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## AS WE SEE IT

### Are Offshore Drugs Dangerous?

If you suffer from type II diabetes, you're likely to be prescribed a drug called Glucophage. This drug lowers glucose and other blood risk factors that cause lethal diabetic complications.

Glucophage works by enhancing cell sensitivity to the effects of insulin. Since type II diabetes is characterized by cellular insulin resistance, the fact that Glucophage helps restore insulin sensitivity makes it a potent weapon against a disease that currently afflicts 16 million Americans.

Glucophage also reduces the amount of glucose produced by the liver and decreases intestinal absorption of sugar.(1) The result is that glycemic control is restored and patients often lose some weight. Clinical studies dating back to the 1950s demonstrate Glucophage's efficacy and safety when properly used.

For several decades, Americans could not legally obtain Glucophage. That's because the FDA said it was toxic and banned its sale in the U.S. The Europeans did not agree that Glucophage posed a health risk and approved its use decades ago. (Glucophage is sold under the name "metformin" in other countries.)

The FDA was proven wrong about Glucophage and the drug was finally approved in December 1994. It is difficult to calculate exactly how many Americans died while Glucophage was kept out of the United States. It is very easy, however, to document that American consumers are being price gouged because of the FDA's error. A one-month supply of Glucophage costs \$4.12 in other countries, while Americans pay \$32.83 for the same quantity.

The reason for this unconscionable price disparity is that Glucophage is old news in Europe, where it has been used since the 1960s. The FDA's delay in approval has enabled Glucophage to enjoy a virtual monopoly in the United States, causing U.S. citizens to pay more than seven times the price this same drug sells for in other countries.

The number of people who die each year from diabetic complications is staggering. American diabetics perished while Glucophage was being safely used throughout the world. Because of FDA ineptitude, U.S. citizens pay grossly inflated prices to obtain a drug (Glucophage) that is more than 30 years old.

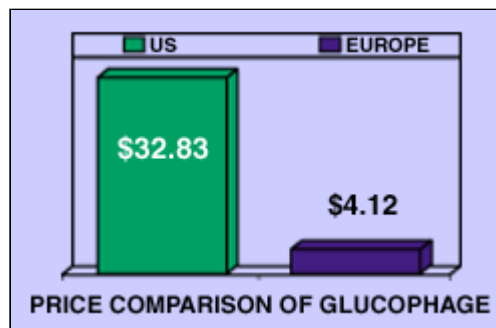
The FDA's latest charade

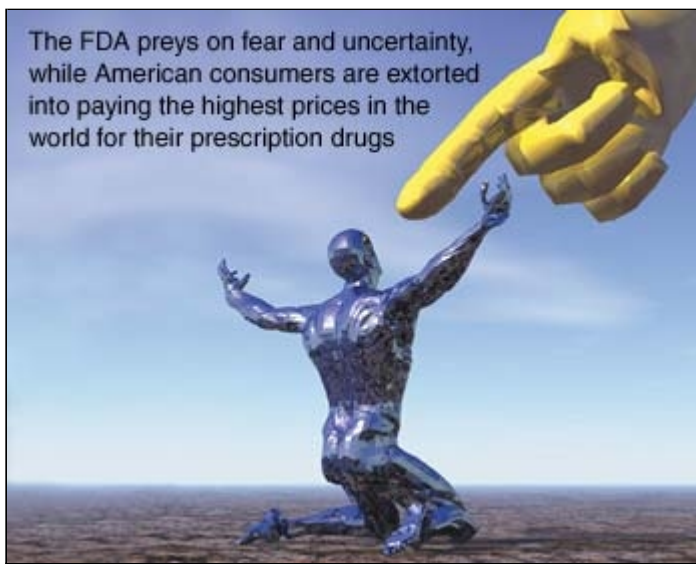
The FDA now has the audacity to ask Congress to ban just about ALL imports of medications from other countries under the guise of "protecting" Americans against dangerous drugs.

On June 7, 2001, the FDA told Congress that they want to halt almost all small shipments of foreign drugs mailed to consumers in the U.S. The FDA wants U.S. Custom Service agents to send back all small foreign drug shipments they find. The only exemption would be for "compassionate use," so that seriously ill patients who have exhausted all approved treatments could order drugs from overseas that are unavailable in the U.S.



William Faloon





The FDA says it needs to turn away all foreign drug shipments because of the sheer volume of drugs being imported. More American consumers are learning they can obtain prescription drugs at a fraction of the price charged in the U.S. The FDA now admits that the number of shipments far exceeds the agency's ability to review them on a case-by-case basis. The FDA told Congress, "We need to be able to make a blanket assessment that these things are not safe for American consumers and should be turned back."

