

  
**NORTON ROSE FULBRIGHT**

April 1, 2015

Via E-Mail (wayne\_fang@njdcourts.gov)

Hon. Freda L. Wolfson  
United States District Judge  
Clarkson S. Fisher Bldg.  
& U.S. Courthouse  
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Trenton, New Jersey 08608

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RECEIVED

APR 15 2015

AT 8:30 \_\_\_\_\_ M  
WILLIAM T. WALSH  
CLERK

Re: *In re: Fosamax (Alendronate Sodium) Products Liability Litigation*  
Master Docket 3:08-cv-00008-FLW-LHG

Dear Judge Wolfson:

Please allow this letter to serve as an update on the overall status of several cases in the Fosamax AFF MDL that involve Defendants Warner Chilcott (US), LLC, Procter & Gamble Pharmaceuticals, Inc.,<sup>1</sup> Sanofi US Services, Inc., and sanofi-aventis U.S. L.L.C.<sup>2</sup> (collectively the "Actonel Defendants"). These cases involve the alleged use of Actonel (risedronate sodium), an oral bisphosphonate, which was approved by the FDA for prevention and treatment of osteoporosis, and is included in the same class of drugs as Fosamax (alendronate sodium).

**OVERALL STATUS OF THE ACTONEL CASES**

The Actonel defendants currently are named in six (6) cases, which involve seven (7) claimants, in the Fosamax AFF MDL. In each of those cases, the plaintiff allegedly ingested Actonel, along with at least one other bisphosphonate (including, in all cases, Fosamax), and sometimes other medicines for the prevention or treatment of osteoporosis.

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<sup>1</sup> On February 1, 2010, Procter & Gamble Pharmaceuticals, Inc. became known as Warner Chilcott Pharmaceuticals Inc. In connection with that name change, Warner Chilcott Pharmaceuticals Inc. served as the successor in interest to Procter & Gamble Pharmaceuticals, Inc. Effective as of January 1, 2011, Warner Chilcott Pharmaceuticals Inc. was merged into Warner Chilcott (US), LLC, and no longer exists as a distinct entity. In connection with this transaction, Warner Chilcott (US), LLC now serves as the successor in interest to Procter & Gamble Pharmaceuticals, Inc.

<sup>2</sup> sanofi-aventis U.S. L.L.C. is the successor in interest to Aventis Pharmaceuticals, Inc. sanofi-aventis U.S. L.L.C. co-promoted Actonel with Procter & Gamble Pharmaceuticals, Inc. until October 30, 2009, after which it co-promoted Actonel with Warner Chilcott Pharmaceuticals Inc. until April 1, 2010. On April 1, 2010, sanofi-aventis U.S. L.L.C. ceased its co-promotion of Actonel, and Warner-Chilcott Pharmaceuticals Inc. assumed full responsibility for the promotion of Actonel.

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### **March 26, 2014 Preemption Order**

On March 26, 2014, Judge Pisano entered an order (the "Preemption Order") holding that claims involving alleged injuries occurring before September 14, 2010, are preempted as to Defendant Merck Sharp & Dohme Corp. ("Merck"). In a related order issued on the same day, Judge Pisano ordered the Clerk of this Court to "terminate the cases" subject to the Preemption Order.

Four (4) Actonel cases (See Attachment A) were identified as subject to the Preemption Order. Of those four (4) cases involving Actonel, three (3) appealed the order to the United States Court of Appeals for the Third Circuit. Those appeals remain pending. Accordingly, the Actonel Defendants contend that none of the four (4) cases listed on Attachment A are currently active in the Fosamax AFF MDL.

### **November 2014 Show Cause Order**

On November 6, 2014, Judge Pisano issued an order entitled "Order to Show Cause Why All Pending Claims Asserting That the 2011 Fosamax Label was a Proximate Cause of Plaintiffs' Injuries Should Not Be Dismissed" (the "November 2014 Show Cause Order"). In the Order, Judge Pisano stated that because it appeared to the Court that the 2011 Fosamax label is adequate as a matter of law, any plaintiffs claiming that an alleged inadequacy in that label is the proximate cause of their alleged injuries must show cause why their individual claims should not be dismissed. No plaintiff in a case involving Actonel filed any objection to Judge Pisano's Order, and the deadline to file an objection to the November 2014 Show Cause Order has passed.

Two Actonel cases, which involve three claimants (See Attachment B), were identified as subject to the November 2014 Show Cause Order. As discussed above, no plaintiff has submitted an objection to that Order. The Actonel Defendants would also respectfully note that the 2011 Actonel label was essentially identical to the Fosamax label with regard to alleged atypical femur fractures. Accordingly, the Actonel Defendants respectfully request that Your Honor enter an Order dismissing these two cases.

### **Anticipated Motion Practice**

Given the inactive status of the six (6) above-referenced cases, the Actonel Defendants do not intend to file any dispositive motions. The Actonel Defendants respectfully note that both the Preemption Order and the November 2014 Show Cause Order would likely control the comparable claims involving the Actonel Defendants, but without waiving their right to do so in the future, do not intend to pursue related motions at this time.

### **CONCLUSION**

In sum, none of these cases are being actively pursued in this Court, whether because they are currently on appeal before the United States Court of Appeals for the Third Circuit, or are subject to dismissal pursuant to one of this Court's previously entered orders.

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Please let me know if you have any questions or would like any additional information regarding the status of claims involving the Actonel Defendants.

Very truly yours,



Lana K. Varney

*with permission HLG/MLG*

LKV  
Attachments

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**Attachment A**

1. *Linda Elison v. Merck & Co., Inc., et al.*, Case No. 3:12-cv-06900, in the United States District Court, District of New Jersey
2. *Jerry Evans, Individually and as the Personal Representative of the Estate of Renee Evans v. Merck & Co., Inc., et al.*, Case No. 3:12-cv-06906, in the United States District Court, District of New Jersey
3. *Linda Hubbard and John Hubbard v. Merck & Co., Inc., et al.*, Case No. 3:12-cv-01967, in the United States District Court, District of New Jersey
4. *Josephine Spallone v. Merck & Co., Inc., et al.*, Case No. 3:13-cv-03741, in the United States District Court, District of New Jersey

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**Attachment B**

1. *Constance Ahlgren v. Merck & Co., Inc., et al.*, Case No. 3:13-cv-06546, in the United States District Court, District of New Jersey
2. *Nancy M. Richmond, et al. v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:12-cv-00946, in the United States District Court, District of New Jersey