Drug Donation: Protecting Industry Philanthropy

A media backlash against companies that donate medicines to countries in need has prompted the World Health Organization to draft guidelines that aim to apply consistent standards to the process.

by Glenna Crooks, PhD

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Through heroic efforts in 1994, Eli Lilly, the Food and Drug Administration (FDA), and several private relief organizations created a near miracle to provide Rwandan refugees with a potent antibiotic to treat wounds suffered in that country's civil war between the Hutus and Tutsis. In a humanitarian gesture, Lilly made available 25 million doses of Ceclor CD, a second-generation cephalosporin, to Rwandan agencies, hospitals, clinics, and ministries of health during the refugee crisis.

The sustained-release product form had not yet fully completed FDA review and approval for introduction in the U.S. market. But then-Commissioner David Kessler, learning of Lilly's donation interest and the needs of the Rwandan people as communicated by the Rwandan government, worked nearly nonstop over a weekend to complete the review. As a result, U.S. private relief agencies received Ceclor CD. Those private voluntary organizations (PVOs), sometimes called nongovernment organizations (NGOs)—MAP International, AmeriCares, and Catholic Medical Mission Board—in turn shipped it to Rwandan ports for the war relief effort.

The result should have been public acclaim for the United States, FDA, and Lilly. All the players should have basked

in the satisfaction of knowing that they surmounted bureaucratic hurdles and met philanthropic intentions. Instead, an unforeseen turn of events unleashed a public relations disaster on everyone involved.

Unfortunately, the United Nations High Commission for Refugees miscalculated the flow of Hutus back to Kigali, Rwanda, where the medicine was waiting for them. Valuable product sat in warehouses, its expiration date approaching. Lilly and the relief organizations attempted to recover the drug supply—they wanted to redeploy it to another location where it could be used, or retrieve and replace it with a fresh supply of fully dated product. Rwandan government authorities, however, thwarted those efforts.

Once the Ceclor CD expired, the Rwandan government released the product to a MAP-partner NGO for destruction amid allegations that Lilly had donated expired drugs. The Nairobi bureau of *Time* magazine reported the government's version of the story ("The Goodwill Pill Mess," 29 April 1996), criticizing Lilly and leaving readers with the impression that Lilly had "dumped" expired, unnecessary drugs so that the company could enjoy a tax write-off for the donation.

How did this happen? How did philanthropy become so controversial, and what can the pharmaceutical industry do to protect itself? This article will describe what happened in the case of this donation, describe how and why this may happen to other pharmaceutical companies, and propose solutions for companies that wish to continue donation programs.

MEDIA ATTACK

In the case of the Lilly donation, company officials and the relief agencies that shipped the product overseas had cooperated with *Time* magazine. In their collective statement, they made it clear that the Rwandan government had requested Ceclor CD and that all the medicine had at least six-months' expiry, with 40 percent having more than one year of dating remaining when shipped.

Further, although not on the World Health Organization's (WHO) Model List of Essential Drugs (EDL), an international formulary document, Ceclor CD was an acceptable substitute for a similar antibiotic on the Model List. In fact, Ceclor CD had superior properties, as it was highly effective in treating skin wounds and would be particularly useful in helping those Hutus who had suffered machete skin wounds.

Unfortunately, although not unpredictably, *Time* omitted those points from the article. The unprinted facts were that in May 1995, by the time Lilly learned that there was expired Ceclor CD in Rwanda, the company took immediate action and requested further information about the remaining lot numbers. In July 1995, when Lilly received the lot numbers, it identified that more than 80 percent of the product had at least two months' dating remaining. Although a Lilly official made these points in prepublication interviews, *Time* excluded them from the article.

Following publication of the story, the magazine received many letters defending Lilly and the donation process. However, *Time* printed one Letter to the Editor—from Lilly—that sought to set the record straight about the appropriateness of the drug. The way *Time* handled the story blackened the eye of the company and hindered similar efforts to assist people and nations in need.

