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Congress of the United States
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COMMITTEE ON
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ASSISTANT REPUBLICAN WHIP

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I applaud the efforts of the FDA for its continued diligence and dedication towards ensuring the safety and efficacy of pharmaceuticals, including those known as DESI drugs. However, I am concerned that blanket actions against DESI drugs could actually have a negative effect on patients who need these treatments.

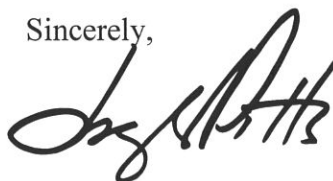
I have recently learned that the FDA has guided the Department of Veterans Affairs to remove any drugs not currently listed in the Orange Book from their formulary, even though some of these drugs may actually be in the process of seeking FDA approval. For example, Salsalate is one of several hundred DESI drugs that the VA is expected to remove from procurement. Salsalate is commonly used among veterans, with more than 16,000 veterans using it each year. Clinicians have been prescribing this medication and patients have been using it for decades in the United States and around the world. In fact, in 2005, when the brand drug Bextra was removed from the marketplace the FDA issued guidance to the VA instructing that Salsalate was a viable alternative to that drug. You may be interested to know that a manufacturer of Salsalate has begun the process of submitting a New Drug Application to the FDA.

It is my concern that as DESI drugs, including Salsalate, become unavailable to veterans, millions of beneficiaries will lose access to medications they, and their clinicians, trust is their best treatment option. I am writing you today to urge you to please reconsider the suggestion sent to the VA regarding all DESI drugs and to consider allowing drugs that are currently undergoing FDA review to remain available on the VA formulary thru the approval process.

Similarly, I urge you to consider an expedited or more-streamlined drug approval process for DESI drugs, so that individuals' access to much-needed medications is not threatened. I believe the FDA is well within their authority in using its discretion to help speed up the process of approving NDAs for DESI drugs. In fact, in April 2006, the FDA indicated in correspondence that the Center for Drug Evaluation and Research is "willing to be flexible in applying statutory requirements" while working with companies who are seeking approval to market previously unapproved marketed drugs.

Again, I appreciate that the FDA wants to guarantee the safety and effectiveness of all drugs prescribed and utilized in this country and I thank you for your attention to this matter. I look forward to hearing a response from you in the coming weeks.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Pitts", written in a cursive style.

Joseph R. Pitts
Member of Congress