Congressman

Rahm Emanuel

H.R. 2427 / S. 1781, Pharmaceutical Market Access Act

Safe Medicines ... at **Affordable Prices ...** in **Every Community**

Much *mis*information has been put out about H.R. 2427/S. 1781, the *Pharmaceutical Market Access Act*. H.R. 2427/S. 1781 will allow the importation of *only* FDA-approved drugs manufactured *only* in FDA-approved facilities, plain and simple.

Counterfeits

Will H.R. 2427/S. 1781 allow counterfeit drugs, or those that have been tampered with or allowed to expire, into the country?

Absolutely not. H.R. 2427/S. 1781 strengthens America's commitment to maintaining the safest pharmaceutical drug market in the world. It will raise America's standard of safety by requiring all pharmaceutical manufacturers to use state-of-the-art, anti-counterfeiting packaging similar to the technology already used by the U.S. Department of the Treasury. If the technology is good enough to secure U.S. currency, it's good enough to secure our pharmaceutical chain-of-custody. In fact, this technology is already used throughout the European Union to secure pharmaceutical packages and costs mere pennies per package. In cases in which such packaging is not used, H.R. 2427/S. 1781 contains language written by the legal team at FDA that requires wholesalers to test each pharmaceutical shipment.

Prescription Drug Imports Today

Are FDA-approved prescription drugs ever imported onto the U.S. market?

Yes. FDA-approved drugs are already frequently (and legally) imported into this country, but only by the manufacturers. In fact, according to the International Trade Commission, $14.7 billion in drugs were imported into the United States in 2000. Isn't it ironic that the drug makers are saying this cannot be done safely?

Under federal law, pharmaceutical manufacturers are the only ones allowed to import FDA-approved drugs into this country. Yet, if an American pharmacist or distributor wants to purchase these FDA-approved drugs at the much-lower prices available in other countries and pass the savings along to their customers, they are prohibited by law from doing so. This has created a sweetheart deal for the pharmaceutical industry in which they have been guaranteed a closed market with no competition. Hence, American consumers in 2002 were charged, on average, 38 percent more than consumers in Canada, 31 percent more than citizens of Great Britain, 45 percent more than French consumers, and 48 percent more than Italian citizens.

Reimportation is a common-sense thing to do. It is pro-business, pro-consumer and pro-American.

Certification of Safety by the HHS Secretary

Does this bill strike the requirement in current law that the Secretary pre-certify, before implementation, that the reimportation system be safe and cost-saving?
Yes. The bill would strike the existing requirement in Section 804 of the Food and Drug Cosmetic Act that prior to implementation, the Secretary of Health and Human Services must assure that reimportation would pose no additional risk to the public's health or safety and would result in 'significant' cost-savings for American consumers. HHS Secretary Tommy Thompson already announced, in July 2001, that he would never make such a certification.

Why? Because it is impossible to make such a certification for any product. It is a "poison-pill" requirement applied to no other imported product, despite significant risk. Take, for example, food imports. For FY 2004, the FDA will be responsible for ensuring the safety of approximately 6 million imported food and food-related products. Under the current food safety system, could the Secretary of HHS certify that imported foods posed no additional risk to the public's health or safety? Not a chance.

Do other imported products require a similar certification?
No. Despite the fact that the FDA inspects only 2-3% of foods imported into the United States there is no similar certification required for food or any other imported product. Yet, despite the tens of thousands of Americans who get sick every year from foods imported from every corner of the world, the FDA claims that we have the "safest food supply in the world." However, according to the Centers for Disease Control, every year 76 million people get sick, more than 300,000 are hospitalized, and 5,000 die from diseases caused by foods. According to the FDA, not a single case has been reported of an American becoming ill from an imported drug. However, the FDA continues to claim that drug importation is dangerous, even though drug manufacturers import about $15 billion of pharmaceuticals themselves each year.

In contrast, H.R. 2427/S. 1781 would only allow the importation of FDA-approved drugs manufactured in FDA-approved facilities from 26 designated countries: the EU, Australia, Canada, Iceland, Israel, Japan, Lichtenstein, New Zealand, Norway, Switzerland, and South Africa.

Second-Tier Markets
Will H.R. 2427/S. 1781 create an alternative stream or "second-tier" of non-FDA-approved drugs in the U.S. system, forcing low-income and working class Americans to buy sub-par medicines?

