleged recalls were not even applicable to many if not all of these Plaintiffs' devices. Indeed, although some Plaintiffs specifically aver that their devices were the subject of an alleged recall -- allegations based on purely speculative, bald-faced assertions rather than actual product identification and verification -- others do not even attempt to make this unsupported allegation. (See, e.g., Second Amended Complaint and Jury Demand, Traficante v. Stryker Corp., Docket No. ATL-L-003572-08, at ¶ 115, annexed hereto as Exhibit A.) Moreover, discovery may show that, of the Plaintiffs whose devices were subject to the alleged recalls, the reasoning for the alleged recall had no bearing whatsoever on Plaintiffs' alleged injuries.

Additionally, with regard to medical causation, the alleged cause of one Plaintiff's squeak is likely to be vastly different than the alleged cause of another Plaintiff's fracture. And the alleged cause of one Plaintiff's fracture most certainly could differ enormously from the alleged cause of another Plaintiff's fracture. And these are only two examples of the range of injuries.

Given the vast distinctions in law and fact regarding each Plaintiff's claim, mass tort designation is improper.

4. There is No Value Interdependence Between Claims

"Value interdependence" between claims is a trait unique to mass torts in which causation and liability of one action often depend upon the success or failure of prior lawsuits. See Resource Book at 1. That phenomenon is not present here due to the varied degree of alleged injuries and product defects and the attendant differences in causation. As noted above, the cause of one Plaintiff's alleged injuries as a result of the Trident™ is likely to be vastly different than the cause of another's alleged injuries due to that Plaintiff's medical history,

anatomy, activity level, and lifestyle. Indeed, it is quite likely that the medical cause of an alleged nuisance "squeak" is in no way related to the medical cause of an alleged fracture. Accordingly, a fact-finder's conclusion as to the cause of one Plaintiff's alleged squeak would (and should) in no way impact a fact-finder's subsequent conclusion as to the cause of another Plaintiff's alleged fracture or abnormal bone growth.

It is clear, then, that there is no value interdependence between the different claims alleged regarding the implantation of a component or combination of components of the Trident™.

5. There is No Degree of Remoteness Between the Court and the Actual Decision-Makers

In mass tort actions, it is quite common for there to be remoteness between the attorneys appearing in Court and the actual decision-makers. See, e.g., http://www.judiciary.state.nj.us/mass-tort/asbestos/counsel.htm (listing sixteen plaintiffs' firms and approximately 227 defense firms as of November 2008). Indeed, the Mass Tort Guidelines recognize this, and consider whether "the simplest of decisions often must pass through layers of local, regional, national, general and house counsel." Resource Book at 1. In the actions alleging damages as a result of the implantation of the Trident™, such remoteness is nonexistent.

HOC is represented by *only* Gibbons P.C. in these actions.[5] Moreover, *twenty of the twenty-five* complaints filed alleging injuries as a result of the implantation of the Trident™ list Ellen Relkin of Weitz & Luxenberg as the attorney representing Plaintiffs.[6]

[5] Gibbons P.C. also represents Stryker and Stryker Sales in the actions in which they have been served.
[6] Plaintiffs' cases are primarily driven by Weitz & Luxenberg in conjunction with the Florida law firm of Aylstock, Witkin, Kreis & Overholtz, PLLC in an effort to generate a mass tort by filing complaints alleging "injuries" resulting from the implantation of a component of combination of components of the Trident™.

Accordingly, the concern of remoteness between the attorneys and the Court does not exist here, and should not factor into the Court's decision regarding mass tort designation.

B. The Criteria Set Forth in the Mass Tort Guidelines for Designating Actions as a Mass Tort Are Not Met Here

1. Most of the Characteristics of a Mass Tort are Nonexistent

One factor considered in the decision to designate actions as a mass tort is whether "all or many of the characteristics" of a mass tort exist. Resource Book at 3. Here, the vast majority of the typical mass tort characteristics are *not* present.

As discussed in detail, supra:

- The number of claims and parties involved is nowhere near the level typical of a mass tort;
- There are not common issues of law or fact among the cases;
- There are vastly diverse injuries and damages alleged;
- There is no value interdependence between Plaintiffs' claims; and
- There is no degree of remoteness between the court and the actual decision-makers in any of the actions.[7]

2. Any Alleged Risk of Inconsistent Rulings is Speculative at Best

The Mass Tort Guidelines consider the possibility of "inconsistent rulings, orders or judgments if the cases are not managed in a coordinated fashion", Resource Book at 3, but the risk of inconsistent rulings in these cases is purely speculative at this juncture. Although twenty-

[7] Although Plaintiffs are geographically dispersed across the county, a factor considered in the decision to designate actions as a mass tort, this fact is purely of Plaintiffs' own making. In an effort to obtain the judge of their choice by filing their actions in the State of New Jersey rather than in their home states, see Section III(D) infra, Plaintiffs have created a dispersement of the parties. The Court should not reward Plaintiffs' judge-shopping by designating these cases as a mass tort simply because Plaintiffs are intentionally widely dispersed throughout the United States.

two of the Trident™ actions are currently pending in Atlantic County, HOC has moved to change venue to Bergen County in sixteen of those actions for the convenience of the parties and in the interests of justice[8], and will be so moving in an additional two cases. Accordingly, the risk of inconsistent rulings is virtually nonexistent if the Court denies Plaintiffs' mass tort designation application, as all but one of the cases will be decided by the courts in Bergen County and Atlantic County.

Nonetheless, the risk of inconsistent rulings can exist in cases involving the same product if they are assigned different judges, regardless of the number of cases pending or where they are pending. However, this fact, which is in no way unique to the cases at issue, does not dictate that such a risk requires that all cases involving the same product be designated as a mass tort. For example, if a motion is brought before "Judge A" of "County A" in "Case A," which alleges injuries as a result of "Widget," it is possible that "Judge A" will issue a ruling inconsistent with a ruling issued regarding an identical motion decided by "Judge B" of "County B" in "Case B," which also alleges injuries as a result of "Widget." Yet it is not likely that two cases involving the same product would ever be deemed a mass tort simply because inconsistent rulings were already made and the risk of additional inconsistent rulings therefore existed. Similarly, although there exists the possibility that inconsistent rulings *may* result in one or more cases, this possibility is not a reason to designate the handful of cases alleging injuries as a result of the Trident™ a mass tort.

