Congress of the United States
Washington, DC 20515

March 27, 2001

Bernard Schwetz, D.V.M, Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Schwetz:

We are writing to express our understanding of the Congressional intent underlying the market exclusivities granted under section 111 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA") and under section 505(j) of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Waxman-Hatch Act").

As you know, efforts to market a generic version of Prozac (fluoxetine) recently resulted in the Court of Appeals for the Federal Circuit upholding a Prozac patent expiring in February 2001 and ruling invalid a second patent expiring in 2003. It is our understanding that the potential grant of six months of pediatric exclusivity under FDAMA to the upheld patent could conceivably nullify the 180 days of generic drug market exclusivity granted under the Waxman-Hatch Act to the generic competitor. We understand that this situation could occur in other instances.

We want to emphasize that Congress did not intend the pediatric exclusivity under FDAMA to nullify or abrogate the generic drug market exclusivity under the Waxman-Hatch Act. The 180-day generic drug exclusivity provision in Waxman-Hatch was intended to give generic drug companies an incentive to challenge questionable patents and to reward them with 180-days of protection from other generic drug companies. If the 180-day period in Waxman-Hatch were interpreted to run concurrently with pediatric exclusivity, that incentive would be destroyed in a significant number of cases, which ultimately will result in higher drug prices to consumers, and which, we are convinced, would be flatly contrary to the intent of both statutes.

We recognize that the Food and Drug Administration (FDA) has done its utmost to interpret and implement the Waxman-Hatch Act consistent with congressional intent. With respect to the 180-days of generic drug market exclusivity, the agency's task has clearly been complicated by a succession of court decisions, although no decision has interpreted the relationship of the pediatric and generic exclusivities. But given its discretion and recognizing the importance of making generic drugs available to patients as quickly as possible, we ask that the agency commit its full attention and appropriate resources to reconciling the laws in a manner which gives generic drug market exclusivity its full effect under the Waxman-Hatch Act.

We appreciate your attention to this matter and look forward to learning of the agency's decision.

Sincerely,

EDWARD M. KENNEDY
United States Senator

JOHN D. DINGELL
Member of Congress

JOHN D. ROCKEFELLER
United States Senator

HENRY A. WAXMAN
Member of Congress

SHERROD BROWN
Member of Congress