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VIA HAND DELIVERY

Hon. Philip S. Carchman, P.J.A.D. Acting Administrative Director of the Courts Richard J. Hughes Justice Complex 25 Market Street Trenton, New Jersey 08625

> Re: Merck & Co., Inc.'s Response to Application for Mass Tort

> > Designation and Centralized Management of Fosamax® Litigation

Dear Judge Carchman:

This letter brief is submitted on behalf of Merck & Co., Inc. ("Merck") in response to the Notice to the Bar dated July 16, 2008 advising of an application for "mass tort designation and centralized management of all Fosamax® litigation in one of the three mass tort sites, and possible coordination with the Zometa/Aredia cases previously designated as a mass tort and assigned to Judge Jamie D. Happas in Middlesex County."

For the reasons set forth herein, Merck opposes mass tort designation of these cases as unwarranted, inappropriate, and, at best, premature. If, however, the Court chooses to designate a Fosamax mass tort at this time, Merck respectfully suggests assignment either to Bergen or Middlesex County.

PRELIMINARY STATEMENT

Jersey Fosamax cases. In fact, the parties, in many instances with the assistance of the courts, have been cooperating in their discovery efforts and coordinating those efforts with a mature federal Fosamax Multidistrict Litigation (the "federal MDL") established in the United States District Court for the Southern District of New York more than two years ago. Without centralized management of the Fosamax cases in New Jersey and with only the stipulation that a suitable confidentiality order be entered in individual cases, Merck has produced almost two million pages of documents to plaintiffs' counsel in Fosamax litigation in New Jersey, and plaintiffs' counsel have been invited by way of cross-notice to attend, and have in fact attended, the depositions of Merck employees taken to date in the federal MDL. In addition, learning from upcoming bellwether trials and rulings on critical motions in the federal MDL will do much to define the landscape for the future course of cases in New Jersey.

Under these circumstances, mass tort coordination of the Fosamax litigation in New Jersey is currently unwarranted. Given the cooperation between the parties, the New Jersey cases can continue to reap the benefits of the federal MDL, providing this Court with the opportunity of re-assessing the need for a designation when the New Jersey and federal litigation landscapes are more settled.

Should the Court determine that further supervision is necessary now, the cases should be assigned to Bergen County or Middlesex County, both of which are significantly more

As this Court is aware, the application for mass tort designation was made by the Honorable Carol E. Higbee, P.J.Cv, of the Superior Court, Law Division, Atlantic County, one of the three current sites designated by the Supreme Court for centralized management of mass torts. The application was made in response to the submission to that court of consent orders to transfer 34 recently-filed Fosamax cases from Atlantic County to Hunterdon County.

convenient geographically for the parties and their counsel. Assignment to Bergen County also makes sense in terms of its existing mass tort docket. In contrast, Atlantic County would not be a suitable vicinage. In addition to lacking support in considerations of caseload and geographic convenience, assignment to Atlantic County poses the risk of creating the appearance of unfairness to Merck as it would follow closely on the heels of the massive Vioxx proceeding in that vicinage.

BACKGROUND

A. Fosamax and plaintiffs' allegations of injury

Fosamax is a United States Food and Drug Administration ("FDA") approved prescription bisphosphonate medication manufactured, marketed, and distributed by Merck.

Fosamax is prescribed primarily for the treatment and/or prevention of osteoporosis in post-menopausal women. It is prescribed to millions of patients every year in the United States, and is sold throughout the world.

Osteoporosis causes bones to become more porous, gradually making them weaker and more brittle. Over 10 million Americans over the age of 50, 80% of whom are women, have osteoporosis, and another 34 million have low bone mass and are at risk of developing osteoporosis and bone fractures. One out of every two women over age 50 will have an osteoporosis-related fracture in her remaining lifetime, with the risk of fracture increasing with age. Hip fractures, in particular, are especially devastating. According to the Surgeon General, 20% of senior citizens with hip fractures will die within a year of the fracture, nearly 20% of hip fracture patients end up in a nursing home, and hip fractures account for 300,000 hospitalizations per year.

The primary injury alleged by plaintiffs is osteonecrosis of the jaw ("ONJ"). ONJ is a rare, ill-defined, and poorly understood disease of unknown etiology. It has been

generally described as an oral cavity lesion characterized by one or more spots of bare jaw bone that persists for more than 6 to 8 weeks. There are multiple risk factors for developing ONJ, including trauma to the jaw, dental surgery, cancer, treatment with corticosteroids, chemotherapy, radiotherapy, and poor oral hygiene. There is no scientifically reliable evidence establishing a causal relationship between treatment with Fosamax and ONJ. The alleged link is based entirely upon individual case reports, not controlled data. In its controlled clinical trials, including more than 17,000 patients and 10 years of data with Fosamax, all of which was provided to the FDA, Merck received *no* reports of ONJ occurring in patients taking Fosamax. There are <u>no</u> epidemiologic studies supporting a causal connection between Fosamax and ONJ.

B. Fosamax cases in New Jersey

There are currently 103 Fosamax cases pending in New Jersey. See Chart entitled "Fosamax® Cases Filed in New Jersey – Sorted by Date Filed," Exhibit A. Facts pertinent to this Court's consideration of the mass tort designation of these cases include the following.

1. Location of parties

Very few of the 103 plaintiffs are from New Jersey; indeed, only 17 are New Jersey residents. <u>Id.</u> Moreover, the plaintiffs are not limited to residents of the mainland United States as thirty, or nearly one-third, are from Puerto Rico. In all, the 103 plaintiffs are from 24 states and Puerto Rico. <u>Id.</u> They hail from distant jurisdictions, including Arizona, California, Florida, Louisiana, Nevada, Texas, and, as noted above, Puerto Rico. <u>Id.</u>

Of the three vicinages that currently are designated as "mass tort" sites, Middlesex County and Bergen County have the closest connection to the 17 plaintiffs who are New Jersey residents, 11 of whom have cases pending in Middlesex County. <u>Id.</u> For all but two of the 17,

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Middlesex County and Bergen County are closer (in most instances much closer) to their homes than is Atlantic County.² See Exhibit B.

Merck's primary New Jersey presence consists of its corporate headquarters in Whitehouse Station (Hunterdon County) and its research facility in Rahway (southern Union County). Thus, Middlesex County is somewhat more convenient geographically than is Bergen County and considerably more convenient than Atlantic County. Id.

2. Case location and status

The cases are pending in seven counties.³ Of the vicinages to which mass torts are currently assigned, there are 34 Fosamax cases in Atlantic County, 32 in Middlesex County, and none in Bergen County. See Exhibit A. Twenty-nine of the 34 cases in Atlantic County were filed by plaintiffs from Puerto Rico; all 34 cases were filed in March 2008, and served in May 2008. Id.

The only judicial activity in the Atlantic County cases to date has been the joint submission by the parties of a consent order to transfer venue to Hunterdon County, which the Court denied pending resolution of her request for mass tort designation and centralized management. In contrast, the Middlesex County cases are much older. Twenty-five of the 32 cases in Middlesex County were filed before the March 2008 filing of the Atlantic County cases, and 22 of those 25 were filed in 2006 and 2007. Id. In addition, the Fosamax cases in

Two plaintiffs reside in Ocean County, in Brick and South Toms River. Although they are slightly closer to New Brunswick than Atlantic City, they are further from Hackensack than they are to Atlantic City or New Brunswick. The counties of residence for the remaining plaintiffs are: Bergen (one plaintiff); Essex (three plaintiffs); Monmouth (two plaintiffs); Morris (one plaintiff); Somerset (one plaintiff); Union (four plaintiffs); and Warren (one plaintiff). In addition, although the complaints did not specify the city of residence for two of the New Jersey plaintiffs (Miriam Rokas and Taghrid Kalifa), Merck's investigation revealed that these two plaintiffs are residents of Hudson County. All of these plaintiffs reside closer to New Brunswick and Hackensack than Atlantic City.

Cases are pending in the following counties: Atlantic (34 cases); Camden (17 cases); Essex (two cases); Hunterdon (nine cases); Middlesex (32 cases); Union (eight cases); and Warren (one case).

Middlesex County and other counties have been the subject of judicial activity. Confidentiality orders have been entered in 14 of the cases in Middlesex County. Confidentiality orders have also been entered to facilitate discovery in 13 other cases in Camden, Essex and Hunterdon Counties. Two other judges in Middlesex County have entered orders suspending the discovery end dates in seven cases in order to allow the parties to coordinate with discovery in the federal MDL. Orders suspending or extending discovery deadlines to allow the parties to coordinate discovery with the federal MDL have also been entered in eight cases in Hunterdon County and in a case in Camden County. In cases where the discovery end date has been suspended or extended, status letters have been sent to judges every three months since the entry of these orders or a telephonic status conference has been held. Substantial discovery has also taken place. Merck has produced almost two million pages of documents to most of the counsel representing plaintiffs in cases filed in New Jersey and plaintiffs' counsel have attended depositions of Merck employees noticed in the federal MDL pursuant to cross-notices served in the New Jersey cases.

There are no trial dates in any of the New Jersey cases. Ten of them currently have discovery end dates in 2008. In five of these ten cases, the parties have not yet sought their automatic 60-day extension by stipulation or an additional extension or suspension of the discovery end date. Three of those 10 are pending in Middlesex County, the only mass tort vicinage in which any of the 10 is pending. Of the 93 cases that do not have a 2008 discovery cut off, 34 (consisting of all of the cases in Atlantic County) have a discovery cut-off of September 9, 2009; 24 have discovery cut-offs earlier in 2009; 19 have discovery end dates after September 9, 2009; 4 have no discovery end date scheduled, and, in 12, the discovery cut-off has been suspended on joint motion filed by the parties to allow them to coordinate discovery with

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the federal Fosamax MDL. Thus, the cases are at varying stages of progress and of varying ages, with the Atlantic County cases being among the most recent, and, therefore, the least developed.

3. Location of counsel

The 103 pending cases have been filed by 10 different law firms. See Exhibit A.

Seven of the 10 firms are located substantially closer to Middlesex County than to Atlantic County. See Exhibit B. The three remaining firms are from the Philadelphia area, and are therefore slightly closer to Middlesex County or equidistant from Atlantic County and Middlesex County, and farther from Bergen County. Two of the three Philadelphia-area firms filed all of their cases in Middlesex County. Overall, more firms (four out of the 10) have filed cases in Middlesex County than any other county.

Merck's counsel is located in Jersey City, New York and Baltimore. For Jersey City and New York counsel, Bergen County and Middlesex County are far closer than Atlantic County. For Baltimore counsel, Atlantic County and Middlesex County are equidistant, and Bergen County farther than both. However, the courthouses in Bergen County and Middlesex County are more accessible to Baltimore counsel through public transportation than is Atlantic County.

