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• L A W O F F I C E S •

700 BROADWAY • NEW YORK, N.Y. 10003
TEL. 212-558-5500 FAX 212-344-5461
WWW.WEITZLUX.COM

ELLEN RELKIN, Esq.
Direct Number: (212) 558-5715
erelkin@weitzlux.com



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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 Multi-County Designation of Cases Involving the Stryker Rejuvenate Hip Stem and the ABG II Modular Hip Stem

Dear Judge Grant:

This letter is submitted on behalf of ten plaintiffs¹ who have cases filed in Bergen County, New Jersey involving the Stryker Rejuvenate and the Stryker ABG II Modular Hip Stems manufactured by defendant Howmedica Osteonics Corporation, a New Jersey corporation, d/b/a Stryker Orthopaedics, hereinafter, Stryker. Plaintiffs seek a Multi-County Litigation designation in accordance with Rule 4:38A. Both of these products were voluntarily recalled by Stryker on July 3rd of this year and it has been estimated that this recalled device was implanted in thousands of individuals in the United States².

¹ *Annette Emelity* - BER-L-006886-12; *Roy Kile* - BER-L-006888-12; *Branko Obradovic* - BER-L-006880-12; *Nancy Rockafellar* - BER-L-006879-12; *Selma Schepps* - BER-L-006884-12; *Timothy Seaman* - BER-L-006878-12; *Sonia Singh* - BER-L-006882-12; *Diane Pingel* - BER-L-005993-12; Gerard Friscia - Bergen County; Ellen-Jane Zelevansky - Monmouth County.

² Stryker is in the best position to quantify the precise number sold in the United States.

Ms Relkin is admitted in New York, New Jersey and District of Columbia, and also affiliated with the following branch office:

200 LAKE DRIVE EAST, SUITE 205 • CHERRY HILL, NJ 08002 • TEL 856-755-1115 • FAX 856-755-1995

Background

In April of this year Stryker Orthopaedics issued a field safety notice concerning hazards that have been identified with the company's Rejuvenate prosthetic hips. Potential health risks prompted Health Canada, the FDA analog in Canada, to issue a recall notice of Stryker Rejuvenate hips in Canada this spring. The notice warns that these artificial hips, made from varying combinations of metal, ceramic and polyethylene, are capable of improperly releasing potentially dangerous amounts of metal debris or metal ions into the bodies of hip replacement recipients. Unlike the metal on metal hips which deal with problems from the articulation of the ball and cup, the problem here involves the junction of the neck where the devices, according to the notice, may be subject to fretting and corrosion, with degraded metal components and metal particles putting patients at risk.

The adverse outcomes include metallosis (a build-up of metallic debris), necrosis (the cell death of affected tissues), and osteolysis (the death of bone cell due to blood supply issues) – any of which can necessitate revision surgery.

On July 3rd Stryker voluntarily recalled the hip stems as the company stated “due to the potential risks associated with modular-neck stems. These risks include the potential for fretting and/or corrosion at or about the modular-neck junction, which may result in adverse local tissue reactions manifesting with pain and/or swelling.”
<http://www.aboutstryker.com/modularneckstems/>

As stated by the Food and Drug Administration (FDA) on its website on July 6, 2012, “Stryker has voluntarily recalled its Rejuvenate and ABG II modular-neck stems.” While modular-neck stems provide surgeons with an option to correct certain aspects of a patient's anatomy and hip biomechanics, given the potential risks associated with fretting and corrosion at the modular neck junction, Stryker Orthopaedics decided to take this voluntary action,”
<http://www.fda.gov/Safety/Recalls/ucm311043.htm>.

Stryker Rejuvenate Litigation in New Jersey

The recall implicated thousands of hip implants. In response to this recall, at least ten cases alleging personal injury as a result of defective hip implants have been filed in New Jersey state courts, and we anticipate that many more cases will be filed in New Jersey in the coming weeks to months. All of the filed cases involve patients who had to have the recalled femoral stems removed and replaced, a very painful and invasive surgery. The plaintiffs only had the original Rejuvenate stem implanted over the past one to three years. Indeed, my firm has numerous additional cases we are reviewing and contemplate filing and I know of several other firms that plan on filing numerous cases including our co-counsel, on some of the filed cases, the law firm of Searcy Denney. The cases filed presently involve two New Jersey plaintiffs residing

in Bergen County and Monmouth County. Other plaintiffs are from Arizona, Florida and Minnesota.

