ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

MAJORITY (202) 225–2927
FACSIMILE (202) 225–2525
MINORITY (202) 225–3641

energycommerce.house.gov

June 30, 2010

The Honorable David Obey
Chairman
Committee on Appropriations
H-218, U.S. Capitol
Washington, DC 20515

The Honorable Jerry Lewis
Ranking Member
Committee on Appropriations
H-218, U.S. Capitol
Washington, DC 20515

Dear Chairman Obey and Ranking Member Lewis:

We write today to urge you to eliminate a provision from the amendment to H.R. 4899, the Supplemental Appropriations Act of 2010, that falls within the jurisdiction of the Committee on Energy and Commerce.

The provisions in Chapter 2, the "Preserve Access to Affordable Generics Act," processed through the Committee on Energy and Commerce in regular order. It was considered in the Subcommittee on Commerce, Trade, and Consumer Protection and considered at full committee during the debate on the Patient Protection and Affordable Care Act. The provision did not, however, make it to the floor. We must insist that the Committee process be respected and that this provision not be attached to an unrelated war funding supplemental.

From a substantive standpoint, the legislative language will achieve exactly the opposite of its intent. The two primary provisions of the legislative language will, in concert, remove current incentives for generic drug companies to challenge drug patents. Consequently, generic drug companies will wait until new drug patents expire before they bring a generic product to market. Consumers will then wait, on average, 5 to 9 years for access to cheaper generic medicines and consumer benefit will arguably be diminished.

The proponents of the legislation argue that so-called "reverse payments" in drug patent challenge cases is anti-consumer by keeping generic formulations off the market longer than might otherwise be the case if the patent challenge prevailed. The most recent analysis, however, shows that these "reverse payments" result in more generics being introduced in the market. According to one study, of the approximately 370 resolved cases in this area over the last decade, only 48 percent favored the patent challenger (the generic drug maker). However, the success rate for patent challengers increased to 76 percent when patent settlements are taken into account.[1] In other words, 76 percent of the patent challengers in those cases secured the right to launch their generic drug prior to the expiration of the branded drug's patent.

Further, although the Federal Trade Commission and the proponents of this legislative language argue that payment settlements are *prima facie* anti-competitive, nearly all courts that have reviewed the issue disagree. The Federal Circuit,[2] the Second Circuit,[3] and the Eleventh Circuit,[4] have each declined to rule these agreements as *per se* illegal. Only the Sixth Circuit found the reverse payment settlement at issue in that challenge to be *per se* illegal.[5] Perhaps the most telling analysis is the Supreme Court's refusal to grant certiorari on cases challenging settlement terms, confirming the prevailing legal view that reverse payments are not *per se* illegal or anti-consumer.

We urge you to exclude this non-related language from the war supplemental funding package and allow the legislative process to work in regular order.

Sincerely,

Joe Barton
Ranking Member

Ed Whitfield
Ranking Member
Subcommittee on Commerce, Trade,
and Consumer Protection

John Shimkus
Ranking Member
Subcommittee on Health

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[1] RBC Capital Markets patent litigation analysis, January 15, 2010, "Analyzing Litigation Success Rates."
[2] *See In re* Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S.Ct. 2828 (2009).
[3] *See In re* Tamoxifen Citrate Antitrust Litigation, 429 F.3d 370 (2nd Cir. 2005), *cert. denied*, 551 U.S. 1114 (2007); *see also* Arkansas Carpenters Health and Welfare Fund et al. v. Bayer AG et al, 604 F.3d 98 (2nd Cir. 2010).
[4] *See* Schering Plough Corp. et al. v. FTC, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (2006); *see also* Valley Drug Co. v. Geneva Pharmaceuticals, Inc. et al., 344 F.3d 1294 (11th Cir. 2003).
[5] *See In re* Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S.Ct. 307 (2004).

cc: The Honorable Henry A. Waxman, Chairman

The Honorable Bobby L. Rush, Chairman
Subcommittee on Commerce, Trade, and Consumer Protection

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health