Those law firms, who have filed cases on behalf of themselves or as local counsel for out-of-state law firms, are Aylstock, Witkin & Krumholz of Pensacola, FL, Cohen Placitella & Roth of Red Bank, NJ, Eichen Levinson & Crutchlow of Edison, NJ, Meredith Chase & Taggart of Trenton, NJ, Oshman & Mirisola, LLP of New York, NY, Sanders Viener & Grossman of Mineola, NY, and Seeger Weiss of Newark, NJ and New York, NY.

Those law firms are Anapol Schwartz of Cherry Hill, NJ, and Philadelphia, PA, Levensten Law Firm, of Philadelphia, PA, and Lopez McHugh of Moorestown, NJ.

These firms are Anapol Schwartz with 11 filed cases all in Middlesex County and Lopez McHugh with three filed cases in Middlesex County.

These firms include Anapol Schwartz (12 cases), Cohen Placitella & Roth (eight cases), Eichen Levinson & Crutchlow (nine cases) and Lopez McHugh (three cases).

C. Caseloads of the mass tort vicinages

According to the 2008 Court Management statistics released on July 29, 2008, Bergen County has 53 active pending mass tort cases, compared to 3,536 in Middlesex County and 3,893 in Atlantic County. See New Jersey Judiciary Court Management, June 2008. As of June 2008, 0% of Bergen County's mass tort cases qualified as backlog, whereas the numbers for Middlesex (20%) and Atlantic (17%) Counties were much higher. Id.

The dockets in the three vicinages for non-mass tort civil cases were comparable. The clearance percentages were nearly equal: Middlesex County (105%); Atlantic County (102.5%); Bergen County (98.6%). <u>Id.</u> The same was true of non-mass tort cases in backlog: Middlesex County (16%); Atlantic County (13%); Bergen County (10%). <u>Id.</u>

D. <u>Proceedings in federal court -- the federal MDL</u>

Approximately 660 Fosamax cases are pending in federal court. On August 16, 2006, the Judicial Panel on Multidistrict Litigation directed that a Multidistrict Litigation be formed before Judge John F. Keenan in the United States District Court for the Southern District of New York -- the federal MDL.

Over the past two years, there has been extensive discovery of Merck in the federal MDL, during which Merck has produced approximately two million pages of documents. Merck has presented three company employees for deposition, and an additional five company employee depositions have been scheduled.

The cited numbers are as of June 2008. Developments since that time have reduced some of those numbers. Specifically, although the majority of Vioxx cases that enrolled in the settlement program had been dismissed without prejudice pending completion of the program by the time of the report, there have been some subsequent similar dismissals. Also, the court in Middlesex County has granted summary judgment in two Hormone Replacement Therapy ("HRT") mass tort cases.

All of this discovery is available to the New Jersey plaintiffs. As a matter of routine, Merck has produced to five New Jersey plaintiffs firms, representing 25 New Jersey plaintiffs, the same documents that it has produced in response to master discovery requests submitted in the federal MDL. In fact, several of the counsel representing plaintiffs in the New Jersey cases are active in the Merck discovery in the federal MDL. There has also been discovery motions practice in the federal MDL, with that court having recently ruled on a sweeping, global motion to compel filed by the plaintiffs.

The Case Management Order in the federal MDL provides for three initial bellwether trials, the first of these anticipated in the second quarter of 2009. Judge Keenan indicated that an important function of the initial trials will be to educate the parties regarding the strengths and weaknesses of their cases to enable them to make future litigation decisions accordingly.¹⁰

Other issues with the potential to affect the future course and scope of the proceedings are being presented in the federal MDL. For example, Merck is presenting to that court its position that a plaintiff's claim is subject to dismissal if she used Fosamax for less than three years. The position arises out of the acknowledgment by plaintiffs' expert, Robert Marx, D.D.S., that, even by his own theory, a person taking Fosamax is not at risk of ONJ until after

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The law firm of Seeger Weiss is on the Plaintiffs' Steering Committee in the MDL. Sanders Viener and Grossman have filed 17 cases directly in the MDL, as have Aylstock Witkin (seven cases), Lopez McHugh (two cases), Levensten Law Firm (two cases) and Seeger Weiss (12 cases). Through removal of cases from state court to federal court, Anapol Schwartz have four cases in the MDL and Cohen Placitella and Meredith Chase & Taggart each have one case in the MDL. Meredith Chase & Taggart is acting as local counsel for Beatie & Osborn of New York City, which is Plaintiffs' Liaison Counsel in the MDL. Accordingly, only two law firms (Eichen Levenson and Oshman & Mirisola) have no cases on file in the MDL at this time.

The Plaintiffs Steering Committee, Merck and the Court will each select one case for trial. All selections are to be made from a trial-selection pool of 25 cases. Thus, the selection process is designed to yield a varied set of initial trials and to enhance the breadth of information available to provide meaningful guidance for future management of the litigation.

three years of continuous use. The Court's decision is likely to provide important precedent for the many other cases in which a plaintiff has used Fosamax for three years or less. ¹¹ Merck will also be filing a motion pursuant to *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), asking the court to exclude plaintiffs' expert testimony concerning the fundamental question of whether use of Fosamax can cause ONJ on various grounds, including primarily that such testimony is unreliable and unsupported by scientific data. Merck anticipates that this motion will be filed in the first quarter of 2009.

ARGUMENT

- I. The Fosamax cases should not be designated as a mass tort at this time.
 - A. Designation as a mass tort is currently unwarranted because the litigation is proceeding efficiently without designation.

Centralized management of the New Jersey Fosamax cases at this time will not further the interests of justice. Out-of-state plaintiffs wanting the benefits of centralized management have the option to sue in the federal MDL, and all but two plaintiffs' counsel who have filed suit in New Jersey also have cases in the federal MDL. For all practical purposes, the federal MDL provides all plaintiffs who choose New Jersey with the efficiencies of coordination in discovery of Merck, which is a central focus of litigation activity at this stage. Moreover, by virtue of the bellwether trials scheduled in the federal MDL for early 2009, and anticipated early rulings on important issues such as the viability of claims based on the use of Fosamax for less than three years as well as the fundamental issue of the admissibility of plaintiffs' evidence that Fosamax can cause ONJ, the justice system is now sorting out the strengths and weaknesses of

Merck previously filed a motion for summary judgment on this issue, but the plaintiff to whom the motion was directed voluntarily dismissed her case with prejudice in response to the motion. Merck intends to ask the federal MDL court shortly to set a schedule for the prompt disposition of other cases involving less than three years continuous use of Fosamax.

the cases. A parallel consolidated proceeding in New Jersey is therefore unnecessary; indeed, the creation of a second judicial center of gravity could have a disruptive effect on the orderly processes currently in place in the federal MDL.¹²

In any event, the decision whether to designate as a mass tort is premature. Under Directive #10-07, the total number of cases is an important factor in deciding whether a mass tort designation is appropriate. The facts pertaining to those cases, including the geographic dispersement of the parties and the issues that the cases present, are also important under the Directive. Here, as a result of the likely effect of the federal bellwether trials and rulings on important motions, there is reason to believe that the facts concerning the number and nature of cases are not yet in. Accordingly, this Court can and should defer its designation decision until the number and identity of remaining cases are more reliably fixed.

In sum, the mass tort determination can be better made when the New Jersey caseload has reached a state more approximating equilibrium. In the interim, the New Jersey cases can continue to benefit from the judicial management, and other efficiencies, arising out of the federal MDL.

B. Designation as a mass tort creates the risk of unnecessarily attracting additional cases to New Jersey.

Although mass tort designations can, in appropriate circumstances, provide a case management benefit, one potential consequence of designation is to encourage the filing of substantial numbers of additional cases. Indeed, one jurist has noted that consolidated proceedings may "provide an overly hospitable environment for weak cases." See Helen E. Freedman, Product Liability Issues in Mass Torts - View from the Bench, 15 *Touro L. Rev.* 685,

The federal MDL is the only other consolidated Fosamax proceeding, as no other state has consolidated cases for centralized management.

688 (1999); see also Deborah R. Hensler, SYMPOSIUM: MULTIDISTRICT LITIGATION AND AGGREGATION ALTERNATIVES: The Role of Multi-Districting in Mass Tort Litigation: An Empirical Investigation, 31 Seton Hall L. Rev. 883, 891 (2001) ("By signaling that courts were prepared to facilitate aggregation and global settlement, judges' practices may also have contributed generally to the growth of mass litigation by increasing its attractiveness to plaintiff attorneys.") This counsels against designating a mass tort if the litigation is being otherwise managed efficiently, and when the decision can be deferred without any disadvantage to the litigants.

The experience with mass torts for which information concerning date of case filing is available on the New Jersey Judiciary's website suggests that the concern for an increase in the number of filings is real.¹³ Data regarding all such mass torts is set forth herein. One informative comparison is the number of filings prior to and after mass tort designation. For the Ortho Evra mass tort litigation, 435, or 84.5%, of the 515 current filings were made after mass tort designation. The numbers are similar for Accutane (324, 77.3%, of the total of 419 filings made after mass tort designation) and Risperdal (1931, or 79.0%, of the 2443 mass tort filings made after designation).

Even for mass torts for which the number of filings before and after are similar, a comparison of the pace of filings is revealing. Although there is no difference in the number of Gadolinium filings before and after consolidation, in the ten months between the filing of the first case and consolidation, the data show a rate of 2.2 filings per month; in the four months after consolidation, filings have been at nearly triple that rate (6.5 per month). In the

The figures cited herein are based on the website's most recent statement of the total number of pending cases as set forth in the case list for each litigation on the Mass Tort site of the New Jersey Judiciary web site. Thus, these figures do not account for cases that have been dismissed.

Zometa/Aredia mass tort, the number of filings prior to consolidation is only slightly higher than the number of filings after consolidation, but in the year prior to mass tort designation, cases were filed at a rate of 3.2 per month whereas in the six months since mass tort designation, cases have been filed at nearly double that rate (6.0 per month). Similar significant increases in the pace of filings during the year following designation compared to the year preceding designation were also found for Accutane (7.6 per month to 12.7 per month), Ortho Evra (6.6 per month to 21.2 per month) and Risperdal (42.5 per month to 87.8 per month). Of the mass torts for which the New Jersey Judiciary website provides the date of case filing, HRT, in which a roughly even number of cases was filed before and after consolidation, is the only litigation in which the rate of filings did not increase dramatically after consolidation.¹⁴

The data for all of these mass torts are summarized as follows:

Mass Tort Litigation	Percentage of Cases Filed Post Designation	Change in Average Rate of Cases Filed Per Month in Year Before and After Designation ¹⁵
Accutane	77.3%	7.6 to 12.7 (+67.1%)
Gadolinium	50.0%	2.2 to 6.5 (+195.5%)
HRT	48.5%	6.3 to 3.0 (-52.4%)
Ortho Evra	84.5%	6.6 to 21.2 (+221.2%)
Risperdal	79.0%	42.5 to 87.8 (+106.6%)
Zometa/Aredia	47.2%	3.2 to 6.0 (+87.5%)

Based on issues of notice, it is very difficult for an HRT plaintiff to argue that her claim accrued later than July 9, 2002, the date of publication of the results of a controlled trial sponsored by the National Institutes of Health purporting to confirm that the combination of estrogen and progestin increases the risk of breast cancer. The mass tort designation was made more than two years later in September 2004, making it unlikely that a significant number of claims would be filed after designation.