The Lilly–*Time* story is the best known example of what can go wrong in a donation—both in logistical and public relations terms. But it is by far not the only one. Other articles have appeared with similar themes, each promoting an anticompany, antidonation perspective. Those articles have been printed in such publications as *Scientific American*, "Not What the Doctor Ordered"; *The New England Journal of Medicine (NEJM)*, "Inappropriate Drug Donations in Bosnia and Herzegovina, 1992 to 1996"; *Penthouse*, "Merchants of Mercy: The Hidden Corporate Beneficiaries of U.S. Humanitarian Aid"; and *Tax Notes*, "Drug Donors Get Deductions for Not-So-Charitable Contributions."

HISTORICAL PERSPECTIVES

Little information exists about when and how donations of pharmaceutical products began. But by 1997, the effort was so significant that it attracted the attention of academic scholars who tried to quantify the nature and levels of donations. The result of a Harvard study soon to be released by principal investigator Michael Reich will provide insights into the donation process and how in-country recipients perceive it.

In recent years, published reports have indicated that not all donations serve the needs of the organizations and people receiving the products. Donors, frequently unfamiliar with local needs and circumstances, can create problems in areas they intend to assist. Specifically, there have been six prevalent problems in donations, including shipments of drugs that

- are expired
- have not been requested
- are irrelevant to the diseases in the country
- arrive unsorted, poorly labeled, or labeled in a language not understood in the country
- are not packaged to protect contents from the environment
- have a disputed declared value.

Those problems have occurred most frequently through well-intentioned but ill-informed donors, as in the following cases of:

- Local church and service groups unfamiliar with pharmaceuticals that purchase and collect medicines and treat them like other commodities, ignoring the needs of dating, refrigeration, and humidity controls.
- Medical missions so desperate for any products that they accept whatever is given. That allows them to maintain their supplies and have pharmaceutical products to barter for other goods.
- Hospitals, clinics, and wholesalers with policies against selling or using short-dated product. Those groups nonetheless want useful products available for others in need.
- New relief organizations targeting particular war-torn areas of the world, reacting to a country's crisis needs but short-cutting the precautions needed for medicines.

As a result, recipient countries and clinics have been left with problems of destruction, disposal, and distribution, creating economic, clinical, and environmental challenges in already stressful and national crisis situations. Most pharmaceutical companies have policies and procedures that minimize the chance of ill- informed donations, and it is more likely that non-pharmaceutical-company donors have been responsible for the unintended effects of some thoughtless donations. Nonetheless, it

is the pharmaceutical industry that is assigned responsibility for problems and bears the burden of public criticism.

GOALS & GUIDELINES

In 1995, as a result of growing evidence of problems, eight organizations initiated discussions through WHO to draft guidelines for drug donations. (See "Draft Guidelines.") The organization formulated the guidelines to correct problems in donations and facilitate the movement of scarce medical supplies to the most needy areas of the globe. WHO adopted the guidelines as a draft in 1996 and is currently evaluating them.

Unfortunately, WHO developed the guidelines without the involvement of many donors and recipients who manage donations and the needs of the poor every day. Despite that, as the draft guidelines became better known, an increasingly wider audience of influential players adopted them. For example, in addition to WHO, the U.S. Pharmacopoeia, the Christian Medical Commission, the Commonwealth Pharmaceutical Association, and the U.S. Department of Defense abide by the guidelines.

Although there are exceptions built into the guidelines, some regulatory bodies have rigidly applied them in some situations. That has restricted the flow of much-needed medical equipment and drugs to the most troubled regions of the world. In one example, Merck & Co. donations through Project HOPE to the former Soviet Union Republics in 1998 were one-quarter of the donations made in 1996 before implementation of the guidelines, principally because of the rigid enforcement of dating and essential drug list requirements. In effect, these well-intentioned guidelines have had an unintended negative effect, according to Brenda Colatrella, manager of product donations for Merck.

INDUSTRY VULNERABILITY

Questionable donations have rarely been traced to particular donors in the past, but U.S.-based companies take the brunt of public outrage resulting from problems. It is easy for a company to be in the line of fire. Ultimately, donated product is imprinted with the company name. Find a tablet disintegrated, damaged, or outdated in warehouses in troubled regions of the world and the only certainty would be the manufacturer's name emblazoned on the product.

