A Message from:

Jez Moulding  
President, North America Pharmaceuticals, Sanofi US

David Meeker  
President and Chief Executive Officer, Genzyme Corporation

Announcement Regarding the Aventis, Inc., sanofi-aventis U.S., LLC, Sanofi US Services, Inc., and Genzyme Corporation (“Sanofi”) Corporate Integrity Agreement

September 10, 2015

As you may be aware, in December 2013, a Sanofi company, Genzyme Corporation, entered into a civil settlement under the False Claims Act with the United States in the connection with the promotion of Seprafilm, which is a device now owned by Sanofi. In addition, in December 2012, Sanofi US Services, Inc. and sanofi-aventis U.S., LLC entered into a separate civil settlement with the United States in connection with the provision of free units of Hyalgan, a knee injection, to physicians. This letter provides you with additional information about the settlement, explains sanofi-aventis U.S., LLC’s, Sanofi US Services, Inc.’s, and Genzyme Corporation’s commitments going forward, and provides you with access to information about those commitments.

In the December 2013 settlement, Genzyme resolved allegations that between January, 2003, and May 18, 2010, Genzyme improperly promoted Seprafilm, and agreed to pay the United States $22.28 million. More information about this settlement may be found at the address linked below. In December 2012, Sanofi U.S. Services, Inc. and sanofi-aventis U.S., LLC paid $109 million to resolve separate False Claims Act allegations.

http://www.justice.gov/justice-news  
http://www.sanofi.us > Health Matters > Websites for Healthcare Professionals  
http://www.genzyme.com > Products > Resources for Healthcare Professionals

To resolve issues surrounding the settlements, Aventis, Inc., sanofi-aventis U.S., LLC, Sanofi US Services, Inc., and Genzyme Corporation entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. This CIA is available at https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp. Under this agreement, these companies agreed to undertake certain obligations designed to promote compliance with Federal health care program and Food and Drug Administration (FDA) requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by any of Sanofi’s representatives to Sanofi’s Compliance Department or the FDA using the information set forth below.

Please call Sanofi at (800) 648-1297 if you have questions about the settlement referenced above or to report any instances in which you believe that a Sanofi representative inappropriately promoted a product or engaged in questionable conduct, including adulteration of a device. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a Sanofi representative to the FDA’s Office of Prescription Drug Promotion at (301) 796-1200 or improper conduct associated with adulteration of a device to the Center for Device and Radiological Health, Office of Compliance at (301) 796-5500. You should direct medical questions or concerns regarding Sanofi products to (800) 633-1610, option 1 (Sanofi US) or (800) 745-4447 (Genzyme).

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