

July 21, 2004

The Honorable Judd Gregg  
Chairman  
Health, Education, Labor and Pensions Committee  
United States Senate  
Room 428  
Dirksen Building  
1st and C Streets, N.E.  
Washington, DC 20510

Re: Hinchey Amendment to Cut \$500,000 from the Appropriations for  
the FDA Office of Chief Counsel

Dear Chairman Gregg:

The undersigned comprise all of the former Chief Counsel to the Food and Drug Administration (in both Republican and Democratic Administrations), except for one who is currently an attorney in the Office of the General Counsel of the Department of Health and Human Services. We are writing to recommend reconsideration of the amendment to the FDA appropriations bill by Representative Hinchey of New York on the floor of the House of Representatives, which would reduce the appropriation for the FDA Office of Chief Counsel by \$500,000 and would increase the appropriation for the Division of Drug Marketing, Advertising, and Communications in the FDA Center for Drug Evaluation and Research by a corresponding amount. We support additional funds for the Division of Drug Marketing, but we believe that the reduction of the appropriation for the Office of Chief Counsel and Representative Hinchey's reasons for penalizing that Office cannot be supported.

FDA's Office of Chief Counsel performs critical functions in the administration and enforcement of the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. The substantial reduction in the funding of that Office, therefore, would materially impair its ability to meet the needs of its client, FDA. Such impairment would be contrary to the public interest.

Representative Hinchey's reasons for penalizing the Office of Chief Counsel and criticizing FDA Chief Counsel Daniel E. Troy are set forth in the House Debate on the FDA appropriations legislation as reported in 150 Cong. Rec. H5598-H5599 (July 13, 2004). Representative Hinchey states that Mr. Troy "has taken the agency in a radical new direction" by submitting amicus curiae briefs in cases in which courts have been asked to require labeling for

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pharmaceutical products that conflicts with FDA decisions about appropriate labeling for those products. Representative Hinchey characterizes this activity as a "pattern of collusion between the FDA and the drug companies and medical device companies" in a way that has "never happened before."

These characterizations are inaccurate.

In Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973), the Supreme Court agreed with the briefs filed by the Department of Justice on behalf of FDA that the agency has primary jurisdiction over new drug issues. In Jones v. Rath Packing Co., 425 U.S. 933 (1977), the FDA took the position in an amicus curiae brief submitted by the Department of Justice that federal food labeling requirements preempt inconsistent state requirements, and the Supreme Court agreed. In subsequent private tort litigation, FDA has taken the position, through amicus curiae briefs filed by the Department of Justice, that FDA decisions regarding drug product labeling and related issues preempt inconsistent state court determinations, and the courts have agreed. E.g., Bernhardt v. Pfizer, Inc., 2000 U.S. Dist. Lexis 16963 (November 16, 2000); Eli Lilly & Co. v. Marshall, 850 S.W. 2d 164 (Texas 1993). All of this was to protect a uniform national system of food and drug law. All of it occurred before Mr. Troy assumed his current position. In none of these cases did any court request FDA's opinion. Thus, there is ample precedent for the actions that Mr. Troy has recently been undertaking. His action is not radical or even novel.

The amicus curiae briefs filed by the Department of Justice at the request of Mr. Troy protect FDA's jurisdiction and the integrity of the federal regulatory process. There is a greater need for FDA intervention today because plaintiffs in courts are intruding more heavily on FDA's primary jurisdiction than ever before. In our judgment, Mr. Troy's actions are in the best interests of the consuming public and FDA. If every state judge and jury could fashion their own labeling requirements for drugs and medical devices, there would be regulatory chaos for these two industries that are so vital to the public health, and FDA's ability to advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded. By assuring FDA's primary jurisdiction over these matters, Mr. Troy is establishing a sound policy of national decisions that promote the public health and, thus, the public interest.

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We therefore recommend that the \$500,000 cut from the appropriations for the FDA Office of Chief Counsel be restored.

Sincerely yours,

Peter Barton Hutt (1972-1975)  
Richard A. Merrill (1975-1977)  
Richard M. Cooper (1977-1979)  
Nancy L. Buc (1980-1981)  
Thomas Scarlett (1981-1989)

cc: Lester M. Crawford, D.V.M., Ph.D.  
Commissioner of Food and Drugs

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**REMARKS**

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