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The Baucus Health Bill – A Mixed Bag for Drug Makers?

Senator Max Baucus (D-MT) Unveils "America's Healthy Future Act of 2009"

By Kenneth Yood & Christine Cohn

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On October 20, 2009, Senator Max Baucus (D-MT), Chairman of the Senate Finance Committee, officially unveiled Senate Bill 1796, "America's Healthy Future Act of 2009." The Baucus bill's objective is grandly stated as no less than "to provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes."

In May of 2009, the pharmaceutical industry made a well-publicized promise to President Obama to provide $80 billion in cost reductions over the next decade to improve drug benefits for Medicare beneficiaries, which the White House and Senator Baucus hailed as a major triumph for seniors in need of more affordable prices for prescription drugs. (Associated Press, June 20, 2009.)

In light of the White House-pharmaceutical industry accord, we wanted to know what the Baucus health plan specifically has in store for drug companies. Presented below is a summary of some of the key features in Senator Baucus' bill that are particularly relevant to the drug industry and which we believe merit close attention as Congress wends its way along the path to final health care reform legislation.

New Annual Tax on Pharmaceutical Industry

The Baucus bill would establish an annual "fee" on drug companies that ostensibly would generate $23 billion from the pharmaceutical industry over the next ten years.

Companies that manufacture or import prescription drugs for sale in the United States currently do not pay any fees to the federal government to help fund the two Medicare trust funds, the Hospital Insurance Trust Fund, and the Supplementary Medical Insurance fund (the "Medicare SMI trust fund"). In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P. L. 108-173), which established the Medicare Part D prescription drug benefit program, expressly prohibits the Secretary of Health and Human Services from directly negotiating drug prices with drug manufacturers or instituting pricing structures for the reimbursement of covered Part D drugs.

Opportunity to "Support" Medicare

"The Baucus legislation would provide certain players in the drug industry with the "opportunity" to support the Medicare SMI trust fund through their payments of $2.3 billion in aggregate annual fees over the next decade. The bill would impose the tax on every entity engaged in the business of manufacturing or importing branded prescription drugs based on that entity's relative market share of branded prescription drug sales. The aggregate fee would be apportioned among the covered entities each year based on each entity's relative market share of branded prescription drug sales in the preceding year. "

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The scope of "branded prescription drug sales" included for purposes of calculating market share is confined to sales of branded prescription drugs to, or in connection with coverage under specified government programs, namely, Medicare Part D, Medicare Part B, Medicaid, the TRICARE retail pharmacy program and programs under which branded prescription drugs are procured by the Department of Veterans Affairs or the Department of Defense. So a covered entity's commercial market share would have no effect on the determination of its annual fee. (Branded prescription drug sales exclude so-called "orphan" drugs, which are FDA-approved drugs and biological products that serve rare disease populations and for which drug makers usually receive tax relief.) The annual fee would not be deductible for purposes of the covered entity's income tax.

The question naturally arises to what extent drug manufacturers and importers will attempt to mitigate their tax burden by shifting resources from securing market share in the affected government programs to commercial insurance plans. The motivation to shift resources away from such programs clearly exists already, because government programs provide lower profit margins. Further, the planned $2.3 billion aggregate annual fee would comprise less than 1 percent of domestic annual drug sales. To the extent the fee generates a disincentive to program participation, that would seem most likely to apply to smaller drug makers, who would presumably have a harder time absorbing the non-tax deductible fee on sales that did not necessarily result in any profit. Overall, however, if the annual fee is actually enacted into law close to the form in which it has been proposed, it seems unlikely to change incentives broadly in the drug industry to participate in federal health care programs.

Increase in Medicaid Prescription Drug Rebates

Cost reductions of $27 billion would supposedly derive from the Baucus bill's increases in Medicaid rebate payments. These are payments that drug manufacturers must provide to state Medicaid programs for outpatient drugs dispensed to Medicaid beneficiaries. Excluded from such rebates are inpatient drugs, drugs dispensed in physicians' or dentists' offices and drugs dispensed by a Medicaid managed care organization when prescription drugs are included in the Medicaid managed care organization's capitation plan.

For purposes of calculating the rebate amounts owed to state Medicaid programs, Medicaid distinguishes between two types of drugs: (1) "single source" and "innovator multiple source drugs," which are drugs that are still under patent which were once covered by patents, and (2) generic drugs. The Baucus plan would increase the flat rebate percentage used to calculate Medicaid's basic rebate for single source and innovator multiple source outpatient drugs. As of January 1, 2010, the flat rebate percentage for these drugs would increase from 15.1 percent to 23.1 percent. The total rebate liability on any single-source or innovator multiple source drug product would be limited to 100 percent of the calculated Average Manufacturer's Price (the "AMP"). The basic rebate for generic drugs would increase from 11 percent to 13 percent of AMP.

Other features of the Baucus plan would require drug manufacturers to pay rebates for drugs dispensed to Medicaid beneficiaries who receive care from Medicaid managed care organizations similarly to the way rebates are required for drugs dispensed to other Medicaid beneficiaries. A new rebate would also be established for new formulations of existing single source or innovator multiple source drugs.