3. <u>These Cases Do Not Require Specialized Expertise and Case Processing</u>

Each of the cases alleging injuries as a result of the implantation of a Trident™ component pending in the Superior Court of New Jersey are straightforward products liability

[8] The Atlantic County court denied four of those motions without prejudice due to Plaintiffs' pending mass tort application, and the other twelve motions are still pending.

matters. Although the product at issue is a state-of-the-art, Class III PMA medical device, the underlying issues attendant with these products liability actions alleging defects in the Trident™ do not require specialized expertise for the adjudication of those issues. Rather, standard products liability issues predominate, including such elements as whether each particular Plaintiff's device was defective, whether any alleged defect existed at the time the device left HOC's hands, and whether each Plaintiff can prove both proximate and medical causation. As these elements are present in each and every action alleging a product defect, specialized expertise and case processing is not required.

4. Centralization of These Actions Will Result in the Inefficient Utilization and Ultimate Waste of New Jersey's Judicial Time and Resources

An important factor in the determination of whether mass tort designation is warranted is "whether centralization would result in the efficient utilization of judicial resources and the facilities and personnel of the court." Resource Book at 3. In these cases, centralization would actually result in the waste of New Jersey's judicial time and resources.

Only *eight* of the twenty-five actions alleging injuries as a result of the Trident™ that are pending in the Superior Court of New Jersey involve Plaintiffs that are residents of the State of New Jersey. The other *seventeen* actions are comprised of Plaintiffs from Connecticut, Delaware, Florida, Georgia, Indiana, Kentucky, Missouri, Ohio, Pennsylvania, South Carolina, Virginia, and Wisconsin. None of the Plaintiffs in these seventeen actions have alleged that any of the operative facts surrounding their alleged injuries occurred anywhere within the State of New Jersey. Rather, these non-resident Plaintiffs chose to file their actions in the State of New Jersey even though they could pursue the same remedies (more conveniently and cost-effectively) in their home states simply to obtain the judge of their choice. See Section III(D),

infra. The ultimate result is that New Jersey's judicial time and resources will be unnecessarily depleted by these foreign Plaintiffs.

On a related note, and as discussed in Section II(C)(4), infra, the seventeen actions involving non-New Jersey residents are subject to dismissal on *forum non conveniens* grounds. Designation of a mass tort in a situation where nearly 70% of the cases will be dismissed is also not an efficient use of judicial time and resources.

Accordingly, mass tort designation will not promote the efficient use of New Jersey's judicial time and resources.

C. Additional Factors Prevent These Cases From Being Designated as a Mass Tort

1. Recent New Jersey Decisions Make New Jersey a Less Attractive Venue for Products Liability Cases

On May 29, 2008, the Appellate Division issued its opinion in McDarby v. Merck & Co., Inc., 401 N.J. Super. 10 (App. Div. 2008). The Appellate Division made a number of rulings, two of which significantly limit plaintiffs' available remedies for products liability claims in New Jersey. First, the Court reaffirmed that the New Jersey Product Liability Act ("PLA") is a plaintiff's sole remedy for a products liability claim. In eliminating the alternative of bringing products liability claims under the New Jersey Consumer Fraud Act ("CFA"), the Court foreclosed the availability of a separate award of treble damages, attorney's fees, and costs. The New Jersey Supreme Court solidified this statement of the law a week later in Sinclair v. Merck & Co., 195 N.J. 51, 54, 65-66 (2008), holding that "the PLA is the sole source of remedy for plaintiffs' defective product claim" and that plaintiffs cannot circumvent the requirements of the PLA by pleading their claims under other legal theories or statutes, including the CFA. Because

of these rulings, each and every CFA claim asserted by Plaintiffs was voluntarily dismissed or dismissed by Court order prior to HOC filing its answers.

Second, the Appellate Division found that the "fraud-on-the-FDA" exception to the PLA's bar on punitive damages awards in connection with FDA-approved products, see N.J.S.A. § 2A:58C-5(c), is preempted by federal law pursuant to the United States Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). In so ruling, the Appellate Division effectively eliminated punitive damages awards in pharmaceutical and medical device cases under New Jersey law. Significantly, seven Plaintiffs recognized the magnitude of this holding, and qualified their claims for punitive damages by stating, inter alia, that they are entitled to punitive damages if the New Jersey Supreme Court reverses the Appellate Division's decision in McDarby. (See, e.g., Second Amended Complaint and Jury Demand, Traficante v. Stryker Corp., Docket No. ATL-L-003572-08, at ¶ 115, Exhibit A.) Significantly, the New Jersey Supreme Court *only* granted certification on the issue of "whether the Federal Food, Drug and Cosmetic Act ... preempts state law tort claims predicated on the alleged inadequacy of warnings contained in Vioxx labeling that was approved by the Food and Drug Administration." McDarby v. Merck & Co., Inc., Docket No. C-204, September Term 2008 62,856, slip op. (N.J. Oct. 3, 2008) (annexed hereto as Exhibit B). Accordingly, these Plaintiffs cannot pursue their punitive damages claims under New Jersey law.

These rulings make New Jersey a significantly less hospitable venue for filing products liability claims, and thus cast further doubt on counsel's prediction of "dozens" more Trident™ filings in New Jersey.

2. Dismissals Pursuant to the United States Supreme Court's Preemption Decision in *Riegel* Warrant the Denial of Mass Tort Designation