The fraud being perpetrated by the FDA is the assertion that medications imported from other countries are automatically illegal, counterfeit or contaminated. This is what the FDA would have said about Glucophage before they approved it in 1994. The facts are that drugs from other countries cost far less and are sometimes more advanced than what is available on the American marketplace.

The FDA told Congress that an estimated 2 million packages containing drugs enter the United States through international mail each year. "The inescapable conclusion is these drugs are virtually all unapproved in the United States.... They may be counterfeit or worse," the FDA said to Congress.

The truth is that most of the drugs the FDA complains about are already FDA-approved and are manufactured by the same companies that sell them to American pharmacies. The FDA is using scare tactics to protect the profits of the pharmaceutical industry...not the health of the public.

Currently, the law says that Customs must contact recipients if it detains drugs at the border. The FDA's new proposal would waive that requirement. In other words, the FDA wants all drugs to be turned away without even providing the U.S. citizen (who paid for the drug) with a notice and opportunity to explain why they need them.(2)

The emperor has no clothes

Drugs the FDA says are safe kill over 100,000 Americans every year, while the agency cannot demonstrate drugs imported from other countries are hurting anyone.

That's not to say that some day an American won't suffer an adverse reaction from an imported drug. After all, many of the drugs being imported are the same FDA-approved medications that are killing over 100,000 Americans every year.(3-5) Could it be that Americans who are smart enough to buy their medications from lower cost foreign suppliers also read the package inserts in order to reduce their risk of suffering an adverse reaction?

The FDA denied Glucophage to Americans for decades, but rapidly approved Rezulin to treat Type II diabetics. Rezulin killed about 391 Americans before it was withdrawn, according to a tabulation done by the Los Angeles Times.(6) Those afflicted with Type II diabetes suffered and died waiting for the FDA's belated approval of the relatively safe drug Glucophage.

#### Life Extension investigates the FDA

In response to the FDA's allegations that all drugs being imported from other countries were "dangerous," I contacted various FDA departments to try to ascertain how many people were actually dying or suffering severe adverse effects from imported drugs.

Most of the FDA staffers were quite courteous in taking my calls and some took the time to look into the

So while the FDA brazenly testified before Congress that all drugs imported from other countries are “dangerous,” the facts show the agency’s assertion is blatantly false and misleading. Today’s drug emperor (the FDA), has no clothes (veracity) in arguing against Americans purchasing their medications from other countries.

The FDA preys on fear and uncertainty, while American consumers are extorted into paying the highest prices in the world for their prescription drugs.

Undoing this travesty

We believe the FDA lacks the moral and scientific legitimacy to deny Americans access to medications that are approved by health ministries in other countries. The FDA’s delay in approving Glucophage is a prime example of why this agency should not be allowed to embargo drugs from other countries.

Bureaucratic barriers at the FDA stifle the development of novel medicines, while drug company influence enables lethal drugs (like Rezulin) to be “approved” by the agency as safe and effective.

There exists a unique opportunity to change this pattern of incompetence, deceit and arrogance. President Bush will soon decide who to nominate as the next FDA Commissioner.

One candidate for the Commissioner’s job has a plan to radically reform the FDA. The name of this candidate is Mary J. Ruwart, Ph.D. In the July 2001 issue of Life Extension, we published information to show that Dr. Ruwart is uniquely qualified to reform an agency that has lost touch with scientific objectivity.

matter for me. The response from most of the staffers was that the agency did not keep a log of adverse effects occurring in Americans who ordered offshore medications, but the actual number of reported adverse effects was small. Most of the FDA staffers asked not to be quoted, but two of them put the following in writing:

Hi Mr. Faloon,

As a follow-up to my earlier e-mail, I have consulted with FDA folks involved with the issues surrounding personal imports being received by U.S. citizens, via mail, from foreign sources.

FDA does not have a final number on how many reports of adverse events due to an imported drug it has received, but the number is small.

These cases are under investigation and so FDA cannot discuss details.

Take care,

Crystal Rice, FDA Press Office

It is imperative that health freedom activists notify President Bush that Dr. Ruwart is the best person to remedy the problems that exist at the FDA. Please mail the letter that appears below on this page to the President at the address we have provided.

Following this letter to President Bush is a letter you can mail to your Senators to urge them to support a bill that will allow Americans to purchase their prescription medications from other countries without FDA interference.

