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REPORT
111–123

PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

FEBRUARY 2, 2010.—Ordered to be printed

Mr. LEAHY, from the Committee on the Judiciary, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany S. 369]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to which was referred the bill (S. 369), to prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, having considered the same, reports favorably thereon, with amendments, and recommends that the bill, as amended, do pass.

CONTENTS

I. BACKGROUND AND PURPOSE OF THE PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

This legislation is intended to prevent anticompetitive agreements in the pharmaceutical industry between brand name and ge-

neric drug manufacturers that may limit, delay, or otherwise prevent competition from generic drugs. These agreements (commonly known as "reverse payment" settlements or "pay-for-delay" agreements) occur as part of the settlement of a patent infringement lawsuit, in which the suit is brought by a brand name drug firm against a generic firm that is seeking to market a generic version of the brand name's drug.

In a reverse payment agreement, the pharmaceutical patent litigation is settled by the brand name drug manufacturer paying the generic drug maker cash or other valuable consideration in exchange for the generic drug maker agreeing to stay off the market for some period of time. In essence, the brand name drug maker pays its competitor not to compete. The agreement may benefit both parties to the settlement, but by preventing competition, competition which otherwise could cause drug prices to fall dramatically, consumers are harmed. In June 2009, the Federal Trade Commission (FTC) estimated that these reverse payment agreements would cost consumers $35 billion and the Federal Government $12 billion over the next decade.[1] Additionally, FTC economists, based on a review of the entire universe of brand-generic settlements, calculate that, on average, settlements with payments delay generic entry 17 months more than settlements without such payments.[2]

The Committee bill, as reported, will provide the FTC with the tools it needs to prevent these agreements. The legislation is necessary because The Drug Price Competition and Patent Restoration Act ("the Hatch-Waxman Act"),[3] enacted in 1984, does not adequately deter reverse payment settlements. The Hatch-Waxman Act was enacted with the intent of encouraging competition from generic drug manufacturers, while protecting legitimate patents. Under the Hatch-Waxman Act, generic drug manufacturers receive accelerated FDA approval of a generic drug upon showing that the generic drug is the bioequivalent to an approved drug. This approval can be sought prior to the expiration of the brand name drug's patent. Generic firms are further incentivized to challenge weak brand name drug patents—those that are likely invalid or not infringed—because the first generic applicant is awarded a 180-day period of marketing exclusivity.[4] A successful patent challenge brings the generic drug to market sooner, and provides a lower cost drug alternative to consumers. Generic drugs are estimated to save consumers between $8 billion and $10 billion each year.[5]

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[1] Jon Leibowitz, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), Speech to the Center for American Progress, Appendix at 13, available at <*http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf*>.

[2] Id.

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585. In 2003, this Act was amended. See Medicare Prescription Drug Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, tit. XI, subtits. A–B, 117 Stat. 2066, 2448–64.

[4] 21 U.S.C. §355(j)(5)(B)(iv). This exclusivity provision was intended to provide an economic incentive for generic drug companies to challenge patent validity and to find alternative, non-infringing forms of patented drugs. While the promise of marketing exclusivity has encouraged generic companies to challenge weak patents, it has also increased the incentive for the brand name firm to enter into a pay-for-delay settlement with the first generic challenger.

[5] Generic Pharmaceutical Association, Facts at a Glance, available at <*http://www.gphaonline.org/about-gpha/about-generics/facts*>. A recent study by Professor C. Scott Hemphill of Columbia Law School, analyzing a subset of brand-generic settlements, estimated that if generic entry on those products were delayed just one year, it would have cost consumers

The Hatch-Waxman Act's success in promoting generic competition is undermined by the emergence of reverse payment settlements. Reverse payment settlements can enrich the brand name and generic drug firms at the expense of consumers who are denied the benefits of competition from lower-cost generic drugs.[6] Paying the first generic applicant to delay its entry effectively blocks other generic challengers from coming to market as well, since the FDA may not approve a subsequent generic application for the same drug product until the first applicant's 180-day exclusivity expires.[7]

The threat reverse payment agreements pose to competition in the pharmaceutical industry has been recognized for some time. In 2003, the Hatch-Waxman Act was amended to require brand name companies and generic applicants to file patent settlement agreements with the FTC and the Department of Justice.[8] As the Committee on the Judiciary's report explained, those amendments sought to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[9]

Recent court decisions have made it more difficult for the FTC or private litigants to challenge reverse payment settlements under the antitrust laws. In 2005, two appellate courts adopted an extremely permissive position on reverse payment settlements.[10] The Eleventh Circuit reversed the FTC's decision in Schering-Plough Corp. v. FTC, applying neither the traditional per se or rule of reason analysis to the agreement.[11] The Second Circuit in In re Tamoxifen Citrate Antitrust Litigation likewise upheld the legality of a reverse payment settlement.[12] In 2008, a third appellate court adopted a similarly lenient view of reverse payment settlements.[13] In that case, In re Ciprofloxacin Hydrochloride Antitrust Litigation, the Federal Circuit held that in the "absence of evidence of fraud before the [Patent and Trademark Office] or sham litigation," the

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billions. C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 COL. L. REV. 629 (May 2009).

[6] The economic incentives behind these deals are related to the market dynamics of the industry. The introduction of a generic drug provides substantial benefits to consumers, but also unique and dramatic economic consequences for brand name firms. Studies of pharmaceutical markets indicate that the first generic competitor typically enters the market at a price that is 20 to 30 percent lower than that of the brand name counterpart. Subsequent generic entrants may enter at even lower prices—discounted as much as 80 percent or more off the price of the brand name drug—and prompt the earlier generic entrants to reduce their prices. Because of the policies of public and private health plans and state generic substitution laws, the generic drug gains substantial market share from the brand name product in a short period of time, anywhere from 44 to 80 percent of brand name sales within the first full year after the generic launch. See Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (July 1998) ("CBO Study"), available at <*http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf*>; see generally David Reiffen & Michael R. Ward, Generic Drug Industry Dynamics (Feb. 2002), available at <*http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf*>.

[7] 21 U.S.C. § 355(j)(5)(B)(iv).

[8] Pub. L. No. 108–173, Tit. XI, Subtit. B, 117 Stat. 2066, 2461.

[9] S. REP. No. 107–167, at 4 (2002), available at <*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_reports&docid=f:sr167.pdf*>.

[10] Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006); In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005), amended, 466 F.3d 187 (2d Cir. 2006), cert. denied, 127 S. Ct. 3001 (2007). For a detailed discussion of the Schering and Tamoxifen cases see the FTC's May 2, 2007 testimony before the U.S. House of Representatives Energy and Commerce Committee's Subcommittee on Commerce, Trade and Consumer Protection, at 15–19, available at <*http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf*>.

[11] 402 F.3d at 1065.

[12] Tamoxifen, 429 F.3d at 370 (2d Cir. 2005), amended, 466 F.3d 187 (2d Cir. 2006).

[13] In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), cert. denied sub nom Ark. Carpenters Health & Welfare Fund vs. Bayer AG, 129 S. Ct. 2828 (2009).

mere presence of a patent entitles the patent holder to purchase protection from competition until patent expiration.[14]

The Schering, Tamoxifen, and Ciprofloxacin rulings have prompted a resurgence in brand-generic settlements in which the parties settle with a payment to the generic company and an agreement by the generic company to delay marketing its product. An FTC staff report of settlements filed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 during the fiscal year ending in September 2007 found that almost half of all of the final patent settlements (14 of 33) involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time.[15]

The Committee bill will provide the FTC with an additional avenue to challenge and prevent anticompetitive agreements. The Committee bill creates a new section 28 of the Federal Trade Commission Act. This new section allows the FTC to initiate a proceeding under the Federal Trade Commission Act to block a reverse payment settlement and to impose civil penalties if the agreement violates the Act.[16] In this proceeding, an agreement settling a patent infringement claim is presumed to be illegal if the company seeking to market a generic drug receives anything of value [17] from a brand name drug manufacturer, and the generic drug company agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug for any period of time. The settling parties are given the opportunity to rebut this presumption by demonstrating by clear and convincing evidence that the procompetitive benefits of the settlement agreement outweigh the anticompetitive effects of the agreement. If the parties do not make such a showing, the presumption of illegality has not been overcome, and the agreement is illegal.[18] A proceeding under this Act must be initiated within three years of the date that the parties notify the FTC of their agreement, as required by 21 U.S.C. § 355.