On February 20, 2008, the United States Supreme Court held that the very small number of Class III medical devices approved pursuant to the FDA's exacting and comprehensive PMA process are exempt from all common law claims that impose requirements that are different from, or in addition to, the FDA's requirements. See Riegel, 128 S. Ct. at 1007, 1011. The Supreme Court found that the preemption clause of the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetics Act "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." Id. at 1002. The Supreme Court in Riegel instructed that the MDA preempts products liability claims, including such claims as failure to warn and defective design. See id. at 1006-07. Relying on the Supreme Court's reasoning in Riegel, various courts have dismissed claims relating to the labeling of the PMA devices at issue, including claims for breaches of express warranties. See, e.g., Horowitz v. Stryker Corp., Civil Action No. CV-07-1572 (DGT), slip op. (E.D.N.Y. Feb. 20, 2009) (annexed hereto as Exhibit C); In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, No. 08-1905 (RHK/JSM), 2009 WL 35467 (D. Minn. Jan. 5, 2009); Parker v. Stryker Corp., 584 F. Supp. 2d 1298 (D. Colo. 2008); Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090 (D. Minn. Aug. 18, 2008); Carter v. Novartis Consumer Health, Inc., 582 F. Supp. 2d 1271 (C.D. Cal. 2008); Adkins v. Cytyc Corp., No. 4:07CV00053, 2008 WL 2680474 (W.D. Va. Jul. 3, 2008); Lake v. Kardjian, No. 03-1267, , --- N.Y.S.2d ----, 2008 WL 5244823 (Sup. Ct. Dec. 17, 2008). Courts have also held that allegations relating to issues such as violations of federal regulations and recalls are insufficient to overcome the MDA's preemption of claims challenging the safety and effectiveness of a PMA medical device. See, e.g., Horowitz, slip op. at *15-16, 19; Medtronic, Inc., 2009 WL 35467, at *6-14; Parker, 584 F. Supp. 2d at 1302; Bausch v.

Stryker Corp., No. 08 C 4248, 2008 WL 5157940, at *4 (N.D. Ill. Dec. 9, 2008); Lake, 2008 WL 5244823, at *2.

The Supreme Court's decision in Riegel directly calls into question whether the actions alleging injuries as a result of the implantation of the Trident™ can even proceed to adjudication on the merits. Accordingly, mass tort designation is not warranted.

3. Coordination With the Huber v. Howmedica Osteonics Corp. Action Pending in the United States District Court for the District of New Jersey Would be Impractical and Inappropriate, and Would Not Further the Goals of Mass Tort Designation

Plaintiffs noted in their January 6, 2009 supplemental submission that the United States District Court for the District of New Jersey recently ruled that breach of express warranty claims are not subject to preemption. (See Request for Mass Tort Designation of Cases Involving the Trident Stryker Hip Implants (Correction), dated January 6, 2009, at 1-2 (referencing and enclosing Huber v. Howmedica Osteonics Corp., Civil Action No. 07-2400 (JLL), slip op. (D.N.J. Dec. 31, 2008)).) Based upon that ruling, Plaintiffs submit that "coordination" with the District of New Jersey "would be productive" despite the fact that a MDL does not exist regarding the Trident™. (See id.; see also Mass Tort App. at 2 (admitting that a Trident™ MDL does not exist).) What Plaintiffs neglected to tell the Court about the recent ruling is that the District of New Jersey considered itself bound by fourteen-year-old Third Circuit precedent in issuing its ruling, but intimated that it could understand how the reasoning of Riegel would support preemption of breach of express warranty claims premised upon the labeling of a PMA device like the Trident™.[9] Huber, slip op. at 7-8. As counsel for HOC in

[9] Plaintiffs also neglected to advise the Court that although Huber began nearly two years ago with a four-count complaint and a claim for medical monitoring, only one count for breach of express warranty seeking purely economic damages remains following two rounds of motion practice. On December 5, 2008, the Huber court again dismissed claims for consumer fraud, and plaintiff voluntarily dismissed the medical monitoring claim with prejudice.

both this litigation and in Huber, the undersigned can accurately represent to the Court that HOC has moved for certification of the Huber decision for immediate interlocutory appeal to the United States Court of Appeals for the Third Circuit, and that briefing on HOC's motion is complete.

If the Third Circuit hears HOC's interlocutory appeal and rules that such breach of express warranty claims are preempted by the MDA, then the Huber action will cease to exist, as the breach of express warranty claim is the *only* remaining cause of action in that litigation. Accordingly, there would be no action with which to coordinate. Yet even if the District of New Jersey does not certify the decision, or if the Third Circuit does not overturn its 1995 case precedent despite the reasoning in Riegel, then coordination would still be exceedingly impractical. *Huber, which was filed in 2007, involves a claim for breach of express warranty only, seeks economic damages only, and does not assert a single personal injury claim.* The cases pending in the Superior Court of the State of New Jersey that are the subject of Plaintiffs' pending mass tort application, however, are solely personal injury claims seeking personal injury damages. Moreover, one of the two representative plaintiffs in Huber specifically dismissed herself from the District of New Jersey action so that she could pursue her personal injury claims in federal court in her home state of Colorado. That Colorado action has since been dismissed in its entirety on preemption grounds pursuant to Riegel. See Parker v. Stryker Corp., 2008 WL 4716879.

Therefore, regardless of whether the District of New Jersey ever adjudicates the merits of the breach of express warranty claim in Huber, Plaintiffs' suggestion of possible coordination of the state court Trident™ actions and Huber is certainly not "required", and is, in fact, impractical and unwarranted.

4. *Forum Non Conveniens* Dismissals are Yet Another Reason to Deny Mass Tort Designation

All but eight of the pending cases are subject to dismissal under the doctrine of *forum non conveniens* because (1) *seventeen* of the pending actions involve Plaintiffs who are not New Jersey residents and (2) all the operative facts -- the implantation of the Trident™, the alleged injuries, the treatment of Plaintiffs' alleged injuries, and the alleged damages -- appear to have taken place in Plaintiffs' home states. (See Transcript of Decision, In re Depro-Provera Contraceptive Injection Litig., Docket No. L-4889-07 MT (N.J. Super. Ct. Law Div. June 27, 2008), annexed hereto as Exhibit D.) It is clearly premature to designate a litigation as a mass tort where only eight of the pending cases may legitimately have been brought in the State of New Jersey.

* * * *

In short, mass tort designation is unwarranted and improper for cases alleging injuries as a result of the implantation of a component or combination of components of the Trident™. First, these cases do not fit the definition of a mass tort. Second, the vast majority of the guidelines for designating actions as a mass tort are not met here. Third, most, if not all, of these cases are subject to dismissal on preemption and/or *forum non conveniens* grounds. Fourth, New Jersey is a much less attractive venue for products liability plaintiffs than it once was, making the prospect of "dozens" of additional filings unlikely. Finally, a MDL does not exist, and coordination with the Huber case in the District of New Jersey is both impractical and inappropriate. Accordingly, the Court should exercise its discretion and deny Plaintiffs' application for mass tort designation.