For some litigations, the time period prior to, or after, designation was less than a year. In those situations, the cited figures represent the rate of filings for the entire time period.

In that the Fosamax litigation is proceeding smoothly without mass tort designation in New Jersey, it is unnecessary to burden the New Jersey court system further with the potentially significant numbers of additional case filings that seem likely to follow any such designation.

II. If the Fosamax cases are designated as a mass tort, they should be assigned to either Middlesex County or Bergen County.

Directive #10-07 provides:

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 centralized management.

If the Fosamax cases are to be designated as a mass tort, application of these factors weighs heavily against selection of Atlantic County, and supports selection of either Bergen County or Middlesex County.

- A. Assignment of the cases to Atlantic County would create the appearance of unfairness and is unsupported by considerations of geographic location and caseload.
 - 1. Assignment to Atlantic County would create the appearance of unfairness to Merck because of the Vioxx mass tort proceeding.

When deciding the location of a mass tort, "issues of fairness" is the first factor under Directive # 10-07. While that term is not defined, it must certainly include ensuring that not only is there fairness in fact but that there also is the appearance of fairness in the process.

It is well-known to this Court that Merck is the defendant in the highly publicized mass tort proceeding in Atlantic County involving the drug Vioxx. As would be expected in a matter of that magnitude, the litigation has been intense and contentious. Some issues from that litigation remain on appeal. Although counsel and the Court were and remain cordial, professional, and respectful towards one another, many issues have been hard-fought. Some of

the attention drawn to Atlantic County by the Vioxx litigation was cast in terms of disadvantageous treatment of pharmaceutical corporate defendants in that vicinage. See American Tort Reform Foundation "Judicial Hellholes 2007" at iv, 16-18. Merck submits that this context creates a risk that assignment to Atlantic County of another Merck mass tort at this time will create the appearance of unfairness to the company, which is an appropriate factor for this Court to consider. ¹⁶

Additional considerations enhance this risk. The application for mass tort designation originated with the Atlantic County court, not with the parties ¹⁷ or any of the other six counties in which Fosamax cases were pending. The Atlantic County court itself appears to have previously acknowledged the geographic inappropriateness of that vicinage, having transferred seven Fosamax cases to Hunterdon County *sua sponte* over 1½ to 2 years prior. ¹⁸

See Orders at Exhibit C. In addition, as described below, see infra §§ II.A.2., II.B., other factors such as geography, caseload, and immaturity of Fosamax cases in the Atlantic vicinage strongly point to either Middlesex or Bergen Counties.

In short, considerations of the appearance of fairness militate against assignment of a Fosamax consolidated proceeding to Atlantic County.

For similar reasons, the filing of additional cases generally attendant to mass designations, see supra, at § I.B., is likely to be more pronounced if Atlantic County is selected as the vicinage for a Fosamax mass tort.

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None of the plaintiffs currently in Atlantic County has expressed an interest to date in remaining there. As noted above, although 34 plaintiffs filed their complaints there in March of this year, they all consented to transfer of their cases to Hunterdon County.

On June 8, 2006, the trial court entered an Order sua sponte transferring Rhys and Dorothy Wass v. Merck & Co., Inc., Docket No. HNT-L-285-06, from Atlantic County to Hunterdon County based on the finding that "plaintiffs are residents of the State of New York, and the defendant is headquartered in Hunterdon County." On February 2, 2007, the trial court entered Orders sua sponte transferring to Hunterdon County six other cases brought by out-of-state plaintiffs. Each of these orders is attached as Exhibit C.

2. Atlantic County is least suitable based on location of parties and attorneys.

The second factor for selection of a vicinage identified in Directive #10-07 is "geographic location of parties and attorneys." This factor suggests that Atlantic County is the least appropriate location of the three mass tort vicinages. For all 17 New Jersey resident plaintiffs, Atlantic County is farther than Middlesex County. See Exhibit B. For all but the two plaintiffs from Ocean County, Atlantic County is farther than Bergen County. Id. With its New Jersey presence in Hunterdon County and Union County, Merck is closest to Middlesex and Bergen Counties and farthest from Atlantic County. Id. Atlantic County similarly is least proximate geographically for plaintiffs' counsel and Merck's counsel. Id. See also page 7, supra.

- B. Bergen County and Middlesex County would each be more suitable as an assigned jurisdiction.
 - 1. Bergen County would be suitable as an assigned jurisdiction due to its favorable civil and mass tort caseload.

Of the three jurisdictions to which a mass tort could be assigned, Bergen County has the most favorable mass tort caseload. The 2008 Court Management statistics demonstrate that Bergen County had only 53 active pending mass tort cases as of June 2008. See New Jersey Judiciary Court Management, June 2008. Even accounting for additional dismissals in the other two vicinages, the Bergen County total is far lower than the 3,536 mass tort cases reported for Middlesex County and the 3,893 mass tort cases reported for Atlantic County. Those statistics also show that 0% of Bergen County's mass tort cases qualified as backlog, while the numbers for Middlesex (20%) and Atlantic (35%) Counties were much higher.²⁰

The 17 New Jersey plaintiffs hail from Bergen County (1), Essex County (3), Hudson County (2), Monmouth County (2), Morris County (1), Ocean County (2), Somerset County (1), Union County (4) and Warren County (2).

As described above, see supra at page 8, there was little difference in the non-Mass Tort civil caseloads of the three vicinages.

The Bergen County caseload, combined with its reasonable geographic proximity for the parties and counsel, make it a sensible venue if consolidation is ordered.

- Middlesex County would be suitable as an assigned jurisdiction due to geographic considerations and its closer connection to the litigation to date.
- a. Geographic considerations and connection to the litigation to date
 Middlesex County would also be suitable as a vicinage for a Fosamax mass tort.

First, Middlesex County has the oldest and most advanced New Jersey cases, with cases filed over two years ago in 2006. Twenty-five of the 32 pending Middlesex County cases were filed before March 2008, which is when all 34 Atlantic County cases were filed. Twenty-two of those 25 were filed in 2006 or 2007. See Exhibit A.

Second, Middlesex County is the venue where more New Jersey plaintiffs have chosen to file their claims. Eleven of the 17 plaintiffs who are New Jersey residents have filed in Middlesex County. Id.

Third, the balance of interest in respect of plaintiffs' counsel, as evidenced by their actions to date, weighs in favor of Middlesex County. Four firms representing 32 plaintiffs have filed lawsuits in Middlesex County, more than any other New Jersey county. By contrast, only one law firm, Sanders Viener, has filed cases in Atlantic County (all on the same day in March 2008) and that firm signed consent orders agreeing to the transfer of all of those 34 cases to Hunterdon County. Id.

Fourth, the location of plaintiffs supports Middlesex County. All of the plaintiffs who live in New Jersey are closer to Middlesex County than to Atlantic County. See Exhibit B.

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Fifth, the location of plaintiffs' counsel supports Middlesex County. Seven of the ten firms that have filed New Jersey lawsuits are substantially closer to Middlesex County than to Atlantic County, though also close to Bergen County.²¹ See Exhibits A and B.

Finally, the location of Merck supports Middlesex County. Merck's corporate headquarters are closer to Middlesex County than to Atlantic County. Merck also has a major research facility bordering on Middlesex County. See Exhibit B.

b. The pendency of the Zometa/Aredia cases in Middlesex County
In the July 3, 2008 letter to the Honorable Philip S. Carchman, P.J.A.D., see,
supra, n.1, the Atlantic County trial court indicated that "the Fosamax litigation should be
reviewed for possible assignment to one Judge and coordination with the Zometa/Aredia cases."

As this Court is aware, the litigation referred to in this letter is a Middlesex County mass tort
proceeding involving the drugs Zometa and Aredia. As of August 4, 2008, there were 89 such
Zometa/Aredia cases.

Thus, Middlesex County is both an appropriate vicinage for a Fosamax coordination and the vicinage of the Zometa/Aredia cases. Should the Court see some benefit in having the same judge coordinate both of these litigations, that would be an additional consideration in favor of Middlesex County. Merck submits, however, that any coordination of the Fosamax litigation should be separate from the Zometa/Aredia litigation as this Court indicated when it approved the Zometa/Aredia coordinated proceeding and, in its January 22, 2008 Order, excluded the case of Bryant, et al. v. Merck & Co., Inc. and Novartis

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See supra, at page 7, fn. 4. The three remaining firms are from the Philadelphia area and are therefore equidistant to Middlesex County and Atlantic County. (Two of those firms selected Middlesex County by filing cases there.) Another firm is from Pensacola, Florida and has one case, which it filed in Hunterdon County. To get to New Jersey, this firm would likely fly to Newark Liberty International Airport. Newark, NJ is closer to Bergen and Middlesex Counties than to Atlantic County.

Pharmaceuticals Corporation, Docket No. MID-L-4985-06, apparently based on Merck's argument that the case involved the use of both Zometa/Aredia and Fosamax. See Supreme Court Order, Exhibit D. Similarly, the federal Judicial Panel on Multidistrict Litigation specifically declined to include Fosamax cases in the federal Zometa/Aredia MDL, finding that the Fosamax cases "do not share sufficient questions of fact with the claims against Novartis [the manufacturer of Zometa and Aredia] to warrant inclusion in" the federal Zometa/Aredia MDL. See Transfer Order in In re: Aredia and Zometa Products Liability Litig., at 2, Exhibit E.

Specifically, although Aredia, Zometa and Fosamax are all considered bisphosphonates, the medications are used to treat vastly different medical conditions that vary in both type and severity. Aredia and Zometa, manufactured by Novartis, were approved for treatment of patients with cancer. In contrast, Fosamax, manufactured by Merck, was approved primarily for the treatment and preventions of osteoporosis. Fosamax is not indicated for the treatment of malignancies of any kind.

Aredia and Zometa are administered intravenously to patients with primarily, advanced breast cancer and multiple myeloma. Depending on the condition being treated, Aredia is administered over a 2- to 24-hour period for a period of days to up to several months. Zometa, depending on the condition being treated, is administered as either a single dose or as a monthly infusion over a period of 15 minutes. In February 2005, Novartis estimated to the FDA that, since Aredia and Zometa were launched in 1991 and 2001, respectively, approximately 2.8 million patients had been treated worldwide with Aredia and/or Zometa. Fosamax is a tablet that is self-administered orally by patients with – or at risk of developing – osteoporosis. It can be taken daily or weekly, depending on the dosage, and it can be safely used by a patient for years. Fosamax was the fourteenth most prescribed drug in 2006, with over 16.5 million prescriptions.

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As such, Fosamax is prescribed to a much larger patient population than either Aredia or Zometa.

