Calendar No. 431

107TH CONGRESS
2d Session

SENATE

REPORT
107–167

THE DRUG COMPETITION ACT OF 2001

JUNE 20, 2002.—Ordered to be printed

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

R E P O R T

[To accompany S. 754]

The Committee on the Judiciary, to which was referred the bill (S. 754) to enhance competition for prescription drugs by increasing the ability of the Department of Justice and the Federal Trade Commission to enforce existing antitrust and competition laws regarding brand name drugs and generic drugs, having considered the same, reports favorably thereon, with an amendment in the nature of a substitute, and recommends that the bill, as amended, do pass.

CONTENTS

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Competition Act of 2001".

SEC. 2. FINDINGS.

Congress finds that—

(1) prescription drug prices are increasing at an alarming rate and are a major worry of many senior citizens and American families;

(2) there is a potential for companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competition and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs; and

(2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.

SEC. 4. DEFINITIONS.

In this Act:

(1) ANDA.—The term "ANDA" means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) ASSISTANT ATTORNEY GENERAL.—The term "Assistant Attorney General" means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BRAND NAME DRUG.—The term "brand name drug" means a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)).

(4) BRAND NAME DRUG COMPANY.—The term "brand name drug company" means the party that received Food and Drug Administration approval to market a brand name drug pursuant to an NDA, where that drug is the subject of an ANDA, or a party owning or controlling enforcement of any patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations of the Food and Drug Administration for that drug, under section 505(b) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(5) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(6) GENERIC DRUG.—The term "generic drug" means a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(7) GENERIC DRUG APPLICANT.—The term "generic drug applicant" means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(8) NDA.—The term "NDA" means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) et seq.).

SEC. 5. NOTIFICATION OF AGREEMENTS.

(a) IN GENERAL.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of the application entering the market, shall each file the agreement as required by subsection (b).

(2) DEFINITION.—An agreement described in this paragraph is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant's ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) FILING.—

(1) AGREEMENT.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand name drug company shall not be required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts; or

(C) employment or consulting contracts.

(2) OTHER AGREEMENTS.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall

file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this Act.

(3) DESCRIPTION.—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

SEC. 6. FILING DEADLINES.

Any filing required under section 5 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 7. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this Act shall be exempt from disclosure under section 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 8. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this Act shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this Act. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company or generic drug applicant fails to comply with any provision of this Act, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission. Equitable relief under this subsection may include an order by the district court which renders unenforceable, by the brand name drug company or generic drug applicant failing to file, any agreement that was not filed as required by this Act for the period of time during which the agreement was not filed by the company or applicant as required by this Act.

SEC. 9. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United State Code, consistent with the purposes of this Act—

(1) may define the terms used in this Act;

(2) may exempt classes of persons or agreements from the requirements of this Act; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this Act.

SEC. 10. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this Act shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any other provision of law, nor shall any filing under this Act constitute or create a presumption of any violation of any antitrust or competition laws.

SEC. 11. EFFECTIVE DATE.

This Act shall—

(1) take effect 30 days after the date of enactment of this Act; and

(2) shall apply to agreements described in section 5 that are entered into 30 days after the date of enactment of this Act.

I. LEGISLATIVE HISTORY

The Drug Competition Act was introduced into the 106th Congress by Senator Leahy on July 27, 2000. Senators Kohl, Schumer, and Durbin joined Senator Leahy as original co-sponsors. No action

was taken on the bill in the 106th Congress, and it was re-introduced in the 107th Congress on April 6, 2001. Senators Feingold, Cantwell, and Grassley have also co-sponsored the bill. The bill was referred to the Committee on the Judiciary.

On October 18, 2001, a motion to favorably report S. 754 was approved unanimously by the Judiciary Committee. The Committee received the Congressional Budget Office analysis, found on pages 7 through 13 of this report, February 2002.

II. THE NEED FOR S. 754

The pharmaceutical industry has been able to reap significant profits by selling vitally important drugs to all consumers, especially senior citizens. However, the industry has recently witnessed the creation of 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. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives. S. 754, along with its companion House bill, H.R. 1530, is designed to put an end to this exploitation of the provision in Hatch-Waxman that grants a short-term protection from competition to the first manufacturer to bring a generic version of a brand name drug to market.

Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices. The law as it stands gives temporary protection from competition to the first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug. The Federal Trade Commission reports that some firms are exploiting that provision of law by entering into secret deals to allow a maker of the generic drug to claim the 180-day grace period in order to block other generic drugs from entering the market, while at the same time getting paid by the brand name manufacturer for withholding sales of the generic version.

S. 754 (and H.R. 1530) would protect consumers by solving the most difficult problem faced by Federal antitrust investigators: learning about the worst of these improper deals in time to do something about them. As Molly Boast, then-Director of the Commission's Bureau of Competition, testified at a May 24, 2001 Judiciary Committee hearing entitled "Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements", the notice that these bills would provide "could be quite helpful in the enforcement mission." The bills would expose the deals abusing the Hatch-Waxman period of protection from competition and subject them to immediate investigation by the Commission or the Department of Justice. And as Ms. Boast also testified, such a regime "might deter the [anticompetitive] agreements outright, but it also certainly would force the firms who were contemplating those agreements to give them much more careful scrutiny for potentially offensive provisions."

The Drug Competition Act of 2001 would facilitate these agencies' confidential review of agreements between brand name manufacturers and potential generic competitors so the agencies could more efficiently, and more effectively, ensure that the antitrust

laws are not being violated. It covers agreements entered into between a company that owns or controls any listed patent for the brand name drug, or that itself is the holder of the "New Drug Application" under the Food and Drug Administration's rules—usually the manufacturer of the brand name drug—and any company that seeks to manufacture the generic version of that drug (but has not yet entered the market), when the agreement concerns the manufacture, marketing, or sale of either the brand name or generic versions of the drug, or when the agreement relates to the 180-day period of protection from competition under Hatch-Waxman. Thus, any agreement that seeks to take advantage of, or inappropriately influence, the 180-day period of protection for a generic manufacturer from competition prescribed by Hatch-Waxman is covered; the Act does not limit its reach to agreements just between the brand name manufacturer and the generic company likely to be its first competitor. Moreover, the burden the Act places on pharmaceutical companies is negligible; it simply requires the firms to file those agreements with the Commission and Department of Justice within 10 business days after the agreement is executed. Failure to file is punishable by a civil penalty of up to $11,000 per day, and by possible unenforceability of the agreements they concern. The bills would not change the Hatch-Waxman Act, amend FDA law or slow down the drug approval process, and existing confidentiality requirements would still apply to the enforcement agencies.

III. VOTE OF THE COMMITTEE

In compliance with paragraph 7(b) of rule XXVI of the Standing Rules of the Senate, the following statements are made concerning the roll call votes in the Committee's consideration of the bill.

S. 754 was ordered reported favorably, as amended by an amendment in the nature of a substitute, by a unanimous voice vote on October 18, 2001. A quorum was present.

IV. SECTION-BY-SECTION ANALYSIS

Section 1.—Section 1 sets out the short title of this bill, the "Drug Competition Act of 2001."

Section 2.—Section 2 states the findings upon which this legislation is based. Specifically, the findings are that rapidly increasing prescription drug costs are creating real problems for American senior citizens and families, that patent holders for brand name drugs can engage in private agreements with generic drug companies that both decrease competition and increase costs for prescription drugs, and that enhancing competition between brand name and generic drug companies can significantly reduce prescription drug costs.

Section 3.—Section 3 states the purposes of this legislation, which are to ensure timely notice to the antitrust enforcement agencies—the Department of Justice and the Federal Trade Commission—regarding agreements between companies with patent rights on brand name drugs and companies who could manufacture generic versions of those drugs, and thus to enhance antitrust enforcement in the pharmaceutical industry.

Section 4.—Section 4 defines the terms used in the Act.

Section 5.—Section 5 is the operative section of the Act, setting forth the requirement that, if a brand name drug company and a generic drug applicant (which is simply a generic drug company that has filed with the FDA an "Abbreviated New Drug Application" in order to produce a generic version of a brand name drug) enter into an agreement that relates in any way to the 180-day period of semi-exclusivity to a generic drug applicant, described in section 355(j)(5)(B)(iv) of title 21, United States Code; or which concerns the manufacture, marketing, or sale of either the brand name drug or its generic equivalent, then both companies must file a copy of the agreement (or a complete written summary of any oral agreement), along with copies of any other related agreements, with the Federal Trade Commission and the Department of Justice.

Section 6.—Section 6 states that the filings required by section 5 shall be made within 10 business days of the execution of the agreement between the brand name drug manufacturer and the generic drug applicant.