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[14] Ciprofloxacin, 544 F.3d at 1336.

[15] Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition (May 2008), available at <*http://www.ftc.gov/os/2008/05/mmaact.pdf*>.

[16] In recent years, the FTC attempted to take legal action under section 5 of the FTC Act to invalidate these agreements. However, as described above, several recent decisions have made it very difficult for the FTC and the drug purchasers who pay higher prices for prescription drug products as a result of these reverse payment settlements to challenge successfully their legality. The *Schering, Tamoxifen, and Ciprofloxacin* decisions have essentially nullified antitrust law in this area and adopted legal rules that permit these agreements. In the wake of these decisions, reverse payment settlements have become prevalent. *See* Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition* (May 2008), *available at* <*http://www.ftc.gov/os/2008/05/mmaact.pdf*;> Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006: A Report by the Bureau of Competition (Apr. 2007), available at* <*http://www.ftc.gov/reports/mmact/MMAreport2006.pdf*>; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), available at* <*http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf*>.

[17] "Anything of value" is intended to include a cash payment or any other consideration of value.

[18] While only the FTC can bring an action to enforce the new section 28 of the FTC Act, the legislation also specifically provides that it should not be construed to modify, impair or supersede the applicability of the antitrust laws. See Section 3(a) of S. 369. Therefore, while there are no private rights of action created by this legislation, the ability of private parties to bring actions under the antitrust laws challenging these agreements is similarly not affected by this legislation.

Under the new section 28(g)(2)(A) of the FTC Act, however, the FTC will have a year from the date of a final administrative order in an action brought under section 28 to pursue an action for civil penalties.

The Committee bill enumerates factors that the fact-finder is to consider in determining whether the parties have met their burden to establish that their agreement's procompetitive effects outweigh its anticompetitive harms. The list is not intended to be exhaustive, and the fact-finder is permitted to consider any other factor it deems relevant to its determination of competitive effects of the agreement under challenge.

The Committee bill also provides that, in evaluating whether the settling drug companies have met their burden to establish that their agreement is procompetitive, the fact-finder shall not presume that entry of the generic drug would not have occurred until expiration of the relevant patent or statutory period of exclusivity. Further, the fact-finder cannot presume that the agreement is procompetitive on the basis that it provided for entry of the generic drug prior to expiration of the patent or statutory exclusivity, although such evidence may be relevant to the fact-finder's determination

Certain forms of consideration are exempted from the presumption of illegality created by this new section. The legislation does not prohibit agreements that include only one or more of the following: (i) the right to market the generic drug prior to the expiration of patent or other statutory exclusivity for the drug (*i.e.*, a settlement that allows the generic drug to enter the market before the patent has expired but does not involve any payment of money or other consideration to the generic drug manufacturer); (ii) a payment to the generic drug company for its reasonable litigation expenses, not to exceed $7,500,000; or (iii) a covenant not to sue on any claim that the generic drug infringes a U.S. patent. It was the judgment of the Committee that these types of settlements should be carved out from the bill as they would not likely pose competitive concerns.[19] The legislation also empowers the FTC to conduct a rulemaking that will exempt certain categories of agreements that contain reverse payments, but which the FTC determines benefit consumers.[20]

The Committee bill contains strong civil penalties that may be levied against parties that enter into patent settlement agreements that violate the Act. A violator faces a civil penalty of up to three

[19] In order to be within the carve-out, a settlement agreement must consist *only* of these three categories of agreements (or a combination of the three). Settlement agreements in which there is additional consideration of any form paid to the generic drug holder are not within the safe harbor and are fully subject to the presumption of illegality contained in the new section 28 of the FTC Act.

[20] The generic drug companies argue that they might be discouraged from entering the market prior to a finding of non-infringement or invalidity if they believe that the law would prevent them from obtaining lawfully a full release of liability as part of a settlement. As a result, the sponsors of the legislation considered adding a carve-out for settlement agreements in which the brand name drug company grants a release of liability for patent infringement to the generic drug company in situations in which the generic drug company has entered the market "at risk"—that is, before adjudication of the patent dispute. In many situations, this form of consideration may not harm consumers or competition. However, these settlements are a new phenomenon in the Hatch-Waxman context, and there may be scenarios in which such a patent settlement could possibly raise competition concerns. Therefore, rather than exempting all such settlements, the Committee expects that the FTC will use the rulemaking authority of new section 28(e) to consider exempting appropriate forms of these agreements after it receives comments from affected parties.

times the value it received from the agreement that is reasonably attributable to a violation of the law. If the brand name company has not received any such value (as in a situation where the evidence shows that, even in the absence of the agreement, generic entry would not have occurred prior to the decision finding the agreement illegal), the penalty to the brand name drug company may be up to three times the value of the consideration it gave to the generic drug company under the patent settlement agreement at issue. The Committee bill lays out additional factors that should be considered in determining the civil penalty as well. The FTC also maintains the authority to issue a cease and desist order enjoining the patent settlement agreement from going into effect or continuing in force.[21] A generic drug company entering into an illegal patent settlement agreement under this statute will also lose its statutory exclusivity with respect to that drug—that is, its exclusive right to market a generic version of the drug for 180 days for having been the first generic drug filer.

The Committee bill does not prohibit settlement of Hatch-Waxman patent litigation. The legislation will only impact those settlement agreements that include both compensation to the generic drug company and delayed generic entry. Parties are free to settle cases based on date of entry alone, or to incorporate any of the legislation's exempted safe harbors into their agreement.

II. History of the Bill and Committee Consideration

The Preserve Access to Affordable Generics was first introduced in the 109th Congress by Senator Kohl on June 27, 2006 (S. 3582).[22] The bill had five cosponsors (Senators Leahy, Grassley, Schumer, Johnson and Feingold). It was referred to the Committee on Commerce, Science and Transportation, where no further action was taken on it during the 109th Congress.

On January 17, 2007, Senator Kohl introduced the Preserve Access to Affordable Generics Act in the 110th Congress (S. 316).[23] The bill had 10 cosponsors (Senators Leahy, Grassley, Schumer, Feingold, Kennedy, Durbin, Johnson, Klobuchar, Obama, and Brown). It was referred to the Committee on the Judiciary. The Committee held a hearing titled "Paying Off Generics to Prevent Competition with Brand Name Drugs" on January 17, 2007. Testimony was received from Jon Leibowitz, Commissioner, FTC; Billy Tauzin, CEO, PhRMA; Merrill Hirsch, Partner, Ross, Dixon & Bell, LLP; Bruce Downey, Chairman and CEO, Barr Pharmaceuticals, Inc.; and Michael Wroblewski, Consumers Union. The bill was re-

[21] Such a cease and desist order could be sought as an administrative remedy before the FTC under section 5(b) of the FTC Act (15 U.S.C. § 45(b)) or in an action in Federal district court under section 13(b) of the FTC Act (15 U.S.C. § 53(b)).

[22] The minority views of Senators Sessions, Hatch, Kyl, Cornyn, and Coburn argue that the Committee bill "prevent[s] parties that disagree on the strength of the patent and other key factors from settling a suit. . . ." As noted above, not all settlements are brought within the ambit of the legislation; parties are free to settle cases based on the date of entry alone or pursuant to the expressly enumerated safe harbors. And the record shows that even a per se ban on reverse payment settlements does not prevent parties from settling cases. From 2000 to 2004 (prior to the Court of Appeals decisions discussed above), there were 20 settlements of pharmaceutical patent litigation which, according to the FTC, did not include payments from the brand name drug manufacturer to the generic competitor. Further, from 2005 to 2007, 41 out of 74 cases settled without a combination of payments and entry restrictions. Thus, it is simply incorrect to argue the Committee bill will destroy the ability of brand name and generic drug companies to settle pharmaceutical patent litigation.

