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The Honorable Patrick Leahy
Chairman
Judiciary Committee
United States Senate
Washington, D.C. 20510

Dear Senator Leahy:

I am pleased to respond to your questions following the recent hearing on "Paying off Generics To Prevent Competition with Brand Name Drugs: Should it be Prohibited."[1] You forwarded the following comments and questions, which I have attempted to answer below. In addition, there were certain questions posed to me at the hearing to which I am also responding.

Written Questions from Senator Kohl

Q: At the hearing you were asked questions about a variety of approaches to solve the problem of reverse payment patent settlements – settlements in which the brand name drug manufacturer pays the generic company in return for a promise by the generic company to keep its generic drugs off the market. You were asked about my legislation, the Preserve Access to Affordable Generics Act (S. 316), which imposes a bright line rule banning these settlements, as well as other approaches proposed by other Senators which would examine these settlements on a case by case basis. Which approach do you believe will best solve the problem to competition posed by these settlements? Do you agree with me that the bright line rule of S. 316 is the best way to ensure a competitive pharmaceutical market?

A: I believe that the bright line approach is the most effective way to protect consumers and competition. On one hand, the harm caused by these agreements is substantial and, absent a bright-line ban, difficult to prevent; on the other hand, history shows that when deprived of the ability to use exclusion payments, brand-name and generic drug companies often reach procompetitive settlements. A bright-line rule will have little or no effect on procompetitive settlements, while eliminating a substantial number of extremely harmful settlements.

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[1] The written testimony submitted for the January 17, 2007 hearing reflects the views of the Federal Trade Commission ("FTC" or "Commission"). However, my responses to these post-hearing questions reflect my own views and do not necessarily reflect the views of the Commission or of any other Commissioner.

Absent a legal prohibition, it will nearly always be in both the brand's and generic's interests to settle their litigation with the brand paying the generic to delay entry for as long as possible. As far as I know, no one has disputed the existence of these powerful incentives. Indeed, even the *Tamoxifen* court – despite blessing such settlements – understood that they created a windfall for the companies at the expense of consumers. 466 F.3d 187, 208 (2d Cir. 2006).

There is an urgent need for Congress to adopt a clear rule that will stop the use of exclusion payments. Under the current case by case approach, recent court decisions have: (1) viewed exclusion payments as a "natural by-product" of the Hatch-Waxman framework; (2) given overriding weight to benefits of settlement; and (3) assumed that – absent fraud or a sham lawsuit – drug patent holders are entitled to pay a generic firm not to compete as long as the exclusion does not exceed the nominal scope of the patent. Unless Congress adopts a clear standard that rejects the lenient treatment of exclusion payments, it is difficult to see how to stop the upsurge in drug patent settlements with payments to the generic and restraints on generic entry. Consequently, the proposal that settlements in Hatch-Waxman patent infringement cases be reviewed and approved by the judge in the patent case – whether under the antitrust laws or some general public interest standard – seems unlikely to protect consumers.

S. 316 provides a clear standard that directly addresses the fundamental problem: brand-name drug firms compensating a generic challenger to accept a settlement with an entry date that the generic firm would not accept based on the strength of the patent alone. S. 316 would essentially take payments to the generic out of the settlement negotiation. It would return the industry to the conditions prevailing during 2000-2004, when companies settled their patent cases, but did so without exclusionary payments.

Questions from Senator Feinstein

Q: Your testimony and the FTC's prepared statement expressed support for the intent of Senator Kohl's proposed legislation. What changes, if any, would you propose to the bill?

A: First, I suggest that the Committee add a provision to address the "bottleneck" problem described in the Commission's testimony. The operation of the Hatch-Waxman Act's 180-day exclusivity creates the potential for a settlement between a brand-name company and a first generic filer to create a bottleneck that prevents *any* generic competition, whether or not there has been an exclusion payment. A subsequent generic filer that faces a bottleneck but has not been sued, or has been offered a covenant not to sue, has no mechanism to relieve that bottleneck. The bottleneck thus postpones consumer access to a lower-priced generic version of the drug, a result that is contrary to the goals of the Hatch-Waxman Act.

Second, there are some technical changes that could clarify what types of arrangements fall within the scope of the ban. For example, it may be helpful to clarify, either in the law or in the legislative history, that the provision allowing settlements that do no more than grant the right to

market the ANDA product includes a settlement in which a generic that has already launched its product agrees to exit the market and the brand agrees to waive any possible damage claims for past sales. In addition, the bill could clarify that it does not preclude settlements where the value given is the right to sell the ANDA product before expiration of a non-patent statutory exclusivity period (such as the exclusivity granted for testing of drugs for pediatric use).

Finally, the legislative process often results in fine-tuning of even very thoughtful initial proposals. As this bill moves through the Senate, we want to work with your Committee.

Q: The Eleventh Circuit held in the Schering-Plough case that there was no antitrust violation when a settlement between a name brand pharmaceutical company and a generic manufacturer prevented the generic company from marketing the competing generic product – because the settlement did not stifle any competition beyond what the patent already prohibited. To reach this conclusion, the court relied on a presumption that patents are valid.

To reach a conclusion that such a settlement is inherently anticompetitive, do we have to assume that the patent is ***not*** *valid?*

If yes, why should we start from an assumption that the patent in question is not valid?