Section 7.—Section 7 provides for protections of the filings made by the drug manufacturers with the antitrust enforcement agencies parallel to those protections provided in the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a(h).

Section 8.—Section 8 describes the enforcement mechanisms authorized by the Act. First, failure to comply with any provision of the Act may subject the responsible party to a penalty of up to $11,000 per day of noncompliance. Second, failure to comply with the notification of the antitrust enforcement agencies required by section 5 of the Act within the 10 days prescribed by section 6 may render the agreement between the parties unenforceable (by the party which failed to file) for the duration of the noncompliance, should the relevant enforcement agency seek such a remedy in Federal court. While such a penalty would likely only be sought, and indeed might only be appropriate, in cases of willfulness or recidivism, the threat of such a sanction should prove an important deterrent in its own right. Third, failure to comply with the requirements of the Act may result in ordered compliance by a United States district court, and/or other appropriate equitable relief, upon application by one of the antitrust enforcement agencies.

Section 9.—Section 9 permits the Federal Trade Commission, with the concurrence of the Assistant Attorney General for Antitrust at the Department of Justice, to issue rules which may define the Act's terms, which may create exemptions from the Act, and which may prescribe other necessary and appropriate rules to effectuate the purposes of the Act.

Section 10.—Section 10 is a savings clause, ensuring that any action or inaction by the antitrust enforcement agencies under this Act will not bar proceedings pursuant to any other provision of law, and also ensuring that the simple act of complying with the Act's filing mandate will not put the filers at any risk of any presumption of wrongdoing.

Section 11.—Section 11 states that the Act shall take effect 30 days after its enactment, and shall concern only agreements executed after its effective date.

V. COST ESTIMATE

SUMMARY

S. 754 would require that both brand name and generic drug companies file certain types of agreements with the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ). S. 754 also would authorize the FTC and the DOJ to assess civil penalties if drug companies fail to file such agreements within 10 business days of executing those agreements.

The Congressional Budget Office (CBO) estimates that the administrative costs of implementing S. 754 would amount to less than $500,000 in 2002. Over the 2002–2007 period, however, discretionary health programs would realize savings from the earlier entry of lower priced generic drugs onto the market. CBO estimates that those savings would exceed the Federal costs of administering the new activities, with net Federal spending subject to appropriation falling by roughly $1 million over the 2002–2007 period.

CBO also expects that enacting S. 754 would affect both direct spending and revenues; therefore, pay-as-you-go procedures would apply to the bill. Most of the changes in direct spending and revenues would stem from lower prices for drugs, which in turn would decrease some Federal expenditures for Medicaid and Federal health insurance programs, and increase Federal revenues because of lower costs for private health insurance. Such effects would be modest, however. We estimate that direct spending would decline by less than $500,000 a year through 2005, by about $1 million in 2006, and by a total of $16 million over the 2002–2012 period. CBO further estimates that Federal revenues would increase by less than $500,000 a year through 2007, with a total increase of $4 million over the 2002–2012 period.

S. 754 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The bill would increase competition among drug manufacturers, in some cases, and that increased competition would decrease costs for state and local Medicaid programs. CBO estimates that state spending for Medicaid would decline by about $2 million over the 2002–2007 period.

The bill contains a requirement on manufacturers of both generic and brand name drugs that would be considered a private-sector mandate under UMRA. CBO estimates that the direct cost of the mandate would not exceed the threshold specified in UMRA ($115 million in 2002, adjusted annually for inflation) in any of the first five years the mandate would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

CBO estimates that implementing S. 754 would decrease net spending subject to appropriation by about $1 million over the 2002–2007 period. We also estimate that the bill would reduce direct spending by about $3 million and increase revenues by about $1 million over that period. The costs of this legislation would fall within budget functions 370 (commerce and housing credit), 400 (transportation), 550 (health), 700 (veterans' benefits and services), and 750 (administration of justice).