WHY COORDINATION IS APPROPRIATE

As set forth in the guidelines, mass tort designation, now known as multi-county designation is warranted when a litigation involves a large number of parties; many claims with common, recurrent issues of law and fact that are associated with a single product; there is geographical dispersment of parties; there is a high degree of commonality of injury; there is a value interdependence between different claims; there is a degree of remoteness between court and actual decision makers in the litigation; among other considerations. This litigation meets all of the above enunciated criteria. There are already 10 filed cases. All cases will involve the recurrent legal issues of design defect, failure to warn, breach of warranty and possibly manufacturing defect. Moreover, there are significant overlapping factual liability issues relating to the nature of the metals in the product and how it was cast or forged; the nature of the defect warranting the recall, the delay in the recall, failure to comply with good manufacturing practices, notice of metallurgical concerns in mixing chromium cobalt components with titanium and other metals, the known risks of metallosis and fretting at taper junctions, among other related factual issues.

WHY BERGEN COUNTY IS AN APPROPRIATE MASS TORT VENUE

Geographical location is one factor to be considered when selecting the best venue in which to centralize a mass tort. *See Mass Torts—Guidelines and Criteria for Designation*, at 3 (Oct. 27, 2003) (describing the three factors to be considered as fairness, geographical location of the parties, and “the existing civil and mass tort caseload in the vicinage”). In the context of multi-county tort management, which is largely conducted through conferences between counsel for the parties and the court, the geographical location of the court should not be the prevailing factor in determining which vicinage is the most appropriate to coordinate the litigation at issue. All of the available venues for multi-county centralization—Atlantic, Bergen, and Middlesex counties—are convenient to regional and international airports (e.g., Philadelphia, Atlantic City, and Newark) and are within a reasonable driving distance from the offices of defendant and their counsel in New Jersey. However, it is doubtless that Bergen County is most convenient for defendant which is headquartered in Northern Bergen County (Mahwah). While plaintiffs’ counsel have some concern about the jury pool given the presence of defendant in the county, Stryker headquarters is more than twenty miles from the Hackensack courthouse and is actually much closer to Suffern, New York (four miles), as it is located near the New York border. Accordingly many of Stryker’s employees are actually New York residents and are not in the potential venire. Further, Bergen County is not as populated with other pharmaceutical and medical device companies as is Middlesex County, home to pharma giants J&J and Bristol Myer Squibb, to name a few.

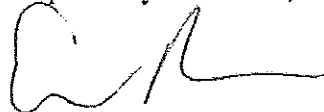
An important factor in this determination should be the “existing civil and mass tort caseload in the vicinage” being considered. *See id.* Presently, per this Court’s website (<http://www.judiciary.state.nj.us/mass-tort/faq.htm#guide>) there are nine (9) multi-county and centralized litigations in the Middlesex County Superior Court (*Asbestos, Ciba-Geigy, Gadolinium, HRT, Ortho Evra, Risperdal/Seroquel/Zyprexa, Zometa/Aredia*), Alloderm and Propecia. In contrast, there are seven (7) multi-county and centralized litigations in Bergen County: NuvaRing, Pompton Lakes, Prudential, Zelnorm, Yaz/Yasmin/Ocella, DePuy ASR Hip Implant and in Atlantic County there are also seven (7) multi-county and centralized litigations involving Accutane, Bristol-Meyers-Squibb, Fosamax, Levaquin, Pelvic Mesh, Reglan, and Stryker Implant. However, some of the Atlantic County litigations, Accutane and Fosamax, involve thousands of plaintiffs.

It should be noted that while there is Stryker Implant centralization in Atlantic County, that litigation involves a different Stryker product – the Stryker Trident which concerned the failure of an acetabular cup as opposed to the femoral stem at issue in this litigation. Further that litigation is mostly resolved with the majority of filed cases having been voluntarily dismissed. While the undersigned who initiated the centralization application for the Stryker Trident litigation would certainly not object to Atlantic County for this litigation as well, the centralization request is being made for Bergen County, primarily due to a lighter docket and the familiarity of Judge Martinotti with the medical issues arising from metallosis in chromium and cobalt hip implants due to his management of the DePuy ASR hip litigation, and the overlapping regulatory issues involved in a medical device cleared for sale on the basis of “substantial equivalence” (the same for the DePuy ASR and the Rejuvenate and ABG II) as opposed to pre-market approval, the method of approval for the Trident litigation.

Additionally, in light of the recent ongoing settlements of the *In Re: Yaz, Yasmin, Ocella Litigation*, Docket No. BER-L-3572-10; Case Code No. 287 (MT), plaintiffs understand that Bergen County will have more resources available to manage the Stryker Rejuvenate and ABG II litigation. Given the magnitude of the Yaz litigation which is promptly resolving, Bergen County’s multi-county staff is equipped to handle this litigation.

In light all the factors and information discussed above, plaintiffs respectfully request that the Supreme Court designate the Rejuvenate and ABG II cases for Multi-County or Centralized Management of such matters in the Bergen County Superior Court.

Respectfully submitted,



Ellen Relkin

cc: Leslie Santora, Chief, Civil Court Programs
The Honorable Brian J. Martinotti

Kim M. Catullo, Esq., Gibbons, P.C., (Counsel for Defendants)
C. Calvin Warriner III, Esq., Searcy Denney, PA