[23] That bill, S. 316 in the 110th Congress, was substantially identical to S. 369 as introduced in the 111th Congress.

ported favorably, without amendment, by voice vote on February 27, 2007. No further action was taken on S. 316 in the 110th Congress.

On February 3, 2009, Senator Kohl introduced the Preserve Access to Affordable Generics Act in the 111th Congress (S. 369). The bill has eight cosponsors (Senators Grassley, Feingold, Durbin, Brown, Collins, Klobuchar, Bill Nelson and Franken). It was referred to the Committee on the Judiciary.

On September 24, 2009, the Committee considered the legislation during its business meeting. Senator Kohl offered an amendment in the nature of a substitute, which was adopted. Among other things, under the substitute amendment, agreements between brand name drug manufacturers and generic drug makers in settlement of patent disputes in which the generic company agrees to delay marketing a generic drug and receives a payment of value are presumed to be illegal (rather than automatically illegal), but in order to be found illegal the FTC must bring a legal action under the FTC Act. During such a legal action, the parties to the agreements at issue can overcome the presumption of illegality if they can establish by clear and convincing evidence that the agreement is procompetitive. The substitute amendment also prescribes penalties for entering into illegal patent settlements, and establishes a three year statute of limitations for the FTC to bring an action under the Act.

On October 15, 2009, the Committee concluded its consideration of the bill. Senator Kohl offered an amendment to (i) modify the penalty provisions in the bill; (ii) modify the effective date so that the Act would only apply to agreements entered into after November 15, 2009; (iii) change the language of the certification used by parties submitting agreements to the FTC; (iv) clarify that the FTC has one year after a final order to seek civil penalties; and (v) make other minor technical changes. The amendment was adopted by unanimous consent. No other amendments were offered to the bill.

The Committee then voted to report the Preserve Access to Affordable Generics Act, as amended, favorably to the Senate. The Committee proceeded by roll call vote as follows:

Tally: 12 Yeas, 7 Nays.

Yeas (*12*): Leahy (D–VT), Kohl (D–WI), Feinstein (D–CA), Feingold (D–WI), Schumer (D–NY), Durbin (D–IL), Cardin (D–MD), Whitehouse (D–RI), Klobuchar (D–MN), Kaufman (D–DE), Franken (D–MN), and Grassley (R–IA).

Nays (*7*): Specter, (D–PA), Sessions (R–AL), Hatch (R–UT), Kyl (R–AZ), Graham (R–SC), Cornyn (R–TX), Coburn (R–OK).

III. Section-by-Section Summary of the Bill

Section 1. Short title

This section provides that the legislation may be cited as the "Preserve Access to Affordable Generics Act."

Section 2. Congressional findings and declarations of purposes

This section contains congressional findings and declarations of purposes.

Section 3. Unlawful compensation for delay

Subsection (a). This subsection creates a new section 28 of the FTC Act, as follows—Sec. 28(a) provides that the Federal Trade Commission may bring a legal action to enforce this section with regard to any agreement in settlement of a patent infringement lawsuit in which a generic drug manufacturer receives anything of value from a brand name drug manufacturer, and the generic drug manufacturer agrees to limit or forego research, development, marketing, manufacturing or sales of the generic drug. Under this section, such agreements are presumed to be unlawful. This presumption can be overcome if the parties to such an agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

Sec. 28(b) lists factors the fact-finder must consider in making this determination.

Sec. 28(c) directs the fact-finder to avoid making certain presumptions.

Sec. 28(d) exempts certain categories of agreements from the presumption of illegality.

Sec. 28(e) gives the FTC rulemaking authority to implement and interpret section 28 and to exempt certain types of agreements if the FTC determines that such agreements will promote competition and benefit consumers. Any such rulemakings may be appealed to the U.S. District Court for the District of Columbia. Further, it provides that a violation of this section shall be treated as a violation of section 5 of the FTC Act. The section also provides that any order of the FTC under this section may be appealed only to the U.S. Court of Appeals to the D.C. Circuit or the Circuit Court of Appeals where the ultimate parent entity of either the brand name or generic drug company is incorporated.

Sec. 28(f) states that nothing in the section supersedes or modifies the antitrust laws relating to unfair methods of competition.

Sec. 28(g) provides for civil penalties for violations of this section sufficient to deter violations, but in no event greater than 3 times the value received by the party that is reasonably attributable to violations of the Act. If no such value has been received by the brand name drug company, the civil penalty shall be not greater than three times the value given to the generic drug company reasonably attributable to violations of the Act. This subsection also lists factors the court is to consider in assessing the civil penalty under this section.

Sec. 28(h) provides definitions.

Subsection (b). This subsection provides that section 28 of the FTC Act applies to all agreements entered into after November 15, 2009. However, the civil penalty provision Sec. 28(g) does not apply to agreements entered into before the date of enactment of this Act.

Section 4. Notice and certification of agreements

This section requires settling parties to supplement their filing to the FTC under the Medicare Prescription Drug Improvement and Modernization Act of 2003, 21 U.S.C. § 355 (note), with any other agreement they enter into within 30 days of entering into that agreement. It also requires the Chief Executive Officer or sen-

ior executive responsible for a patent settlement agreement to certify that the filing is true, complete, and accurate.

Section 5. Forfeiture of 180-day exclusivity period

Under this section, generic drug companies violating the new section 28 of the FTC Act forfeit their right to a 180-day period of exclusivity of marketing of their generic drug.

Section 6. Commission litigation authority

This section allows the FTC to litigate cases and appeals under the new section 28 of the FTC Act under its own name, without a requirement that it first give the Attorney General the right to prosecute such an action.

Section 7. Statute of limitations

This section requires the FTC to bring any action to enforce section 28 of the FTC Act within three years of being notified of the agreement under the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Section 8. Severability

This section provides if any provision of this Act is found unconstitutional, the remainder of the Act will be unaffected.

IV. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

The Committee sets forth, with respect to the bill, S. 369, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

JANUARY 28, 2010.

Hon. PATRICK J. LEAHY,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 369, the Preserve Access to Affordable Generics Act. If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

S. 369—Preserve Access to Affordable Generics Act

Summary: S. 369 would impose significant restrictions on certain agreements to settle a claim of patent infringement between manufacturers of brand-name and generic drugs relating to the sale of a drug product. CBO anticipates that enacting S. 369 would accelerate, on average, the availability of lower-priced generic drugs affected by such agreements and generate savings to public and private purchasers of prescription drugs.

CBO estimates that implementing S. 369 would:

- Reduce direct spending by $0.7 billion over the 2010–2014 period and by $1.8 billion over the 2010–2019 period.

- Increase federal revenues by $0.1 billion over the 2010–2014 period and by $0.2 billion over the 2010–2019 period. (Social Security payroll taxes, which are off-budget, would account for almost 30 percent of those totals.)
- Reduce spending subject to appropriation by $0.1 billion over the 2010–2014 period and by $0.2 billion over the 2010–2019 period, assuming that appropriation action reflects the estimated reductions in costs.

Considering both the direct spending and revenue effects, CBO estimates that enacting S. 369 would reduce unified budget deficits by approximately $0.8 billion over the 2010–2014 period and by roughly $2.0 billion over the 2010–2019 period.

Pursuant to section 311 of S. Con. Res. 70 (110th Congress), CBO estimates that S. 369 would not cause a net increase in deficits in excess of $5 billion in any of the four 10-year periods beginning after fiscal year 2019.

