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ONE HUNDRED TENTH CONGRESS

# Congress of the United States

## House of Representatives

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February 1, 2008

The Honorable Andrew C. von Eschenbach, M.D.  
Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane, Room 15-47  
Rockville, MD 20857

Dear Dr. von Eschenbach:

I am writing to request a briefing on the status of the inspections performed by the Food and Drug Administration (FDA) of all facilities owned by the Shanghai Pharmaceutical Group that manufacture drugs or any other FDA-regulated products intended for export to the United States. According to the *New York Times*, the Chinese authorities have launched a criminal investigation into tainted leukemia drugs produced by a division of the Shanghai Pharmaceutical Group, Shanghai Hualian.<sup>1</sup>

Shanghai Hualian makes at least one drug, mifepristone, for export to the United States.<sup>2</sup> This drug is not manufactured at the facility that is under investigation. According to an FDA statement quoted in the *New York Times* article, the facility where mifepristone is produced passed FDA inspection in May 2007.<sup>3</sup> However, the article suggests that Shanghai Pharmaceutical Group may produce other drugs or drug ingredients intended for export to the U.S. For example, the article says that another unit of this corporation has filed papers "declaring its intention to sell at least five active pharmaceutical ingredients to manufacturers for sale in the United States."<sup>4</sup>

I urge you to ensure that all of these facilities are inspected as quickly as possible. In order to understand FDA's plans to ensure that the drugs or drug ingredients manufactured for

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<sup>1</sup> *Tainted Drugs Linked to Maker of Abortion Pill*, New York Times (Jan. 31, 2008).

<sup>2</sup> *Tainted Drugs Linked to Maker of Abortion Pill*, New York Times (Jan. 31, 2008).

<sup>3</sup> *Tainted Drugs Linked to Maker of Abortion Pill*, New York Times (Jan. 31, 2008).

<sup>4</sup> *Tainted Drugs Linked to Maker of Abortion Pill*, New York Times (Jan. 31, 2008).

The Honorable Andrew C. von Eschenbach, M.D.  
February 1, 2008  
Page 2

the U.S. market by Shanghai Pharmaceutical Group are safe and effective, I would like your staff to brief my staff on your oversight of all FDA-approved facilities owned or operated by the Shanghai Pharmaceutical Group. If FDA plans to restrict the release of any of this information because of concern that the release of this information would compromise the security of these facilities, your staff should be prepared to explain in detail the justification for this restriction.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X.

Please have your staff contact Sarah Despres at (202)225-5056 to schedule a briefing. This briefing should be scheduled no later than Friday, February 22, 2008.

Sincerely,



Henry A. Waxman  
Chairman

cc: Tom Davis  
Ranking Minority Member