The development, testing, manufacturing and marketing of intravenous cancer medications (Aredia/Zometa) on the one hand, and oral osteoporosis medications (Fosamax) on the other, are also vastly different. Each was developed for different reasons, and for markedly different users and thus have different clinical trials and different marketing components.

Similarly, there are two distinct groups of medical professionals to whom the two sets of medications are primarily marketed – oncologists (Aredia and Zometa) and general practitioners (Fosamax). Significant differences exist in these two types of medical practice, including the type of knowledge associated with the practice, the medical journals read by each, the patients treated, and the length of time spent treating the two markedly different patient groups.

In short, although Aredia and Zometa, on the one hand, and Fosamax, on the other hand, are bisphosphonates, they were developed for different reasons, tested in different patient populations, are prescribed to different patient populations, and administered in different ways, for different medical conditions, by different physicians specialties. Accordingly, even if the Fosamax cases are designated as a mass tort and assigned to Middlesex County, they should not be coordinated with the Zometa/Aredia mass tort. Further, the claims against Merck relating to Fosamax and the claims against Novartis relating to Zometa and Aredia in Bryant, et al. v.

Merck & Co., Inc. and Novartis Pharmaceuticals Corporation, Docket No. MID-L-4985-06 should be severed and each should be sent to their respective coordinated proceedings.

Alternatively, the case, in its entirety, should remain outside of either coordinated proceeding.

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III. The case of <u>Pastorius v. Merck & Co., Inc.</u>, Docket No. ESX-L-6696-07 should be excluded from any mass tort designation of Fosamax cases.

The case of <u>Pastorius v. Merck & Co., Inc.</u> involves an allegation of injury caused by both Merck's Fosamax and Procter & Gamble Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC's Actorel. While both drugs are oral bisphosphonates, the Complaint reveals that the alleged injury is not temporally related to Plaintiff's use of Fosamax. See Exhibit F. There is a nearly four-year gap between Plaintiff's last alleged use of Fosamax in November 2001 and her - injury in August 2005. Specifically, as set forth in the complaint, Plaintiff used Fosamax for only approximately 9 ½ months, from February 2001 until November 2001. Id. at paragraph 26. After Fosamax, she was prescribed Actonel for approximately 4 years, from November 2001 through October 2005. Id. at paragraph 27. Plaintiff's alleged injury was diagnosed on August 26, 2005. Id. at paragraph 28. Including the Pastorius case in any Fosamax coordination will only delay the resolution of the <u>Pastorius</u> case for Merck and embroil Procter & Gamble Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC in a mass tort because they have been named as a defendant in a single case with Merck. In addition, involving two pharmaceutical companies with competing bisphosphonates in the same coordinated proceeding, especially given the facts here, complicates discovery by unnecessarily expanding the risk of exposing each to the other's commercially sensitive documents. Again, if this Court designates the Fosamax coordination, the claims against Merck relating to Fosamax and the claims against Procter & Gamble Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC relating to Actonel in Pastorius should be severed, or alternatively, the case, in its entirety should be excluded from a coordinated proceeding involving Fosamax.

CONCLUSION

For the foregoing reasons, this Court should not designate the Fosamax cases as a mass tort at this time. If the Court does choose to designate the Fosamax cases now, the litigation should be assigned to either Bergen County or Middlesex County. If a designation is made, the claims against each pharmaceutical defendant in Bryant.et/al.v./ Merck & Co., Inc. and Novartis Pharmaceuticals Corporation, Docket No. MID-L-4985-06 and Pastorius v./ Merck & Co., Inc., Docket No. ESX-L-6696-07 should be severed or the cases in their entirety should be excluded from any Fosamax coordinated proceeding.

Respectfully submitted,

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6/20/2008	6/20/2008	6/20/2008	6/12/2008	5/1/2008	4/29/2008	4/18/2008	4/3/2008	4/1/2008	3/28/2008	3/28/2008	3/28/2008	3/28/2008	3/28/2008	3/28/2008	3/28/2008	
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1325 Spruce Street Philadelphia, PA 19107	1325 Spruce Street Philadelphia, PA 19107	1325 Spruce Street Philadelphia, PA 19107	1040 Kings Highway North Suite 304 Cherry Hill, NJ 08034	712 East Main Street Suite 2A Moorestown, NJ 08057	1325 Spruce Street Philadelphia, PA 19107	1325 Spruce Street Philadelphia, PA 19107	712 East Main Street Suite 2A Moorestown, NJ 08057	1040 Kings Highway North Suite 304 Cherry Hill, NJ 08034	100 Herricks Road Mineola, NY 11501		100 Herricks Road Mineola, NY 11501					

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Penniston, Dorothy H.		Thornton, Geniel	Stelmack, Gloria J.	Pierre-Louis, Ghislaine	McWilliams, Donald Ray	Kubitz, Sandra	Harper, Kathy	Baucom, Rachel	Sparling, Monica B.	Vara-Dannen, Theresa	Points, Violet Lee	Martineau, Isabel	
Dorothy H. Penniston v. Merck & Co., Inc.	Betty Ward v. Merck & Co., Inc.	Geniel Thornton v. Merck & Co., Inc.	Gloria J. Stelmack v. Merck & Co., Inc.	Ghislaine Pierre-Louis v. Merck & Co., Inc.	Donald Ray McWilliams v. Merck & Co., Inc.	Sandra Kubitz v. Merck & Co., Inc.	Kathy Harper v. Merck & Co., Inc.	Rachel Baucom v. Merck & Co., Inc.	Monica B. Sparling v. Merck & Co., Inc.	Theresa Vara-Dannen and Christopher Dannen, her husband v. Merck & Co., Inc.	Violet Lee Points v. Merck & Co., Inc.	Isabel Martineau and Roland Martineau, her husband v. Merck & Co., Inc.	
Camden	Union	Middlesex	Camden	Camden	Camden								
L-3308-08	L-2244-08	L-2243-08	L-2242-08	L-2241-08	L-2247-08	L-2240-08	L-2246-08	L-2245-08	L-5087-08	L-3280-08	L-3284-08	L-3258-08	
6/25/2008	6/25/2008	6/25/2008	6/25/2008	6/25/2008	6/25/2008	6/25/2008	6/25/2008	6/25/2008	6/23/2008	6/20/2008	6/20/2008	6/20/2008	
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The Levensten Law Firm, P.C.	Oshman & Mirisola, L.L.P.	Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C.	The Levensten Law Firm, P.C.	The Levensten Law Firm, P.C.	The Levensten Law Firm, P.C.								
1325 Spruce Street Philadelphia, PA 19107	42 Broadway 10th Floor New York, NY 10004	1040 Kings Highway North Suite 304 Cherry Hill, NJ 08034	1325 Spruce Street Philadelphia, PA 19107	1325 Spruce Street Philadelphia, PA 19107	1325 Spruce Street Philadelphia, PA 19107								

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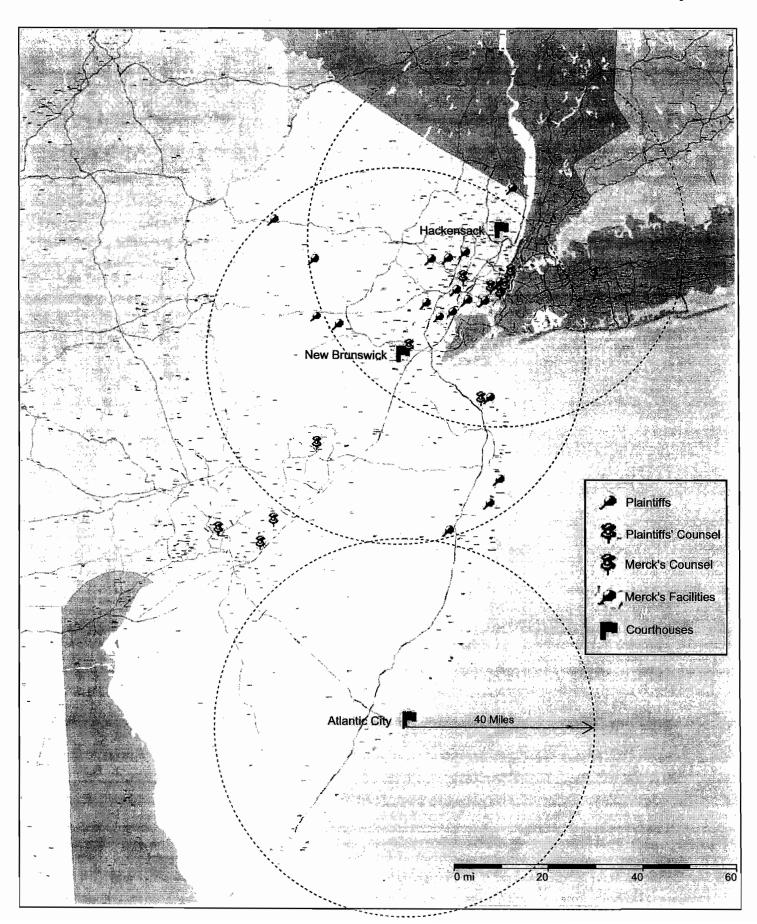
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New Jersey Residents Who Have Filed Fosamax Lawsuits and Plaintiffs' and Defendant's Counsel Who Have Offices in or near New Jersey



RECEIVED AND FILED

JUN 08 2006

ATLANTIC COUNTY

By the Court:	
RHYS WASS and DOROTHY WASS,	SUPERIOR COURT OF NEW JERSEY LAW DIVISION
Plaintiff(s),	ATLANTIC COUNTY
vt.	DOCKET NO. ATT-1-4082-06
MERCK & CO., INC.,	Civil Action
Defendant(s).	ORDER TO TRANSFER VENUE

CAROLE HIGBERY J.CV



SUPERIOR COURT OF NEW JERSEY ATLANTIC COUNTY - LAW DIVISION

	HUT
Marilyn Lamer & Robert Lamer	
PLAINTIFF	CIVIL ACTION ORDER OF DISPOSITION RECEIVED AND
iνe.	93_17 FILED
Merck & Co Inc.	DOCKET NO: ATLE-17111-06 FEB 02 2007
DEFENDANT	ATLANTIC COUNTY LAW DIVISION
IT IS ON THIS day of	Color ORDERED that this matter is
hereby disposed and subject to the condition parties due to the following:	s of any formal consent stipulation hereinafter filed by the
80 Comp. Name Change 81 Comp. Other Summary Proceeding 08 Default Judgment 82 Default Judgment Proof Hrg.	12 50-Day Dismissal 17 Settled by Stat. Arts/50 day dism. 27 Settled Friendly Hearing Comp. 23 Settled not sched, for Trial, Arb., other
Completed 10 Dism. By Ct. w/prejudice 12 Dism. By Ct. w/o prejudice	CDR/Friendly Hrg. Not Comp. 25 Settled while sched, for Stat. Arb. 26 Settled while sched, for other CDR 24 Settled while sched, for Trial
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Plaintiff failed to appear. Action dismissed to personant failed to appear. Strike Defenda Plaintiff and Defendant failed to appear. Action	nt's pleadings. Defenses are suppressed.
	Q lices !!
	CAROL EZHIGBEE, PJ.CV.
cc: Marc D. Grossman, Esq.	CIVIL CIVIL
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RECEIVED/FILED
SUPERIOR COURT OF MJ
HUNTERSCHI COUNTEUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY - LAW DIVISION
2001 FEB 13 AM II: 59

Allison Rosenberg PLAINTIFF vs. Merck & Co Inc.	DEFUTY CLERK CIVIL DIVIDIDATION ORDER OF DISPOSITION HNT L 94-07 DOCKET NO: ATLL-17112-06 FEB 02 2007
DEFENDANT	ATLANTIC COUN LAW DIVISION 20 0 ORDERED that this matter is it it is of any formal consent stipulation hereinafter filed by the
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Plaintiff falled to appear. Action dismiss Defendant failed to appear. Strike Defe Plaintiff and Defendant failed to appear.	sed for Lack of Prosecution indant's pleadings. Defenses are suppressed. Action dismissed, defenses suppressed.
	CAROL E. HIGBEE, P.J.CV.

