# Latest Legislative Attempt on Reverse Payment ANDA Settlements

By Kevin E. Noonan – February 27, 2012

On February 9th, Congressman Bobby Rush (former "defense minister" of the Black Panther Party and representative for the Illinois 1st Congressional District; at right) joined Congressman Henry Waxman (below) in introducing the latest legislative measure directed at preventing reverse payment settlements of lawsuits under 35 U.S.C. § 271(e)(2) between branded innovator pharmaceutical companies and their generic competitors. The bill, named the "Protecting Consumer Access to Generic Drugs Act of 2012" (H.R. 3995), was introduced "[t]o prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes." The two Congressmen were also joined by Reps. Chris Van Hollen (D-MD), Frank Pallone (D-NJ), G.K. Butterfield (D-NC), and fellow Illinois Rep. Jan Schakowsky.

The bill would prohibit "any person" to be a party to an agreement "resolving or settling a patent infringement lawsuit" in which an ANDA filer "receives anything of value" and the ANDA filer agrees "not to research, develop, market, or sell, for any period of time, the drug" that is the subject of the ANDA and the patent infringement lawsuit. The bill excepts settlements where the only "value" received by the ANDA filer is the ability to market the drug before expiration of the patents in the infringement lawsuit or before expiration of "any other statutory exclusivity that would prevent the marketing of such drug," presumably including exclusivities under the Federal Food, Drug and Cosmetic Act (FFD&CA), or waiver of damages accrued by ("at-risk") sales of a drug before the lawsuit is settled. (This section 2 of the bill is blithely entitled "Unfair and Deceptive Acts and Practices related to New Drug Applications.")

Rep. Rush describes the intent of these provisions on his home page. "Currently," he explains, "these arrangements have generally been held to be legal but they hurt consumers and increase the cost that taxpayers pay to fund Medicare and Medicaid." These settlements "cost[] consumers billions of dollars" (noting that the Congressional Budget Office estimates that the cost "could be" "roughly 3 billion dollars over ten years" to taxpayers, raising the (unanswered) question of why that estimate is so carefully qualified. The Congressman also believes that:

We should be concerned about what patients and the federal government are not getting out of these anticompetitive arrangements. Consumers and patients, a good many of whom are elderly and on fixed incomes are not getting access to more affordable generic drugs to help treat their conditions. And, the government is not getting the benefit of lower drug prices and related cost savings for Medicare and Medicaid that would help significantly in reducing our federal deficit.

His intention is clearly stated: "My bill would outlaw these settlement abuses and work to reverse the heavy tolls that they take on consumers' wallets and the Federal treasury from having to pay more money over a longer period of time for brand name drugs and authorized generics."

While certainly heart-felt, these sentiments fly in the face of careful economic analyses by several Federal Courts of Appeal that (in individual cases) lawful reverse payments actually reduce costs for consumers (in the long run) and avoid wasteful investment by innovator companies in litigation rather than innovation (see "Reverse Payments in Generic Drug Settlements" - Part I, Part II, Part III). Indeed, the only governmental agency more committed than some Congressmen to the need to eliminate the "scourge" of reverse payment settlements is the Federal Trade Commission, which posits that reverse payments only occur when the underlying patents are invalid or unenforceable (thus cynically refusing to consider that sound economics rather than nefarious lawyering is the basis for innovator companies to enter into reverse payment settlements).


It is thus a mixed blessing that H.R. 3995 specifies (Sec. 3) that violation of its provision fall within the FTC's purview rather than under the Sherman Act as an agreement in restraint of trade. This portion of the bill states that such an agreement will considered "an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce" under Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45). The FTC is given rulemaking authority to implement these enforcement provisions, and the power to exempt agreements on a case-by-case basis that it finds "to be in furtherance of market competition and for the benefit of consumers," regardless of how unlikely the Commission's current stance on these agreements makes that eventuality. The bill also provides that an ANDA filer found to be in violation of the reverse payment provisions shall forfeit the 180-day exclusivity period provided by the FFDCA (Sec. 4), and in Sec. 5 that all agreements shall be filed with the Department of Justice and the FTC including "any other agreements the parties enter into within 30 days of entering into an agreement [settling an ANDA suit as currently provided by 21 U.S.C. 3155] (*i.e.*, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)." This certification must be made by the CEO or other officer "responsible for negotiating any agreement" required to be filed under the MMA under penalty of perjury. The bill specifically spells out that this certification specify that it "(1) represent[s] the complete, final, and exclusive agreement between the parties; (2) include[s] any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include[s] written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing'".

The bill stands a chance of passage if only because it seems to promise reduction in drug prices and in the cost of drugs to the Federal government. As with much of what is happening in the country these days, it is long on short-term gain and short on long-term consequences, and contrary to the overwhelming experience of these agreements when scrutinized by courts in the context of antitrust litigation. While restricting enforcement to the FTC may prevent every state attorney general or aggrieved citizen from filing a lawsuit based on the Sherman Act (and avoid except for the perjury provisions the threat of criminal sanction), the bill represents another piece of political drama that may actually have much more negative consequences economically than the benefits it purports to pursue. Perhaps the improbability of its passage in view of the current political climate is a blessing. But it should not be too much to ask that our representatives actually consider all the consequences before they attempt to impose limits on the flexibility of innovator and generic companies to iron out their differences and provide both new drugs and generic copies of old drugs within the prevailing regulatory regime.