

No. 48

July 16, 2002

S. 812 – Greater Access to Affordable Pharmaceuticals Act of 2001

Calendar No. 491

S. 812 was reported with an amendment from the Health, Education, Labor, and Pensions Committee on July 11, 2002, by a vote of 16-5; voting ‘nay’ were Senators Gregg, Frist, Enzi, Bond, and DeWine; no written report was issued.

NOTEWORTHY

- On July 15, Senator Daschle moved to proceed to S. 812, and filed a cloture petition on the motion. The bill would make changes to pharmaceutical patent protections and the approval of generic drugs that would make the less expensive generics available to consumers sooner.
- It is expected that Senators will offer amendments to S. 812 to create a Medicare prescription drug benefit. Other expected amendments include prescription drug reimportation, Medicare “givebacks”, changes to Medicaid reimbursement rates, and medical malpractice reform. Budget Act points of order will lie against many of these amendments [see explanation, below]. No points of order will lie against S. 812.
- The Democrat-controlled Senate has failed so far this year to take formal action on Medicare prescription drug benefits – no budget, no committee markup, no floor debate. In contrast, the House passed a budget calling for the creation of this benefit and, on June 28, passed legislation conforming to the budget by a vote of 221-208. That bill established a comprehensive, permanent prescription drug benefit under Medicare.
- The Senate’s failure to adopt a budget this year means we are still operating under last year’s budget. That budget set aside \$300 billion for the creation of a prescription drug benefit. It required that 1) the bill had to be reported out of the Finance Committee and 2) its total cost over the years 2003-2011 had to be less than \$300 billion. Since Senator Daschle has chosen to not bring up a new budget resolution or take up a Finance-reported bill that conforms to last year’s resolution, any prescription drug plan offered is now subject to the higher 60-vote threshold. Senator Daschle’s actions endanger the ability of the Senate to follow the lead of the House and pass a prescription drug benefit this year.

HIGHLIGHTS

- **S. 812 would increase competition among brand-name and generic drug manufacturers**, and thereby lower prices for consumers. Many brand name drug manufacturers – and some generic firms – are abusing the system that protects drug patents and approves generic drugs.
- **S. 812 would limit brand name drug manufacturers’ ability** to stall the approval of generic versions of their drugs. At the same time, it would prevent brand name firms from essentially paying generic firms to keep their products off the market.
- Most controversial is a **private right of action S. 812 would create** that would allow generic firms to challenge the validity of patents early. Though it would not authorize monetary damages, many Republicans feel the right of action is unnecessary and would lead to excessive litigation.
- However, S. 812 does not address the Food and Drug Administration (FDA)’s cumbersome drug approval process.

BACKGROUND

Pharmaceutical advances have fueled increased use of prescription drugs, which in turn has fueled increased attention to their price. Particularly interested are seniors, who comprise a large portion of America’s pharmaceutical consumers. Various legislative strategies have emerged to lower the price of prescription drugs to seniors and other consumers. These include removing government obstacles to competition among drug companies; creating a prescription drug benefit in the Medicare program; removing trade barriers to allow American-made drugs to be reimported from countries where they are priced lower; and reforming the Food and Drug Administration’s drug approval process.

Promoting Competition Among Pharmaceuticals (S. 812)

The FDA's approval process is time-consuming and expensive for drug manufacturers that engineer innovative therapies. Since the FDA's current regulatory model was imposed in the 1960s, the cost of bringing a new drug to market has risen to 12 years and \$802 million, according to Tufts University. These costs are passed on to consumers through higher prices for drugs.

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as "Hatch-Waxman") grants innovative drug companies patent extensions (up to 14 years) as compensation for lost patent time while their products are tied up in the FDA's approval process. These extensions further increase costs for consumers by blocking competition from generic drug makers.

The Greater Access to Affordable Pharmaceuticals Act (S. 812) is an attempt to prevent brand-name companies (and in some cases generic firms) from gaming this system to the detriment of consumers. By bringing generic versions of expensive drugs to market sooner, S. 812 aims to use competitive pressures to bring down the cost of prescription drugs for patients, employers, and government health programs.

Under current law, a brand-name drug manufacturer can file numerous patents for the same drug in the FDA "Orange Book." A firm can do so up to the point its original patent expires, effectively extending its market exclusivity for years. A generic firm that believes one or more of these patents are invalid may challenge them when submitting a generic drug application to the FDA. The patent holder may then sue the challenger for patent infringement. By law, this automatically triggers a 30-month hold on the generic drug application. The more patents a brand name firm files, the more patents a generic firm must challenge, and the longer the brand name can block its competition.