CBO expects that the reporting requirements under the bill would deter or result in the earlier identification of certain agree-

ments that violate antitrust laws and delay the entry of lower priced generic drugs onto the market. As a result, we assume that the bill would promote the timely entry of generic products onto the market and thereby reduce the average price of certain prescription drugs over the next 10 years. However, we believe that S. 754 likely would affect average prices for a relatively small share of the overall prescription drug market. CBO believes that the incentive to enter into such agreements has been tempered significantly by current FTC initiatives to identify illegal agreements delaying generic entry and by recent court cases brought by states and health insurers. In addition, charges by the FTC of anticompetitive practices surrounding four agreements from the late 1990s have resulted in consent agreements for two of those four cases. Under current law, the two brand name and the two generic drug companies party to those consent agreements must follow reporting requirements similar to those outlined in the bill. Moreover, the proposed reporting requirements only apply to certain new agreements between brand and generic companies entered into after enactment.

CBO estimates 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 programs subject to appropriation—such as health insurance provided to active workers through the Federal Employees Health Benefits (FEHB) program, the Coast Guard, the Public Health Service (PHS), and health programs of the Departments of Veterans Affairs (VA) and Defense (DoD)—would total less than $500,000 in 2002 and $2 million over the 2002–2007 period.

Lower prices would also reduce direct spending—for Medicaid and for health insurance provided to annuitants by FEHB, DoD, and the Coast Guard—by less than $500,000 in 2002, by $3 million over the 2002–2007 period, and by $16 million over the 2002–2012 period. CBO assumes that savings to Federal health programs would increase over time because the bill only would affect new agreements, which are more likely to relate to drugs losing patent protection in later years.

S. 754 would affect revenues in two ways. First, the bill would increase governmental receipts (i.e., revenues) because it would create new civil penalties for those entities that violate the new reporting requirements. Based on information from the FTC and the Antitrust Division of the DOJ, CBO estimates that the increase in revenues would be negligible because of the limited number of cases expected.

Secondly, the bill would also affect revenues because CBO assumes that part of the savings from lower health insurance costs would be passed on to workers as increases in taxable compensation. Lower prices for prescription drugs under the bill would reduce premiums for private health insurance (compared with premiums under current law). CBO estimates the bill would increase Federal revenues by less than $500,000 in 2002, by $1 million over the 2002–2007 period, and by $4 million over the 2002–2012 period.

BASIS OF ESTIMATE

For this estimate, CBO assumes that the bill will be enacted in spring of 2002 and that outlays will follow historical spending rates for the authorized activities.

Spending Subject to Appropriation

S. 754 would require that brand name and generic drug manufacturers report certain agreements to the FTC and the DOJ within 10 days after the agreements are executed. Affected agreements would include those related to the manufacturing, marketing, and sale of either the brand or generic version of the product. In addition, agreements related to the 180-day period of exclusive marketing rights that may be granted to certain generic manufacturers by the Food and Drug Administration (FDA) must also be filed.

Assuming the appropriation of necessary amounts, CBO estimates that enacting S. 754 would result in higher outlays for discretionary programs of less than $500,000 for 2002. Over the 2002–2007 period, however, Federal health programs would realize savings from the earlier entry of lower priced generic drugs onto the market. We estimate that those savings would exceed the Federal costs of administering the new activities. As a result, net Federal spending subject to appropriation would fall by roughly $1 million over the 2002–2007 period.

Effect on administrative costs. Implementing S. 754 would raise the administrative costs of the FTC and the Antitrust Division of the DOJ. The two agencies would need staff to issue new regulations and review the filings from drug companies. Based on information from the FTC and the Antitrust Division, CBO estimates that these additional costs would amount to less than $500,000 per year.

Effect on average prices paid by Federal health programs for prescription drugs. Once the marketing protections of brand name drugs expire (usually at the end of a product's patent life), generic drugs generally enter the market at a lower price compared with the brand name drug. Recent FTC investigations have charged that agreements between certain innovator and generic drug companies were anticompetitive and delayed the market entry of generic drugs for which the generic firms sought marketing approval from the FDA before the expiration of listed patents. The reporting requirements under the bill would enhance the ability of the FTC and the DOJ to regulate those types of agreements and enforce antitrust law.

CBO estimates that eliminating the delay in the entry of lower priced generic drugs would reduce costs for Federal discretionary health programs drugs by less than $500,000 in 2002 and by $2 million over the 2002–2007 period, assuming that appropriations are reduced accordingly. Programs of the PHS and the VA would be affected, as would pharmacy costs incurred by FEHB, DoD, and the Coast Guard for active workers.

