Consumer Federation of America

# *NEWS RELEASE*

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**SCHUMER/ MCCAIN BILL WILL STOP PRESCRIPTION DRUG INDUSTRY FROM BLOCKING ACCESS TO CHEAP, SAFE GENERIC DRUGS**

Washington, D.C. – At a news conference this morning, the Consumer Federation of America enthusiastically endorsed bipartisan legislation to increase the timely availability of safe, cost-effective generic drugs. The Greater Access to Affordable Pharmaceuticals Act of 2000, introduced by Senators Charles E. Schumer and John McCain, would prohibit number of practices commonly used by "brand name" prescription drug manufacturers to unnecessarily delay the introduction of generic drugs onto the market once a drug patent has expired.

"I commend Senators Schumer and McCain for introducing this important legislation," said retired Senator Howard M. Metzenbaum, the chairman of the Consumer Federation of America. "Every time a drug company blocks a safe, generic drug from getting into the hands of the American people, they are placing a tax on the uninsured, the poor, the sick and the elderly."

Americans already save a tremendous amount of money on generic drugs. The Congressional Budget Office estimates that consumers save $8 billion to $10 billion a year by purchasing generic drugs.

"This bill would allow Americans to save even more money on generic drugs," said Metzenbaum. "It is outrageous that the same companies that charge Americans the highest drug prices in the industrialized world would use secret payoffs, flimsy legal maneuvers and back room deals to eliminate generic competition, line their pockets and harm consumers."

The bill would stop or restrict a number of practices used by prescription drug manufacturers to thwart competition, including: the use of nuisance "Orange Book" lawsuits and citizen petitions, and payoffs to generic manufacturers to withhold a generic alternative from the market. The legislation also contains a "Sense of Congress" resolution opposing the use of appropriations riders to extend drug patents.

**Consumer Federation of America**

September 14, 2000

The Honorable Charles E. Schumer
United States Senate
Washington, D.C. 20510

The Honorable John McCain
United States Senate
Washington, D.C. 20510

***RE: SUPPORT GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT***

Dear Senators Schumer and McCain:

The Consumer Federation of America strongly supports your proposal to increase the timely availability of safe, cost-effective generic drugs. **The Greater Access to Affordable Pharmaceuticals Act of 2000 will stop brand name prescription drug manufacturers from using flimsy legal maneuvers to block the introduction of generic alternatives onto the market once a drug patent has expired**.

This legislation couldn't come at a more important time. Drug companies charge more for prescription drugs in this country than in any other industrialized nation. Drug prices are increasing much faster than inflation or overall healthcare costs. Roughly 70 million Americans have no prescription drug coverage at all, including one-third of the elderly. Millions more—both young and old—have inadequate drug coverage.[i]

Americans save a tremendous amount of money on generic drugs, thanks in large part to the passage of the Drug Price Competition and Patent Restoration Act (also known as the Hatch-Waxman Act) in 1984. The Congressional Budget Office (CBO) estimates that drug prices drop by an average of 25% upon the introduction of a generic drug. CBO concluded that Americans saved $8 to $10 billion in 1994 alone by purchasing generic drugs.[ii]

The Hatch-Waxman Act represents a careful balancing act. It was designed to increase timely access to generic drugs, while ensuring that drug manufacturers have adequate patent protection to justify substantial investment in research and development. In other words, the Act promotes innovation and affordability.

However, as sales of generics have grown, brand name drug manufacturers have become very adept at upsetting this balance through the use of frivolous legal tactics that delay the introduction of generic drugs. This bill prevents drug companies from undermining the intent of the Hatch-Waxman Act in several ways.

**First, the legislation would block nuisance "Orange Book" lawsuits**. Brand companies frequently file lawsuits when their patents expire, claiming that generics

cannot be manufactured while additional patents are in force. Such lawsuits, whether sound or not, automatically trigger a delay in the introduction of the generic alternative for up to 30 months.

Brand name manufacturers often record multiple patent claims that have nothing to do with whether the generic drug is therapeutically equivalent to the brand drug. Sometimes, these patents are trivial, relating, for instance, to the color of the medication.

The Food and Drug Administration (FDA) merely stores these patent claims in its registry, called the Orange Book. It does not verify whether the patents are actually related to the active ingredients of the drug. As a result, many brand name firms file patent lawsuits automatically, merely to delay introduction of a generic drug.

This bill will only allow manufacturers to list patents that relate to the active ingredients of drugs and the primary methods of using them. "Formulation" patents, which merely tinker superficially with the drug's contents, are would not be considered for generic approval. The bill also allows generics to remain on the market while patent lawsuits are pending, thus removing much of the incentive for brand manufacturers to file frivolous lawsuits. In the event that a brand name company wins such a suit, it could seek a licensing fee from the generic firm.

**Secondly, the Act takes several important steps to prevent anti-competitive payoffs by brand name manufacturers, in which generic firms agree to withhold their drug from the market**. This type of collusion turns the intent of the Hatch-Waxman act on its head and can cost consumers as much as a million dollars a day. Such payoffs occur because the law grants the generic firm that is first to file an application for a generic alternative a monopoly of 180 days—no other generic manufacturer can sell the drug for that period. This bill would allow this period of market exclusivity to be transferred to a second generic firm if the company that was "first to file" reaches a financial settlement with the brand name manufacturer.

**This bill would also prohibit the abuse of "citizen petitions" to delay introduction of generic drugs**. Citizen petitions allow individuals or interested parties to challenge the approval of a drug on health and safety grounds. Brand name drug manufacturers are increasingly filing citizen petitions merely to keep generic competition at bay. The FDA is required by law to consider each petition individually, which can delay the introduction of a generic alternative for a very long time. This bill raises the standard for consideration of these petitions, so that that the petitioner must demonstrate substantial scientific proof that the approval of a new drug application would represent a serious threat to health and safety.

**The Consumer Federation strongly supports the bill's "Sense of Congress" resolution opposing patent extension riders**. Appropriations riders to extend patents on individual drugs have become an annual ritual in Congress. This year, both Columbia University and the drug manufacturer Schering Plough have been urging Congress to sneak through patent extensions in appropriations bills. The Hatch-Waxman Act contains a procedure for extending drug patents up to five years, if the

manufacturer can prove that such an extension is justifiable. This provision establishes a Congressional policy opposed to such an "end run" around the FDA and the law.

The bill would also expand the definition of generic equivalence to include several classes of drugs not covered by current law. As "bioequivalence" under current law is determined by the absorption of a drug in a patient's blood stream, it is difficult to make a determination about the generic alternatives to many types of medications, such as dermatological and inhaled medicines.

The drug industry has repeatedly used delaying tactics to unjustly deny access to generic drugs. **This is not only a threat to the pocketbook of many Americans, but to their health.** When faced with unaffordable drug costs, many people will go without needed medications or reduce the consumption of these drugs below the prescribed level. We commend you for introducing legislation to increase the flow of safe, cost-effective generic drugs to Americans in need.

Sincerely,

Travis B. Plunkett
Legislative Director

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[i] Alan Segar, Ph. D.., Deborah Socolar, M.P.H; Boston University; *Affordable Medications for Americans: Problem, Causes and Solutions*; July 27, 1999.

[ii] Congressional Budget Office; *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*; July 1998.