S. 812 would limit such abuse by allowing only one 30-month hold per generic application, and only for those patents that are filed in the 30 days after FDA approval of the brand name drug. For patents that would not trigger the 30-month hold, the bill would allow brand name firms 45 days to seek a preliminary injunction against consideration of the generic application. The generic could be approved as soon as the injunction is denied, revoked, or a court determines the generic would not infringe on the patent.

Further, S. 812 would create a private right of action allowing firms who have filed a generic application to bring suit against a brand name firm to have them correct or delete incorrect "Orange Book" listings. An amendment by Senator Collins, adopted in committee, ensures plaintiffs would not be eligible for monetary damages.

Another abuse of Hatch-Waxman surrounds a 180-day period of market exclusivity granted to generic firms. Generally, the first generic firm to challenge a brand name patent receives the exclusive right to market the generic version of the drug for 180 days. However, the law allows the brand name and generic firms to delay the start of this period. As such, brand name firms have paid generic firms *not* to go to market. One firm reportedly collected 65 percent of its income from such arrangements over a four-year period. S. 812 would restrict firms' ability to delay the start of the 180 days and

enact due diligence criteria with which generic applicants must comply or lose their right to the market exclusivity.

While it is important to prevent special interests from using the law to harm consumers, S. 812 fails to curb the excesses of the most powerful special interest involved: the FDA. Over the past 40 years, this federal agency has increased the cost and duration of its drug approval process. Costing innovative firms over \$800 million per drug and devouring patent time, FDA regulatory creep is one of the primary reasons manufacturers rush to extend their patents. The growth in the cost of the FDA approval process delays patient access to new pharmaceuticals and makes them more expensive when they arrive. The chief benefit of S. 812 is that if enacted, it would force drug companies to focus on the real problem: costly and unnecessary over-regulation by the FDA.

[For a more detailed overview of the regulation of patents and approval of generic drugs, see “The ‘Hatch-Waxman’ Act: Selected Patent-Related Issues,” Congressional Research Service, [RL31379](#), Apr. 1, 2002.]

Proposals for A Medicare Prescription Drug Benefit

Senator Daschle has indicated that, having failed to produce a budget resolution including a Medicare prescription drug benefit and/or allow a bill to be marked up by the Senate Finance Committee, the debate over S. 812 will substitute for a real debate over creating a Medicare prescription drug benefit.

Medicare is a nationwide health insurance program that offers health insurance protection for 40 million older Americans and disabled persons. The program provides broad coverage for the costs of many, primarily acute, health services. However, there are many gaps in program coverage, one of the most notable being that Medicare has a very limited prescription drug benefit. While most beneficiaries have some form of private or public health insurance to cover expenses not met by Medicare, many of these plans do not offer drug coverage.

On several occasions, the Congress has considered adding more comprehensive prescription drug coverage to Medicare. The issue was debated extensively in the 106th Congress and played a critical role in the 2000 Presidential elections. The FY 2002 budget resolution adopted by Congress provided up to \$300 billion over the years 2003-2011 for Medicare reform and a prescription drug benefit.

The budget adopted by the House this year also set aside funds – \$350 billion – for a prescription drug benefit. The Senate Democrat leadership, however, chose not to bring up a budget this year. The Democrats’ failure to produce a budget this year means last year’s budget resolution, H. Con. Res. 83, continues to govern floor consideration of a Medicare prescription drug proposal. H.

Con. Res. 83 established two conditions for Senate consideration: 1) the proposal must be reported by the Senate Finance Committee and 2) the proposal's cost cannot exceed \$300 billion.

The Democrat alternative, S. 2625 sponsored by Senators Graham (of Florida) and Kennedy, fits neither condition. It was not reported by the Finance Committee and it costs considerably more than \$300 billion. Due to this failure, the Democrat plan is subject to a 60-vote point of order, as is any effort to enact a Medicare Prescription drug plan this year. The result is the floor debate will be largely a political exercise rather than a serious effort to create a new prescription drug benefit. Below are summaries of the competing plans.

House Bill

The House passed its bill, H.R. 4954, on June 28, 2002, by a vote of 221-208. The bill establishes a comprehensive, permanent prescription drug benefit under Medicare. Specifically, the measure provides \$310 billion over 10 years for a prescription drug plan. All Medicare-eligible seniors may join the plan. The Congressional Budget Office (CBO) estimates that premiums under the program will be about \$33 per month.