S. 369 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

S. 369 would impose a mandate on the private sector by limiting agreements between brand-name and generic drug manufacturers to settle a claim of patent infringement. CBO estimates that the aggregate direct cost of complying with this mandate would exceed the threshold established by UMRA for private-sector mandates ($141 million in 2010, adjusted annually for inflation) in each year, beginning with 2010.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 369 is shown in the following table. The costs of this legislation fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

CBO expects that enacting S. 369 would accelerate, on average, the availability of generic drugs that are the subject of specific types of agreements to settle a claim of patent infringement between manufacturers of brand-name and generic drugs. The legislation would affect settlement agreements entered into after November 15, 2009, that involve certain kinds of compensation flowing from the manufacturer of a brand-name drug to the manufacturer of the generic version of the drug. Earlier entry of lower-priced generic drugs would reduce the average price of prescription drugs over the next 10 years. CBO expects that lower drug prices would reduce the costs of federal programs that purchase prescription drugs or provide health insurance that covers prescription drugs. CBO estimates that savings to mandatory health programs—such as Medicare and Medicaid and for health insurance provided to certain retirees by the Federal Employees Health Benefits (FEHB) program and TRICARE for Life program operated by the Department of Defense—would total $0.7 billion over the 2010–2014 period and $1.8 billion over the 2010–2019 period.

Lower prices would also generate savings to federal health programs subject to appropriation—such as health insurance provided to federal employees through the FEHB program, and the health programs of the Departments of Veterans Affairs and Defense—totaling $0.1 billion over the 2010–2014 period and $0.2 billion over the 2010–2019 period. CBO estimates that the Federal Trade Commission (FTC) would also realize discretionary savings because of

lower administrative expenses for the agency under the bill of $7 million over the 2010–2019 period.

	By fiscal year, in millions of dollars—											
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010–2014	2010–2019
CHANGES IN DIRECT SPENDING												
Estimated Budget Authority	−30	−170	−160	−170	−140	−120	−110	−220	−290	−340	−670	−1,750
Estimated Outlays	−30	−170	−160	−170	−140	−120	−110	−220	−290	−340	−670	−1,750
CHANGES IN REVENUES												
Effect from Health Insurance Premiums:												
On-budget	5	10	10	10	10	10	10	15	20	20	45	120
Off-budget	3	5	5	5	5	5	5	5	10	10	23	58
Subtotal	8	15	15	15	15	15	15	20	30	30	68	178
Collection of Civil Penalties	0	0	2	5	5	5	5	5	4	4	12	35
Total Changes in Revenues:												
On-budget	5	10	12	15	15	15	15	20	24	24	57	155
Off-budget	3	5	5	5	5	5	5	5	10	10	23	58
Total Changes	8	15	17	20	20	20	20	25	34	34	80	213
NET IMPACT ON THE DEFICIT FROM CHANGES IN DIRECT SPENDING AND REVENUES												
Net Change in the Deficit [1]												
On-budget	−35	−180	−172	−185	−155	−135	−125	−240	−314	−364	−727	−1,905
Off-budget	−3	−5	−5	−5	−5	−5	−5	−5	−10	−10	−23	−58
Total Changes	−38	−185	−177	−190	−160	−140	−130	−245	−324	−374	−750	−1,963
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Federal Health Programs:												
Estimated Authorization Level	−5	−20	−25	−20	−20	−15	−10	−25	−35	−35	−90	−210
Estimated Outlays	−5	−20	−25	−20	−20	−15	−10	−25	−35	−35	−90	−210
Federal Trade Commission:												
Estimated Authorization Level	*	*	*	−1	−1	−1	−1	−1	−1	−1	−2	−7
Estimated Outlays	*	*	*	−1	−1	−1	−1	−1	−1	−1	−2	−7
Total Changes:												
Estimated Authorization Level	−5	−20	−25	−21	−21	−16	−11	−26	−36	−36	−92	−217
Estimated Outlays	−5	−20	−25	−21	−21	−16	−11	−26	−36	−36	−92	−217

[1] Negative numbers indicate a reduction in budget deficits.
* = between 0 and −$500,000.

S. 369 would affect revenues in two ways. First, the bill would increase governmental receipts (i.e., revenues) because it would create new civil penalties for parties that violate the bill's requirements. Secondly, the bill would also affect revenues because CBO expects that lower prices for prescription drugs would reduce premiums for private health insurance and we assume that part of the savings from lower health insurance costs would be passed on to workers as increases in taxable compensation. Taken together, CBO estimates that the bill would increase federal revenues by $0.1 billion over the 2010–2014 period and by $0.2 billion over the 2010–2019 period.

Basis of estimate: S. 369 would impose significant restrictions on settlement agreements to resolve patent litigation between manufacturers of brand-name and generic drugs relating to the sale of a drug product. Under current law, such settlement agreements must be reported to the FTC. The FTC may challenge those agreements in court by alleging that they constitute an illegal restraint of trade.

S. 369 would limit agreements to settle a claim of patent infringement where the manufacturer of the generic version of the drug receives anything of value from the manufacturer of the brand name drug and the generic drug manufacturer agrees to limit or forego research, development, manufacturing, marketing, or sale of the generic drug for any period of time. The bill would allow the FTC to initiate an enforcement proceeding where such settlement agreements between drug companies would be presumed anti-competitive and unlawful; they would only be allowed if the parties can demonstrate by clear and convincing evidence that the competitive benefits of the agreement outweigh the anti-competitive effects of the agreement.

The bill, however, would permit a brand manufacturer to grant certain types of consideration to the manufacturer of the generic version of the drug under settlement agreements. Such exemptions include the right to market the generic drug before the expiration of patents or statutory exclusivities that aim to prevent such marketing. The legislation also would allow the FTC to establish additional exemptions through rulemaking procedures.

S. 369 also would establish significant penalties to deter parties from entering into certain settlement agreements. Such penalties include the assessment of civil penalties and the forfeiture by a violator of any rights to the award of 180 days of market exclusivity to the generic drug company granted such exclusivity by the Food and Drug Administration (FDA) for meeting certain statutory requirements. The new restrictions under S. 369 would apply to all agreements entered into after November 15, 2009. (Provisions relating to civil penalties, however, only apply to agreements entered into after the date of enactment.) For the estimate, CBO assumes that S. 369 will be enacted in early 2010.

Based on discussions with drug industry experts, CBO expects that limiting the compensation of manufacturers of generic drugs within settlement agreements between drug companies in the manner specified by S. 369 would lead to the earlier entry of some generic drugs. Since profits of manufacturers of brand-name drugs are so high relative to those of generic drug manufacturers, CBO believes that there is an incentive for brand manufacturers to com-

pensate generic manufacturers for delaying the availability of the generic drug within such agreements. If the generic company that is party to such an agreement is eligible for 180 days of marketing exclusivity, plans to enter the market by competing generic manufacturers could also be delayed.

Under the restricted terms of compensation allowed under S. 369, we anticipate that the expected date of market entry for generic drugs affected by such agreements, on average, would be earlier regardless of whether that date is ultimately determined by a court ruling (because the parties decide to litigate instead of settling with an agreement subject to those new terms) or by a different settlement agreement negotiated between the parties.

Direct Spending

Through imposing significant restrictions on certain types of compensation in agreements to settle a claim of patent infringement between manufacturers of brand-name and generic drugs, enactment of S. 369 would accelerate the availability of lower-priced generic drugs. CBO estimates that change would reduce federal direct spending for mandatory health programs such as Medicare, Medicaid, payments for annuitant premiums under the FEHB program, and the Defense Department's TRICARE for Life program by $0.7 billion over the 2010–2014 period and by $1.8 billion over the 2010–2019 period.

To estimate the savings from earlier entry of generics, CBO focused on the share of national spending for prescription drugs that might both face competition by generic products over the next 10 years and involve settlement agreements of patent litigation with terms of compensation limited by the bill. We assumed that those products make up roughly one-quarter of the current market that may face competition by generic drugs. (CBO estimates that the value of the total drug market in the United States that may experience generic competition through 2019 is greater than $100 billion.) Based on information from FTC, CBO assumes that S. 369 would accelerate the entry of generic drugs affected by the bill by roughly 17 months, on average. During that period, CBO expects that the availability of lower-priced generic drugs would reduce total spending for the drug by roughly one-half. After accounting for the fact that S. 369 would only restrict settlement agreements entered into after November 15, 2009, CBO estimates that earlier entry of generic drugs affected by the bill would reduce total drug expenditures in the United States by roughly $8 billion over the 2010–2019 period.