A: No, the conclusion that exclusion payment settlements harm consumers does not rest on any assumption that the brand name drug company's patent is invalid or not infringed. Indeed, it does not rest on any assumptions or legal presumptions about the likely outcome of the parties' patent dispute. Rather, it is premised on the critical fact that, at the time of the agreement, the outcome of the patent case was uncertain, but the brand company "bought" additional protection beyond that uncertainty.

This approach is in keeping with two well-established antitrust principles. First, the competitive effects of an agreement are to be assessed as of the time it was entered. *See, e.g.*, XI Herbert Hovenkamp, ANTITRUST LAW ¶ 1901, at pp. 185-86 (1998). Second, as the Commission's written statement discusses, antitrust law protects potential, as well as actual, competition. Thus, a payment to induce a potential competitor not to compete is a harm recognized by the antitrust laws. The published economic literature on the topic likewise treats an alleged infringer as a potential competitor. *See e.g.* Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 Rand. J. Econ. 391, 395 (2003).

The Commission's written statement draws an analogy to a scenario in which the brand-name drug firm pays a generic company to withdraw its application for FDA approval. Such conduct is harmful to consumers and warrants condemnation, even though we do not know whether the particular application would have been approved, or whether the generic would have succeeded in manufacturing and marketing its product.

Put another way, if you play blackjack in Las Vegas, and then find out the game was fixed, you

have been cheated, even though you cannot prove that you would have won in an honest game. You were deprived of the opportunity of a fair chance.

Consumers are likewise harmed if they lose the prospect of early generic entry that a "fair game" would provide – that is, arms-length negotiations between brand and generic companies, without the distorting effects of payments to induce the generic to agree not to compete. Eliminating such payments will preserve the generic's incentive to seek early entry.

Follow-up to Question Posed by Chairman Leahy at the January 17, 2007 Hearing

Q: Why did the Department of Justice oppose the FTC's petition for certiorari in the Schering case?

A: The Department's brief to the Supreme Court agreed that the appropriate treatment of exclusion payment settlements is an important issue that warrants the Court's attention. However, among other reasons, the Department concluded that certain aspects of the 11th Circuit's opinion meant the case was not a good vehicle for the Court to resolve the issues.

I do not know whether the increase in these settlements would affect the Department's position on the issue of exclusion payment settlements. But, the urgency of the issue has become even clearer. The concerns about the likely impact of the 11th Circuit's ruling expressed at the time of the Commission's petition may have been seen as merely theoretical. The evidence released in the report on settlements filed in 2006 – 14 out of 28 settlements and 9 out of 11 settlements with first filers – shows that pay-for-delay tactics are an all too common practice.

Follow-up to Question Posed by Senator Hatch at the January 17, 2007 Hearing

Q: Would it be sufficient to remove the ability of parties to a settlement to benefit from the barrier to entry arising from the 180-day exclusivity or is an outright prohibition on "reverse payments" necessary?

A: The 180-day exclusivity rules certainly create an incentive for delayed-entry settlements with the first generic applicant, because the first filer's exclusivity creates, as a practical matter, an insurmountable barrier to entry by later applicants. Certain changes to the rules governing the 180-day exclusivity could reduce the current incentives that make it so attractive for brand-name companies to pay substantial sums to the first generic applicant to settle. Such changes, however, by themselves would not eliminate the incentives for drug companies to use exclusion payments to settle.

The incentives to settle with exclusion payments exist wholly apart from the exclusivity period. Those incentives arise from the unique competitive dynamic that exists between branded and generic drugs (stemming in large part from state substitution laws). When lower-priced, generic entry occurs, there is a rapid and dramatic loss to the branded firm that far exceeds what the

generic entrant earns. Consumers reap the savings. Consequently, both brand and generic firms are better off if they share profits and avoid competition.

Although one might expect that, absent the 180-day exclusivity barrier, brand-name firms could not successfully use exclusion payments – on the theory that it would become too expensive for brand-name drug firms to pay off multiple generic applicants – that is not the case. The absence of the exclusivity period would mean the total expected profits of all generic firms likely would be significantly lower than the profits of the first generic entrant, and therefore, so would the level of payment needed to secure agreement to a deferred entry date. In other words, it likely would cost a brand less to pay five generic companies (none of whom has the exclusivity) than pay one filer with the exclusivity.

Even if the law were changed so that settlement by the first filer caused the 180-day exclusivity right to pass to the next generic applicant, and a settling first filer with final FDA approval was prohibited from entering until expiration of the 180-day period – which you suggested in your remarks – the difference between the brand's lost profits and individual generic's profits are so great that the brand would be able to pay off many generic filers before it became unprofitable for the brand to make these payments. Moreover, many products – separate and apart from the patent – are difficult to manufacture or must meet specific regulations. As a result, those products will only have very limited generic entry in any event, meaning the brand may only have to pay-off two or three generic firms.

Nevertheless, it is important to fix both the exclusion payment and bottleneck problems.

Again, I appreciate your concerns about preserving competition in the marketplace and the need to evaluate the role of exclusion payments on competition in the pharmaceutical industries. Thank you for this opportunity to respond to the Committee's questions.

Sincerely,

Jon Leibowitz by MBK

Jon Leibowitz
Commissioner