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THREE MORE STRIKES ON PRESCRIPTION DRUGS

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Congress continues to struggle with the issue of making prescription drugs more affordable for seniors—a debate that will get more heated as the general election nears. Three bills now before Congress that address this issue offer scant encouragement.

The International Prescription Drug Parity Act (H.R. 1885/S. 1191), sponsored by Representative Marion Berry (D–AR) and Senator Byron Dorgan (D–ND), would allow wholesalers to import in bulk any prescription drug approved by the Food and Drug Administration. The Prescription Drug Fairness Act (S. 2464), introduced by Senator Slade Gorton (R–WA), would prohibit U.S. drug manufacturers from selling products to foreign buyers for less than they charge domestic buyers. The Medicare Prescription Drug Plan (S. 2319), introduced by Senators Robert Smith (R–NH) and Wayne Allard (R–CO), would permit seniors to enroll in a new Medicare drug benefit program if they agree to combine their Part A and Part B deductibles. All three approaches fall short of offering seniors what they truly deserve—a comprehensive reform of Medicare that integrates drug coverage into a plan resembling the successful Federal Employees Health Benefits Program (FEHBP) currently enjoyed by Members of Congress, their staffs, and 9 million other federal employees.

Reimportation of Drugs (H.R. 1885/S. 1191). Supporters of this bill assert that allowing more "free trade" in pharmaceuticals would cause prices to come down in the United States. They assume that allowing Americans to take advantage of the price controls in other countries would make drugs cheaper in America. This approach is mistaken; it would likely have little downward effect on U.S. prices and could actually *raise* prices for American consumers. If such reimportation occurred, drug companies would have to raise prices in foreign markets to avoid undercutting the U.S. market. This could lead to fewer exports of their products. To make up for the lost sales, the companies might have to raise prices in the U.S. market.

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Raising prices in foreign markets also would increase the likelihood that foreign governments would resort to compulsory licensing and simply ignore the intellectual property rights of U.S. drug firms. This occurred in Canada under the Liberal government of Pierre Trudeau. It also occurred in the United Kingdom as recently as the 1980s. If compulsory licensing became commonplace overseas, more pressure would be exerted to raise drug prices in America as companies struggled to recoup their losses abroad.

The bill would amend current law to allow reimportation of domestically approved prescription drugs. The Prescription Drug Marketing Act of 1987 prohibited this kind of reimportation. House

Energy and Commerce Committee Chairman John Dingell (D–MI) and others appropriately expressed concern about the quality of prescription drugs obtained from abroad. H.R. 1885 would relax current standards, leaving U.S. consumers vulnerable to unsafe foreign manufacturing practices.

Notwithstanding the fact that the effect of this bill, contrary to its sponsors' intent, would be to raise drug prices for U.S. consumers, it also would infringe on patent holders' rights. It would run up against patent protections encoded in U.S. law, the North American Free Trade Agreement (NAFTA), and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of International Property Rights (TRIPS).

If a foreign distributor violates terms of the private licensing agreement signed with the original manufacturer and those terms forbid reimportation, the patent holder has legal recourse for contract violation and patent infringement. Title 35 U.S.C. Section 271, for example, states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or *imports into the United States* any patented invention during the term of the patent therefore, infringes the patent [emphasis added]." This legal provision grants patent holders of U.S. intellectual property rights remedies available from the International Trade Commission (ITC). Article 1709 of NAFTA also enforces the intellectual property rights enjoyed by patent holders, as do Articles 27 and 28 of the WTO TRIPS agreement.

Fairness (S. 2464). This legislation would prohibit U.S. pharmaceutical manufacturers from selling their products to foreign wholesalers for less than the prices they charge domestically. Constant fluctuations in world currencies would make this legislation all but impossible to enforce. Also, claims for price discrimination could come from any entity that purchased the prescription drugs, including individuals, states, drug wholesalers, independent pharmacies, chain pharmacies, or the federal government. Each claimant would only have to prove that one sale of one drug in one currency was "below" that of one sale of one drug to one wholesaler in America.

Like H.R. 1885, S. 2464 could result in *higher* prices for American consumers due to decreased sales abroad. It would do nothing to provide coverage for seniors. Finally, it would prevent drug companies from giving away, or selling at below cost, their products to impoverished countries (as, for example, AIDS drugs are sold to Africa today).

Voluntary Medicare Benefits (S. 2319). S. 2319 would add a voluntary prescription drug benefit to Medicare. For those who enroll, Part A and Part B deductibles (currently $768 and $100, respectively) would be collapsed into one $675 deductible. In exchange, they would receive a drug benefit equal to 50 percent of drug costs up to $5,000.

But this bill would not reform the troubled Medicare system. It not only would keep the Health Care Financing Administration (HCFA) in charge of Medicare, but actually would give HCFA *more* power, allowing it to manage the new drug benefit. Yet a recent hearing by the House Budget Committee's Health Care Task Force outlined how HCFA's excessive rules, regulations, and mandates on providers harm the delivery of medical care—findings that are consistent with those of other committees and outside groups. A properly reformed Medicare system would eliminate HCFA's oversight responsibilities.

Conclusion. In its final report to Congress, the National Bipartisan Commission on the Future of Medicare presented an answer to the Medicare prescription drug problem that a bipartisan majority of its commissioners endorsed: Make Medicare a program that is modeled after the FEHBP. As this analysis of these bills shows there is no magic bullet on prescription drugs. Anything short of overall Medicare reform will, at best, result in a less than satisfactory solution to the vexing problem of prescription drug costs.

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