A settlement agreement with compensation flowing from the brand manufacturer to the generic manufacturer is just one of several possible outcomes to patent litigation. Limiting such settlement agreements would cause the expected rewards from challenging a patent to decline, on average. CBO expects that such a decline in expected returns would lead to fewer challenges of patents. In some instances, fewer generic challengers would lead to a higher average price following generic entry. CBO estimates that such price increases would increase total drug spending in the United States by roughly $2 billion over the 2010–2019 period. On net, CBO estimates that S. 369 would reduce total expenditures on

prescription drugs in the United States by about $6 billion over the 10-year period.

To estimate the net effect of the bill on federal spending by health programs that pay for prescription drugs, CBO applied the expected rate of savings generated nationally to each program. (We also took into account that prices paid by federal programs are generally lower than prices paid by private payers for brand-name prescription drugs.) CBO estimates that enacting S. 369 would reduce direct spending for federal health programs by $0.7 billion over the 2010–2014 period and by $1.8 billion over the 2010–2019 period.

Revenues

CBO estimates that enacting S. 369 would increase federal revenues by $0.1 billion over the 2010–2014 period and by $0.2 billion over the 2010–2019 period. That estimate reflects two effects:

- Higher federal tax revenues resulting from employers passing lower costs for employer-sponsored health insurance to workers as increases in taxable compensation; and
- Collection of civil penalties associated with violations of new requirements imposed by the bill that would be recorded as federal revenues.

Health Insurance Premiums. As explained above, CBO expects that enacting S. 369 would reduce the average cost for prescription drugs. That change would lower costs for private health insurance plans. CBO anticipates that the reduction in costs for private health insurance plans would result in lower insurance premiums, thus reducing the amount spent by employers for tax-favored health insurance and increasing the amount spent on taxable wages. That wage effect would increase federal revenues from income taxes and payroll taxes by an estimated $0.1 billion over the 2010–2014 period and $0.2 billion over the 2010–2019 period. Social Security payroll taxes, which are off-budget, would account for about 30 percent of those totals.

Collection of Civil Penalties. Under the bill, the FTC would have the authority to assess civil penalties on entities that enter into a settlement agreement that is subsequently ruled anti-competitive. The magnitude of those penalties would be tied to the value received by the parties to the agreement. CBO assumes that cases for which penalties would be assessed would take 2 or more years to resolve, thus we anticipate that the collection of penalties would start in 2012. CBO assumes that some firms would initially test the evidentiary standards for lawful agreements, and as those standards become clearer, fewer agreements would trigger penalties. Based on our estimates of profits garnered by firms who enter such agreements, CBO estimates that the bill would increase collections of civil penalties by about $35 million over the 2012–2019 period.

SPENDING SUBJECT TO APPROPRIATION

CBO estimates that implementing S. 369 would reduce spending subject to appropriation by $0.1 billion over the 2010–2014 period and by $0.2 billion over the 2010–2019 period.

Spending by Federal Health Programs for Prescription Drugs. Accelerating the entry of the lower-priced generic drugs would reduce the costs to administer certain discretionary health programs,

including those of the Veterans Health Administration, the Indian Health Service, and the Department of Defense. It also would lower payments by federal agencies for health insurance premiums for employees enrolled in the FEHB program. CBO estimates that implementing S. 369 would reduce discretionary spending by those programs by about $0.1 billion over the 2010–2014 period and by $0.2 billion over the 2010–2019 period, assuming that appropriation actions reflect the estimated reductions in costs.

Administrative Costs of the Federal Trade Commission. Based on information from the FTC, CBO expects that the agency's rulemaking and enforcement activities relating to settlement agreements between drug companies would decrease over time as the number of settlements requiring enforcement activities declines. CBO estimates that any resulting cost reductions would be insignificant for the first three years after enactment of S. 369; thereafter, CBO estimates the agency's costs would be reduced by about $1 million per year. Assuming that appropriation actions reflect these reductions, CBO estimates that discretionary spending would fall by about $2 million over the 2010–2014 period and by $7 million over the 2010–2019 period.

Estimated impact on State, local, and tribal governments: S. 369 contains no intergovernmental mandates as defined in UMRA. CBO estimates that enactment of this bill would result in a decline in State Medicaid spending of less than $50 million over the 2010–2014 period.

Estimated impact on the private sector: S. 369 would impose a mandate on brand-name and generic drug manufacturers by limiting agreements to settle a claim of patent infringement if, in those agreements, the generic manufacturer receives anything of value and agrees to limit or forgo research, development, manufacturing, marketing, or sale of the generic drug for any period of time. Such agreements would be presumed illegal unless drug manufacturers present clear and convincing evidence that the competitive benefits of the agreement outweigh the anticompetitive effects.

CBO anticipates that limiting such agreements would result in earlier generic entry into the market and, as a result of lower drug prices, decreased profits for drug manufacturers. Under UMRA, the cost of this mandate to drug manufacturers would be the forgone profit, which CBO estimates to be about $350 million in 2010 and $2.4 billion over the 2010–2014 period. Thus, the costs of the mandate would significantly exceed the threshold established by UMRA for private-sector mandates ($141 million in 2010, adjusted annually for inflation).

Previous CBO estimate: On November 20, 2009, CBO transmitted a cost estimate for H.R. 3962, the Affordable Health Care for America Act, as passed by the House of Representatives on November 7, 2009. H.R. 3962 also contains a provision that would impose restrictions on certain settlement agreements between manufacturers of brand-name and generic drugs. (That provision can be found in section 2573 of the bill.)

Differences in the estimated costs of the provision in H.R. 3962 and S. 369 reflect differences in the legislation. A key difference in the proposals is that the provision in H.R. 3962 would not allow the parties the opportunity to demonstrate that the competitive benefits of the settlement agreement outweigh the anticompetitive

effects. CBO's estimate for the provision in H.R. 3962 also reflects interactions with other policies in the bill (such as the expansion of health insurance coverage and other drug policies.)

Estimate prepared by: Federal Spending: Federal Health Programs—Julia Christensen and Anna Cook, Federal Trade Commission—Susan Willie; Federal Revenues: Zachary Epstein; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Patrick Bernhardt and Anna Cook

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

V. Regulatory Impact Evaluation

In compliance with rule XXVI of the Standing Rules of the Senate, the Committee finds that no significant regulatory impact will result from the enactment of S. 369.

VI. Conclusion

The Preserve Access to Affordable Generics Act, S. 369, will prevent anticompetitive pharmaceutical patent settlement agreements between brand name and generic drug companies. This legislation will provide the FTC with a strong remedy to block anticompetitive patent settlements that harm consumers, and also provide a strong deterrent against drug companies entering into these agreements in the first place.

VII. MINORITY VIEWS

MINORITY VIEWS OF SENATORS SESSIONS, HATCH, KYL, CORNYN, AND COBURN

Although this bill has been substantially improved since it was first introduced, we cannot support it in its current form. The original bill would have created a per se violation of the antitrust laws where the parties to a drug patent infringement suit settle the suit in a way that gives something of value to the generic company other than the right to go to market earlier. The reported bill replaces an express per se ban with a presumption that such agreements are anticompetitive and invalid. Because of the way that the bill enforces that presumption, however, we believe that the bill would amount to a de facto per se ban on covered settlements—and would entail all of the evils attendant to a per se ban.

To be clear, we would support creating a legal presumption against drug patent settlements—in effect, requiring the parties to such settlements to show why the terms of the settlement are reasonable and will not harm consumers. Such a test would require the parties to explain what consideration is being transferred between them under the agreement, to estimate the value of that consideration, and to give a neutral and legitimate reason for the exchange. We think that such a test would ferret out settlements that are anticompetitive and designed simply to delay generic market entry, while still allowing the parties to enter into settlements that are reasonable.