Others involved in the supply chain more easily escape scrutiny and accountability. Even when companies do not donate the product themselves—as when relief agencies purchase medicines for donation or when hospitals, wholesalers, and others donate inventory—companies are forced to accept responsibility for the final disposition of products that have long since left their control.

Anti-industry activists have claimed that donations are nothing more than inventory dumping in exchange for tax deductions.

Finally, companies' philanthropic gestures are drowned by accusations of corporate welfare. Anti-industry activists have claimed that donations are nothing more than inventory dumping in exchange for tax deductions.

The donation supply chain is a complex operation. It involves several divisions within companies and several departments within divisions, company foundations, not-for-profit organizations, and the recipient medical missions and governments that receive the medicines.

Taken as a whole, the donation supply chain constitutes a system as large and diverse as any Fortune 100 company. It includes the marketing, public relations, government affairs, inventory management, shipping, and tax and tariff operations of at least three independent organizations. The volume and variety of products, the numbers of transactions and shipments, and the numbers of staff in the United States and overseas have never been fully quantified. But estimates range upwards of several billion dollars of products and services.

Natural disasters and changes in political systems, such as the case of the former Soviet Union, eastern Europe, and Africa during the last decade, escalate the demand for donated products. In the face of growing international needs, the number of relief organizations and donation transactions is also growing. Yet despite the complexity and size of the donation process, the donation players are independent, autonomous groups and individuals. They have no common agreed-upon vision, no mission statement, no standard policy and operating procedures, no accountability structure, and no ongoing monitoring.

Given the complexity of the operations, the number of transactions involved, and the troubled regions of the world served, it should be no surprise that problems have occurred. Under increased scrutiny by WHO, and more recently by the U.S. Congress, it would be no surprise if more major crises were to surface.

COMPANIES RESPOND

In early 1996, soon after publication of the draft guidelines, major pharmaceutical companies met to review them and propose changes. PVOs that received the donations and shipped them to needy areas of the world also met. Each had concerns with the guidelines and sought changes to them. They worked cooperatively with FDA's representative to WHO, Dr. Stuart Nightengale, and were somewhat successful. As a result, the current draft version adopted by the World Health Assembly in 1996 contained modifications that supported a more flexible approach to managing donations.

In April 1997, some of the world's leading players in donations gathered at Notre Dame University to discuss the draft WHO guidelines. Several major U.S. companies joined NGOs, PVOs, recipients, WHO representatives, and activists for the first broad-based discussion of the guidelines. The Notre Dame conference was the first important step in constructing a multilateral international dialogue on donations. The attendees agreed on a number of points:

- Patients are most affected by donations, but they have the least input or clout. In-country providers need to take more responsibility to assure that requests address patient needs.
- There are problems in donations, but there are also many unsubstantiated stories of donation problems that damage the overall effort.

■ EDL is more useful for purchasing products than for donating them. The 12-month dating guideline needs more flexibility, taking into consideration the product, donation circumstances, and patients' needs.

■ Any guidelines should address emergency donations, large shipments, and medical mission teams separately.

■ Packaging should be appropriate for hot, humid climates and contain labeling that the in-country health team can understand.

■ Once product arrives in the destination country, its shipments to needy areas should be expedited.

■ All the players need to work together to improve communications, accountability, training, education, and ongoing guideline review and modification.

■ Uniform record keeping would enhance the methods of measuring benefits and uncovering errors in the donation process.

The Notre Dame meeting also was the first candid public discussion by pharmaceutical companies about the challenges of dealing with negative publicity. Saddled with the burden of proof that they did not cause donation problems, companies have been forced to conduct their own investigations of frequently unfounded allegations. All too often they have been left to manage the cleanup of negative public opinion, without the assistance of their partners in the PVO and recipient communities.

It was in that context that some company representatives admitted that under continued, burdensome threats to company operations and image, they may consider terminating product donation programs. Workers in the medical mission field acknowledge that halting the programs would present a crisis of unimaginable proportions.

