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April 1, 2015

RECEIVED

VIA EMAIL: wayne\_fang@njd.uscourts.gov

Hon. Freda L. Wolfson, U.S.D.J.  
United States District Court - District of New Jersey  
402 East State Street, Room 2020  
Trenton, NJ 08608

APR 15 2015  
AT 8:30 \_\_\_\_\_ M  
WILLIAM T. WALSH  
CLERK

Re: In re: Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)  
Case No. 08-cv-08 (FLW) (LHG)

Dear Hon. Freda L. Wolfson:

Thank you for the opportunity to update the Court on the status of cases in the Fosamax MDL involving Roche Laboratories Inc., Hoffmann-La Roche Inc., Genentech, Inc., and GlaxoSmithKline LLC (collectively the "Boniva defendants").<sup>1</sup> Those cases involve the alleged use of Boniva (ibandronate), a monthly bisphosphonate in the same class of drugs as various daily or weekly treatments such as Fosamax (alendronate).

The Boniva defendants are named in eleven pending cases that are part of the Fosamax MDL.<sup>2</sup> In all of those cases, the plaintiff was on at least one other bisphosphonate (including, in all cases, Fosamax), and sometimes other medicines for postmenopausal osteoporosis.

**March 26, 2014 Preemption Order**

As you know, Judge Pisano ruled on March 26, 2014 (the "preemption order"), that cases alleging injuries occurring before September 14, 2010, are preempted as to Merck. Judge Pisano, in a subsequent order on the same day, ordered the Clerk of this Court to "terminate the cases" subject to the order.

Six Boniva cases (See Attachment "A") were identified as subject to the preemption order. Another case (*Burghardt*) was not listed on the preemption order yet was nonetheless dismissed, apparently as part of the preemption ruling based on her usage and injury date.

<sup>1</sup> Boniva was promoted and distributed by Defendant Roche Laboratories Inc. Hoffmann-La Roche Inc. held the New Drug Application ("NDA") for Boniva. GlaxoSmithKline LLC only co-promoted Boniva.

<sup>2</sup> In the last year, 42 Boniva cases have been voluntarily dismissed without prejudice from the Fosamax MDL.

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Prior to filing notices of appeal, Judge Pisano issued a subsequent order on April 17, 2014, directing any plaintiff alleging claims against the Boniva defendants to file a request to reopen such cases within thirty (30) days. Only one plaintiff with a pending claim (*Haslam*) made such a request.

All six of the cases involving Boniva have appealed the order, including the *Haslam* case. In their appeal, some of those plaintiffs have asked the appellate court to be allowed to pursue cases against the non-Fosamax defendants. Those requests remain pending, and the Boniva defendants contend that these cases are not currently active. *Burghardt* has also filed an appeal.

#### **November 6, 2014 Label Adequacy Order**

In an order dated November 6, 2014 (the "label adequacy order"), Judge Pisano stated that because it appeared to the Court that the 2011 Fosamax label was adequate as a matter of law, any plaintiffs claiming that an alleged inadequacy in that label proximately caused their injuries must show cause why their claims should not be dismissed. The deadline to file an objection to the order has passed, and no plaintiff in a Boniva case has filed any objection to the label adequacy order.

Four Boniva cases (See Attachment "B") were identified as subject to the label adequacy order. As noted, no plaintiff has submitted an objection to that Order. The Boniva label was essentially identical to the Fosamax label as to atypical femur fractures. Accordingly, an Order dismissing these four cases is requested by the Boniva defendants.

#### **Miscellaneous**

One case (See Attachment "C") involves several plaintiffs who were listed on one or the other of the preemption and label adequacy orders, but the sole plaintiff in that case who alleged Boniva usage has been dismissed from the case. Accordingly, the Boniva defendants need to be dismissed from that case.

#### **Conclusion**

In sum, none of these cases are being actively pursued, whether because they are on appeal, failed to request a reinstatement of their claims against the Boniva defendants, or because they have been terminated by the Court's previous orders.

The Boniva defendants have no immediate plans to file any dispositive motions, given the current inactive status of the cases. We do believe that both the preemption and label adequacy orders would be largely controlling of comparable claims involving Boniva, but, without waiving any rights to do so, do not see an imminent need to pursue those motions at this time.

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Respectfully,

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# **ATTACHMENT A**

1. *Ruth Berlin, et al. v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:11-CV-05720, in the United States District Court, District of New Jersey
2. *Rosemary Bishop, et al. v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:12-CV-01344, in the United States District Court, District of New Jersey
3. *Judith Broadstone v. Merck & Co., Inc., et al.*, Case No. 3:12-CV-06841, in the United States District Court, District of New Jersey
4. *Martha Haslam, et al. v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:12-CV-05018, in the United States District Court, District of New Jersey
5. *Donna Mouser v. Merck & Co., Inc., et al.*, Case No. 3:12-CV-06365, in the United States District Court, District of New Jersey
6. *Theresa Thomas-Walsh, et al. v. Merck & Co., Inc., et al.*, Case No. 3:12-CV-00707, in the United States District Court, District of New Jersey

## Other Case

1. *Pamela Burghardt, et al. v. Merck & Co., Inc., et al.*, Case No. 3:13-CV-07894, 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. *Jane Hoover, et al. v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:11-CV-06650, in the United States District Court, District of New Jersey
3. *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
4. *Brenda M. Stiles v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:12-CV-05640, in the United States District Court, District of New Jersey

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# **ATTACHMENT C**

1. *Rosemary Bishop, et al. v. Merck Sharp & Dohme Corp., et al.*, Case No. 3:12-CV-01344, in the United States District Court, District of New Jersey