The agreements that would be affected by S. 754 relate only to drugs filed with "paragraph IV certifications" in their applications for marketing approval. A generic manufacturer that submits an application to the FDA for marketing approval of a generic drug must address or "certify" their intent with regard to each patent identified with the innovator product and listed with the FDA. The

certification procedure was set in place by the Hatch-Waxman Act; certifications are based on four "paragraphs" found in the statute. A paragraph IV certification states that the listed patent is invalid or will not be infringed by the purposes for which approval is being pursued. By filing an application to market a generic drug under a paragraph IV certification, the company may seek approval to market a generic drug before the expiration of a patent listed with the brand name product.

Under certain conditions, the first generic manufacturer that submits a substantially complete application to the FDA challenging an innovator's patent claim under a paragraph IV filing may be awarded 180 days of generic market exclusivity. The FDA cannot approve any other generic versions of the drug during that 180-day period. The generic exclusivity period begins after a court decision finding the challenged patent invalid, unenforceable, or not infringed, or the date of first commercial marketing of the generic product, whichever is earlier.

The generic drug firm must notify the innovator firm when it files a paragraph IV certification, and the innovator then has 45 days to bring a lawsuit to defend its patent protections. If the innovator sues, the FDA cannot approve the application of the generic version for 30 months (unless the patent expires, or a court rules that the patent is invalid or is not infringed). A court may modify that 30-month period.

Both the initial introduction of the generic version of the drug and the subsequent marketing of competing generic versions of the drug could be delayed if the innovator and the generic drug firm reach an agreement under which the generic firm delays or abstains from marketing its version of the drug. Such agreements may be attractive to both firms, because the price charged for the generic version of a drug generally is significantly lower than the price charged for the brand name version, and the price of the generic version drops further when competing versions enter the market. Therefore, the profit lost by the innovator firm following the entry of the generic version generally substantially exceeds the profit gained by the generic firm; both firms could be made better off by sharing some of that difference in profits instead of competing.

Delaying or preventing the initial introduction of the generic version of a drug by the firm that filed the paragraph IV certification and delaying the entry of generic versions marketed by other firms would both result in higher costs for prescription drugs to consumers and to the government.

To estimate the costs associated with the lower drug prices paid by Federal purchasers anticipated under the bill, CBO assumed that the recent cases identified as anticompetitive by the FTC may provide some insight into the average amount of sales affected by agreements delaying the entry of generic drugs that were in play *before* the recent crackdown by the FTC. (CBO estimated that the average value of a drug affected by those agreements at roughly $1 billion in 2001, based on 1998 average drug sales in the year of the agreement identified by the FTC and grown by 10 percent annually.) However, we assumed that the number of illegal agreements delaying generic entry have been greatly reduced by the FTC investigations under current law and by other litigation brought by

states and health insurers. Furthermore, charges by the FTC of anticompetitive practices surrounding four agreements from the late 1990s have resulted in consent agreements for two of those four cases. Under current law, the two brand name and the two generic drug companies party to those consent agreements must follow reporting requirements similar to those outlined in the bill.

CBO assumes that S. 754 would affect agreements concerning roughly two drugs per year, on average. Based on an average expected value of almost $200 million in sales in 2001, CBO forecasts the future sales of drugs associated with illegal agreements by assuming that the same percent of sales for brand drugs losing market exclusivity in future years (as estimated in 2001) may be illegal in nature and potentially delay generic entry. We assume the average length of delay that would be eliminated through the deterrence of those agreements or their more timely identification under the bill would be about one year.

Reducing the incidence of illegal agreements that delay generic entry would result in the accelerated introduction of lower priced generic products and translate into program savings. Recent market trends suggest a more rapid loss of market share to generics and a more significant reduction in average price after generic entry than previously estimated by CBO. To estimate the savings associated with this bill, pending further study of these market dynamics, we assume that generic products, on average, account for roughly 50 percent of total market volume and cost about 50 percent of the brand price after one year on the market.

CBO expects that the share of spending in the prescription drug market affected by the reporting requirements under S. 754 likely would be small. As mentioned above, we anticipate that FTC's ongoing activities and the existence of similar reporting requirements for four companies mandated in the consent agreements stemming from past investigations will significantly reduce the number of illegal agreements entered into by competitors and will assist the government with the identification of many of the illegal agreements that persist. Moreover, the proposed reporting requirements under the bill only apply to new agreements related to drugs with paragraph IV certifications entered into after enactment.

