OFFICE OF
THE COMMISSIONER

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 4, 2012

The Honorable Harry Reid
Senate Majority Leader
522 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Senate Republican Leader
317 Russell Senate Office Building
Washington, DC 20510

Gentlemen:

I understand that efforts may be made on the Senate floor to tack two bills—concerning so-called REMS (Risk Evaluation and Mitigation Strategies) practices by drug manufacturers and so-called PFD (Pay-For Delay) settlements by drug manufacturers—onto the FDA Safety and Innovation Act, which is considered "Must Have" legislation because it reauthorizes the FDA's ability to collect user fees. I oppose both efforts.

First, the effort to tack substantive REMS legislation onto "Must Have" legislation will not do consumers any favors. The REMS legislation advocated by staff at the Federal Trade Commission (FTC) would give the FTC jurisdiction to challenge the refusal of a pioneer drug company to provide product samples to generic manufacturers if the FDA determined that the generic company's protocols were safe. The FTC advocated this approach because it disagreed for various reasons with the bill passed by the Health Education Labor & Pensions Committee (HELP). Neither proposal should be tacked on to other legislation on the Senate floor and should instead be considered by the Help Committee on their own merits.

Second, the effort to tack PFD legislation onto "Must Have" legislation may not be in the public interest either. The Fair and Immediate Release of Generic Drugs Act (Fair Generics Act) provides that a generic company waives its 180-day marketing exclusivity if it enters into certain agreements with pioneer drug companies. Senator Bingaman offered a version of the bill as an amendment to the FDA Safety and Innovation Act during the Senate Health Committee's consideration of the legislation but later withdrew the amendment. Senator Bingaman has indicated that he will try to introduce his bill again when the FDA Safety and Innovation Act is considered by the full Senate. This again is not what the Commission has proposed. It has advocated instead legislation that could adopt an approach requiring the parties to justify their settlement. My primary concern is that the bill would impede pioneer and generic pharmaceutical firms from settling patent disputes to a greater extent than the burden shifting approach would do so. There is not a consensus among antitrust scholars or economists that

impeding such settlements would be in the public interest. To the contrary, in *FTC v. Watson Pharmaceuticals, Inc.*, the Eleventh Circuit held that even where the strength of the patent was problematic, a settlement may be desirable.[1] Before any legislation on this subject is adopted, legislators should carefully consider the viewpoints of all stakeholders. It should not simply be tacked onto "Must Have" legislation on the Senate floor.

Third, any claim that these proposed bills would yield substantial consumer savings is without substantiation. The Congressional Budget Office (CBO) did indeed predict that a ban of PFD settlements under the antitrust laws would have that effect. But the CBO has not scored the Fair Generics Act, which might hamper PFD delays by different means, and has not predicted the amount of consumer savings that would accrue as a result of any REMS legislation.

Tom Rosch

[1] No. 10-12729, 2012 U.S. App. LEXIS 8377 at *45 (11th Cir. Apr. 25, 2012).