



Center for Regulatory Effectiveness

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October 9, 2003

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
Room 615F
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Thompson:

I am writing to compliment you on the leadership you have demonstrated on the drug diversion issue. You and your team have been proactive in investigating and seeking solutions to the public health problems associated with drug diversion, and the related crimes of adulteration, tampering and counterfeiting. The just-released Interim Report from the FDA's Counterfeit Drug Task Force, along with the upcoming public meeting, are the most recent tangible results of your initiative on this issue. As someone who has extensive personal experience in federal regulatory management, I particularly appreciate that you were on top of this issue prior to all of the media attention, including the recent articles in the *Wall Street Journal*.

The Center for Regulatory Effectiveness (CRE), a regulatory watchdog, has been closely following the drug diversion issue for some time. Established in 1996 by former senior career officials from the White House Office of Management and Budget, CRE supports improving the effectiveness of the regulatory process through a number of mechanisms including, participation in regulatory proceedings, advocating specific regulatory improvements and seeking structural improvements in the regulatory process. Additional information about CRE and our activities may be found on our website at www.TheCRE.com.

Last July, consistent with our mission of improving the effectiveness of federal regulations and with our work on drug diversion, we released the enclosed working draft white paper, *Dirty Deals: The Drug Diversion Trade, How it Victimizes the Vulnerable and How to Stop It*. The paper may be downloaded from our website at http://thecre.com/emerging/20030721_drug.html. Since that time, we circulated our paper and received comments from diverse stakeholders.

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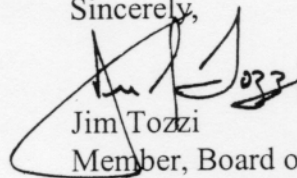
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The FDA Task Force's Interim Report makes a number of invaluable observations and recommendations. However, based on our work, we have identified a number of additional important regulatory steps that need to be given serious consideration by your Department. Key among our recommendations for curtailing drug diversion are:

- ▶ The Food and Drug Administration (FDA) ensure that there are no further delays in fully implementing the pedigree provisions contained in their December 1999 Final Rule.
- ▶ The Office of Pharmacy Affairs (OPA) require that 340B covered entities make public, in a manner consistent with patient privacy, records documenting that discounted drugs have been administered to only eligible patients.
- ▶ Manufacturers shall disclose the identities of their authorized distributors.

Pursuant to your publication of the *Federal Register* notice of the Public Meeting, CRE will not only be providing our comments on the issues you have raised but also, since this is a continuing project of the Center, we will be providing you with additional information on a regular basis. To this end, we will be contacting your staff to ensure that the information in communicated through an appropriate channel.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Tozzi", is written over a circular stamp or mark.

Jim Tozzi
Member, Board of Advisors

Enclosure