For a legal-presumption rule to work, however, the parties must be afforded a forum in which they can quickly and fairly test whether they have overcome the presumption and whether the agreement is valid. Unfortunately, under the reported bill, settlements would be made presumptively unlawful, but the bill does not create a process for quickly resolving whether the agreement is unlawful. The issue would not be resolved until the FTC brings an action to challenge the settlement, which could be years after the settlement was entered into. Moreover, the current bill requires the brand and generic companies to rebut the presumption that the agreement is unlawful by clear and convincing evidence. This is a heavy burden that is not appropriate for commercial litigation and that tilts the scales in a lawsuit sharply in the government's favor.

As a practical matter, few companies will ever agree to subject their settlements to the reported bill's procedures. Generic and brand companies simply are not going to take the risk that, years after they have entered into a settlement, they will be sued by the FTC, will be unable to overcome the presumption of invalidity by clear and convincing evidence, and will have their agreement declared invalid and will be subjected to treble damages. Parties

enter into settlement agreements so that they can have legal certainty. There is no certainty—and no reason to enter into the settlement—if the agreement will be presumed unlawful, with no way to promptly determine whether the presumption of invalidity has been overcome.

Parties also settle cases so that they can avoid the burden and expense of litigation. The reported bill invites the parties to end their litigation against each other, only to begin years of discovery and litigation against the FTC.

In its practical effect, the bill reported by this committee still amounts to a per se ban on settlements of patent-infringement suits between brand and generic companies.

We are opposed to a per se ban. There are many valid reasons for a generic drug company to settle a patent infringement suit for things of value other than the right to go to market earlier. In the course of discovery and litigation, the generic company may conclude that the patent that it is challenging is fairly strong, and that it only has a 10% chance of winning. It thus makes sense for the generic company to settle for a modest amount of money (an amount that reflects the 10% chance of winning) rather than litigating to conclusion. And in this situation, the brand company who owns the patent may be unwilling to let the generic company go to market earlier—if that company thinks that it will win the infringement suit, it will be better off litigating the case rather than giving the generic company part of its valuable monopoly. This puts the generic company in a terrible position, where it can either continue what is very likely pointless litigation, or walk away with nothing.

By effectively preventing the parties from settling, it is likely that this bill will discourage generic drug companies from bringing challenges to brand companies' patents in the first place—and as a result, the bill will ultimately reduce competition and raise prices for drugs that are currently subject to invalid or low-quality patents.

This point is brought into relief in a letter that Senator Sessions recently received from Wockhardt USA, a smaller generic drug company that is based in New Jersey.[1] The letter describes the considerable expense borne by a generic drug company in challenging a brand company's patent: "Patent challenges already cost approximately $4 to $7 million to pursue, and with upwards of 5 challenges occurring at any one time (at least for Wockhardt), the costs can get out of control quite quickly." As a result, generic companies must think carefully about whether to bring suit—and they rely on the possibility of settlement when making their decision:

> Since Wockhardt and other similarly situated companies must marshal limited resources, a thorough cost versus risk analysis must be conducted before committing to bringing suit against a well-funded branded company. Integral to that analysis is consideration of the possibility of settlement.

[1] A copy of this letter is included as an attachment to these views.

This particular generic drug company takes a dim view of the impact that this bill will have on its ability to challenge brand patents and bring generic drugs to market. First it notes that it is often difficult if not impossible for parties to settle if they only are allowed to do so by allowing the generic to go to market earlier:

> the overly simplistic view adopted by this legislation fails to take into account the different positions of the parties on a number of critical issues to any settlement discussion: risk aversion, financial resources, underlying knowledge of the strength of a patent and other variables, such as knowledge of the market. The differences in perception on these and other issues and their effect on parties coming to an agreement on an appropriate entry date will most certainly make it very difficult, and perhaps impossible, to reach a settlement.

The letter contends that as a result, the committee-reported bill will effectively deter generic drug companies—particularly small ones—from bringing challenges to branded drugs in the first place:

> effective removal of settlement as an option, as contemplated by S. 369, significantly complicates the risk analysis currently undertaken and leaves small manufacturers with insufficient incentive to pursue challenges except in the clearest (and rarest) of cases where the cost would almost certainly be rewarded.

This particular company has concluded that "S. 369, in its current form, would chill competition, discourage generic challenges and subsequently drive up the cost of affordable medicines."

Obviously, this result is the exact opposite of that which this bill is intended to achieve. It nevertheless seems that there is a high risk, if not outright likelihood, that the bill in its current form will achieve exactly this result. By preventing parties that disagree on the strength of a patent and other key factors from settling a suit, the bill will deter generic companies from embarking on the expensive path of challenging a brand patent in the first place, and will ultimately result in fewer generic drugs entering the market.

Again, there is much with regard to this bill that the sponsors and we agree on: brand-generic patent settlements should be subject to careful scrutiny, and it is appropriate to create a presumption against such settlements and force the parties to provide a legitimate justification for all of the consideration being exchanged. But by failing to provide for prompt resolution of whether a settlement is invalid, and by stacking the deck against the settling parties, this bill amounts to an effective per se ban on settlements. Such a ban would benefit neither the companies nor consumers. It would ultimately reduce generic market entry and raise prices for consumers—a result that we think all would agree is to be avoided.

JEFF SESSIONS.
ORRIN HATCH.
JON KYL.
JOHN CORNYN.
TOM COBURN.

ATTACHMENT TO MINORITY VIEWS OF SENATORS SESSIONS, HATCH, KYL, CORNYN, AND COBURN

WOCKHARDT,
PARSIPPANY, NJ,
November 2, 2009.

Re The Preserve Access to Affordable Generic Drugs Act (S. 369).

Hon. PATRICK LEAHY,
Chairman, Senate Judiciary Committee,
Washington, DC.

DEAR MR. CHAIRMAN: I am the Senior Vice President and Head of Global Legal Affairs for Wockhardt, a global pharmaceutical and biotechnology company. Wockhardt, through its subsidiaries in Parsippany, New Jersey and Morton Grove, Illinois, is an active participant in the United States generic pharmaceuticals market. We take great pride in our role in saving American consumers and taxpayers billions of dollars each year in prescription drug costs, and it is in that spirit that I write to you today to express my deep reservations about 8.369, "The Preserve Access to Affordable Generic Drugs Act".

Given that most of the pharmaceutical companies with a "presence" in Washington generate significantly more revenue than Wockhardt, we felt it critical to provide another perspective—that of a smaller generic whose strategy and decision-making process will most certainly and significantly be adversely affected by S. 369. In theory, and according to its proponents, S. 369 will reduce the anti-consumer practice of brand-name drug manufacturers using "pay-off" agreements to keep cheaper generic equivalents off the market by making such practices presumptively illegal. While this may look promising in theory, in practice, this overly broad and sweeping approach will cause a significant decline in patent challenges in the United States, resulting in strengthened market monopolies for branded companies and, unfortunately, limited competition.

What is most surprising about the evolution of this particular legislation is the legal standard that has somehow found its way into the analysis. Looking back throughout history, with a particular focus on antitrust law, courts traditionally apply a per se rule only when considerable judicial experience identifies a category of conduct that almost invariably reduces output and raises price. In the present situation, however, the proponents of S. 369 do not seem to be advocating this legislation because they seek to codify an emerging judicial consensus about a harmful category of conduct. In fact, the situation is quite the opposite. A review of the legal landscape over the past several years reveals that there is a growing judicial consensus that many of these settlements are not categorically problematic. Many economists, jurists and legal scholars have studied, analyzed and evaluated these settlements and consistently concluded that there are obvious pro-consumer effects to these settlements. Even the Federal Trade Commission ("FTC"), at one time, has joined in this conclusion. Former FTC Chairman Deborah Platt Majoras acknowledged this in stating, "Undoubtedly, there can be significant pro-competitive benefits of settling patent litigation between brand and generic manufacturers. Further, we recognize the importance of settlements generally to the judicial system." Neither these "significant procompetitive benefits" nor the understanding that the per se standard is inappropriate is reflected in the FTC's current support of S. 369. I would submit that simply because a settlement between a brand and generic company has the potential to have an anti-competitive effect, does not warrant this type of shift, while seemingly completely ignoring the benefits these types of agreements have had on the cost of health care in this country to date.

