

**Congress of the United States**  
Washington, DC 20510

March 9, 2011

Dr. Margaret Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

It has come to our attention that generic versions of Lipitor<sup>®</sup> (atorvastatin calcium), the most widely prescribed drug in U.S. history, may be eligible for FDA approval as early as June 28, 2011 – a mere four months away.

Lipitor<sup>®</sup>, a \$7.24 billion a year drug according to IMS, has enjoyed 15 years of U.S. sales without facing generic drug competition. The last 15 years of exclusive market position have provided a substantial reward for innovation – an important purpose under the Hatch-Waxman Act's aim to balance incenting the development of new drugs while also enhancing the availability of generic drugs.

Although generic versions of Lipitor<sup>®</sup> may be eligible for approval as early as June 28, 2011, we are concerned that current regulatory circumstances could significantly delay entry of new generic products into the marketplace. We are eager to avoid such delays because, each year, it is estimated that the government alone spends \$2.54 billion on Lipitor<sup>®</sup> through Medicaid, Medicare Part D, and Veteran's Affairs expenditures. It is estimated also that the public could save more than \$3.97 billion to \$6.7 billion a year upon generic entry, which equates to \$10.9 million to \$18.3 million a day in potential savings.

With several so-called "blockbuster" drugs coming off patent or becoming otherwise eligible for approval in the coming year, we have a strong interest in ensuring a swift approval process for their generic counterparts that may be poised to enter the market. In 2003, Congress amended the Food, Drug and Cosmetics Act (FDC) to change provisions concerning 180-day generic drug exclusivity. Specifically, the law was changed to a "use it or lose it" system that prevents a first filer's exclusivity from being indefinitely "parked" and creating a bottleneck to generic competition. It appears that with respect to Lipitor<sup>®</sup>, some filings that predate those amendments to the FDC may be poised to delay the introduction of generic atorvastatin into the marketplace

without a timely determination from FDA. It is our understanding that without a determination from FDA on previous filings, new Abbreviated New Drug Applications (ANDAs) cannot be approved, and therefore true generics will be unable to enter the market. Accordingly, we urge FDA to take timely action now with respect to outstanding regulatory issues that may delay entry of generic versions of this medication, the significant volumes of which will require substantial advance preparation to ensure patients have access on the earliest eligible date.

Given the tremendous savings that access to generic atorvastatin will afford both consumers and the government, we urge you to act now to clarify the relevant regulatory issues in this matter so the public can receive access to a more affordable generic version of Lipitor on the earliest possible date.

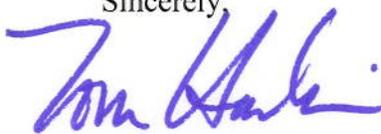
As always, we fully expect FDA to follow applicable law when making regulatory decisions, and urge you to consider the importance of timely decisions given the high stakes in this instance.

Thank you for your time and attention to this critically important matter. We look forward to receiving a written reply within one week.

Sincerely,



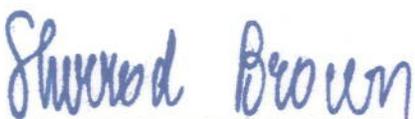
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United States Senate



Tom Harkin  
United States Senate



Charles E. Schumer  
United States Senate



Sherrod Brown  
United States Senate



Debbie Stabenow  
United States Senate