The bill provides for lower drug costs to seniors in two fashions. First, it creates a drug discount program where seniors may participate in competing purchasing plans run by private groups. The CBO estimates seniors could save 20-25 percent off the full price on prescriptions purchased through these plans. Second, the bill offers a cost-share plan with the following criteria:

- A \$250 deductible;
- 80-percent coverage for \$251 - \$1,000 spent on prescription drugs;
- 50-percent coverage for \$1,001 - \$2,000 spent on prescription drugs; and
- 100-percent coverage for any prescription drug costs above \$3,700.

Third, the bill fully subsidizes premium and cost-sharing for seniors whose incomes are up to 150 percent of poverty. Seniors who qualify for this assistance will be responsible only for a \$2 copayment on generic and preferred drugs and a \$5 copayment on non-preferred drugs. The bill phases out the premium subsidy between 150 percent of poverty and 175 percent.

Finally, the bill provides \$40 billion over 10 years to modernize the Medicare system, including improving the Medicare+Choice program, increasing payments to rural providers, and establishing an independent agency to administer the prescription drug benefit.

Graham/Kennedy Plan

The Senate Democrat bill, S. 2625, offers seniors a temporary benefit starting "no sooner" than 2004 and ending in 2010. Participating seniors would pay a \$25 monthly premium and would not be subject to a deductible. In return, Medicare would cover all their prescription drug costs minus the following fixed copays:

- \$10 for generic drug purchases;
- \$40 for preferred brand-name drugs; and
- \$60 for non-preferred brand-name drugs.

The bill would have the Department of Health and Human Services contract with private entities to manage the drug benefit, including selecting the list of drugs eligible for the benefit. While seniors *may* have two or more entities from which to align themselves, there appears to be little incentive for either seniors or the entity to reduce costs. Within the three categories, Seniors pay a fixed fee regardless of which drug they choose. Meanwhile, contracting drug providers who reduce their costs will see their payments from Medicare cut by a like amount. (Since this legislation was not reported by the Finance Committee, there is no hearing record or committee report.)

Sponsors of the Democrat alternative suggest the bill will cost about \$450 to \$500 billion in the seven years it is offered – 2004 to 2010. There is, however, no CBO score at press time due to the plan’s unique copayment structure. (The House Democrat plan, with a traditional percentage copay and a lower out-of-pocket limit, would cost \$800 billion through 2012; see attached chart.)

Concerns With Graham-Kennedy

There are numerous concerns with the Graham/Kennedy proposal, including its massive cost and the temporary nature of its benefits.

Costs Too Much: Stretched out over the full 10 years, S. 2625 would increase Medicare spending by more than \$600 billion – perhaps by as much as \$800 billion – making it one of the most expensive spending plans ever considered by the United States Senate. The plan’s initial cost, combined with its failure to encourage savings by either the drug purchasers or seniors, raise concerns that its passage will drive future legislation to either cut back Medicare benefits, force a tax increase, or both.

Temporary Benefit: In a transparent effort to reduce the cost of their plan, Senators Graham and Kennedy have made their prescription drug benefit temporary. While other alternatives offer a permanent prescription drug benefit, the Graham-Kennedy plan expires in 2010. Moreover, while the plan claims to begin in 2004, many observers, including the Administration, argue that there is little chance the complex program could be implemented in time. With a 2005 starting date, Graham-Kennedy is just a six-year benefit. (The tax plan offered last year was also temporary, but contrary to Graham-Kennedy, it was made temporary to conform with reconciliation rules – specifically the Byrd Rule – rather than to make it less expensive. The Graham-Kennedy bill could have been brought up under Reconciliation, but again, Senate Democrats failed to bring a budget to the floor.)

“Tripartisan” Plan

One of the more interesting aspects to the upcoming Senate debate is the existence of the so-called “Tripartisan” bill sponsored by Senators Snowe, Grassley, Breaux, and Jeffords, all members of the same Finance Committee bypassed by Senator Daschle when he chose to bring the Medicare prescription drug debate directly to the floor.