III. In the Unlikely Event that the Court is Inclined to Grant Mass Tort Designation Over HOC's Objections, Venue in Bergen County Rather Than Atlantic County is Appropriate

The Resource Book specifically states, "Issues of fairness, geographical location of parties and attorneys, and the existing civil and mass tort caseload in the vicinage will be considered in determining to which vicinage a particular mass tort will be assigned for central management." Resource Book at 4. Although HOC strenuously objects to these handful of cases being designated as a mass tort, HOC requests that if the Court grants mass tort designation, it assign the cases to Bergen County for adjudication because (1) the Mass Tort Guidelines indicate that Bergen County is the best venue to preside over the litigation, and (2) Plaintiffs are admittedly and unfairly engaging in blatant and inappropriate judge shopping by adamantly arguing in favor of Atlantic County as the proper vicinage.

A. The Geographic Location of the Parties Dictates that Venue in Atlantic County is Improper

Despite the fact that the geographic location of the parties and attorneys is one of three factors considered in determining the assignment of a mass tort, Plaintiffs posit that geographic location should comprise only a minor facet of this Court's decision regarding the assignment of venue because "mass tort management ... is largely conducted through conferences between counsel for the parties and the court...." (Mass Tort App. at 3). It is clear that Plaintiffs do not want the Court to consider the geographic location of either the parties or the parties' attorneys because not one of the parties or attorneys resides or works in Atlantic County. See infra. Accordingly, Atlantic County would be an inappropriate vicinage for a potential mass tort.

HOC -- the *only* New Jersey resident party in the vast majority of cases alleging damages as a result of the implantation of the Trident™ -- maintains its principal place of business in Mahwah, Bergen County, New Jersey. HOC never maintained its principal place of business in

Atlantic County, New Jersey. HOC developed, marketed and introduced into the United States certain components of the Trident™ via HOC's headquarters in Bergen County, New Jersey. HOC's employees and representatives with knowledge of the issues or facts related to the claims asserted by Plaintiffs are employed in Mahwah, Bergen County, New Jersey. FDA submission documents and other tangible items that may be pertinent to Plaintiffs' claims are located in Mahwah, Bergen County, New Jersey.[10]

As noted above, *seventeen* of the twenty-five cases currently pending in the Superior Court of New Jersey involve Plaintiffs who are not even residents of the State of New Jersey. *None* of the eight cases involving New Jersey residents involve residents of Atlantic County.[11] However, at least one action, Koenig v. Stryker Corp., Docket No. BER-L-4377-08, involves Plaintiffs who are residents of Hackensack, Bergen County, New Jersey. Significantly, *none* of the Plaintiffs in these actions allege that (1) they received medical treatment in Atlantic County; (2) any of the pertinent events giving rise to their allegations occurred in Atlantic County; or (3) witnesses and/or evidence, including Plaintiffs' treating physicians and medical records, are located in Atlantic County.

Accordingly, the geographic location of the parties dictates that of all of the counties in the State of New Jersey, Bergen County -- which maintains a resident mass tort judge -- bears the

[10] As noted earlier, Stryker and Stryker Sales are Michigan corporations, and maintain their principal place of business in Kalamazoo, Michigan. Stryker and Stryker Sales do not design, manufacture, assemble, equip, test, inspect, service, maintain, repair, advertise or market the Trident™ or any components thereof; nor do Stryker or Stryker Sales design, manufacture, assemble, equip, test, inspect, service, maintain, repair, advertise or market medical devices of this type. Accordingly, these defendants have been erroneously sued in the few cases in which Plaintiffs named them as defendants.

[11] Plaintiff in Phillian v. Howmedica Osteonics Corp., Docket No. BER-L-3305-08, merely represented in her complaint that she is a resident of the State of New Jersey. Upon information and belief, Plaintiff Valorie Phillian resides in Butler, Morris County, New Jersey. See http://www.whitepages.com/search/FindPerson?extra_listing=mixed&form_mode=opt_b&post_back=1&firstname_begins_with=1&firstname=valorie&name=phillian&street=&city_zip=&state_id=NJ&localtime=survey.

strongest nexus to the parties in each and every one of the twenty-five cases alleging injuries from the Trident™ pending in the Superior Court of New Jersey.

B. The Geographic Location of the Attorneys Further Exemplifies that Venue in Atlantic County is Improper

The geographic location of the parties' attorneys further evidences that Bergen County is a far more convenient forum for the litigation of these actions than is Atlantic County. With the exception of one attorney with one action who is located in Philadelphia, Pennsylvania[12], every other attorney litigating these actions and admitted to the New Jersey bar maintains his/her office in Northern New Jersey, New York, New York, and/or Central New Jersey.

Gibbons P.C. - Counsel for HOC work in Gibbons P.C.'s offices in Newark, New Jersey and New York, New York. Each of these cities is significantly closer to Bergen County than it is to Atlantic County.

Weitz & Luxenberg - Ellen Relkin, the principal attorney at Weitz & Luxenberg representing Plaintiffs in twenty cases in Armstrong, Carrithers, Cumpstone, DeLaVergne, Dence, Gundersen, Haskett, Ibanez, Johnson, Kennedy, Kersey, Knecht, Maenner, McArthur, Nelson, Pearce, Pozega, Ragni, Tannenbaum, and Tucker, works in Weitz & Luxenberg's New York, New York office -- a city vastly closer to Hackensack, New Jersey than to Atlantic City, New Jersey. See http://www.weitzlux.com/ellenrelkin/findalawyer/legalservice_92.html. Ms. Relkin has also previously represented to the Court that she maintains her office in New York, New York. See http://www.judiciary.state.nj.us/mass-tort/ortho/orthocounsel_020808.pdf.

Seeger Weiss LLP - Christopher Seeger, attorney for one Plaintiff in Resnick, has represented to the Court on numerous occasions that he works in Seeger Weiss's Newark, New Jersey and New York, New York offices. See http://www.judiciary.state.nj.us/mass-tort/accutane/ACCUTANE_COUNSEL_LIST_062207.pdf; http://www.judiciary.state.nj.us/mass-tort/bextra-celebrex/bextra_celebrex_vioxx_counsel_072108.pdf; http://www.judiciary.state.nj.us/mass-tort/ortho/orthocounsel_020808.pdf; http://www.judiciary.state.nj.us/mass-tort/vioxx/vioxx_counsel_090808.pdf;

[12] Michael Weinkowitz, counsel for one Plaintiff in Traficante, works at Levin, Fishbein, Sedran & Berman in Philadelphia, Pennsylvania. See http://www.lfsblaw.com/contact.jsp.

http://www.judiciary.state.nj.us/mass-tort/zometa-aredia/zometa_counsel_list_120308.pdf.