Marc D. Grossman, Esq.

HUNTERDOX COUN SUPERIOR COURT OF NEW JERSEY ATLANTIC COUNTY - LAW DIVISION 2007 FEB 13 PM 12: 00 Beverly Schaefer DEPUTY CLEPK PLAINTIFF CIVIL DEKABIAGION RECEIVED AND ORDER OF DISPOSITION DOCKET NO: ATLEL-17114-06 FEB 02 2007 Merck & Co inc. ATLANTIC COUNTY DEFENDANT LAW DIVISION ORDERED that this matter is IT IS ON THIS day of hereby disposed and subject to the conditions of any formal consent stipulation hereinafter filed by the parties due to the following: 12 50-Day Dismissal 80 Comp. Name Change 17 Settled by Stat. Arb/50 day dism. 81 Comp. Other Summary Proceeding 27 Settled Friendly Hearing Comp. 08 Default Judgment 23 Settled not sched, for Trial, Arb., other 82 Default Judgment Proof Hrg. CDR/Friendly Hrg, Not Comp. Completed 10 Dism. By Ct. w/prejudice . 25 Settled while sched, for Stat. Arb. 26 Settled while sched, for other CDR 12 Dism. By Ct. w/o prejudice 24 Settled while sched, for Trial . 11 Dism. Rule 1:13-7 09 Summary Judgment 45 Inactivated 14 Transferred to Hunterdon County 04 Partially Tried 15 Transferred to Another Court 18 Reinstated 05 Tried to Comp. w/Jury 28 Settled by other CDR 19 Settled/Confirmation of Arb. Award 07 Tried to Comp. w/o Jury 54 Settled - Mediation 53 Settled Prior to Mediation 29 Settled - Conf. w/Judge 57 Settled Prior to Settlement Conf. 30 Voluntary Dismissal - Voluntary Binding Arbitration Plaintiff failed to appear. Action dismissed for Lack of Prosecution Defendant falled to appear. Strike Defendant's pleadings. Defenses are suppressed. Plaintiff and Defendant failed to appear. Action dismissed, defenses suppressed.

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Marc D. Grossman, Esq.

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•	HUNTERUCH SOBERIOR COURT OF NEW JERSEY
	2007 FEB 13 PH 12: 02
Helen Marovich	- N N
PLAINTIFF	DEPUTY CLERK
PLAINTIPP	CIVIL ACTION
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Merck & Co Inc.	DOCKET NO: ATLL-17145.06 FER 0.2 2007
MERCK & CO INC.	I TO A E TOOL
DEFENDANT	ATLANTIC COUNT LAW DIVISION
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IT IS ON THIS day of	Pel 200/ ORDERED that this matter is
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Plaintiff failed to appear. Action dismiss	
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•	CAROL E. HIGBEE, P.J.CV.

Marc D. Grossman, Esq.

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7	ATLANTIC COUNTY - LAW DIVISION
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PLAINTIFF	CIY! DIYISCIVIL ACTION
vs.	
	CROSER OF DISPOSITION RECEIVED AND
	DOCKET NO. ATLANAS DE
Merck & Co Inc.	FEB 02 2007
DEFENDANT	ATLANTIC COUN
1-	· LAW DIVISION
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•	CAROL E. HIGBEE, P.J.CV.
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Marc D. Grossman, Esq.

RECEIVED/FILEO SUPERIOR COURT OF NU HUNTURS J. I COUNTY

SUPERIOR COURT OF NEW JERSEY ATLANTIC COUNTY - LAW DIVISION

2007 FEB 13 P	X 12: 02
Mercedes C. Gonzalez	
PLAINTIFF CHIE GIVE	ELY L-112-07
ve.	DRDER OF DISPOSITION RECEIVED AND
•	4-1/2-07 FILED
Merck & Co Inc.	FEB 0.2 2007
DEFENDANT	ATLANTIC COUN LAW DIVISION
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hereby disposed and subject to the conditions of an parties due to the following:	20 ORDERED that this matter is by formal consent stipulation hereinster filed by the
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30 Voluntary Diemissal - Voluntary Binding Arbitrs	
Plaintiff failed to appear. Action dismissed for Laci Defendant failed to appear. Strike Defendant's ple Plaintiff and Defendant failed to appear. Action dis	adings, Defenses are suppressed.

Marc D. Grossman, Esq.

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SUPREME COURT OF NEW JERSEY

On application made pursuant to Rule 4:38A and the Mass Tort Guidelines

promulgated by Directive #10-07 in accordance with that Rule, it is hereby ORDERED

that all pending and future actions seeking damages or other relief arising out of the use

of the drugs Zometa or Aredia, except the matter of Bryant et al v. Merck & Co., &

Novartis Pharmaceutical Corp., MID-L-4965-06, are designated as a mass tort for

centralized case management purposes; and

It is FURTHER ORDERED that any and all such complaints that have been filed

in the various counties and that are under or are awaiting case management and/or

discovery shall be transferred from the county of venue to Superior Court, Law Division,

Middlesex County and assigned to the Honorable Jamie D. Happas, with the assistance of

Special Master Agatha N. Dzikiewicz, and that, pursuant to N.J. Const. (1947), Art. VI,

sec. 2, par. 3, the provisions of Rule 4:3-2 governing venue in the Superior Court are

supplemented and relaxed so that all future such complaints, no matter where they might

be venued, shall be filed in Middlesex County and assigned to Judge Happas; and

It is FUTHER ORDERED that Judge Happas shall oversee all management and

trial issues for such cases and may, in her discretion, return such cases to the original

county of venue for disposition; and

It is FURTHER ORDERED that no Mediator or other Master may be appointed

in this litigation without the express approval of the Chief Justice.

For the Court,

/s/ Stuart Rabner

Chief Justice

Dated: January 22, 2008

APR 18 2006

FILED CLERK'S OFFICE

RELEASED FOR PUBLICATION

DOCKET NO. 1760

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION

BEFORE WM. TERRELL HODGES,* CHAIRMAN, JOHN F. KEENAN, D. LOWELL JENSEN, J. FREDERICK MOTZ,* ROBERT L. MILLER, JR., KATHRYN H. VRATIL AND DAVID R. HANSEN,* JUDGES OF THE PANEL

TRANSFER ORDER

This litigation currently consists of fifteen actions pending in the Eastern District of New York, fifteen actions in the Southern District of New York, four actions in the Middle District of Tennessee and one action in the Western District of Oklahoma, as listed on the attached Schedules A and B.¹ Before the Panel is a motion, pursuant to 28 U.S.C. § 1407, brought by plaintiff in one Eastern District of New York action for coordinated or consolidated pretrial proceedings of all actions in the Eastern District of New York or the Southern District of New York. Moving plaintiff avers that plaintiffs in the other actions and potential tag-along actions in those two districts support the motion. Plaintiffs in at least four additional potential tag-along actions pending, respectively, in four districts² also support the motion. All defendants - Novartis Pharmaceuticals Corp. (Novartis), Merck & Co., Inc. (Merck), Procter & Gamble Pharmaceuticals, Inc. (P&G), and sanofi-aventis U.S. LLC (Aventis) - oppose the motion. Plaintiffs in the four Middle District of Tennessee actions and a Northern District of Florida potential tag-along action also oppose the motion. In the event the Panel orders centralization over their objections, these plaintiffs and defendant Novartis would support centralization in the Middle District of Tennessee.

On the basis of the papers filed and hearing session held, the Panel finds that the actions in this litigation listed on Schedule A involve common questions of fact, and that their centralization under Section 1407 in the Middle District of Tennessee will serve the convenience of the parties and witnesses

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Judges Hodges, Motz and Hansen took no part in the decision of this matter.

The Panel has been notified of 35 related actions pending in multiple federal districts. In light of the Panel's disposition of this docket, 34 of these actions will be treated as potential tag-along actions. See Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).

² Middle District of Florida, Middle District of North Carolina, Northern District of Ohio, and Western District of Texas.

and promote the just and efficient conduct of this litigation. The Schedule A actions assert claims against Novartis arising from ingestion of Aredia and/or Zometa, prescription medications used in the treatment of cancer. Specifically, these actions present complex common factual questions concerning, among other things, 1) the development, testing, manufacturing and marketing of the two Novartis drugs, and 2) Novartis's knowledge concerning their alleged adverse effects, in particular, the potential for each drug to cause osteonecrosis of the jaw. Centralization under Section 1407 is necessary in order to eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary.

The Panel further finds that centralization of the actions listed on Schedule B would neither serve the convenience of the parties and witnesses nor further the just and efficient conduct of this litigation at this time. Four of these actions are brought solely against Merck and concern its drug Fosamsax. The fifth action, which involves the drug Actonel, is brought against P&G and Aventis. Both Actonel and Fosamax, so-called oral bisphosphonates, are used in the prevention or treatment of osteoporosis and are available without prescription. Movants have failed to persuade us that any common questions of fact between the actions against Novartis and the actions against the other defendants are sufficiently numerous to justify Section 1407 transfer of the latter group. Alternatives to transfer exist that can minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings. See, e.g., In re Eli Lilly and Company (Cephalexin Monohydrate) Patent Litigation, 446 F.Supp. 242, 244 (J.P.M.L. 1978); see also Manual for Complex Litigation, Fourth § 20.14 (2004). For the same reasons, the Panel is persuaded that claims against Merck in three Schedule A actions³ do not share sufficient questions of fact with the claims against Novartis in those actions to warrant inclusion in the MDL-1760 proceedings.