The Tripartisan bill reduces Medicare prescription drug costs through a voluntary prescription drug benefit that: 1) allows seniors to align themselves with competing Medicare prescription drug plans through which they would access their drugs; and 2) establishes a Medicare copay for prescription purchases under the following formula:

	<u>Senior Cost</u>
Monthly Premium	\$24
Deductible	\$250
Cost Sharing	50% between \$251 and \$3,450
Benefit Cap	\$3,450
Catastrophic Limit	\$3,700 of out-of-pocket costs

In addition to the standard benefit, the Tripartisan plan also provides comprehensive low-income protections, a voluntary “Enhanced Medicare” alternative with benefits resembling employer-sponsored plans, rules to govern Medigap policies under the new plan, and changes to the current Medicare+Choice program to make it more competitive.

Several major incentives distinguish the Tripartisan plan from Graham-Kennedy. First, the copay paid by Medicare is a percentage of the beneficiaries’ drug costs, not a fixed amount. This encourages seniors to shop for the best, lowest priced alternative. Second, the private entities providing the drug coverage under the Tripartisan plan must compete with other plans to attract seniors, thereby assuring better benefits and service. Finally, the Tripartisan payment system to its prescription drug plans is designed to encourage savings – whereas, no such incentives are in Graham-Kennedy.

Of course, the major distinction between the Tripartisan and Graham-Kennedy plans is the cost. The Tripartisan plan is estimated to cost taxpayers \$370 billion over the next 10 years. Unlike Graham-Kennedy, the Tripartisan plan is a full, permanent benefit that does not sunset after 2010.

Hagel-Gramm Plan

Another Republican sponsored plan has been offered by Senators Hagel and Gramm. The Hagel-Gramm proposal has two main planks. First, it makes available to all Medicare participants prescription drug discount cards that the sponsors estimate will reduce prescription drug costs by up to 35 percent.

Second, the bill targets for assistance low-income seniors and those with excessively high prescription drug costs. For low-income seniors, the bill provides nearly 100 percent coverage of any

prescription drug costs above \$1,500. For upper-income seniors, the limit is set much higher. Below is the scale:

<u>Out-of-Pocket Limit</u>	<u>Poverty Level</u>
\$1,500	< 200% of Poverty Level
\$3,500	Between 200% and 400%
\$5,500	Between 400% and 600%
20% of Income	Above 600%

The rationale is that Medicare should not offer the same subsidy to Bill Gates that is offered to seniors living at the poverty level. Moreover, workers living at the poverty level will not see their payroll taxes used to subsidize the prescription drug costs of millionaires. Sponsors of the Hagel-Gramm bill estimate it will cost \$160 billion over the next 10 years.

Additional Issues

In addition to the above plans, Senators Smith (NH) and Allard have offered legislation which would establish a voluntary prescription drug benefit under the existing Medicare program. Their plan would unify the deductibles under Medicare parts A, B, and the new prescription drug plan at \$675, while offering seniors 50 percent of drug costs above that level, up to \$5,000.

Finally, so-called Medicare “give-backs” – increased payments to health care providers under Medicare – also likely will be considered. The House-passed bill included \$40 billion over 10 years to modernize the Medicare system, including increasing payments to health care providers.

BILL PROVISIONS

S. 812 was introduced on May 1, 2001, by Senator Schumer. The Committee on Health, Education, Labor, and Pensions reported the bill, by a vote of 16-5, on July 11, 2002, with an amendment in the nature of a substitute by Senator Edwards (cosponsored by Senator Collins).

Sec. 1. SHORT TITLE

Sec. 2. FINDINGS

Sec. 3. FILING OF PATENT INFORMATION WITH THE FDA

- Technical: Consolidates all of the requirements for filing patent information with FDA into 505(c)(2), which are currently in both 505(b)(2) and (c)(2).
- Filing patent information begins 30 days after New Drug Application (NDA) approval, not before.
- Clarifies the information required (e.g., requires method-of-use filings to identify the approved use for which the applicant claims a patent, and requires clarification of the types of claims in a patent). Provides a cause of action for generic drug applicants to ask a court to order that the brand-name applicant amend its application to correct or delete patent information.
- Prohibits enforcement of a patent for which the required information is not timely filed.

Sec. 4. ONE 30-MONTH STAY PER GENERIC APPLICATION FOR CERTIFICATIONS RELATING TO PATENTS ISSUED BY NDA APPROVAL

- Permits only one 30-month stay per generic application, on only the patents for which patent information is filed at FDA 30 days after the date of NDA approval.
- For patents for which no 30-month stay is available, a brand-name drug company may file a patent infringement action seeking a preliminary injunction within 45 days, which delays the effective date of approval to one of four specified dates –
 - the date a district court denies a preliminary injunction; or
 - if a district court grants a preliminary injunction –
 - the date of a court decision holding the patent invalid or not infringed;
 - the date a court revokes the preliminary injunction; or
 - the date of patent expiration if the patent is held valid and infringed.
- If the patent owner does not bring a patent infringement action within 45 days, generic approval can be effective on day 45, and the patent owner may not subsequently bring an infringement action for that patent against the generic drug.
- The amendment is effective with respect to any paragraph IV certification made in a generic application after the date of enactment.