Skoblar Law Office - Robert Skoblar, counsel for husband and wife Plaintiffs in Koenig, works in his office in Hackensack, Bergen County, New Jersey. Hackensack is the very city in which the Bergen County Courthouse is located.

Bloomberg, Steinberg & Bader - Seth Bader, attorney for one Plaintiff in Phillian, works in Hackensack, Bergen County, New Jersey. His law firm maintains offices in Hackensack, New Jersey and New York, New York. See http://www.baderlawfirm.com. Both offices are significantly closer to the Bergen County Courthouse than they are to the Atlantic County Courthouse.

Martin Kane Kuper, LLC - Todd Drayton, attorney for husband and wife Plaintiffs in Titus, works in his firm's office in East Brunswick, New Jersey. A simple Mapquest search indicates that it takes twice the amount of time to travel to Atlantic City from East Brunswick as it does to travel to Hackensack from East Brunswick. Compare http://www.mapquest.com/maps?1z=08816&2c=Atlantic+City&2s=NJ with http://www.mapquest.com/maps?1z=08816&2c=Hackensack&2s=NJ.

C. The Atlantic County Court's Existing Caseload Also Makes Atlantic County a Much Less Desirable Forum

According to the Court's website, Bergen County is only presiding over three mass torts -- Depo-Provera, Mahwah Toxic Dump Site, and Digitek. See http://www.judiciary.state.nj.us/mass-tort/index.htm. In the Depo-Provera mass tort, the Court dismissed 156 of the 159 pending cases on *forum non conveniens* grounds. (See Transcript of Decision, In re Depro-Provera Contraceptive Injection Litig., at 6:24-7:3, 139:2-22, Exhibit D; see also http://www.judiciary.state.nj.us/mass-tort/depo-provera/orders_decisions.htm.) Despite Plaintiffs' postulating to the contrary, Atlantic County is currently presiding over five *active* mass torts -- Accutane, Bextra/Celebrex, Bristol-Myers Squibb Envionmental, Fosamax, and Vioxx. See http://www.judiciary.state.nj.us/mass-tort/index.htm.

Plaintiffs state that Atlantic County is the "most appropriate vicinage" because twenty-two of the pending twenty-five cases are currently venued in Atlantic County and have been

assigned to Judge Higbee. However, the current venue status of those cases is simply the result of Plaintiffs' own making. By their own admission, Plaintiffs recently filed a flurry of their cases in Atlantic County with the intention of having Judge Higbee assigned as a judge. See Section III(D), infra. HOC immediately moved to change venue to Bergen County in sixteen of those cases (1) because of their complete lack of nexus to Atlantic County and (2) for the convenience of the parties. Judge Higbee denied four of those motions without prejudice due to Plaintiffs' pending mass tort application. The remaining twelve motions are still pending before Judge Higbee.

Plaintiffs also erroneously and misleadingly state that Judge Higbee is already familiar with the claims at issue because "nearly all of the Stryker hip implant cases filed in New Jersey are already before the Honorable Carol E. Higbee, P.J.Cv., in Atlantic County...." (Mass Tort App., at 4.) Plaintiffs should know better than to make blatant misrepresentations regarding the cases before Judge Higbee. First, discovery has not begun in *any* of the twenty-two cases currently pending before Judge Higbee -- HOC only filed its answers in twenty of the twenty-two Atlantic County cases on February 6, 2009 and February 9, 2009. Accordingly, these Plaintiffs' responses to Uniform Interrogatories are not even due until March 9, 2009 and March 11, 2009.[13] See R. 4:17-1(b)(2). Moreover, HOC's answers in the remaining two Atlantic County cases are not due until March 10, 2009 and March 13, 2009. Second, although HOC has moved in sixteen Atlantic County cases for change of venue, twelve of those motions remain pending. With regard to the four motions upon which Judge Higbee ruled, she did not even reach the merits, but rather denied the motions without prejudice pending this Court's decision on Plaintiffs' application for mass tort designation. (See Orders dated January 23, 2009, annexed

[13] The only Trident™ cases in which initial discovery deadlines have passed are Phillian and Titus, actions pending in Bergen County and Middlesex County, respectively. These cases haven been pending since on or about April 30, 2008 and June 12, 2008, respectively.

hereto as Exhibit E.) Finally, although HOC moved to dismiss claims as subsumed by the PLA in the five original Atlantic County cases, Judge Higbee never reached the merits of those motions either, as one Plaintiff filed an amended complaint omitting those claims in response to the motion and the other four Plaintiffs ultimately conceded that the claims were not viable and submitted orders of dismissal to the Court for execution. Accordingly, it is respectfully submitted that Judge Higbee has no more experience with the merits of these specific actions than does any other mass tort judge. Plaintiffs' statements to the contrary are false.

D. Plaintiffs Are Engaging in Unfair and Inappropriate Judge Shopping

Forum shopping is highly disfavored by our nation's courts, including the courts of the State of New Jersey. Yet that is precisely the practice in which Plaintiffs have admittedly engaged.

Two months before Plaintiffs ever applied to this Court for designation as a mass tort, HOC moved to change venue from Atlantic County to Bergen County in four of the five then-pending actions in Atlantic County.[14] In opposing those motions, Plaintiffs expressly admitted not only to forum shopping, but to going one step further to actual judge shopping. (See, e.g., Plaintiff's Brief in Opposition to Defendants' Motion to Dismiss Counts 2, 5, 6, 7, 8, 9 and 10 of the Complaint Pursuant to Rule 4:6-2 and to Transfer Venue to Bergen County Pursuant to R. 4:3-3, Traficante v. Stryker Corp., Docket No. ATL-L-003572-08, ("Venue Opp.") at 12, annexed hereto as Exhibit F.) In their own words, Plaintiffs admitted that they filed their actions in Atlantic County for the sole purpose of obtaining Judge Higbee to preside over their actions:

> ***Plaintiff intentionally filed (as will every plaintiffs attorney contacted to date who intends to file in state court in New Jersey), in Atlantic County for the same reason that so many pharmaceutical product liability and other cases were assigned***

[14] HOC has since filed an additional twelve motions to change venue from Atlantic County to Bergen County.

