

JAMES M. JEFFORDS, VERMONT, CHAIRMAN

DAN COATS, INDIANA  
JUDG GREGG, NEW HAMPSHIRE  
BILL FRIST, TENNESSEE  
MIKE DEWINE, OHIO  
MICHAEL B. ENZI, WYOMING  
TIM HUTCHINSON, ARKANSAS  
SUSAN M. COLLINS, MAINE  
JOHN W. WARNER, VIRGINIA  
MITCH McCONNELL, KENTUCKY

EDWARD M. KENNEDY, MASSACHUSETTS  
CHRISTOPHER J. DODD, CONNECTICUT  
TOM HARKIN, IOWA  
BARBARA A. MIKULSKI, MARYLAND  
JEFF BINGAMAN, NEW MEXICO  
PAUL D. WELLSTONE, MINNESOTA  
PATTY MURRAY, WASHINGTON  
JACK REED, RHODE ISLAND

MARK E. POWDEN, STAFF DIRECTOR  
SUBAN K. HATTAN, DEPUTY STAFF DIRECTOR  
NICK LITTLEFIELD, MINORITY STAFF DIRECTOR AND CHIEF COUNSEL

<http://www.senate.gov/~labor/>

# United States Senate

COMMITTEE ON LABOR AND  
HUMAN RESOURCES

WASHINGTON, DC 20510-6300

2522 '98

July 23, 1998

Dr. Michael Friedman  
Acting Commissioner  
Food and Drug Administration  
5600 Fishers Lane (HF-28)  
Rockville, MD 20857

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, rm. 1-23  
Rockville, MD 20857

**Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices; Docket No. 98N-0222**

Dear Dr. Friedman,

I am writing to comment on the Food and Drug Administration's (FDA) proposed rule of June 8, 1998, implementing section 401 of the Food and Drug Administration Modernization Act of 1997. I want to commend FDA for its commitment to implementing the Food and Drug Administration Modernization Act of 1997 in a timely manner.

As the ranking member of the Senate Labor and Human Resources Committee, I was intimately involved in development of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and specifically of section 401. As such, I want to highlight important considerations and concerns that I believe were a crucial part of our compromise on this issue.

Congressional Intent

First, I would like to comment generally on the intent of Congress. Congress intended this provision to allow dissemination of information under specific limited circumstances. Congress was particularly concerned that current incentives for companies to invest in research and to submit supplemental applications be maintained and enhanced. Because dissemination by drug companies of information regarding uses which have not yet been shown to meet FDA's standard for safety and efficacy raises important public health questions, Congress limited this provision in duration and requested follow up studies to determine the utility of this provision and its impact on the public health. In light of these concerns, FDA's should be consistent with the law and assure that patients be protected.

98N-0222

C37

**Public Participation**

FDA should provide for public access to information made available under section 401 to the maximum extent feasible. The patients' groups are essential stakeholders in the exemptions granted under section 401 and their participation is crucial to successful implementation of this provision.

**Journal articles**

Congress intended for FDA to have a role in assessing the scientific acceptability of journal articles and reference texts distributed pursuant to section 401. The statute requires that the information be a "copy of an article, peer-reviewed by experts qualified by scientific training or experience . . . which is about a clinical investigation . . . and which would be considered to be scientifically sound by such experts." Where appropriate, the FDA may require the manufacturer to disseminate additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide objectivity and balance, or the Secretary may provide her own objective statement. Thus, the statute clearly envisions that the Secretary be provided sufficient information to assess the clinical investigation. This opportunity is especially important in order for the Secretary to meaningfully assess the need for balancing information and to assess whether the information is false or misleading.

**Exemptions to filing supplements**

Congressional intent is clear. Congress intended that dissemination be predicated on submission of a supplemental use application. Exceptions to this rule are limited in scope and should be infrequent. Any interpretation to the contrary would undermine the essential compromise reached in this legislation. As stated in the conference report, "there *may be limited circumstances* when it is appropriate to exempt a manufacturer from the requirement to file a supplemental application." (emphasis added.)

The authority that Congress gave to the Secretary regarding factors to be taken into account in granting exemptions is permissive, not mandatory. Congress intended the Secretary to exercise substantial discretion in granting exceptions and that only when the interests of public health are served by allowing the exemption and there is no significant possibility that a supplemental application will be filed should FDA grant such an exemption.

Sincerely,



Edward M. Kennedy