Inefficient government thrives on citizen apathy, so please take the time to mail out the letters to President Bush and your two Senators.

For longer life,



William Faloon

Also read: [How you can stop the drug price ripoff](#)

Mr. Faloon,

You asked how many adverse reaction to drugs imported from other countries have been reported to the FDA. The answer is that the FDA does not have a firm number at the present time, but the number is small.

Jeffrey Shuren, M.D., Medical Officer in the Food and Drug Administration's Office of Policy, Planning and Legislation.

I then asked for specifics about the testimony given to Congress that stated that ALL imported drugs were dangerous. I was told that in order to obtain additional information, we would have to file a Freedom of Information Act (FOIA) request. We have filed an FOIA request and are

awaiting the FDA's response about the specific imported drugs it told Congress are so "dangerous."

We will evaluate the FDA's response to our FOIA request and report the findings in a future issue of this publication.

References:

1. Physician's Desk Reference 2001, p. 1005.
2. Statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration, before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce, U.S. House of Representatives, June 7, 2001. <http://www.fda.gov/ola/2001/drugimport0607.html>
3. Lazarou J, et al. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA 1998 Apr 15;279(15):1200-5.
4. Bates DW. Drugs and adverse drug reactions: how worried should we be? JAMA 1998 Apr 15;279(15):1216-7.
5. Cimons M. "FDA Moves to Reduce Accidental Drug Deaths." LA Times May 10, 1999. Home Edition Section: PART A Page: A-1.
6. Willman David "Rise and Fall of the Killer Drug Rezulin" Life Extension magazine, Sept. 2000, p. 31-39.

Note: Glucophage is not for everyone. To read safety precautions about this drug, log on to [www.glucophage.com](http://www.glucophage.com)

Date: \_\_\_\_\_

President George W. Bush  
The White House  
Washington, D.C. 20500

Dear President Bush:

I request that you appoint Mary J. Ruwart, Ph.D., as the next Commissioner of the U.S. Food and Drug Administration.

The reason for the urgency of this appointment is that serious institutional problems exist within the FDA that cause Americans to suffer and die needlessly. Dr. Ruwart has identified what's wrong with the FDA and has proposed practical solutions. I am concerned that anyone else you appoint will continue a "business as usual" approach that will not result in the kind of reform that is needed to prevent disease, injury and death by over-regulation.

In her application to you, Dr. Ruwart stated, "My goal will be to facilitate the conversion of the FDA from a bureaucratic regulatory regime into a market-oriented support system that maximizes our access to life-saving medications."

The public is becoming increasingly aware that the FDA is largely responsible for the high cost of prescription drugs in the U.S. When Americans are diagnosed with serious diseases, many seek therapies that have not yet been approved by the FDA. I find it deplorable that the agency that is supposed to protect the American public has become a major impediment to its access of new life-saving therapies.

The most important issue to me is my health and the cost of prescription drugs. I therefore urge you to make a historic and humane decision by appointing Dr. Ruwart as the next Commissioner of the Food and Drug Administration.

Please let me know your position on this issue.

Sincerely,

\_\_\_\_\_  
Signature

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ ST \_\_\_\_\_ ZIP \_\_\_\_\_

Date: \_\_\_\_\_

The Honorable \_\_\_\_\_  
United States Senate  
Washington, D.C. 20510

Dear Senator:

Americans pay the highest prices in the world for their prescription medications. Shifting high drug prices to Medicare only means that the burden is transferred to the taxpayer. The House of Representatives just passed the FY 2002 Agriculture Appropriations bill that includes a provision to allow Americans to import FDA-approved drugs from other countries. The price of these identical medications is 30% to 70% lower than what Americans are being forced to pay today.

I urge you to support Senator Paul Wellstone's amendment to the Agriculture Appropriations bill as long as it follows the Gutknecht House language that allows Americans to obtain prescription drugs from other countries for personal use. The House version of this bill stops the FDA from blocking the importation of lower cost medications from other countries. Please make sure this same language included in the Senate version of this bill. As your constituent, I am asking you to vote on the Fiscal Year 2002 Agriculture Appropriations bill that includes the Gutknecht language. Passage of this bill (with the personal importation provisions included) will make a significant impact on resolving the health care cost crisis that threatens to bankrupt this country.

Please let me know your position on this critically important issue.

Sincerely,

\_\_\_\_\_  
Signature

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ ST \_\_\_\_\_ ZIP \_\_\_\_\_

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