We conclude that the Middle District of Tennessee is an appropriate transferee forum for this litigation. The Middle District of Tennessee has 1) pending actions, including putative nationwide class actions, in which pretrial matters have been proceeding; and 2) the endorsement of some plaintiffs and the common defendant, in the alternative. Furthermore, centralization in this forum permits the Panel to effect the Section 1407 assignment to a suggested transferee district that is currently handling few other multidistrict litigation dockets.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the Middle District of Tennessee are transferred to the Middle District of Tennessee and, with the consent of that court, assigned to the Honorable Todd J. Campbell for coordinated or consolidated pretrial proceedings with the actions listed on Schedule A and pending in that district.

³ Shirley Grizzle v. Novartis Pharmaceuticals Corp., et al., S.D. New York, C.A. No. 1:06-366; Burdette Burt v. Novartis Pharmaceuticals Corp., et al., S.D. New York, C.A. No. 1:06-368; and Jack Cuthbert v. Novartis Pharmaceuticals Corp., et al., S.D. New York, C.A. No. 1:06-387.

IT IS FURTHER ORDERED that claims against Merck in the three Southern District of New York actions listed in footnote 3 are simultaneously separated and remanded to the Southern District of New York.

IT IS FURTHER ORDERED that, pursuant to 28 U.S.C. § 1407, transfer is denied with respect to the actions listed on Schedule B.

IT IS FURTHER ORDERED that this docket, originally named MDL-1760 – In re Bisphosphonate Drugs Products Liability Litigation, is renamed as follows: MDL-1760 – In re Aredia and Zometa Products Liability Litigation.

FOR THE PANEL:

John F. Keenan Acting Chairman

SCHEDULE A

MDL-1760 - In re Aredia and Zometa Products Liability Litigation

Eastern District of New York

Zena Biocca v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-170
Linda H. Johnson v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-176
Mindy J. Knopf v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-188
John Bartoli v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-189
Margaret Cartelli v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-191
Elaine Guilbeau v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-192
Michel Hendrix v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-194
Glenn Hiller v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-195
Victor Kalily v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-196
K. Thomas Punnose v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-199
Loretta Gee v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-257
Runette Champion v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-258
Mayra Martinez v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-259
Karlene Hogan, etc. v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-260
Arlene Perkins v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-261

Southern District of New York

Helen E. Shrum v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-363
Nancy Radin v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-364
Shirley Grizzle v. Novartis Pharmaceuticals Corp., et al., C.A. No. 1:06-366
Patsy Carter v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-367
Burdette Burt v. Novartis Pharmaceuticals Corp., et al., C.A. No. 1:06-368
Jacqueline Wilson v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-369
Gary Fry v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-370
Linda Wallace v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-371
Charles Ulatowski v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-373
Gary Stevens v. Novartis Pharmaceuticals Corp., C.A. No. 1:06-374
Jack Cuthbert v. Novartis Pharmaceuticals Corp., et al., C.A. No. 1:06-387

Western District of Oklahoma

Linda Ingram, etc. v. Novartis Pharmaceuticals Corp., C.A. No. 5:05-913

Middle District of Tennessee

Angela Wood, et al. v. Novartis Pharmaceuticals Corp., C.A. No. 3:05-716 Terry Anderson, et al. v. Novartis Pharmaceuticals Corp., C.A. No. 3:05-718 Susan Becker, et al. v. Novartis Pharmaceuticals Corp., C.A. No. 3:05-719

SCHEDULE B

MDL-1760 - In re Aredia and Zometa Products Liability Litigation

Southern District of New York

Margaret Peggy Harth v. Merck & Co., Inc., C.A. No. 1:06-361
Ramon L. Harrison v. Merck & Co., Inc., C.A. No. 1:06-365
Suzanne Dengel v. Merck & Co., Inc., C.A. No. 1:06-372
Lena Simmons v. Proctor & Gamble Pharmaceuticals, Inc., et al., C.A. No. 1:06-454

Middle District of Tennessee

Gwendolyn Wolfe, et al. v. Merck & Co., Inc., C.A. No. 3:05-717

SEEGER WEISS LLP 550 Broad Street, Suite 920 Newark, NJ 07102-4573 (973) 639-9100 telephone (973) 639-9393 facsimile Attorneys for Plaintiff RECEIVED and FILED Office of the Superior Court Clark by Deputy Clark of the Superior Court

AUG 24 2007.

ESSEX

DEBRA LYNN PASTORIUS,

Plaintiff,

v.

MERCK & CO., INC., PROCTER & GAMBLE PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S. LLC,

Defendants.

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ESSEX COUNTY

DOCKET NO.: L-6696-07

CIVIL ACTION

COMPLAINT &
JURY TRIAL DEMANDED

Plaintiff, DEBRA LYNN PASTORIUS, by and through her attorneys, alleges the following upon information and belief (including an investigation made by and through Plaintiff's counsel), except those allegations that pertain to Plaintiff, which are based on personal knowledge.

BACKGROUND

1. This is an action for damages suffered by Plaintiff, as a direct and proximate result of the negligent and wrongful conduct of Merck & Co., Inc. ("Merck"), Procter & Gamble Pharmaceuticals, Inc. ("P&G") and sanofi-aventis U.S. LLC ("sanofi-aventis") (hereinafter collectively referred to as "Defendants"), in connection with the design, development,

manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the pharmaceutical products known as Fosamax and Actonel (hereinafter referred to as "Fosamax," "Actonel" or collectively, "the subject products").

- 2. At all times material hereto, Merck was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Fosamax.
- 3. At all times material hereto, P&G and sanofi-aventis were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Actonel.

JURISDICTION AND VENUE

- 4. This is an action for damages that exceed the jurisdictional minimum of this Court.
- Venue is proper in this County pursuant to Rule 4:3 in that Defendants do business in Essex County.
- 6. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq. ("Products Liability Act"), and the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq. ("Consumer Fraud Act"), to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries Plaintiff has sustained as a

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result of Defendants' acts and omissions in violation of New Jersey's Products Liability Act and Consumer Fraud Act.

PARTIES

- 7. Plaintiff, Debra Lynn Pastorius, is a resident of Mesa, Arizona.
- 8. The Defendant, Merck, is a New Jersey corporation, which has its principal place of business at One Merck Drive, P. O. Box 100, Whitehouse Station, New Jersey 08889-0100 and does business in Essex County.
- 9. The Defendant, Procter & Gamble, is an Ohio corporation, which has its principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202 and does business in Essex County.
- 10. The Defendant, sanofi-aventis, is a New Jersey corporation, which has its principal place of business at 55. Corporate Drive, Bridgewater, New Jersey 08807 and does business in Essex County.

FACTUAL ALLEGATIONS

11. Fosamax and Actonel fall within a class of drugs known as bisphosphonates. Bisphosphonates inhibit the breakdown or turnover of bone and are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are given

to certain patients with advanced cancers that have metastasized to the bone as a component of their treatment therapy, but are not indicated for use in non-cancerous conditions such as osteoporosis.

- 12. The Pood and Drug Administration ("FDA") approved Fosamax for the treatment of osteoporosis and Paget's disease in September 1995.
- 13. The FDA approved Actonel for the treatment of Paget's disease in March 1998, and soon after for post-menopausal osteoporosis as well.
- 14. Fosamax is the world's top-selling bisphosphonate and Merck's second-best selling drug, with more than 22 million prescriptions in 2005 amounting to \$3.2 billion in sales.
- 15. Actonel is the world's second best-selling bisphosphonate, earning \$2.1 billion in 2005.
- 16. Shortly after the approval of Fosamax and Actonel, reports of osteonecrosis of the jaw in cancer patients being treated with bisphosphonates began to emerge.
- 17. Osteonecrosis of the jaw is a serious and painful medical condition in which bone tissue does not heal after minor trauma, resulting in exposed bone. Complications include ulcerations of the lining of the mouth, infection,

fracture and permanent disfigurement. Once osteonecrosis occurs, it is virtually impossible to reverse.

- 18. In 2004, an article in the Journal of Oral and Maxillofacial Surgery confirmed a causal link between bisphosphonate use in cancer patients and the occurrence of osteonecrosis of the jaw.
- 19. Dentists and oral surgeons are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) on any patient taking a bisphosphonate.
- 20. Defendants knew or should have known that Fosamax and Actonel, as a nitrogenous bisphosphonates, shared the class effects of other nitrogenous bisphosphonates.
- 21. Defendants knew and or should have known that bisphosphonates, including Fosamax and Actonel, inhibit endothelial cell function, inhibit vascularization of the affected area, and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature. As a result, a minor injury or disease can develop into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

- 22. Despite this aforementioned knowledge, Defendants failed to implement further study of the risk of osteonecrosis of the jaw relative to Fosamax.
- 23. At all times material hereto, Defendants knew or should have known that the risks of the subject products included severe and permanently disfiguring side effects.
- 24. At all times material hereto, the Defendants, by and through their agents, servants and/or employees, failed to warn physicians and consumers, including Plaintiff, of the risk of developing osteonecrosis of the jaw when using their respective products.
- 25. At all times material hereto, the Defendants, by and through their agents, servants, and/or employees, negligently and recklessly marketed, distributed and sold the subject products without adequate warnings of their serious side effects and unreasonably dangerous risks.

Plaintiff's Use Of Fosamax and Actonel

- 26. Plaintiff, Debra Lynn Pastorius, was prescribed and took Fosamax from on or about February 9, 2001 through on or about November 30, 2001.
- 27. Plaintiff, Debra Lynn Pastorius, was prescribed and took Actonel from on or about November 30, 2001 through on or about October 31, 2005.

- 28. As a direct and proximate result of using the subject products, Plaintiff was diagnosed with osteonecrosis of the jaw on August 26, 2005.
- 29. Plaintiff, Debra Lynn Pastorius, as a direct and proximate result of using the subject products, has suffered permanent disfigurement, pain, suffering and other damages as a result of her injuries.
- 30. Plaintiff, Debra Lynn Pastorius, would not have used the subject products and would not have suffered injury had Defendants properly disclosed the risks associated with the subject products.

COUNT I Products Liability Act - Failure to Warn

- 31. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 32. Defendant Merck designed, tested, manufactured, marketed, sold and/or distributed Fosamax. As such, it had a duty to warn the using public, including Plaintiff, of the health risks associated with using Fosamax.
- 33. Fosamax was under the exclusive control of Merck and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the

consumer. The promotional activities of Merck further diluted or minimized the warnings given with Fosamax.

- 34. Fosamax was defective and unreasonably dangerous when it left the possession of Merck in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw. Even though Merck knew or should have known of the risks and reactions associated with Fosamax, it still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.
- 35. Plaintiff used Fosamax for its intended purpose, i.e. for the prevention or treatment of osteoporosis.
- 36. Plaintiff could not have discovered any defect in Fosamax through the exercise of reasonable care.
- 37. Merck, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field, and further, Merck had knowledge of the dangerous risks and side effects of Fosamax.
- 38. Plaintiff did not have the same knowledge as Merck and no adequate warnings were communicated to her.
- 39. Merck had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with Fosamax.

By negligently and/or wantonly failing to adequately warn of the dangers of use of Fosamax, Merck breached its duty.

