# A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements[1]

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**August 10, 2010**

The Congressional Budget Office (CBO) has estimated that increased restrictions on so-called "reverse payment" patent settlements between pharmaceutical companies would save the Federal government billions of dollars over the next decade. In this short paper, we show that the CBO's estimate of potential savings is likely to be significantly overstated.

## Background

Recently, the U.S. House of Representatives passed a measure that would further restrict so-called "reverse payment" patent settlements between branded and generic pharmaceutical companies. The measure would make presumptively unlawful any patent settlement agreement where the generic company "receives anything of value" and "agrees to limit or forego research, development, manufacturing, marketing, or sales of the [allegedly infringing generic] product for any period of time."[5] The measure, which is modeled closely on S. 369, the Preserve Access to Affordable Generics Act, an earlier bill sponsored by Senator Kohl, has now been attached to the FY2011 Financial Services Appropriations bill. Earlier this year, the CBO estimated that S. 369

[1] This preliminary response was supported by funding from the Pharmaceutical Research and Manufacturers of America (PhRMA). The views and opinions expressed in this study are solely those of the authors and do not necessarily reflect the views and opinions of PhRMA or any of the organizations with which the authors are or have previously been associated. Compass Lexecon LLC has served as economic consultants to branded and generic manufacturers regarding the competitive effects of patent settlements.

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[5] S. 369. The measure would exempt settlements with payments for litigation costs up to $7.5 million. Settlements where the branded company provides net consideration to the generic company have been commonly referred to as "reverse payment" settlements.

would save the Federal government, on net, $0.9 billion during the 2010-2015 period and $2.7 billion during the 2010-2020 period.[6]

The cost savings projected by the CBO depend critically on at least three assumptions.

- First, based on an earlier "study" by the FTC,[7] the CBO assumed that the bill would accelerate entry of generic drugs affected by the bill by an average of 17 months.[8]
- Second, the CBO appears to have implicitly assumed that restrictions on reverse payment settlements in existing law will be entirely ineffective over the next 10 years and that anticompetitive settlements can only be prevented by the further restrictions in S. 369.
- Third, the CBO assumed that substantial restrictions on reverse payment settlements would decrease generic manufacturers' incentives to challenge branded patents and as a result reduce generic entry in some cases.

This memo shows that the CBO's analysis of S. 369 is flawed and likely substantially overestimates the budgetary savings, if any, that would result from additional restrictions on "reverse payment" settlements.[9]

### 1a. The FTC Study's Conclusion That Reverse Payment Patent Settlements Delay Generic Entry by 17 Months, Relative to Patent Settlements without Reverse Payments, Is Not Reliable

The FTC study concludes that reverse payments delay entry of generic pharmaceutical manufacturers by 17 months (or 1.42 years) because, according to the FTC analysis, generic entry under the subset of patent settlement agreements with reverse payments is on average 17 months later than entry under the subset of agreements without reverse payments.[10] The CBO analysis adopts this assumption – and this assumption is critical to the CBO's cost estimate.

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[6] The CBO's initial score of S. 369, in January 2010, measured savings of $0.8 billion from 2010-2014 and $2.0 billion from 2010-2019 (CBO, "Cost Estimate: S. 369, Preserve Access to Affordable Generics Act", January 28, 2010, hereinafter "CBO Cost Estimate"). In June 2010, the CBO issued an updated score (CBO, "S. 369: Preserve Access to Affordable Generics Act (Updated Table)", June 16, 2010). The estimate was updated to reflect the passage of health care reform legislation and to extend the estimates to 2020.

[7] Federal Trade Commission, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," January 2010 ("FTC Study"). The results of the study were first reported in a speech by Commissioner Liebowitz (see http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf, downloaded on June 23, 2009).

[8] CBO Cost Estimate, p. 5.

[9] Orszag and Willig have critiqued the FTC's methodology in an earlier memo (see Orszag, Jonathan and Robert Willig, "A Preliminary Economic Analysis of FTC Chairman Leibowitz's June 23rd Speech," June 24, 2009).

[10] FTC Study, p. 9.

As a matter of economics, there is no sound rationale for assuming that the inclusion of a payment from the branded to the generic manufacturer as part of the settlement agreement *caused* the observed differences in entry dates by the generic manufacturers. First, as detailed below, the reverse payment may well have been crucial for enabling a settlement that avoided litigation, rather than displacing a settlement without reverse payments. Second, even if there would have been an alternative settlement, the FTC analysis is unreliable. The reason: Settlements with and without reverse payments may differ in certain aspects of the underlying patent disputes. For example, if settlements with reverse payments occur more often when the branded manufacturer possesses a stronger patent than in settlements without reverse payments, later entry under the reverse payment settlements may just reflect the average difference in patent strengths rather than any payment for delay. Similarly, patent settlements with and without reverse payments may differ in the average patent life remaining or the point in time after an initial challenge at which the settlement is reached. Such differences would render invalid the comparison of entry delay between the two types of settlements.[11] By ignoring the fact that the universe of settlements that involved a reverse payment may differ in important respects from the universe of settlements without such payments, the FTC study (and thus, the CBO cost estimate) has oversimplified the analysis in a way that has material bearing on its utility and reliability for predicting generic entry or estimating costs under alternative rules. It is just not possible to make reliable inferences about the effect of reverse payments on entry delay without properly accounting for the other salient differences between settlements in the two categories.