S. 369, for all practical purposes, enacts a per se standard by shifting the burden to companies entering into a settlement to prove, by clear and convincing evidence, that a settlement is pro-competitive, and it would remove from the trier of fact the ability to determine whether a patent is valid and a valuable intellectual property right. Together, these burdens would add layers of cost, time, and risk to the current process, substantially harming small generic manufacturers' ability to aggressively pursue challenges. Since Wockhardt and other similarly situated companies must marshal limited resources, a thorough cost versus risk analysis must be conducted before commiting to bringing suit against a well-funded branded company. Integral to that analysis is consideration of the possibility of settlement.

Determining whether to challenge a patent is often exacerbated by the complexity of the products and patents at issue, and the outcomes of even the best cases are uncertain. As such, effective removal of settlement as an option, as contemplated by S. 369, significantly complicates the risk analysis currently undertaken and leaves small manufacturers with insufficient incentive to pursue challenges except

in the clearest (and rarest) of cases where the cost would almost certainly be rewarded. It simply cannot be assumed that brand and generic companies will even be able to reach agreements moving forward under this legislation.

As various critics of this proposed legislation have pointed out, the overly simplistic view adopted by this legislation fails to take into account the different positions of the parties on a number of critical issues to any settlement discussion: risk aversion, financial resources, underlying knowledge of the strength of a patent and other variables, such as knowledge of the market. The differences in perception on these and other issues and their effect on parties coming to an agreement on an appropriate entry date will most certainly make it very difficult, and perhaps impossible, to reach a settlement.

In fact, this sort of incentive re-alignment is out of sync with the balancing of rights originally sought under the Hatch-Waxman statute. Inherent and systemic conflicts will always exist between patent law and antitrust law, but the Hatch-Waxman statute was and continues to be successful in challenging monopolies in the interest of American consumers. However, if faced with the risks and costs associated with settlement under S. 369, generic companies will have to make an earlier and very complicated assessment as to whether to challenge a patent and how much it will cost to litigate that case all the way through appeal. With the shifting of the burden, there will be no result other than a substantial increase in expenses and litigation budgets (not to mention additional waste of judicial resources), which cannot be sustained by companies like Wockhardt. Patent challenges already cost approximately $4 to $7 million to pursue, and with upwards of 5 challenges occurring at any one time (at least for Wockhardt), the costs can get out of control quite quickly. We will have to evaluate very closely whether we can sustain our current program should this legislation be implemented.

In fact, the costs noted above appear not to factor in costs associated with trying to prove to a trier of fact that a settlement is pro-competitive. It is not at all clear how the process is to work and how it will be implemented, but one thing is certain: these additional layers of significant time, cost and risk will cause Wockhardt and similarly situated generic companies to challenge fewer patents. Fewer patent challenges will result in fewer product offerings and will most certainly adversely impact the downward pressure on drug prices associated with multiple generic entrants.

To provide some perspective, Wockhardt, despite our relatively small market share, received 23 Abbreviated New Drug Application ("ANDA") approvals from the FDA in 2008 alone, placing us, we believe, among the top 5 companies in the world in that regard. Since 2005, we have filed 106 ANDAs with the FDA, 14 of which have resulted in litigation and several of which having been settled in the past eighteen months. Those settlements each will result in our launching of the generic product in advance of the expiration date associated with the relevant patents. However, should S. 369 be implemented, our number of challenges will most certainly shrink significantly due to the factors previously set forth above. For context, think about a market with only two or three participants, as opposed to four, five, six or greater.

In conclusion, one observer noted that public policy must "take into account and balance all three relevant social policies—pro-competition, pro-patent and pro-settlement—and formulate rules leading to the lowest net social cost when all relevant costs are factored." (Daniel A. Cranem Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 FLA. L. REV. 747, 750 (2002)). While the current regulatory framework encourages patent challenges and rewards generic companies for engaging in the research and development and litigation necessary to bring products to market and lower the prices of medicines, S. 369, in its current form, would chill competition, discourage generic challenges and subsequently drive up the cost of affordable medicines.

Thank you for considering our views.

Sincerely,

JEROME D. JABBOUR.

MINORITY VIEWS FROM SENATOR HATCH

For years, the Senate Judiciary Committee has been considering legislation that would curtail abuses that may exist in the way pharmaceutical companies enter into patent litigation settlements. Unfortunately, in an effort to curb anti-consumer practices, the proponents of the Preserve Access to Affordable Generics Act (S. 369) fail to acknowledge that consumers benefit when generic and brand companies are able to set aside reasonable differences and reach agreements that allow generics to enter the marketplace earlier.

When Representative Henry Waxman and I were drafting the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act," we created a system that allows generic manufacturers to challenge patents when they believe the patents should not prevent them from entering the market and we provided them incentives to make every effort to get to the market early. There is no doubt that consumer access to generic medicines is expedited any time these important products come to market prior to the patents expiring.

What seems to have been forgotten during consideration of S. 369 is the reality that patent litigation settlements between brand and generic drug companies give consumers the ability of using generic drugs earlier than can be anticipated. In other words, generic competition is infused into the market sooner rather than later—providing savings to the health care system. This was the purpose of the Hatch-Waxman Act, and it has worked. Consequently, it is important that before we change the law, we have a clear understanding of the proposed legislation and a complete appreciation of the consequences of its implementation.

While it is true that S. 369 no longer has a bright-line rule that all settlements are per se illegal, the hurdles that would be imposed on settling parties could effectively discourage proconsumer settlements. Specifically, the legislation provides that certain patent settlement agreements are presumed to have anti-competitive effects and are unlawful. That presumption can only be overcome if the parties demonstrate by "clear and convincing" evidence that the precompetitive benefits of the agreement outweigh the anti-competitive effects. This high burden of proof creates a strong disincentive for parties to settle. Additionally, the "clear and convincing evidence" standard, as opposed to the traditional preponderance of the evidence standard, gives the Federal Trade Commission (FTC) an unprecedented and unfair amount of discretion. It unduly benefits the Commission by making it very difficult for companies to rebut the presumption even in cases that have merit.

Adding to the power of the FTC is the fact that S. 369 requires violators to pay a civil penalty of up to three times the value of the consideration given to the generic manufacturer. Historically the

FTC has used injunctions and disgorgement as enforcement tools. The authority under S. 369 to penalize drug manufacturers by making them pay potentially millions of dollars in fines is overbroad and unnecessary.

If S. 396 is enacted in its current form, generic companies that might have brought actions in the past and ultimately settled for early entry may be deterred from doing so. Moreover, the bill could create uncertainty among industry participants, their investors, and the public. And that uncertainty—as to the duration of patent protection, ability to resolve good faith disputes, and investment in new applications for existing medicines—will have a significant adverse impact on innovation and the quality of health care in the United States.

ORRIN G. HATCH.

VIII. CHANGES TO EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 369, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

TITLE 15—COMMERCE AND TRADE

* * * * * * *

CHAPTER 2—FEDERAL TRADE COMMISSION; PROMOTION OF EXPORT TRADE AND PREVENTION OF UNFAIR METHODS OF COMPETITION

SUBCHAPTER I—FEDERAL TRADE COMMISSION

FEDERAL TRADE COMMISSION ACT (15 U.S.C. §§ 41 et seq.)

* * * * * * *

SEC. 16 (15 U.S.C. § 58). COMMENCEMENT, DEFENSE, INTERVENTION, AND SUPERVISION OF LITIGATION AND APPEAL BY COMMISSION OR ATTORNEY GENERAL

(a) PROCEDURE FOR EXERCISE OF AUTHORITY TO LITIGATE OR APPEAL.—

(1) Except as otherwise provided in paragraph (2) or (3), if—

(A) before commencing, defending, or intervening in, any civil action involving this subchapter (including an action to collect a civil penalty) which the Commission, or the Attorney General on behalf of the Commission, is authorized to commence, defend, or intervene in, the Commission gives written notification and undertakes to consult with the Attorney General with respect to such action; and

(B) the Attorney General fails within 45 days after receipt of such notification to commence, defend, or intervene in, such action;

the Commission may commence, defend, or intervene in, and supervise the litigation of, such action and any appeal of such action in its own name by any of its attorneys designated by it for such purpose.