Absolutely not – it will do just the opposite. H.R. 2427/S. 1781 will correct the two-tiered system that already exists due to the vicious pricing practices of the drug giants by ensuring that all Americans have access to safe, effective and affordable drugs. Some opponents of this legislation have claimed that it would create a two-tiered system of medicines in this country – those that are certified by the FDA, that the wealthy and those with comprehensive insurance can afford, and unsafe drugs that only poor Americans would buy. The reality is that this scenario is more likely to exist today – since so many Americans cannot afford prescription drugs at the

premium prices charged here, poor Americans are more likely to buy drugs through illegal means, skip doses, or cut pills in half, seriously undermining their effectiveness.

The plain fact is that more than one million Americans already purchase their medicines from outside the American market and there has not been one reported death or illness from Americans taking such products. In fact, Americans appear to be more likely to be harmed by counterfeit or tainted drugs from within the United States than from those purchased from pharmacies in Canada and elsewhere.

"Importing Price Controls"

Will H.R. 2427/S. 1781 "import price controls" from other countries?
Quite the contrary - it opens markets and ends the price controls established by the stranglehold the drug makers hold over American consumers. H.R. 2427/S. 1781 merely extends the benefits of free trade to buyers of prescription drugs. Drug manufacturers already benefit from free trade by buying the ingredients for their products at the lowest prices on the world market, and in fact, many of the ingredients they use can be imported free of tariffs. This bill would merely enable American consumers to make the global economy work for them, too.

Research and Development

Will this bill damage the ability of prescription drug makers to invest in research?
No – though it may cause them to rethink the astronomical amounts they spend on marketing and advertising. About 20 cents of each prescription drug dollar is spent on research and development. Pharmaceutical companies' after-tax profits - and after expenditures for R&D - averaged 17 percent from 1994 to 1998, compared with 5 percent for all other industries, according to a December 1999 report from the Congressional Research Service.

Drug makers also spend a significant portion of their budgets - $15.7 billion in 2000 - on product promotion. In fact, according to a July 2001 report by Families USA, the 9 pharmaceutical companies marketing the 50 top-selling medications spent more on marketing, advertising, and administration than they did on research and development.

American taxpayers already heavily subsidize pharmaceutical research through the tax code. For instance, in 1996 alone, the pharmaceutical industry was able to reduce its tax liability by $3.8 billion using a variety of tax credits. According to CRS, drug makers pay significantly less in taxes than other industries: The average effective tax rate for pharmaceutical companies was 16.2 percent from 1993 to 1996, compared to the average effective tax rate of 27.3 percent for all other major industries.

Perhaps most importantly, taxpayer-funded research at the National Institutes of Health led directly to the development of 7 of the 21 most important drugs introduced in recent years, and an additional 8 more drugs used NIH-developed knowledge and techniques. Why should Americans have to pay anywhere from 2 to 10 times more than Canadians or Europeans for drugs developed with their hard-earned tax dollars?

The truth is that drug companies do not set U.S. prices to cover research costs; they set them to maximize profits. They can set drug prices at extraordinary levels in our country because current law protects them from competition.

Cost-savings

Will the savings realized by pharmacists and wholesalers be passed on to consumers?
Absolutely - the pharmacy marketplace is highly competitive. Community pharmacies generally have modest gross margins – in the neighborhood of 1-2% - and low profits. In addition, their customers who do not have insurance coverage for prescription drugs are extremely price sensitive and will take their business to mail-order or internet companies or elsewhere if the lower prices are not passed on. As a result, pharmacists will have little choice but to pass the lower costs on to their customers.

Prescriptions

Will H.R. 2427/S. 1781 allow individuals to access medications without a prescription*?*
Not at all. Opponents of this legislation have charged that this bill would allow individuals to order unlimited sums of medication without any prescription – this is untrue. The entire Federal Food Drug and Cosmetic Act remains in effect under this legislation, including all regulations for accessing prescription drugs.

Medicare Prescription Drug Benefit

How will this legislation help Medicare beneficiaries who could still have difficulty paying for their medicines even if the bill were enacted?
This legislation will make Medicare prescription drug coverage more feasible and affordable for American taxpayers. According to a Boston University School of Public Health study, our nation could save more than $38 billion annually if American consumers could buy medications at Canadian prices - money which could be used to provide significant help to Americans who are currently without prescription drug coverage. In addition, this bill would help the more than 70 million younger Americans who don't have health insurance coverage for part or all of the year and who therefore must pay for their medications out of their own pockets.

REMEMBER: An unaffordable drug is neither safe nor effective!
According to the Kaiser Family Foundation, nearly 30 percent of all Americans seniors who are prescribed drugs do not fill their prescriptions because they cannot afford to. An unaffordable drug is neither safe nor effective.