

## Drug Donations: *Not* What the Doctor Ordered?

Client: NurseVillage.com

It seems like it should be the perfect match: Pharmaceutical companies, retailers, hospitals, and wholesalers have expiring drugs they need to remove from their shelves; countries in crisis all over the world need the medicines they have to offer. Sometimes the match *is* made correctly, and all is well. In these cases, the donating companies get tax deductions, and victims of famine, disease, or war get the pharmaceutical products they need.

But it doesn't always happen that way.

A humanitarian agency in the Republic of Georgia received an unsolicited donation of 20 tons of silver sulphadiazine ointment. Not only was it more ointment than the newly independent republic could ever use, none of it could be used at all because the contents of the entire shipment had expired the previous year. It took several months to burn all the tubes of unusable product.

Then there was the Zambian mission hospital that received a donation of amphetamine-based appetite suppressants. If there was anything the Zambians *didn't* need to do, it was lose weight—especially with the help of amphetamines.

### **Sometimes, even when you're right, you're wrong**

The stories go on and on, describing tons of useless supplies sent all over the world, creating more trouble than they're worth. And sometimes, even when the intentions are good, the outcome isn't. Consider the tale of Eli Lilly and Company. In 1994, Lilly teamed with several humanitarian organizations to provide 25 million doses of Ceclor CD for refugees from Rwanda's civil war. With all good intentions, Lilly responded to the Rwandan government's request for antibiotics, which, among other things, was to be used to treat the machete wounds of Rwandans injured in battle.

In its efforts to deliver the drugs, Lilly even had the cooperation of the FDA, which at the time had not quite completed its review of Ceclor. Because the drug had not been cleared, David Kessler, the FDA commissioner at the time, worked nearly non-stop over a weekend to conduct the FDA review. This allowed the drugs to be delivered to the appropriate relief agencies in time to respond to the Rwandan's request.

Unfortunately, the United Nations overestimated how quickly refugees would return to Kigali, Rwanda, where the Ceclor was waiting. Although the product had at least six months of life left when delivered, it sat unused in warehouses as its expiration date neared. Lilly attempted to retrieve the expiring portion of the shipment so it could be routed to another location for immediate use, and so they could deliver newer product. Rwandan authorities restricted those efforts, and eventually the drugs expired. The Rwandans then released the Ceclor for destruction, in a hail of allegations that Lilly donated expired drugs. A U.S. magazine picked up the Rwandan government's version of the story, and what began as a humanitarian act was reduced to a public relations nightmare for everyone who worked so hard to do a good deed.

### **Ample precedent for a negative perception**

Although the people involved in facilitating the Lilly transaction—and many other transactions like it—had good intentions, they had to battle the perception that there are companies who use drug donations simply to rid themselves of excess stock. And there's evidence that the perception can sometimes be true: A 1999 study by the Harvard School of Public Health, titled *An Assessment of US Pharmaceutical Donations: Players*,

*Processes, and Products*, found that one-third of donated drugs were within a year of expiring, and two-fifths were not requested by the recipients.

This form of “philanthropy” proliferates because there are definite incentives for companies to donate drugs, rather than destroy them. The standard tax deduction for donation of non-pharmaceutical inventory is limited to the actual cost of the donated items. But in the drug industry, donations can yield tax deductions of up to two times the product cost. When this tax boon is added to the savings garnered from not having to go through expensive legal channels to destroy outdated drugs, the incentive to “dump” drugs on unsuspecting recipients is enormous.

But even though these incentives exist, inappropriate drug donations aren’t necessarily the fault of the pharmaceutical manufacturers. Others in the supply chain, such as hospitals and wholesalers, are often to blame. The products usually can’t be traced back to these smaller entities, so they can get rid of unwanted product without taking responsibility for any negative results. In contrast, most large pharmaceutical manufacturers exercise responsibility in advance and have strict policies that stop them from making inappropriate donations. They also have nothing to gain from the public relations fallout that accompanies failed transactions, so the incentive for them to “dump” drugs is greatly reduced. Unfortunately, the manufacturers’ names are on the labels, so guilty or not, they usually take the rap.