**1b. The FTC Study Ignores the Costs of Banning Reverse Patent Settlements**

We have each written research papers analyzing the economics of "reverse payment" patent settlements. In our research, we have demonstrated that the claims, made by some, that *all* reverse payment patent settlements delay entry of generic drugs and therefore increase prescription drug costs, are not accurate.[12] Indeed, S. 369 acknowledges this by allowing the settling parties to rebut the presumption that a settlement is anticompetitive by demonstrating "that the procompetitive benefits of the agreement outweigh the anticompetitive effects."[13] Our research papers describe the economic conditions under which reverse payment patent settlements may increase prescription drug costs and the conditions under which reverse payment patent settlements may produce *more competition*, thereby *decreasing* prescription drug costs.

[11] Moreover, every patent dispute and every settlement has some unique features that are difficult to account for in comparing settlements.

[12] Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry," *Annals of Health Law*, Vol. 19, Issue 2, Winter 2010, pp. 367-400 ("Dickey, Orszag, and Tyson 2010"); Robert Willig and John Bigelow, "Antitrust Policy Toward Agreements that Settle Patent Litigation," *The Antitrust Bulletin*, Fall 2004, pp. 655-698 ("Willig and Bigelow"); and John Bigelow and Robert Willig, "'Reverse Payments' in Settlements of Patent Litigation: Schering Plough, K-Dur and the FTC," *The Antitrust Revolution: Economics, Competition, and Policy*, 5th Edition (2008).

[13] S 369.

The FTC study (and therefore the CBO cost estimate, when relying on it) ignores the fact that patent settlements with reverse payments may actually accelerate generic competition for numerous drugs. We have examined the highly simplified economic models that can lead to the conclusion that reverse payment settlements will always reduce competition. These economic models ignore important economic realities that can make reverse payment settlements procompetitive. Such realities include, but are not limited to, (a) risk aversion, (b) information asymmetries, (c) differences in expectations, and (d) differences in discount rates.[14]

In fact, our analyses show that without a payment from the branded manufacturer to the generic manufacturer, the parties may be unable to reach agreement on a settlement – even if a settlement would lower prescription drug costs by bringing a generic version to market sooner than would occur if the case were resolved by a court decision. If reverse payment settlements are overly restricted in these cases, the parties may be unable to reach settlement and may litigate the dispute to the end. Such litigation can engender significant delays in the possibilities for competition, even if the generic manufacturer were ultimately to prevail, as patent litigation may persist over an extended period of time and generic companies face significant risks in entering before the patent litigation has been resolved.[15] And if the generic manufacturer were to lose the litigation, entry would occur only after – and perhaps long after – entry would have occurred in the presence of a patent settlement with a reverse payment. In these cases, reverse payment settlements lead to lower prescription drug costs.

That reverse payments are important to facilitating settlement is consistent with data showing that the number of settlements in total increased dramatically around the time (late 2006) that courts began taking a more permissive stance on reverse payment settlements.[16] The FTC study states, "Over the FY2004 to FY2008 time period, the percentage of drugs that settled per year (not including injectibles) increased from 7% to 18%, with most of the increase following the Eleventh Circuit's *Schering* decision."[17] By noting that the court's decision approving a reverse payment settlement led to *more* settlements, the FTC has implicitly suggested that the newly encouraged settlements with reverse payments did not displace settlements without reverse payments, but instead *increased* settled litigation that would not have settled at all in the absence of reverse payments.

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[14] For a more detailed discussion of how these complexities affect the economic conclusions, see Dickey, Orszag, and Tyson 2010, pp. 391-397. The underlying research is in Willig and Bigelow, op.cit.

[15] The FTC study argues that even if the alternative to settlements with reverse payments were litigation, the average time to entry under litigation is indicated by the average time to entry under settlements without reverse payments. This is logically false, because the data suggest that many of the cases that were settled with reverse payments could not have been settled at all without reverse payments. Thus, these cases are better proxied by the cases that were actually litigated, not the cases that were actually settled without reverse payments.

[16] RBC Capital Markets, "Pharmaceuticals: Analyzing Litigation Success Rates," January 15, 2010, p. 3; FTC Study, p. 9.

[17] FTC Study, p. 9.

The effect of ignoring these cost savings is potentially substantial. To the extent that a reverse payment is essential to enable the parties to settle litigation, it can lead to generic drugs entering years before they would at the end of a protracted litigation. Suppose, for example, that the expected remaining duration of the litigation, including typical appeals is 1.5 years, and that the patent has 12 more years after the end of litigation until it expires. Suppose also that the generic wins litigated patent suits 50% of the time.[18] This suggests that the expected time to generic entry with litigation is 1.5 + 0.5*0 +0.5*12 = 7.5 years. In comparison, a reverse payment that facilitates a settlement with generic entry, say 4 years into the future, would lead to generic entry a full 3.5 years *earlier*.[19] This is in dramatic contrast to the inaccurate FTC and CBO view that reverse payments slow generic entry by 17 months. To the extent that reverse payments are essential for settlement in a substantial fraction of cases, under the assumptions in the above hypothetical, significantly restricting reverse payments as S. 396 would do would in fact *cost* the Federal government billions of dollars in increased expenditures on prescription drugs, in contrast to the billions of dollars in savings estimated by the CBO.

