



Center for Regulatory Effectiveness

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January 13, 2004

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:

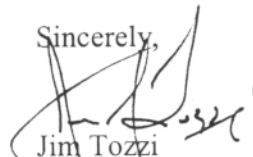
April 1, 2004 is a key date for protecting Americans from the dangers posed by diverted, adulterated and counterfeit drugs. The nation's pharmaceutical supply will start becoming safer on April 1st because this is the effective date of the FDA Final Rule implementing pedigree requirements. 68 FR 4912. These pedigree papers will document the complete distribution chain for drugs and allow wholesale purchasers to verify that they are buying products with a clear legitimate history.

The substantial and growing public health threat posed by adulterated and drug diversion has been widely discussed in numerous fora, including an in-depth five part investigative reporting series in *The Washington Post*. The *Post* articles also discussed the repeated delays in implementation of the pedigree requirements.¹

The need for pedigree paper requirements is further heightened by the expansion of the 340B discount drug program to inpatients on certain public hospitals by Sec. 1002 of the Medicare Prescription Drug and Modernization Act of 2003. Discounted pharmaceuticals are a major source of diverted drugs, an issue also discussed in the *Post* series. Thus, the need for swift implementation of pedigree documentation requirements is greater than ever given the new expanded availability of discounted drugs.

If your Department takes no additional action, the rule becomes effective April 1st. It would take an intervention by your Department to prevent this regulation from going into effect; we trust you will not take such action.

Sincerely,



Jim Tozzi
Member, Board of Advisors

¹ Gilbert M. Gaul and Mary Pat Flaherty, "Pharmaceutical Roulette: A Vast Unregulated Shadow Market," *The Washington Post*, October 19, 2003, p. A1.