(2) Except as otherwise provided in paragraph (3), in any civil action—

(A) under section 53 of this title (relating to injunctive relief);

(B) under section 57b of this title (relating to consumer redress);

(C) to obtain judicial review of a rule prescribed by the Commission, or a cease and desist order issued under section 45 of this title;

(D) under the second paragraph of section 49 of this title (relating to enforcement of a subpena) and under the

fourth paragraph of such section (relating to compliance with section 46 of this title); [or]

(E) under section 57b–2a of this title; *or*

(F) under section 28;

the Commission shall have exclusive authority to commence or defend, and supervise the litigation of, such action and any appeal of such action in its own name by any of its attorneys designated by it for such purpose, unless the Commission authorizes the Attorney General to do so. The Commission shall inform the Attorney General of the exercise of such authority and such exercise shall not preclude the Attorney General from intervening on behalf of the United States in such action and any appeal of such action as may be otherwise provided by law.

(3)(A) If the Commission makes a written request to the Attorney General, within the 10-day period which begins on the date of the entry of the judgment in any civil action in which the Commission represented itself pursuant to paragraph (1) or (2), to represent itself through any of its attorneys designated by it for such purpose before the Supreme Court in such action, it may do so, if—

(i) the Attorney General concurs with such request; or

(ii) the Attorney General, within the 60-day period which begins on the date of the entry of such judgment—

(I) refuses to appeal or file a petition for writ of certiorari with respect to such civil action, in which case he shall give written notification to the Commission of the reasons for such refusal within such 60-day period; or

(II) the Attorney General fails to take any action with respect to the Commission's request.

(B) In any case where the Attorney General represents the Commission before the Supreme Court in any civil action in which the Commission represented itself pursuant to paragraph (1) or (2), the Attorney General may not agree to any settlement, compromise, or dismissal of such action, or confess error in the Supreme Court with respect to such action, unless the Commission concurs.

(C) For purposes of this paragraph (with respect to representation before the Supreme Court), the term "Attorney General" includes the Solicitor General.

(4) If, prior to the expiration of the 45-day period specified in paragraph (1) of this section or a 60-day period specified in paragraph (3), any right of the Commission to commence, defend, or intervene in, any such action or appeal may be extinguished due to any procedural requirement of any court with respect to the time in which any pleadings, notice of appeal, or other acts pertaining to such action or appeal may be taken, the Attorney General shall have one-half of the time required to comply with any such procedural requirement of the court (including any extension of such time granted by the court) for the purpose of commencing, defending, or intervening in the civil action pursuant to paragraph (1) or for the purpose of refusing to appeal or file a petition for writ of certiorari and the

written notification or failing to take any action pursuant to paragraph 3(A)(ii).

(5) The provisions of this subsection shall apply notwithstanding chapter 31 of Title 28, or any other provision of law.

(b) CERTIFICATION BY COMMISSION TO ATTORNEY GENERAL FOR CRIMINAL PROCEEDINGS.—Whenever the Commission has reason to believe that any person, partnership, or corporation is liable for a criminal penalty under this subchapter, the Commission shall certify the facts to the Attorney General, whose duty it shall be to cause appropriate criminal proceedings to be brought.

(c) FOREIGN LITIGATION.—

(1) COMMISSION ATTORNEYS.—With the concurrence of the Attorney General, the Commission may designate Commission attorneys to assist the Attorney General in connection with litigation in foreign courts on particular matters in which the Commission has an interest.

(2) REIMBURSEMENT FOR FOREIGN COUNSEL.—The Commission is authorized to expend appropriated funds, upon agreement with the Attorney General, to reimburse the Attorney General for the retention of foreign counsel for litigation in foreign courts and for expenses related to litigation in foreign courts in which the Commission has an interest.

(3) LIMITATION ON USE OF FUNDS.—Nothing in this subsection authorizes the payment of claims or judgments from any source other than the permanent and indefinite appropriation authorized by section 1304 of Title 31.

(4) OTHER AUTHORITY.—The authority provided by this subsection is in addition to any other authority of the Commission or the Attorney General.

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SEC. 28 (15 U.S.C. § 58). *PRESERVING ACCESS TO AFFORDABLE GENERICS*

(a) IN GENERAL.—

(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

(2) PRESUMPTION.—

(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

(i) an ANDA filer receives anything of value; and

(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the pro-competitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

'(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

(4) the revenue the ANDA filer would have received by winning the patent litigation;

(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

(6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and

(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the fact finder's determination under this section.

(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

(1) The right to market the ANDA product in the United States prior to the expiration of—

(A) any patent that is the basis for the patent infringement; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

(e) REGULATIONS AND ENFORCEMENT.—

(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will further market competition and benefit consumers. Judicial review of any such regulation shall be in the

United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 C.F.R. 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit or supersede the right of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

(g) PENALTIES.—

(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the NDA holder, the penalty to the NDA holder shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

(2) CEASE AND DESIST.—

(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such

person, partnership or corporation at any time before the expiration of one year after such order becomes final pursuant to section 5(g).

(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

(A) the nature, circumstances, extent, and gravity of the violation;

(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

(C) other matters that justice requires.

(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

(h) DEFINITIONS.—In this section:

(1) AGREEMENT.—The term "agreement" means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term "agreement resolving or settling a patent infringement claim" includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

(3) ANDA.—The term "ANDA" means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(4) ANDA FILER.—The term "ANDA filer" means a party who has filed an ANDA with the Food and Drug Administration.

(5) ANDA PRODUCT.—The term "ANDA product" means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

(6) DRUG PRODUCT.—The term "drug product" means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

(7) NDA.—The term "NDA" means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(8) NDA HOLDER.—The term "NDA holder" means—

(A) the party that received FDA approval to market a drug product pursuant to an NDA;

(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA; or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(9) PATENT INFRINGEMENT.—The term "patent infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

(10) PATENT INFRINGEMENT CLAIM.—The term "patent infringement claim" means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

(11) STATUTORY EXCLUSIVITY.—The term "statutory exclusivity" means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act .

(b) EFFECTIVE DATE.—Section 28 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 28(a)(1) of that Act entered into after November 15, 2009. Section 28(g) of the Federal Trade Commission Act, as added by this section, shall not apply to agreements entered into before the date of enactment of this Act.

SEC. *29.*

This subchapter may be cited as the "Federal Trade Commission Act".

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TITLE 21—FOOD AND DRUGS

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CHAPTER 9—FEDERAL FOOD, DRUG AND COSMETICS ACT

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SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

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§ 355. New Drugs

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(j) ABBREVIATED NEW DRUG APPLICATIONS.—

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(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating

that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under *section 271(e)(4)(A) of Title 35*;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which

an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or *section 355a* of this title, or there is a 7-year period of exclusivity for the listed drug under *section 360cc* of this title.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under *section 2201 of Title 28*, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with *section 2201 of Title 28*, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated *section 28 of the Federal Trade Commission Act or* the antitrust laws (as defined in *section 12 of Title 15*, except that the term includes *section 45 of Title 15* to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safe-

ty and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

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Historical and Statutory Notes

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Amendments

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Federal Trade Commission Review

Pub. L. 108–173, Title XI, 1111 to 1118, Dec. 8, 2003, 117 Stat. 2461–64, provided that:

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section

505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act [subsec. (j)(2)(A)(vii)(IV) of this section] and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c) [of this note]. The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act [subsec. (j)(5)(B)(iv) of this section] as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act [subsec. (j)(2)(A)(vii)(IV) of this section] with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c) [of this note]. The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act [subsec. (j)(5)(B)(iv) of this section] as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) [of this note] to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) [of this note] to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and [the Commission the] *the Commission—*

(A) the agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to

an agreement that is required in subsection (a) or (b) [of this note] to be filed in accordance with this subsection**[**.**]***; and*

(B) any other agreements the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) [of this note] to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include 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."

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