



April 8, 2008

HEALTH JOURNAL
By MELINDA BECK



Why You Can't Tell Where Your Medication Was Made

April 8, 2008; Page D1

(See Corrections & Amplifications item below.)

Bananas come with those little stickers listing their country of origin. Why not pharmaceuticals?

That's what some consumers -- and even some physicians -- are asking since the Food and Drug Administration linked the deaths of 19 people to contaminated batches of the blood thinner heparin from China.

"I'm just concerned in general about products coming from China," says Beth Najberg, who designs corporate training programs in Chicago. She looked for the origin of her generic thyroid medication -- levothyroxine -- on the manufacturer's Web site, but didn't learn much.

Indeed, the FDA requires drug companies to disclose only the name and place of business of the manufacturer, packer *or* distributor of prescription medications. Active and inactive ingredients must be listed on the label, but not the raw materials or their origins, which are considered "commercial confidential." (Mylan Inc. says its levothyroxine is made in Morgantown, W.Va., but sources aren't listed for raw materials.)



Pfizer

Most modern medications are synthesized from chemicals in laboratories, but some include biological agents as diverse as whale sperm, and human blood parts. Suppliers range from itinerant fishermen to giant chemical companies. Besides the active ingredients, a single pill may include dozens of fillers and bulking agents, each of which has its own global supply chain.

Drug companies say making such information public would be neither practical nor helpful to consumers, and that what counts is that any medication sold in the U.S. must meet Good Manufacturing Practices set by the FDA. "The requirements, if it's made in Nutley, N.J., or a foreign country, are exactly the same," says Lori Reilly, vice president for policy and research at Pharmaceutical Research and Manufacturers of America, a drug-industry trade group.

But ensuring that those rules are met is up to the companies. The FDA doesn't have the resources to regularly inspect overseas facilities, where 80% of the active ingredients in U.S. drugs now originate. The Government Accountability Office says that at the current rate, it would take the FDA 13 years to inspect each existing foreign establishment once. The House Energy and Commerce Committee is reworking a bill that would ramp up the FDA's inspections overseas and is considering calls to require drug labels to list country-of-origin for active ingredients.

Would requiring more public disclosure about sourcing enhance safety? Even consumer watchdog groups aren't sure. "The devil is in the details. Would you list the finished product, or the raw ingredient or the raw-er ingredient?" asks Peter Lurie, deputy director of the health research group at Public Citizen.

"What level of detail would be meaningful to consumers?" asks Karen Riley, an FDA spokeswoman. "What does it mean that most heparin in the world is coming from China and you need heparin?" Unlike toys and toothpaste, drugs usually aren't optional or interchangeable.

Drug companies say what consumers can do is be alert to counterfeit pharmaceuticals -- particularly from outside the U.S. Pfizer Inc. says it has confirmed fake versions of its drugs in at least 75 countries, and in the legitimate supply chain in at least 25 countries. Industry executives offer these tips:

Buy from a U.S. state-licensed pharmacy you trust. Be especially wary of any online sellers that don't include contact information, don't require a doctor's prescription or don't bear a seal from the Verified Internet Pharmacy Practice Sites, or VIPPS.

Look closely at the pills. Just as with knockoff handbags, there are often telltale imperfections in counterfeit pills. "There should be no chips. Any embossing should be centered and properly done," says Wayne Pines, a former FDA spokesman who is now a consultant to drug companies. Changes in the color, taste or smell can also be red flags.

Check that any "tamper-evident" packaging is intact. Misalignments or sticky residue can indicate that a seal has been broken and replaced.

If you are taking a medication for a specific symptom, monitor how you feel. If your drug isn't working the way it is supposed to, let your doctor know.

Email healthjournal@wsj.com³.

Corrections & Amplifications:

Commercial trade in whale-derived products has been banned by the Convention on International Trade in Endangered Species of Wild Fauna and Flora since the last 1980s. This Health Journal column incorrectly said that whale sperm was among the many biological products used in some pharmaceuticals.

URL for this article:

<http://online.wsj.com/article/SB120759560791495641.html>

Hyperlinks in this Article:

- (1) <http://forums.wsj.com/viewtopic.php?t=2050>
- (2) <http://forums.wsj.com/viewtopic.php?t=2050>
- (3) <mailto:healthjournal@wsj.com>

Copyright 2008 Dow Jones & Company, Inc. All Rights Reserved

This copy is for your personal, non-commercial use only. Distribution and use of this material are governed by our **Subscriber Agreement** and by copyright law. For non-personal use or to order multiple copies, please contact Dow Jones Reprints at 1-800-843-0008 or visit www.djreprints.com.