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Fifty Percent (50%) Discount for Eligible Medicare Part D Beneficiaries in the "Donut Hole"

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 established the Medicare Part D prescription drug benefit program. In 2009, the standard benefit includes a $295 deductible and 25 percent coinsurance until the enrollee reaches $2,700 in total covered drug spending. Upon reaching that threshold, the beneficiary confronts the infamous "donut hole." The donut hole confers responsibility on the beneficiary for 100 percent of drug costs up to $3,454.75 in out-of-pocket expenditures. If the beneficiary's drug costs exceed that amount, he or she qualifies for the catastrophic drug benefit, which reduces the beneficiary's share to 5 percent of drug costs. The drug plan pays 15 percent and the Medicare program pays 80 percent of the remaining covered costs for the benefit year.

Part D plan sponsors are allowed to offer benefit packages that differ from the standard benefit, as long as they are actuarially equivalent, and to offer "enhanced" benefit packages that provide more generous coverage. Some plans offer coverage for the donut hole, but provide benefits only for generic, not brand-name drugs, and then only for a subset of the generic drugs listed on plan formularies. So beneficiaries cannot currently purchase gap coverage offering both generic and brand-name drug benefits. The Senate Finance Committee's Report that accompanied introduction of the Baucus bill asserts that insurers have not offered such coverage because such coverage would likely attract sicker, more expensive beneficiaries with higher drug spending, which would prompt insurers to set higher premiums overall.

The Baucus plan would establish a discount program for Part D beneficiaries whose drug expenditures push them into the donut hole. Beginning July 1, 2010, qualifying beneficiaries would automatically receive a 50 percent discount off the negotiated price for brand-name prescription drugs that are included in their Part D plan's formulary. (Beneficiaries who get certain low-income subsidies, are enrolled in retiree drug plans or earn more than $85,000 in 2009 would not be eligible for the discount.) The discount would be made at the point of sale and manufacturers would have to pay the discount to pharmacies no later than 14 days after the date of dispensing the discounted drug.

Manufacturers would have to enter into agreements with the Secretary of Health and Human Services in order to participate in the Medicare Part D program. A manufacturer's drugs sold and marketed in the United States would not be covered by Part D unless it agreed to participate in the discount program. The bill makes these conditions of Part D coverage inapplicable to any drugs determined by the Secretary to be essential to the health of beneficiaries or for which the Secretary finds there are "extenuating circumstances" in the period between July 1, 2010 and September 30, 2010.

In The "Donut Hole"

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The bill also charges the Secretary of Health and Human Services with the task of auditing Part D-participating manufacturers for compliance with the rules governing the discount program. Manufacturers who do not comply with the discount would be subject to civil money penalties assessed and collected by the Secretary, subject to notice and appeal rights. The bill authorizes the Secretary to prohibit a manufacturer's drugs from being covered under Medicare Part D based on the manufacturer's repeated non-compliance.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") has estimated that the 50 percent discount on branded drugs will save Medicare patients $34 billion over 10 years. (The New York Times, Aug. 26, 2009).

Study of Barriers to Utilization of Generic Medicine in Medicaid

Another noteworthy provision of the bill requires the Government Accountability Office (the "GAO") to conduct a study of state laws that have a negative impact on drug utilization in federal health care programs. The GAO's study, due to be submitted to Congress no later than April 1, 2012, would be required to consider, at a minimum, the impact of restrictions on pharmacists' ability to provide generic drug substitutes for prescribed name-brand drugs and carve-outs of certain classes of drugs from generic substitution.

Absent Features

Our summary of the Baucus bill's significant features affecting the pharmaceutical industry would not be complete without a list of some of the more conspicuously absent items:

- The prohibition, described above, against the Medicare program's direct negotiation of drug prices on behalf of Medicare beneficiaries remains in effect under the Baucus bill.

- The Medicare Prescription Drug, Improvement and Modernization Act of 2003 transferred coverage of drug benefits for "dual eligibles" (patients eligible for both Medicare and Medicaid) from Medicaid to Medicare Part D. Unlike the Medicare program, the federal government can negotiate prices on behalf of Medicaid beneficiaries directly with drug companies. According to some lawmakers, such as Representative Henry A. Waxman (D-CA), the addition of dual eligibles to Medicare's drug rolls resulted in a multibillion-dollar windfall to the drug industry and a sudden price increase of 30 percent, on average, for the same drugs formerly paid for by Medicaid.

- Allowing reimportation of cheaper branded drugs from Canada. Senate Majority Leader Harry Reid (D-NV) pledged earlier this year to allow the Senate to vote on a measure lifting the import ban before taking up broad health care reform legislation, but he later backed away from that promise. (The Wall Street Journal, Sept. 23, 2009.)

Although the Baucus bill is not likely to be the final version of health care reform legislation, its key provisions affecting the drug industry may well appear in the package ultimately submitted for President Obama's signature. Senator Reid's own legislation, now being debated on the Senate floor, maintains all of the provisions described above, with the exception of the mandated GAO study.

In any event, as health care reform goes through what may be countless iterations before final passage, one thing remains clear. The federal government will try to pay for expansion of health care coverage through cost-cutting measures and the levying of new fees, which drug manufacturers are well-advised to monitor.