- 40. Although Merck knew of the defective nature of Fosamax, it continued to design, manufacture, market, and sell Fosamax without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Fosamax.
- 41. As a direct and proximate result of Merck's failure to adequately warn or other wrongdoing and actions of Merck described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.
- 42. Defendants P&G and sanofi-aventis designed, tested, manufactured, marketed, sold and/or distributed Actonel. As such, they had a duty to warn the using public, including Plaintiff, of the health risks associated with using Actonel.
- 43. Actonel was under the exclusive control of P&G and sanofi-aventis and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer. The promotional

activities of P&G and sanofi-aventis further diluted or minimized the warnings given with Actonel.

- 44. Actonel was defective and unreasonably dangerous when it left the possession of P&G and sanofi-aventis in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw. Even though P&G and sanofi-aventis knew or should have known of the risks and reactions associated with Actonel, they still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.
- 45. Plaintiff used Actonel for its intended purpose, i.e. for the prevention or treatment of osteoporosis.
- 46. Plaintiff could not have discovered any defect in Actonel through the exercise of reasonable care.
- 47. P&G and sanofi-aventis, as manufacturers of pharmaceutical products, are held to the level of knowledge of experts in the field, and further, P&G and sanofi-aventis had knowledge of the dangerous risks and side effects of Actonel.
- 48. Plaintiff did not have the same knowledge as P&G and sanofi-aventis and no adequate warnings were communicated to her.
- 49. P&G and sanofi-aventis had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with

Actonel. By negligently and/or wantonly failing to adequately warn of the dangers of use of Actonel, P&G and sanofi-aventis breached their duty.

- 50. Although P&G and sanofi-aventis knew of the defective nature of Actonel, they continued to design, manufacture, market, and sell Actonel without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Actonel.
- 51. As a direct and proximate result of the failure of P&G and sanofi-aventis to adequately warn or other wrongdoing and actions of P&G and sanofi-aventis described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II Products Liability Act - Defective Design

52. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

- 53. Merck is the manufacturer, seller, distributor, marketer, and/or supplier of Fosamax, which is defective and unreasonably dangerous to consumers.
- 54. Fosamax was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by Merck, and was expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Merck.
- 55. Fosamax was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.
- 56. Although Merck actually knew of the defective nature of Fosamax, it continued to design, manufacture, market, and sell Fosamax so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by Fosamax.
- 57. As a direct and proximate result of the design defects of Posamax, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.
- 58. P&G and sanofi-aventis are the manufacturers, sellers, distributors, marketers, and/or suppliers of Actonel, which is defective and unreasonably dangerous to consumers.

- 59. Actonel was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by P&G and sanofi-aventis, and was expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by P&G and sanofi-aventis.
- 60. Actonel was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.
- 61. Although P&G and sanofi-aventis actually knew of the defective nature of Actonel, they continued to design, manufacture, market, and sell Actonel so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by Actonel.
- 62. As a direct and proximate result of the design defects of Actonel, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III Products Liability Act - Breach of Implied Warranty

- 63. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 64. Merck manufactured, marketed, sold, and distributed Posamax specifically for the prevention of osteoporosis.
- 65. At the time Merck marketed, sold, and distributed Fosamax for use by Plaintiff, Merck knew of the purpose for which it was intended and impliedly warranted Fosamax to be of merchantable quality and safe and fit for such use.
- 66. Contrary to such implied warranty, Fosamax was not of merchantable quality and was not safe or fit for its intended use.
- 67. Plaintiff purchased and used Fosamax for the prevention of osteoporosis.
- 68. Plaintiff reasonably relied on the skill, superior knowledge, and judgment of Merck as to whether Fosamax was of merchantable quality and safe and fit for its intended use.
- 69. Due to Merck's wrongful conduct as alleged herein,
 Plaintiff could not have known about the risks and side
 effects associated with Fosamax until after Plaintiff used
 it.

- 70. As a direct and proximate result of Merck's breach of implied warranty, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.
- 71. P&G and sanofi-aventis manufactured, marketed, sold, and distributed Actonel specifically for the prevention of osteoporosis.
- 72. At the time P&G and sanofi-aventis marketed, sold, and distributed Actonel for use by Plaintiff, P&G and sanofi-aventis knew of the purpose for which it was intended and impliedly warranted Actonel to be of merchantable quality and safe and fit for such use.
- 73. Contrary to such implied warranty, Actonel was not of merchantable quality and was not safe or fit for its intended use.
- 74. Plaintiff purchased and used Actonel for the prevention of osteoporosis.
- 75. Plaintiff reasonably relied on the skill, superior knowledge, and judgment of P&G and sanofi-aventis as to whether Actonel was of merchantable quality and safe and fit for its intended use.
- 76. Due to the wrongful conduct of P&G and sanofiaventis as alleged herein, Plaintiff could not have known

about the risks and side effects associated with Actonel until after Plaintiff used it.

77. As a direct and proximate result of the breach of implied warranty of P&G and sanofi-aventis, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss

WHEREFORE, Plaintiff demands judgment against each

Defendant, individually, jointly and severally for

compensatory and punitive damages, together with interest,

costs of suit, attorneys' fees and all such other relief as

the Court deems proper.

COUNT IV Breach of Express Warranty

- 78. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 79. The aforementioned manufacturing, designing, distributing, marketing and promoting of Fosamax was expressly warranted to be safe for Plaintiff and members of the public generally. At the time of the making of the express warranties, Merck had knowledge of the purpose for which Fosamax was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

- 80. Fosamax does not conform to Merck's express representations because it is not safe or effective and produces serious side effects.
- 81. Merck placed Fosamax into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including Plaintiff, of the risks associated with its use.
- 82. Merck had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of Fosamax, including a duty to:
 - a. Ensure that Fosamax did not cause the user unreasonably dangerous side effects;
 - b. Warn of dangerous and potentially fatal side effects;
 - c. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiff.
- 83. Plaintiff's physicians prescribed and Plaintiff purchased and used Fosamax and reasonably relied upon Merck and their agents to disclose known defects, risks, dangers and side effects of Fosamax.

- 84. Plaintiff's physicians, the FDA and/or Plaintiff had no knowledge of the falsity or incompleteness of Merck's statements and representations concerning Fosamax when Plaintiff purchased it as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Merck.
- 85. Merck was under a duty to disclose the defective and unsafe nature of Fosamax to physicians, the FDA, consumers and users, such as Plaintiff. Merck had sole access to material facts concerning the defects, and Merck knew that physicians, the FDA, consumers and users, such as Plaintiff, could not have reasonably discovered such defects.
- 86. By the conduct alleged, Merck expressly warranted to Plaintiff and her physician that Fosamax was merchantable and fit for the purpose intended in violation of N.J.S.A. 12A:2-313 et seg.
- 87. As a direct and proximate result of Merck's breach of express warranty, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.
- 88. The aforementioned manufacturing, designing, distributing, marketing and promoting of Actonel was expressly warranted to be safe for Plaintiff and members of the public

generally. At the time of the making of the express warranties, P&G and sanofi-aventis had knowledge of the purpose for which Actonel was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

- 89. Actonel does not conform to the express representations of P&G and sanofi-aventis because it is not safe or effective and produces serious side effects.
- 90. P&G and sanofi-aventis placed Actonel into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including Plaintiff, of the risks associated with its use.
- 91. P&G and sanofi-aventis had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of Actonel, including a duty to:
 - a. Ensure that Actonel did not cause the user unreasonably dangerous side effects;
 - b. Warn of dangerous and potentially fatal side effects:
 - c. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiff.

- 92. Plaintiff's physicians prescribed and Plaintiff purchased and used Actonel and reasonably relied upon P&G, sanofi-aventis and their agents to disclose known defects, risks, dangers and side effects of Actonel.
- 93. Plaintiff's physicians, the FDA and/or Plaintiff had no knowledge of the falsity or incompleteness of the statements and representations of P&G and sanofi-aventis concerning Actonel when Plaintiff purchased it as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by P&G and sanofi-aventis.
- 94. P&G and sanofi-aventis were under a duty to disclose the defective and unsafe nature of Actonel to physicians, the FDA, consumers and users, such as Plaintiff. P&G and sanofiaventis had sole access to material facts concerning the defects, and P&G and sanofi-aventis knew that physicians, the FDA, consumers and users, such as Plaintiff, could not have reasonably discovered such defects.
- 95. By the conduct alleged, P&G and sanofi-aventis expressly warranted to Plaintiff and her physician that Actonel was merchantable and fit for the purpose intended in violation of N.J.S.A. 12A:2-313 et seg.
- 96. As a direct and proximate result of the breach of express warranty by P&G and sanofi-aventis, Plaintiff has

sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V

Punitive Damages Under Common Law and Products Liability Act

- 97. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 98. Although Merck knew or recklessly disregarded the fact that Fosamax causes debilitating and potentially lethal side effects, Merck continued to market Fosamax to consumers, including Plaintiff, DEBRA LYNN PASTORIUS, without disclosing these side effects.
- 99. Merck knew of the defective nature of Fosamax, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Fosamax.
- 100. Merck intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of Fosamax to ensure

their continued and increased sales. This intentional and/or reckless failure to disclose information deprived Plaintiff of the information necessary for her to weigh the true risks of using Fosamax against the benefits.

- 101. Merck's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Merck and deter it from similar conduct in the future.
- 102. Although P&G and sanofi-aventis knew or recklessly disregarded the fact that Actonel causes debilitating and potentially lethal side effects, P&G and sanofi-aventis continued to market Actonel to consumers, including Plaintiff, without disclosing these side effects.
- 103. P&G and sanofi-aventis knew of the defective nature of Actonel, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Actonel.
- 104. P&G and sanofi-aventis intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of Actonel to ensure their continued and increased sales. This

intentional and/or reckless failure to disclose information deprived Plaintiff of the information necessary for her to weigh the true risks of using Actonel against the benefits.

105. The aforementioned conduct of P&G and sanofi-aventis was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish P&G and sanofi-aventis and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI Violations of New Jersey Consumer Fraud Act

- 106. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 107. The subject products are "merchandise" as that term is defined by N.J.S.A. 56:8-1(c).
- 108. Unfair methods of competition and unfair or deceptive acts or practices are defined and declared unlawful in N.J.S.A. 56:8-1, et seq.:
- 56:8-2. Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice.

 The act, use or employment by any person of any unconscionable

commercial practice, deception, fraud, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

- 109. Merck is the manufacturer, marketer, and/or distributor of Posamax.
- 110. Merck knew or should have known that the use of Fosamax causes serious and potentially life-threatening side effects.
- 111. Merck's promotion of Posamax, which included misrepresentations and the active concealment of information about its defects and dangers, created or reinforced a false impression as to its safety and placed all users of Fosamax at risk for serious and potentially lethal side effects.
- 112. Merck's misrepresentations and active concealment of information about the defects and dangers of Fosamax were undertaken with the intent that the general public, including Plaintiff, would rely on such misrepresentations and omissions.
- 113. Plaintiff was prescribed and used Fosamax primarily for personal, family, or household purposes and suffered an

ascertainable loss of money as a result of Merck's use or employment of the methods, acts, or practices alleged herein.