### **Donation dangers**

Although the act of donating drugs may seem philanthropic—and often genuinely is—the effects of inappropriate donations or “dumping” can be downright dangerous on the receiving end. When developing countries receive pharmaceuticals or even cosmetics with labels in languages they don’t understand, the results can be disastrous. Without proper labeling, it’s difficult for recipients to tell hemorrhoid cream from toothpaste, lip balm from suppositories.

And when well intentioned but inexperienced parties, such as church or service groups, collect pharmaceuticals and aren’t cognizant of dating, refrigeration, and humidity-control issues, there is plenty of room for error. Even when qualified medical entities are involved, shortcuts sometimes are taken around normal procedures, out of the desperation that results from dire circumstances in the recipient country. And it’s the patients who suffer, as they’re put at risk by expired, inadequate, or inappropriate drugs. Not only do they sometimes receive substances that aren’t right for their symptoms or are dangerous, but the presence of the unsuitable drugs can eliminate the desire to search for better alternatives.

Fortunately, many times the outdated or otherwise inappropriate drugs are destroyed before they can do any harm. But the destruction creates an additional burden on the recipient, who then has to use costly disposal methods. This creates expense where there previously wasn’t any. And if less-than-legal destruction methods are used to circumvent the costs, elimination of the unwanted drugs could spawn environmental effects that may not be quantifiable. Worse yet, in some cases the drugs aren’t destroyed at all—these escapees from the system end up on the Black Market, where they find their way to patients, sometimes resulting in injury and death.

### **What’s being done**

So what’s the answer? It’s simple in theory but difficult in practice: Every drug donation transaction must adhere to the highest possible standards. Fortunately, the World Health Organization (WHO) has quantified those standards, with the help of eight international humanitarian agencies, including the United Nations, the Red Cross, and the International Council of Churches. Together they established the following four core principles that should govern any donation effort:

- There should be maximum benefit to the recipient.
- The wishes and authority of the recipient must be respected.
- There should be no double standard in quality.
- There should be effective communication between the donor and the recipient.

They also developed 12 donor guidelines, and wisely included exceptions to the rules. These guidelines form a basic structure for the donation process, but it's still up to the entities involved to make sure they are well informed, that the right parties are involved (see sidebar), and that only the highest intentions motivate the donations.

*Sidebar*

### **We Can't Give Up on Drug Donations!**

Although there are pitfalls involved with donating drugs, it's important that the world community not stop the flow of these free resources. For the many countries that count on them, the results would be disastrous. With care and appropriate due diligence, drug donations *can* be conducted safely and effectively, and therefore do immeasurable good.

If the hospital or agency you work for is considering donating drugs or other medical items, here are some tips for conducting win-win donation transactions:

#### **Understand the guidelines**

Having a thorough understanding of the World Health Organization (WHO) [guidelines](#) is a great place to start, and will steer donation efforts in the right direction. For pharmaceutical industry commentary on the WHO's guidelines, read the [IFPMA Issue Paper](#), published by the International Federation of Pharmaceutical Manufacturers Associations.

#### **Work with established relief organizations**

There are large private voluntary organizations (PVOs) that have proven track records for making effective drug donations. Working with these entities reduces the learning curve and increases the chance that donations will get to appropriate recipients. The major PVOs are:

[AmeriCares](#)

[Catholic Medical Mission Board](#)

[International Medical Corps](#)

[MAP International](#)

[Project HOPE](#)

#### **Learn about drug philanthropy**

The following resources provide additional information about pharmaceutical donations:

[An Assessment of US Pharmaceutical Donations: Players, Processes, and Products](#)

[Essential Drugs Monitor](#)

[Recommendations for Donors](#)