> ***here as Mass Torts. That reason is the skill, creativity and ability to bear on the discovery and trial of this type of case by Judge Higbee.***

(Id. (emphasis added).) In fact, Plaintiffs praised Judge Higbee's accolades on seven additional occasions in their opposition, including:

- "Judge Higbee is well-respected on the bench and in the bar for her knowledge, professionalism and fairness when presiding over complex pharmaceutical product and medical device liability litigation." (Id. at 8-9.)
- Judge Higbee "has vast experience presiding over complex pharmaceutical litigation." (Id. at 9.)
- Judge Higbee "has presided (including trials) over Vioxx, Accutane and Bextra/Celebrex litigation." (Id.)
- "The experience in the Vioxx and other Mass Torts formally assigned to Judge Higbee in Atlantic County has been one of efficiency and fairness." (Id. at 11.)
- "The Honorable Judge Higbee will provide Defendants with a fair and expeditious trial." (Id. at 13.)

Plaintiffs have engaged in the same judge shopping in their application for mass tort designation. Tellingly, Plaintiffs devote an entire section of their application -- indeed, the vast majority of their four-page application -- to arguing why Judge Higbee should preside over this potential mass tort while providing only five sentences comprised solely of bare conclusions as to why the actions should be designated as a mass tort in the first place. (See Mass Tort App. at 3-4.) Plaintiffs specifically state that "the Honorable Carol Higbee has extensive experience in not just managing but also trying complex medical product liability actions" and that "Judge Higbee also played a key role in the global settlement of the Vioxx litigation and in the

settlement of the Bextra/Celebrex litigation and has critical experience in settlement of complex, mass tort actions." (See id. at 4.)

Although HOC is certainly aware of Judge Higbee's knowledge of and experience in presiding over mass torts and products liability actions, such knowledge and experience are not factors to be considered in an application for mass tort designation. Moreover, each of the judges assigned to preside over mass torts in the State of New Jersey -- including one in Bergen County, New Jersey -- possesses knowledge of and experience in presiding over mass torts, including those products liability mass torts involving medical devices and pharmaceuticals. Indeed, Plaintiffs effectively disparage every other mass tort judge in the State of New Jersey when they (1) state that they solely filed in Atlantic County in an effort to obtain Judge Higbee as a judge, and (2) focus on Judge Higbee's experience, intimating that no other mass tort judge possesses her experience. It is unfortunate that by making their blatant, judge shopping arguments, Plaintiffs have placed Judge Higbee, a fine jurist, in an untenable position.

If a judge's experience and knowledge were to weigh in as factors in this Court's determination of the propriety of assigning venue, then a dangerously slippery slope would emerge -- forum shopping would become rampant, as plaintiffs seeking mass tort designation would simply highlight the experience of the judge of their choice in an attempt to obtain that judge, without even considering the Mass Tort Guidelines for venue selection. In fact, this is exactly what Plaintiffs ***admitted*** doing in their oppositions to the motions to change venue, and what Plaintiffs have ***admitted*** to doing in their application for mass tort designation. (See Venue Opp. at 12; Mass Tort App. at 3-4.)

Plaintiffs' actions in this regard are an affront to this Court's long and well-respected history of independence and integrity. Plaintiffs are effectively attempting to dictate to this

Court how to staff the Trident™ cases in a manner that is favored and hand-picked by Plaintiffs. Plaintiffs' attempt at judge shopping seeks to completely undermine the independence of this Court. Plaintiffs' actions cannot be countenanced.

IV. Conclusion

For the reasons set forth above, HOC respectfully submits that mass tort designation for Trident™ cases in New Jersey is unwarranted and improper under Rule 4:38A and the Mass Tort Guidelines (Directive # 10-07). Indeed, these cases do not rise to the level of a mass tort, nor do they meet the criteria for such a designation. HOC therefore vigorously maintains its objection to a mass tort designation. However, if the Court deems mass tort designation warranted, which it is not, then HOC submits that these cases should be transferred to Bergen County for further proceedings as set forth herein.

Respectfully submitted,

Kim M. Catullo /BSR

Kim M. Catullo

Enclosures

cc: Michelle V. Perone, Esq. (w/ encl. via hand delivery)
Ellen Relkin, Esq. (w/o encl. via e-mail; w/ encl. via overnight delivery)
Seth Bader, Esq. (w/o encl. via e-mail; w/ encl. via overnight delivery)
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MAR 16 2009
GLENN A. GRANT, J.A.D.
ACTING ADMINISTRATIVE DIRECTOR

March 13, 2009

VIA OVERNIGHT DELIVERY

Hon. Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts
Richard J. Hughes Justice Complex
25 W. Market Street
Trenton, New Jersey 08625-0037

Re: Response to Plaintiffs' Third Submission re: Application for Mass Tort Designation and Centralized Management of Litigation Involving Stryker Trident Hip Implants and Assignment to Atlantic County

Dear Judge Grant:

Gibbons P.C. represents Howmedica Osteonics Corp. ("HOC") in the cases pending in New Jersey Superior Court alleging injuries from the implantation of a component, or some combination of components, of the Trident Ceramic on Ceramic Acetabular System.

On or about December 30, 2008, Plaintiffs applied for mass tort designation of these actions and for centralization of the actions in the Superior Court of New Jersey, Law Division, Atlantic County before the Honorable Carol E. Higbee. On or about January 6, 2009, Plaintiffs submitted their first supplemental submission in support of their mass tort and Atlantic County centralization application. On or about January 22, 2009, Your Honor issued a Notice to the Bar regarding Plaintiffs' application, and specifically and unambiguously stated, "Anyone wishing to comment on or object to this application should provide such comments or objections ... **by March 2, 2009.**" (Notice to the Bar, available at http://www.judiciary.state.nj.us/notices/2009/n090126a.pdf (emphasis in original).)

