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Andrew C. von Eschenbach, M.D.
Acting Commissioner
US Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. von Eschenbach:

Today, *Bloomberg News* reported that “almost two percent of U.S. prescriptions dispensed last year, or as many as 73 million, were for unapproved medicines...” The FDA is responsible for ensuring that drugs are safe and effective and going after companies that mislead the public and refuse to have their products evaluated. As you know, there are a few very specific circumstances in which prescription drugs do not need to have FDA approval prior to going to market. For the most part, drugs that are marketed and sold without FDA approval are illegal drugs.

The public health may be at risk and yet it appears that the FDA is not taking aggressive action to stop the marketing and sales of thousands of illegal unapproved drugs. The FDA should either ask these companies to provide evidence that their products are safe and effective or the FDA should order them off the market.

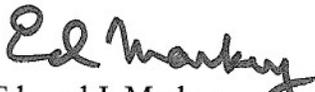
In order to better evaluate the FDA’s process for ensuring that products on the market are safe and effective and removing unapproved drugs, I respectfully request your assistance in providing answers to the following questions:

1. What process does the FDA have in place to identify unapproved and illegally marketed drugs in U.S.?
2. How many of the following enforcement actions has the FDA taken to ensure that companies are not selling, marketing, or making false claims about unapproved and illegal products in each of the past five years?
 - a. requesting voluntary compliance;
 - b. providing notice of action in a *Federal Register* notice;
 - c. issuing an untitled letter;
 - d. issuing a Warning Letter;
 - e. seizing products;
 - f. initiating an injunction; or
 - g. taking other regulatory actions.

3. How much did the FDA spend on such enforcement actions against unapproved products for each of the past five years?
4. Please provide a list of all of the unapproved drugs that are currently on the market. For each product, please identify:
 - a. The name of the unapproved product;
 - b. the company that manufactures the product;
 - c. whether the FDA believes the product is being marketed illegally;
 - d. when the FDA first became aware of the product;
 - e. whether the product is subject to an ongoing Drug Efficacy Study Implementation proceeding or ongoing Over-The-Counter (OTC) drug monograph proceeding (i.e., an OTC product that is part of the OTC drug review for which an effective final monograph is not yet in place) or subject to the 1962 Grandfather clause or the 1938 grandfather clause;
 - f. whether the company registered the product with the FDA; and
 - g. what actions the FDA has taken to ensure their safety and effectiveness.
5. How would a consumer know if the product that he/she is taking has been approved by the FDA or is unapproved?
6. If lack of resources limits the FDA's ability to take action against unapproved illegal products, what additional resources does the FDA need in order to identify unapproved drugs on the market and to ensure that products on the market are safe and effective?

Thank you for your attention to this important issue. I respectfully request a response by December 1, 2006. If you have any questions regarding this request, please do not hesitate to contact Ms. Katharine Reinhalter at 202-225-2836. I look forward to your prompt reply.

Sincerely,


Edward J. Markey
Member of Congress