Sec. 5. EXCLUSIVITY FOR ABBREVIATED NEW DRUG APPLICANTS

- The court decision date on which the 180-day period of generic exclusivity begins to run is clarified to be either –
 - the date of the final decision of a court from which no appeal can or has been taken, other than a petition for review by the Supreme Court; or
 - the date of a settlement order that includes a finding that the patent is invalid or not infringed.
- Adopts a combination of rolling and “use-it-or-lose-it” exclusivity. If a forfeiture event occurs –
 - The 180-day period is forfeited by the first applicant to have filed a paragraph IV certification.
 - Any subsequent generic application that included a paragraph IV certification is made effective without regard to the 180-day period, except that if the first such generic to be made effective is the second applicant to have filed a paragraph IV certification, it gets the 180-day exclusivity, subject to forfeiture.
- The conditions for forfeiture of 180-day exclusivity are –
 - Failure to market the generic drug within 60 days of the later of when the approval is made effective or the last final decision in any patent litigation;
 - Withdrawal of the application;
 - Amendment of the certification from paragraph IV to paragraph III;
 - Failure to obtain approval of the generic drug within 30 months after the generic application is filed;
 - Failure to challenge a newly listed patent; or
 - An FTC finding of unlawful conduct in violation of section I of the Sherman Act.
- The amendment is effective for generic applications with paragraph IV certifications filed after the date of enactment, except that generic applicants who filed before the date of enactment forfeit the 180-day exclusivity period if the FTC finds they have violated section I of the Sherman Act.

Sec. 6. FAIR TREATMENT FOR INNOVATORS.

- Enhances the information that a generic applicant who makes a paragraph IV certification must provide to the patent holder and brand drug company so the patent owner can better assess the merits of a generic applicant's assertion that a patent is invalid or not infringed, while preserving the generic applicant's ability to adapt its case if there is litigation, in light of discovery, for example.
- Clarifies that a preliminary injunction in a drug patent infringement case may be granted notwithstanding the availability of monetary damages.

Sec. 7. BIOEQUIVALENCE.

- Clarifies that FDA's current bioequivalence regulations shall continue in effect as an exercise of FDA's current statutory authority.
- Clarifies that FDA may nonetheless amend those regulations.

Sec. 8. REPORT

- Requires FTC to submit a report to Congress within five years of enactment on whether the Act —
 - has enabled products to come to market in a fair and expeditious manner; and
 - has promoted lower drug prices and greater access to drugs through competition.

ADMINISTRATION POSITION

No Statement of Administration Policy on the Senate bill was available at press time.

COST

The Congressional Budget Office (CBO) had not prepared a cost estimate of S. 812 by press time.

OTHER VIEWS

Many Republican Senators have taken strong exception to provisions allowing generic manufacturers to challenge patents in court. Senator Gregg has stated that this provision should be revised on the floor in favor of an administrative process for challenging patents. Nonetheless, Senator Gregg said, “This is certainly a bill that at some point should be passed,” [*Congressional Quarterly*, 7/15/02].

POSSIBLE AMENDMENTS

- Graham-Kennedy. Medicare prescription drug benefit (see Background section for details).
- Snowe/Grassley/
Breaux/Jeffords. Medicare prescription drug benefit (see Background section for details).
- Hagel-Gramm. Medicare prescription drug benefit (see Background section for details).
- Smith (NH)-Allard. Medicare voluntary prescription drug benefit (see Background section).
- Dorgan. Allowing re-importation into the U.S. of drugs approved by the FDA and exported to Canada.
- Gregg. Replacing a private right of action for generic manufacturers with an administrative procedure for challenging patents.

McConnell.	Medical malpractice reform.
Rockefeller.	Increasing Medicaid reimbursement levels (FMAP).
Johnson.	Drug price controls.
Wellstone.	Drug price controls.
Stabenow.	Federal authorization for “Maine RX” and other state programs.
Stabenow.	Limits on drug company advertising.
Unknown.	Medicare “give-backs.”

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Attachment: table, entitled “2002 Prescription Drug Plans”