To the extent that illegal agreements delaying generic entry persist under current law, many drugs with patent expiration expected in the next five years, for example, have already had paragraph IV certifications filed by generic firms. Therefore, the likelihood of potentially illegal agreements to be already in place would be strong for many of the high-sales drugs with market exclusivity expiring in the near term. But as noted above, this bill only applies to new agreements. Over time, however, the effectiveness of the reporting requirements would increase. Even with the reporting requirements outlined in S. 754, it is also unclear what other means drug companies may pursue that effectively delay generic entry while staying within the legal limits of the law.

Direct Spending

CBO estimates that S. 754 would reduce Federal direct spending over the 2002–2012 period by $16 million. The manner in which the bill would affect the price of drugs for discretionary health programs discussed earlier would also affect direct spending by Fed-

eral health programs characterized as mandatory (that is, not requiring appropriation action). CBO estimates that implementing the new reporting requirements would reduce direct spending (for Medicaid and for annuitants covered by health insurance offered through FEHB, DoD, and the Coast Guard) by less than $500,000 in 2002, $3 million over the 2002–2007 period, and $16 million over the 2002–2012 period.

Revenues

CBO estimates that S. 754 would increase Federal revenues by less than $500,000 in 2002, by $1 million over the 2002–2007 period, and by $4 million over the 2002–2012 period. The bill would affect Federal revenues in two ways. First, S. 754 would increase revenues because it would create new civil penalties for those manufacturers that fail to comply with the new reporting requirements. Based on information from the FTC and the DOJ, CBO estimates that the increase in revenues would be negligible because of the limited number of cases expected.

Secondly, CBO also assumes that changes in drug prices would affect the costs of private health insurance premiums, and a portion of those amounts would be returned to workers through changes in taxable compensation. S. 754 would reduce costs for employer-sponsored health plans because of the lower costs of pharmacy benefits stemming from the more timely entry of cheaper generic drugs. Lower pharmacy costs translate into lower premium payments for employer-sponsored plans and thus higher taxable compensation for employees.

CBO assumes that 60 percent of the change in the cost of health premiums would be offset by behavioral responses of employers and employees. The remaining 40 percent would be passed through to workers as changes in taxable compensation and would lead to changes in Federal tax revenues.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The following table displays CBO's estimate of the effects of S. 754 on direct spending and receipts. We estimate the effects on direct spending through 2005 would be less than $500,000 a year. We also estimate that the effects on revenues would be less than $500,000 a year through 2006. For the purposes of enforcing pay-as-you-go procedures, only the effects through 2006 are counted.

By Fiscal Year, in Millions of Dollars

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Change in outlays	0	0	0	0	–1	–2	–2	–2	–2	–2	–2
Change in revenues	0	0	0	0	0	0	1	1	1	1	1

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 754 contains no intergovernmental mandates as defined in UMRA. The bill would increase competition among drug manufacturers, in some cases, and that increased competition would decrease costs for state and local Medicaid programs. CBO estimates that state spending for Medicaid would decline by about $2 million over the 2002–2007 period.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains a private sector mandate on manufacturers of both generic and brand name drugs. It would require drug companies to submit specific contracts between brand name and generic firms that relate to generic drugs for which a paragraph IV certification under the Food, Drug, and Cosmetic Act has been filed with the FDA. Although the requirements would add administrative and legal costs, those costs would be minimal. CBO estimates that the direct cost of the mandates on both generic and brand name drug manufacturers contained in the bill would not exceed the annual threshold specified in UMRA ($115 million in 2002, adjusted annually for inflation) in any of the first five years the mandate would be effective.

ESTIMATE PREPARED BY:

Federal Costs:

Effects on Drug Prices—Julia Christensen
FTC—Ken Johnson
DOJ—Lanette Walker

Impact on State, Local, and Tribal Governments: Leo Lex

Impact on the Private Sector: Judith Wagner

ESTIMATE APPROVED BY:

Peter H. Fontaine
Deputy Assistant Director for Budget Analysis

VI. Regulatory Impact Statement

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee made the following evaluation of the regulatory impact which would be incurred in carrying out S. 754.

We estimate that some regulatory actions would be required of the Federal Trade Commission and the Department of Justice related to indicating the types of documents which those agencies would receive in implementing S. 754.

VII. Changes in Existing Law

In compliance with paragraph 12 of Rule XXVI of the Standing Rules of the Senate, the Committee finds no changes in existing law caused by passage of S. 754.

○