In accordance with Your Honor's directive, HOC submitted its objection to Plaintiffs' application on March 2, 2009. Without seeking leave, and in direct contravention of Your Honor's Notice to the Bar, Plaintiffs unilaterally submitted their *third* submission (i.e., their *second* supplemental submission) by letter dated March 9, 2009 -- one week *after* the final deadline for submissions to comment on or object to the mass tort application.

It is patently unfair (and improper) for Plaintiffs to have a third bite at the apple when (1) they chose to severely limit their arguments in their initial application and first supplemental application as to the propriety of mass tort designation while instead focusing their attention on their attempt to venue and judge shop by having their actions specifically directed to Atlantic County and, more specifically, the Honorable Carol E. Higbee; and (2) HOC is unable to respond substantively to Plaintiffs' allegations in their latest submission due to the expiration of the deadline for submissions.

Accordingly, HOC respectfully requests that Your Honor disregard Plaintiffs' third submission, as it is clearly untimely and improper.

Respectfully submitted,

Kim Catullo ISBN

Kim M. Catullo

Enclosures

cc: Michelle V. Perone, Esq. (via overnight delivery)
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March 9, 2009

Via Federal Express

Hon. Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts
Administrative Office of the Courts
of the State of New Jersey
Richard J. Hughes Justice Complex
25 W. Market Street
Trenton, New Jersey 08625

Re: Request for Mass Tort Designation of Cases Involving the Trident Stryker Hip Implants

Dear Judge Grant:

Please consider this letter in reply to Defendant's Opposition to Plaintiffs' Application for Mass Tort Designation and Centralized Management of Litigation Involving Stryker Trident Hip Implants. I will not dignify some of the arguments in the twenty-seven page opposition with a point by point reply, and instead focus on the key issues.

I. THE NEED FOR CENTRALIZATION

A. The Medical Device Act preemption issue strongly merits centralization

The history of the recent Stryker litigation throughout the country is the most compelling basis for why centralization is necessary. Within the past six months six

separate judges have had to decide very similar preemption motions involving the same device in five separate courts. Incredibly, two different New Jersey federal judges, Judge Jose Linares and Judge Dennis Cavanaugh have had to expend judicial resources deciding similar preemption motions involving the same device and it is inexplicable that those cases were not heard before the same Judge. Defendants, represented by the same counsel nationally, certainly could have filed a petition for multi-district litigation or sought consolidation, but it would appear that Defendants Stryker and Howmedica prefer to re-litigate the same issues in multiple courts, enhancing their chance for some favorable rulings, and burdening the judiciary with repetitive litigation.

Below is the chronology of the various preemption decisions involving this device:

October 1, 2008 - Parker v. Stryker, 584 F. Supp. 2d 1298 (D. Co. 2008) (claims preempted under the MDA, decision on appeal) **Ex. A**

December 9, 2008 - Bausch v. Stryker, 2008 WL 5157940 (claims preempted under MDA) (Case is pending motion for reconsideration) **Ex. B**

December 31, 2008 - Judge Linares, Huber v. Howmedica, 2008 WL 5451072 (D.N.J.) Class action case for plaintiffs with implanted Trident System hip implants alleging breach of express warranty based on claims that the device had only a .5% rate of defect in which the device would emit an audible sound when the actual rate is much higher. The court dismissed other claims but found that the breach of express warranty claim is not preempted under Third Circuit jurisprudence. **Ex. C**

February 11, 2009 - Chief Judge Hamilton, United States District Court, Southern District of Indiana; Hofts v. Howmedica, F. Supp. 2d___, 2009 WL 331470 - holding that the claims are *not* preempted by the Medical Device Amendments of 1976 **Ex. D**

February 20, 2009 - Horowitz v. Stryker, 2009 WL 436406 (E.D.N.Y. 2009). Failure to warn and design defect claims dismissed as preempted. Leave granted to replead claims for breach of warranty. **Ex. E**

March 5, 2009 - Judge Cavanaugh, Delaney v. Stryker Orthopaedics 2009 WL 564243 (D.N.J.) - dismissing certain claims, but preserving the breach of express warranty cause of action if properly re-plead. **Ex. F**

Certainly, the New Jersey judiciary, a pioneer in mass tort management, recognizes the efficiency of consolidation of mass-tort cases and would not condone burdening judges from Bergen, Middlesex, Atlantic and Ocean counties and potentially other counties to decide the very same issue with the potentiality of divergent rulings on the same legal issue.

In defendants quest to argue that there will not be more Stryker cases filed in NJ and hence the twenty + cases on file are not numerous enough to warrant a mass tort, defendant raises yet an entirely additional specious argument, claiming that because in its view New Jersey law is no longer as favorable to plaintiffs due to the elimination of punitive damages and Consumer Fraud Act claims in McDarby v. Merck, that therefore plaintiffs claim that they intend to file more cases in New Jersey was disingenuous. (Defense opposition letter page 13) This bizarre logic is factually and chronologically challenged. McDarby was decided in May 2008 yet most of the cases which have been filed involving the Trident implants were filed *after* that date and done with full knowledge about the new constraints for those claims as I was one of the counsels in McDarby and briefed and argued the appeal. Moreover, McDarby, affirming a $4.5 million compensatory verdict, was very much a plaintiff win, providing appellate support for the heeding presumption in the pharmaceutical/learned intermediary context; providing a new exception to the FDA presumption of adequacy, and appropriately recognizing an enlightened approach to the causation standard of substantial contributing factor and to scientific evidence admissibility. Thus it is absurd for a defense lawyer to be opining where plaintiffs' counsel intends to pursue their litigation.

