

CQ Transcript
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PROMO:

GENERIC DRUGS: Senate panel examines agreements in which brand-name drug makers pay generic manufacturers to delay the entry to generics into the market.

UNINSURED: Interest groups, lawmakers unveil proposals to help reduce the number of the uninsured.

GENETIC DISCRIMINATION: Senate committee scheduled to vote on genetic discrimination legislation.

INTRO:

The Senate Judiciary panel held a hearing into deals between brand-name pharmaceutical manufacturers and generic drug makers, where the brand-name company pays a generic manufacturer to delay putting a generic on the market. Several interest groups and lawmakers unveiled their plans to help provide health care insurance to millions of the uninsured, and the Senate Health, Education, Labor and Pensions (HELP) panel has scheduled a vote on legislation that would ban genetic discrimination.

GENERIC DRUGS

Question 1: The Senate Judiciary Committee conducted a hearing that examined deals between brand-name drug makers and generic drug manufacturers that delay the entry of generics into the market. Could you tell us about that?

Answer: At the hearing, committee chairman Patrick Leahy, D-Vt. said that ending such “collusion” between drug makers would be a high priority for the committee. Democrats, backed by Federal Trade Commissioner Jon Leibowitz, expressed support for legislation to accomplish that goal.

Question 2: How do these arrangements work between brand name and generic manufacturers?

Answer: At issue are deals arising from a provision of the 1984 Hatch-Waxman legislation that is meant to encourage generic drug manufacturers to challenge invalid or narrow patents on brand-name drugs. The first generic-drug company to successfully mount such a challenge gets six months on the market free from competition by other generic drug makers. Brand-name companies can sign agreements with challengers, delaying the start of the exclusive marketing period in return for cash. The generic-drug manufacturer benefits because those payments exceed the revenue it would have received from selling its drug, and the brand-name company comes out ahead because the payments are smaller than the revenue that would be lost to generic competitions.

Question 3: What's the impact on consumers?

Answer: Critics contend that consumers lose billions from such agreements, and an antitrust crackdown by the FTC and other parties all but stopped such payments from the years 2000 to 2004. But some recent court decisions have allowed such settlements to begin again. An FTC analysis released at the hearing found that of the 28 settlements between brand-name and generics firms in fiscal 2006, 14 involved payments or other forms of compensation to the generics firm and delayed marketing of the generic drug. Drug industry lobbyists testifying at the hearing defended some of the payments as pro-consumer, and said that the kind of legislation favored by the FTC would have prevented generic drug manufacturers from entering into settlements that have allowed some generics to enter the market faster and save consumers billions.

UNINSURED

Question 4: As the new Congress begins more groups have begun to announce proposals to help reduce the number of Americans without health care insurance. Could you update us?

Answer: Groups representing the elderly, insurers, business interests and unions are unveiling their proposals that would reduce the number of uninsured Americans, with hopes that Congress will take note and either pass these plans or integrate them into emerging legislation on Capitol Hill. For example, AARP, The Business Roundtable and the Service Employees International Union have formed a coalition to address the affordability of health care. Another group, whose members include America's Health Insurance Plans, Families USA and the American Medical Association and the U.S. Chamber of Commerce, unveiled a plan that would use tax credits and expand existing programs, such as Medicaid and the State Children's Health Insurance Program, or SCHIP.

Question 5: Lawmakers are also coming forward with their ideas. What's new there?

Answer: A bipartisan, bicameral group introduced legislation that would provide grants to individual states, groups of states and portions of states to test various health reform strategies. Grants could fund initiatives including tax credits, Medicaid or SCHIP expansions or health savings accounts, all part of a "toolbox" of ideas that states could use to provide coverage.

Question 6: How will these ideas play out in the debate over the uninsured?

Answer: They certainly reflect the high level of interest in lowering the number of uninsured, which is now over 46 million. But with funding always a problem – and Democrats' pledge to follow "pay-as-you-go" or PAYGO rules which requires that spending be offset by spending cuts or tax increases – finding the money to provide health care coverage will be difficult. Yet it is still significant that such a wide range of groups are pressuring Congress to address the issue.

GENETIC DISCRIMINATION

Question 7: A Senate health panel is scheduled to vote this week on legislation that would ban discrimination based on genetics. Could you give us the details?

Answer: Sen. Edward M. Kennedy, D-Mass, chairman of the Senate Health, Education, Labor and Pensions (HELP) panel, said his panel will vote on the measure on Jan. 24. The bill, which is sponsored by Sen. Olympia J. Snowe, R-Maine, is broadly supported. Both President Bush and the Secretary of Health and Human Services have called for its passage. Those endorsements and plus the bill's past success in the Senate – the chamber passed similar bills twice, in 2005 and 2003 on unanimous votes -- give it a good chance of passage once again.

Question: Why is such legislation needed?

Answer: Proponents such as Kennedy say that without stronger legal protections against genetic discrimination, patients will not make full use of the medical advances made possible by the sequencing of the DNA code. The bill would prohibit health insurers and employers from requiring genetic tests of patients or workers. It also would forbid insurers from basing decisions on coverage or premiums on genetics information, and would bar employers from firing or hiring based on DNA.

Question 8: What are prospects in the House?

Answer: The House has never voted on the issue and that chamber's version – which is largely identical to the Senate bill – has been referred to three committees: Education and Labor, Energy and Commerce and Ways and Means.

Question 9: What do opponents say about the bill?

Answer: Business groups say the measure is unnecessary because states already have their own laws protecting people from discrimination based on their genes. The House and Senate bills would not preempt state laws, which would add new regulatory burdens for business, opponents claim. The U.S. Chamber of Commerce has successfully fought the bill in the House, arguing that the proposal has many unintended consequences, including frivolous litigation.