**2. All Cost Savings from Preventing Anticompetitive Reverse Payment Settlements Should Not Be Attributed to the *Incremental* Restrictions in S. 369**

Under current law, pharmaceutical manufacturers that settle patent litigation are required to report information on settlements to the FTC and the Department of Justice (DOJ).[20] The antitrust authorities (or private plaintiffs) can challenge such settlements where they believe them to be anticompetitive. Indeed, challenging such settlements has been a priority of the FTC for many years.

While several courts have issued opinions in recent years that are relatively permissive towards reverse payment settlements, even these opinions have concluded that at least some types of reverse payment patent settlements are unlawful.[21] Moreover, how the legal landscape will develop on this issue over the next decade is impossible to predict.[22]

[18] This is consistent with the results of a recent study, which found that generic manufacturers won 48% of the patent cases that went to trial (RBC Capital Markets, "Pharmaceuticals: Analyzing Litigation Success Rates," January 15, 2010, p. 4).

[19] This is consistent with the spend-weighted average time to generic entry under reverse payment settlements according to a study by Professor Scott Hemphill (see his Congressional testimony on the subject, http://energycommerce.house.gov/Press_111/20090331/testimony_hemphill.pdf).

[20] "Medicare Prescription Drug, Improvement, and Modernization Act of 2003," §1112.

[21] See, for example, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060 (11th Cir. 2005).

[22] For example, the Second Circuit recently affirmed a lower court decision finding that a reverse payment patent settlement was not unlawful, but the Court invited plaintiffs to petition for a rehearing en banc to potentially reconsider the Second Circuit's position on these settlements (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 2nd Cir. 2010).

Yet the CBO's cost estimate depends importantly on accurately estimating the extent to which patent settlement agreements that would be undeterred under the current legal environment would be prevented by the additional restrictions in S. 369. While the CBO report does not describe its methodology in detail, the CBO appears to attribute all savings from reducing reverse payment settlements to the additional restrictions – implicitly assuming that none of these settlements would be caught or deterred under existing law. Because existing law will catch or deter at least some anticompetitive reverse payment settlements, this assumption is inappropriate and is another reason why the CBO overstates savings from S. 369.

### 3. A Decrease in Patent Challenges Will Increase Federal Expenditures

The cost savings realized from the introduction of generic drugs depends importantly on generic manufacturers' challenges of weak patents on branded drugs. These challenges invariably lead to lengthy, expensive litigation with branded companies. As the CBO analysis acknowledges, generic companies' incentives to commence such patent challenges arise from the expected rewards that may come from such litigation.[23] To the extent that further restrictions on reverse payment settlements reduce such expected rewards (*e.g.*, by denying the generic manufacturer one option for exiting lengthy, costly litigation), then generic manufacturers would have reduced incentives to challenge branded patents in the future. Patent challengers can be small pharmaceutical firms that may lack the capital to withstand a long, drawn-out patent fight in court. Faced with a greater likelihood of expensive and protracted litigation, these firms may just forgo the challenge. Well-resourced generic companies may also have different business assessments of challenging patents in the face of protracted litigation with little possibility of an out-of-court resolution.

This would lead to fewer generic entrants and, all else equal, higher drug prices. Even if the effect on a particular generic manufacturer's decision were relatively small, the collective impact on future generic competition could be substantial. The CBO appears to agree, estimating that the effect of these decreased incentives stemming from S. 369 would raise drug prices by $2 billion between 2010 and 2019.[24]

### 4. Conclusions

For the reasons articulated above, the CBO's estimate of cost savings from S. 369's additional restrictions on reverse payment patent settlements likely substantially overestimates the degree of potential cost savings. While reverse payment settlements can be anticompetitive under some circumstances (and current law facilitates challenges of anticompetitive settlements by the FTC, as discussed above), under many circumstances reverse payment patent settlements between branded and generic manufacturers can benefit competition and consumers, particularly by

[23] CBO Cost Estimate, p. 6.
[24] CBO Estimate, p. 6. The CBO's June 2010 updated estimate did not separately break out the updated estimate of the magnitude of this effect.

averting continued litigation that may well delay generic entry substantially. Because the CBO methodology relies on the claims of the FTC study, it largely ignores the cost savings that would flow from these procompetitive benefits. Moreover, the CBO methodology fails to account for existing restrictions on reverse payment patent settlements and inappropriately attributes all savings to the incremental restrictions in S. 369. Finally, as the CBO acknowledges, restricting generic manufacturers' ability to settle lengthy, expensive patent litigation will reduce generic companies' incentives to bring such patent challenges in the first place and as a result increase drug costs and hence federal spending.