Second, defendant overtly implies that I exaggerated about the number of cases in "counsel's bald statement that her firm has 'more than seventy additional cases we are reviewing and comp template filing." I represent that that statement as to future filings is entirely correct, and the reason I have only filed one additional case since the centralization application deals with critical emerging issues on preemption. As noted above, there have been disparate rulings on the issue of whether the Medical Device Act preempts these cases given the manufacturing defect and violation of governmental regulations exception set forth in Riegel v Medtronic 128 S.Ct. 999 (2008)

Due to the confusion arising from the United States Supreme Court's ruling in Riegel which found that in the absence of violation of federal regulations or manufacturing defects, MDA approved Class III devices are immunized from failure to warn claims, key members of the Senate and the House have introduced legislation to correct the Supreme Court's misapprehension of legislative intent underlying the original Medical Device Act. The clear and stated purpose of the new legislation, the Medical Device Safety Act, is to undo the Riegel holding. As stated by a press release of the House Committee on Energy and Commerce on March 5:

> U.S. Reps. Frank Pallone, Jr. (D-NJ), Chairman of the Energy and Commerce Subcommittee on Health, and Henry A. Waxman (D-CA), Chairman of the Energy and Commerce Committee, today introduced legislation in the House that will reverse a U.S. Supreme Court decision that denies injured patients the ability to seek compensation for their injuries and gives medical device makers blanket immunity. In February 2008, the U.S. Supreme Court, for the first time, immunized medical device companies from lawsuits brought by patients who are injured by certain medical devices. In Riegel v. Medtronic, Inc., the Court found that those claims are barred by a preemption clause included in the Medical

Device Amendments of 1976 (MDA). This decision ignores both congressional intent and 30 years of experience in which federal regulation, through the U.S. Food and Drug Administration (FDA), and tort liability played complementary roles in protecting consumers from device risks. See **Ex. G**

Being fully cognizant that this bill was going to get introduced, and is likely to succeed, given that an earlier iteration was introduced last year and co-sponsored by then Senator Obama who will thus obviously sign any such legislation that is passed by the legislature, see **Ex. H,** in the appropriate representation of my clients, I made (as have other plaintiffs' counsel) a strategic decision to not yet file cases that do not need to be filed for statute of limitations or other purposes. For, in the event the New Jersey judge who eventually rules on this issue does find preemption or partial preemption, it is in the interest of the plaintiffs to not have their case dismissed by a preemption decision and avoid the legal question of whether the Act applies retroactively to a case that is already dismissed. While we feel optimistic that on the merits New Jersey courts would not dismiss the cases because this litigation involves a manufacturing defect as opposed to a pure warnings issue (the devices at issue were recalled specifically because they contained adulterated material), there is no sound basis to risk an adverse preemption decision given the pendency of this corrective legislation. Thus, defendant's speculative claim that I was misleading this Court and lied about the number of additional cases is extremely offensive and lacking the professionalism one expects from a seasoned New Jersey practitioner.

B. A Judge with experience in complex mass tort and FDA related discovery is appropriate

Defendant's argument that the case does not require specialized expertise and case processing is plainly silly. Pharmaceutical and medical device cases involving FDA regulated products involve complex cases foreign to most judges. There is a clear learning curve in managing these cases and issuing discovery orders involving FDA related documents, clinical trials and the electronic discovery involved that are best handled by a seasoned jurist who has tried multiple pharmaceutical cases already.

C. Coordination with federal courts by a centralized Judge is prudent

Defendants seek to rebut one of the stated purposes of centralization, coordination with federal courts, by arguing that coordination between any assigned mass tort judge with the United States District Court for the District of New Jersey in the Huber v. Howmedica Osteonics Corp. case is not appropriate since Huber is merely a class action case for breach of warranty and not a personal injury claim. Despite the fact that there will be significant overlapping discovery, astoundingly, defendants neglect to apprise this Court of yet another federal court case pending before the District of New

Jersey (Judge Cavanaugh) which is in fact a personal injury claim for a shattered implant. Four days ago Judge Cavanaugh ruled that the breach of express warranty claim could proceed if properly re-plead. Even though the decision post-dates the defendant's 27-page submission to this Court, the key fact is that defendant and its counsel was fully aware of the pendency of that case and woefully neglected to mention it to the Court while arguing that Huber is not worth coordinating since it is not a personal injury claim.

D. Complex discovery issues are predominant

Regardless of whether all plaintiffs have the same injury or some have variants (some squeaking and clicking; some needing replacement surgery; and some suffering fractures) there still will be essentially the same liability discovery involving review of the clinical trial data for this device, the adverse reaction data, the manufacturing quality control data, the correspondence and communications with the FDA and the marketing to the orthopedic community and the representations and/or warranties made by the company to the doctors and patients. Similarly, the inevitable battles as to privilege logs and claimed trade secret documents are best handled centrally. Hence consolidation of those issues is important to avoid duplicative complex and time consuming discovery battles.

II. Location of the Centralization

Defendants presume to argue that Bergen County is more convenient for plaintiffs' counsel (after also presuming which state's law is best for plaintiffs) . First, Weitz & Luxenberg's four lawyer New Jersey office is in Cherry Hill which is substantially closer to Atlantic County and while I work more often in the New York office, court filings are generated from and delivered via Lawyers' Service by our Cherry Hill Office. Further, living in Essex County proximal to the Parkway, going in the direction against traffic, I need to leave about the same amount of time to drive to Atlantic City than to Hackensack for a morning court appearance due to the potential of an hour long delay for the New York commuters approaching the George Washington Bridge. Moreover, the attorney from Seeger Weiss who is now most involved in the litigation, Jeffrey Grand, resides in Monmouth County which is convenient to Atlantic County.

With regard to the Court dockets, obviously the AOC is best equipped to assess where to deploy its resources. From reviewing the applications on the Mass Tort Web site for the pending Nuva-Ring Application, given that both parties requested Northern New Jersey and the Acting Administrative Director of the Courts on its own initiative seeks a mass tort designation, it would appear that Bergen County will likely be the venue for the Nuva-Ring litigation, giving Bergen County the most recent mass torts of Digitek (with the first case management conference to be held on March 27) and Nuva Ring.

Conclusion

For the reasons set forth herein and in the earlier submissions, it is respectfully submitted that this case warrants mass tort centralization and that Atlantic County is an appropriate choice[1].

Respectfully,

Ellen Relkin

cc: Michelle V. Perone, Esq., Chief, Civil Court Programs
The Honorable Carol Higbee
Kim M. Catullo, Esq., Gibbons, P.C.
Christopher Seeger, Esq., Seeger Weiss
Michael Weinkowitz, Esq., Levin, Fishbein, Sedran & Berman
Douglas Kreis, Esq., Aylstock, Witkin, Kreis & Overholtz
Seth Bader, Esq., Bloomberg, Steinberg & Bader
Todd Drayton, Esq.
Robert Skoblar, Esq.

[1] Defendant's claim that Plaintiffs essentially insult all other Judges in New Jersey by suggesting mass tort status and that the preference for Atlantic County disrespects the other esteemed Mass Tort Judges is nonsensical.