114. The aforesaid promotion of Fosamax by Merck constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Merck, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

115. Merck knew of the growing public acceptance of the misinformation, or incomplete information, and misrepresentations regarding the safety and efficacy of Posamax, but remained silent due to the large profits being earned.

116. As a direct and proximate cause of Merck's acts of consumer fraud, Plaintiff has suffered ascertainable loss — economic loss that includes the purchase price of Fosamax and other out-of-pocket healthcare related costs — for which Merck is liable to Plaintiff for treble her actual damages.

117. P&G and sanofi-aventis are the manufacturers, marketers, and/or distributors of Actonel.

118. P&G and sanofi-aventis knew or should have known that the use of Actonel causes serious and potentially lifethreatening side effects.

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- 119. The promotion of Actonel by P&G and sanofi-aventis, which included misrepresentations and the active concealment of information about its defects and dangers, created or reinforced a false impression as to its safety and placed all users of Actonel at risk for serious and potentially lethal side effects.
- 120. The misrepresentations and active concealment of information about the defects and dangers of Actonel by P&G and sanofi-aventis were undertaken with the intent that the general public, including Plaintiff, would rely on such misrepresentations and omissions.
- 121. Plaintiff was prescribed and used Actonel primarily for personal, family, or household purposes and suffered an ascertainable loss of money as a result of the use or employment of the methods, acts, or practices of P&G and sanofi-aventis alleged herein.
- 122. The aforesaid promotion of Actonel by P&G and sanofi-aventis constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment,

suppression, or omission in connection with the sale or advertisement of merchandise or services by P&G and sanofiaventis, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

123. P&G and sanofi-aventis knew of the growing public acceptance of the misinformation, or incomplete information, and misrepresentations regarding the safety and efficacy of Actonel, but remained silent due to the large profits being earned.

124. As a direct and proximate cause of the acts of consumer fraud of P&G and sanofi-aventis, Plaintiff has suffered ascertainable loss — economic loss that includes the purchase price of Actonel and other out-of-pocket healthcare related costs — for which P&G and sanofi-aventis are liable to Plaintiff for treble her actual damages

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment as follows:

- a. Awarding actual damages to Plaintiff incidental to her purchase and ingestion of the subject products in an amount to be determined at trial;
- b. Awarding treble and/or punitive damages to Plaintiff;
- c. Awarding pre-judgment and post-judgment interest to Plaintiff;
- d. Awarding the costs and expenses of this litigation to Plaintiff;
- e. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and
- f. Granting such other relief as the Court deems necessary, just and proper.

JURY TRIAL DEMANDED

The Plaintiff demands a trial by jury on all issues.

Dated: August 22, 2007.

SEEGER WEISS LLP

By:

Christopher A Seeger
David R. Buchanan
Elizabeth A. Wall
550 Broad Street, Suite 920
Newark, New Jersey 07102-4573
(973) 639-9100 tel.
(973) 639-9393 fax.

CERTIFICATION PURSUANT TO R. 4:5-1

Plaintiff, by her attorneys, hereby certifies that the matter in controversy is not the subject of any other pending or contemplated judicial or arbitration proceedings. Plaintiff is not currently awars of any other parties that should be joined in this particular action. In addition, Plaintiff recognizes her continuing obligation to file and serve on all parties and the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: August 22, 2007

SEEGER WEISS LLP

By

Christopher A Seeger
David R. Buchanan
Elizabeth A. Wall
550 Broad Street, Suite 920
Newark, New Jersey 07102-4573
(973) 639-9100 tel.
(973) 639-9393 fax.

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Christopher A. Seeger is hereby designated as trial counsel in this matter.

Dated: August 22, 2007

SEEGER WEISS LLP

Bv:

Christophe A. Seeger
David R. Buchanan
Blizabeth A. Wall
550 Broad Street, Suite 920
Newark, New Jersey 07102-4573
(973) 639-9100 tel.
(973) 639-9393 fax.

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiff is mailing a copy of this Complaint and Jury Demand to the Office of the Attorney General, CN-006, Trenton, New Jersey, within ten (10) days of the filing of this Complaint and Jury Demand.

Dated: August 22, 2007

SEEGER WEISS LLP

By:

Christopher A. Seeger David R. Buchanan Elizabeth A. Wall 550 Broad Street, Suite 920 Newark, New Jersey 07102-4573 (973) 639-9100 tel. (973) 639-9393 fax.

CIVIL CASE INFORMATION STATEMENT

(CIS)

Use for initial Law Division
Civil Part pleadings (not motions) under Rule 4:5-1
Pleading will be rejected for filing, under Rule 1:5-6(c),
if information above the black bar is not completed or
if attorney's signature is not affixed.

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if attomey's signature is not affixed. BATCH NUMBER: TELEPHONE NUMBER COUNTY OF VENUE ATTORNEY/PRO SE NAME ٠٠٠٠ م (973) 639-5301 CHRISTOPHER A. SEEGER ESSEX DOCKET NUMBER (When available) FIRM NAME (If applicable) SEEGER WEISS LLP OFFICE ADDRESS DOCUMENT TYPE COMPLAINT 550 BROAD STREET, SUITE 920 JURY DEMAND **NEWARK, NJ 07102** YES NO NAME OF PARTY (e.g., John Doe, Plaintiff) CAPTION DEBRA LYNN PASTORIUS, Plaintiff, v. MERCK & CO., INC., PROCTOR DEBRA LYNN PASTORIUS, Plaintiff & GAMBLE PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S. LLC, Defendants. K NO IS THIS A PROFESSIONAL MALPRACTICE CASE? YES CASE TYPE NUMBER (See reverse side for listing) IF YOU HAVE CHECKED "YES," SEE N.J.S.A. 2A:59A-27 AND APPLICABLE CASE LAW REGARDING YOUR OBLIGATION TO FILE AN AFFIDAVIT OF MERIT. RELATED CASES PENDING? IF YES, LIST DOCKET NUMBERS YES K NO DO YOU ANTICIPATE ADDING NAME OF DEFENDANT'S PRIMARY INSURANCE COMPANY, IF KNOWN YES KNO ANY PARTIES (arising out of same transaction or occurrence)? NONE UNKNOWN THE INFORMATION PROVIDED ON THIS FORM CANNOT BF INTRODUCED INTO EVIDENCE. CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION IF YES, IS THAT DO PARTIES HAVE A CURRENT, EMPLOYER-EMPLOYEE FRIENDMEIGHBOR DTHER (explain) FAMILIAL BUSINESS PAST OR RECURRENT RELATIONSHIP? YES NO DOES THE STATUTE GOVERNING THIS CASE PROVIDE FOR PAYMENT OF FEES EYES NO
BY THE LOSING PARTY?
USE THIS EPACE TO ALERT THE COURT TO ANY SPECIAL CASE CHARACTERISTICS THAT MAY WARRANT INDIVIDUAL MANAGEMENT OR ACCELERATED
DISPOSITION: DO YOU OR YOUR CLIENT NEED IF YES, PLEASE IDENTIFY THE ANYDISABILITY ACCOMMODATIONS? YES NO REQUESTED ACCOMMODATION: WILL AN INTERPRETER BE NEEDED? YES KNO IF YES, FOR WHAT LANGUAGE: ATTORNEY SIGNATURE

SIDE 2



CIVIL CASE INFORMATION STATEMENT (CIS) Use for initial pleadings (not motions) under Rule 4:5-1

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SE TYPES (Choose one and enter	number of case type in a	appropriate space	on the reverse side.)	
Touck 1	150 days' discovery				
	51 NAME CHANGE				
	75 FORFEITURE				
	2 TENANCY				
		her than Tenancy, Contract, C	ondernation, Complex	c Commercial or Construction	on)
	2 BOOK ACCOUNT (del		• · · · · · · · · · · · · · · · · · · ·		,
5	5 OTHER INSURANCE	CLAIM (INCLUDING DECLAR	VATORY JUDGMENT	ACTIONS)	
	6 PIP COVERAGE			•	
	10 UM or UM CLAIM				
5.	11 ACTION ON NEGOTIA	UBLE INSTRUMENT			
	12 LEMON LAW				
	1 SUMMARY ACTION				
	2 OPEN PUBLIC RECO	RDS ACT (SUMMARY ACTIO	N)		
\$4	99 OTHER (Briefly descri	na hadre of action)			
	•				
Track II	300 daye' discovery				
	S CONSTRUCTION				
	9 EMPLOYMENT (other	then CEPA or LAD)			
	9 CONTRACT/COMMER				
60	AUTO NEGLIGENCE	- PERSONAL INJURY			
60	5 PERSONAL INJURY				
		- PROPERTY DAMAGE			
69	89 TORT-OTHER				
Track III -	- 450 days' discovery				
	S CIVIL RIGHTS				
	1 CONDEMNATION				
	2 ASSAULT AND BATTE	ERY .			
60	4 MEDICAL MALPRACT	ICE			
	6 PRODUCT LIABILITY				
	7 PROFESSIONAL MAL	PRACTICE			
	8 TOXIC TORI				
	9 DEFAMATION		E DOOTEONION ACT	(OFDA) CAREE	
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	17 INVERSE CONDEMN 18 LAW AGAINST DISCR	MINATION (LAD) ÇASES			
•	10 EVAN WOMING! DISCH	IMMATION (END) CASES			
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		IVIRONMENTAL COVERAGE	LITIGATION		
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Revised effective 09/2008, CN10517

SUPERIOR COURT OF MI 445 HAPPIN LUTTER TING JR BLVD NEWARK BJ-97102

TRACE ASSIGNMENT NOTICE

COURT TELEPHONE NO. (973) 693-5651 COURT HOURS

> DATE: AUROST 14, 2007 SE: PASTORIUS VE MERCE & CO INC SOCKET: ESK L -805576 87

THE ABOVE CASE HAS BEEN ASSIGNED TO: TRACE 3.

DISCOVERT IS 450 DATE AND RUNS FROM THE FIRST ANSWER OR SO DATE FROM SERVICE ON THE FIRST DEFENDANT, VEICHWER COMES FIRST.

THE PRETRIAL JUDGE ASSIGNED 18: NOW THOMAS B. NCCORNACK

17 TOW RAVE ANT QUESTIONS, CONTACT TEAR 664 AT: (973) 693-6469 ENT 6527.

IF YOU RELIEVE THAT THE TRACK IS IMAPPROPRIATE FOR MUSI FILE A CERTIFICATION OF COUR CAUSE MITHIN SO DAYS OF THE FILING OF YOUR PLEADING.
FLAINTIFY MIST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE WITH E.4:52-2.

ATTENTION:

ATT: CHRISTOPH A. STEERE SERVER WEISS LLP 556 RECAR ST WENDER NJ 07102

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