Testimony of Phil Goldberg,
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Against Oregon S.B. 764

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My name is Phil Goldberg and I am an attorney at the law firm of Shook Hardy & Bacon, LLP. I co-chair our firm's Public Policy Practice in our Washington, D.C. office and regularly write and testify on legislation and legal issues where liability decisions impact important public policies. I am testifying on my own behalf, and the views expressed below are solely mine.

Much of the discussion supporting this legislation focused on frustration with pharmaceutical patents and prices. There also seemed to be concern about the cost and length of prolonged litigation over the transition of prescription medicines from branded to generics. This legislation, though, would not address any of these issues. Worse, it could actually make it needlessly more difficult for this transition to occur, delaying Oregonians' access less expensive generic drugs.

Federal Law Uses Patents, Incentives and Litigation to Transition Drugs to Generic

In 1984, led by Congressman Henry Waxman (D-CA) and Senator Orrin Hatch (R-UT), Congress developed a regulatory regime based on economic incentives and patents to facilitate the development and sales of prescription drugs. The Drug Price Competition and Patent Term Restoration Act of 1984 is often referred to as the "Hatch-Waxman Act." It recognizes that focusing on the best health care result requires both innovation and affordability.

The good news is that we are seeing major investments in new medicine technology that is producing life-saving and life-affecting medicines. At the same time, more than 90 percent of prescriptions medicines are now filled by generics.

The system the federal government set up for the transitioning prescription drugs from branded to generic, which is the sole issue here, is based on economic incentives, as well as litigation. The generic drug manufacturer starts the process of seeking FDA approval to market a generic version of a drug by certifying that all patents it would like to use over the drug are "invalid" or will not be infringed by the manufacture, use or sale of the generic drug. This filing is known as a paragraph IV certification and is an act of patent infringement under the Hatch-Waxman Act.

The company holding the patents to the drug, its processes and methods then brings a lawsuit to assert its patent rights. If it does so within 45 days, the FDA stays approval of the generic for 30 months while the branded and generic try to agree to terms for the drug's transition. The Hatch-Waxman Act provides an incentive for a generic manufacturer to be the first to file a paragraph IV certification and take this route: once the generic is approved, it gets 180 days of exclusivity where no other generic can entire the market in order to earn back the costs of the litigation.

This 180 days exclusivity period is provided by federal law; it is not evidence of any "pay for delay" in a settlement agreement between the branded and generic drug manufacturers.

The Litigation Involves Complex Health and Legal Matters and Are Difficult to Settle

The transition from the branded to the generic is messy. Litigation is rarely a good way to make public health decisions. But shutting down a useful off-ramp to this litigation, as S.B 764 would do, does not advance public health care goals—it only makes the litigation worse.

The key to the federal regime is the ability of companies to settle the many moving parts and pieces of this transition. First, a drug's initial patent may be expiring, but there may be active patents on other technologies that improve the drug's efficacy, make it easier to administer, or reduce side effects. The generic manufacturer wants the settlement to include access to all of the technology so its generic equivalent can provide comparable therapeutic benefits as the branded.

Second, the two sides have to come up with a fair date for the generic to enter the market given that some patents may be expiring and others may not for years. Picking a date for all of the patents to transfer helps get generic drugs to patients quicker than if the full legal process had to play out. The date of generic entry is not an indication that they are delaying their market entry. It is an indication that the generic manufacturer is getting early access to certain patents.

Third, the two companies need to decide if either side gets money in the settlement. The generic may pay the branded manufacturer for early access to the full set of patents, or the branded may pay the generic based on other factors, such as avoiding prolonged litigation costs.

The focus of this legislation is solely on the last part: where a branded manufacturer pays the generic company, which is called a "reverse payment" because in normal litigation plaintiffs generally do not pay defendants. But, this litigation is not normal. The generic firm triggers the action by filing the certification, and the litigation is the federally fabricated process to facilitate the transition. So, normal plaintiff-defendant dynamics do not apply here.

S.B. 764 Eliminates Useful Settlement Options and Will *Delay* Access to Generic Drugs

S.B. 764 makes all reverse payment settlements presumptively illegal, even when they have a legitimate purpose. Thus, enacting S.B. 764 interferes with the ability of branded and generic manufacturers to settle patent disputes, thereby *delaying* the transition from branded to generic.

Discouraging legitimate avenues to settlement is wrong for America's health care. It throws needless roadblocks into the transition to generics. Some may not like that pharmaceutical companies have patents or exclusivity periods, or that brandeds can pay generics, but the best health care solution *under the current federal regime* is for generics to have access to all of this technology when they go on the market—not fight over patents for years.

The key is to distinguish useful reverse payments from "pay for delay." To guard against "pay for delay," in 2013 the U.S. Supreme Court—led by Justices Stephen Breyer, Ruth Bader Ginsburg, Elena Kagan and Sonia Sotomayor (commonly referred to as the liberal justices)—set the rules for when these "reverse payment" settlements can be used and, importantly, explained why reverse payments settlements have "value" in dealing with "the patent litigation problem." The case is *Federal Trade Commission v. Actavis, Inc.* and Justice Breyer wrote the opinion.

The Justices concluded that only *large and unjustified* reverse payments suggest anticompetitive behavior—what the proponents of S.B. 764 call "pay for delay." Other reverse payments settlements, which S.B. 764 would also ban, have *value* in helping resolve the litigation.

> The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences

By making all reverse payment settlements presumptively illegal, S.B. 764 would chill *useful* reverse payments settlements. This legislation throws the proverbial baby out with the bathwater.

State and Federal Authorities Already Invalidate True "Pay for Delay" Settlements

States, including Oregon, along with the Federal Trade Commission (FTC) already are the cops on this beat. The FTC reviews 140 drug patent settlements every year for anti-competitiveness. It is reported that the *Actavis* ruling had its desired effect: the FTC has found major reductions in settlements that could be termed "pay for delay." And, it files lawsuits to stop them.

Oregon and other states can also file antitrust suits to stop a reverse payment prescription drug settlement they believe is problematic under state antitrust law. Oregon antitrust laws already make it illegal to engage in a settlement that restrains trade or commerce or monopolizes any part of trade or commerce. The penalties are high: civil fines, equitable remedies and treble damages.

To be clear, Oregon and other states already have powerful tools to stop reverse payment settlements that are truly anticompetitive. Also, state attorneys general offices often work together when they believe such a settlement exists and is against the public interest.

Making all reverse payments presumptively illegal directly contradicts efforts by the liberal Justices to distinguish between good and bad settlements. They said whether a payment violates antitrust laws must be "a conclusion that flows from the analysis and not . . . its starting point." Thus, this bill undermines the ability of the companies, FTC and states to strike the right balance.

Conclusion: S.B. 764 Is Not Useful, Overbroad and Off-Point

The best health care answer here is for legitimate prescription drug patent settlements to be encouraged and anticompetitive settlements to be discouraged and overturned. The mere inclusion of a reverse payment is beside the point. I have no doubt S.B. 746's sponsors are well-intentioned and are frustrated over drug patents and prices. This bill, though, does not address patents and prices. What it does is hinder the ability of branded and generic drug companies to reach settlement and transition drugs to generic as seamlessly as possible. Thank You.