In the interim, although most companies have failed to take steps to restrict their donations, many are limiting PVOs selected to receive donations. Known as the "Big Four"—MAP International, AmeriCares, Catholic Medical Mission Board, and Project HOPE—these PVOs are the largest, oldest, and best equipped to manage the logistics and record-keeping required to

DRAFT GUIDELINES

The World Health Organization (WHO) has developed Guidelines for Drug Donations, which reflect a consensus of eight major international agencies active in humanitarian emergency relief efforts. In addition to WHO, the agencies are the Office of the United Nations High Commissioner for Refugees, United Nations Children's Fund, International Committee of the Red Cross, International Federation of the Red Cross and Red Crescent Societies, Medicins sans Frontieres, Churches' Action for the Health of the World Council of Churches, and OXFAM. WHO has not yet adopted the guidelines but expects to consider them at its November 1998 meeting.

1 All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent by the recipient.

2 All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.

3 The presentation, strength, and formulation of donated drugs should, as much as possible, be similar to those commonly used in the recipient country.

4 All donated drugs should be obtained from a reliable source and comply with quality standards in both the donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.

5 No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.

6 After arrival in the recipient country, all donated drugs should have a remaining shelf life of at least one year.

7 All drugs should be labeled in a language that is easily understood by health professionals in the recipient country; the label on the each individual container should at least contain the International Nonproprietary Name (INN, or generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions, and expiry date.

8 As much as possible, donated drugs should be presented in larger quantity units and hospital packs.

9 All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list that specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight, and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.

10 Recipients should be informed of all drug donations that are being considered, prepared, or actually under way.

11 In the recipient country, the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.

12 Costs of international and local transport, warehousing, port clearance, and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.

Extracted from The Guidelines for Drug Donations, WHO.

protect donation operations and company reputations.

Since the conference, companies working with relief agencies have developed voluntary principles to address the issues of expiry, labeling, packaging, distribution, and destruction. The board of directors of the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted those principles at its April 1998 meeting.

CHANGING TACTICS

The dialogue created at Notre Dame changed the landscape of the debate. It was the first time that donors, relief agencies, missionaries, and recipient countries discussed their common interests. It was the beginning of potentially fruitful debates about the best methods to manage a global multiorganizational, multicultural effort to ease suffering and save lives with donated pharmaceuticals.

If companies plan to continue to make donations, they must address the management challenges that exist within the world's health care network.

To political observers, the response was predictable. Attacks against the industry took on a different tone. By late 1997 and into 1998, industry critics opened fire in a new direction. This time, they took aim at the tax deductions for donations. They claimed that the deductions were the driving force in company decisions to donate and, in the case of problem shipments of drugs, were examples of corporate welfare gone bad.

The claims reached the readership of the *NEJM* in a December 1997 article on problem donations in Bosnia–Herzegovina. In that story, an international team of researchers reported that as much as 50–60 percent of medical supplies sent to Bosnia and Herzegovina between 1992 and 1996 were "useless or unusable." They cited the discovery of World War II medical supplies and expired and inappropriate drugs among the thousands of tons of humanitarian aid deployed to the site. They stated that the ". . . relief effort may have been used to dump outdated supplies."

That article sparked congressional reaction in January 1998, when Reps. Dennis J. Kucinich (D., Ohio) and Fortney H. "Pete" Stark (D., California) requested an Internal Revenue Service (IRS) investigation into drug companies and other medical suppliers whose goods landed in Bosnia and Herzegovina during the crisis. The threatened IRS investigation served as a wake-up call to donor companies, alerting them to the fact that their philanthropy was being questioned. IRS did not immediately respond to the Stark and Kucinich request for an investigation.

Within a week, an article in the IRS community publication *Tax Notes* exonerated the major U.S. pharmaceutical companies. The article reported that a researcher who examined the drug donation records on-site confirmed that at least the large U.S. companies could not be blamed for the donations: "He [the researcher] did eliminate the big companies, such as Eli Lilly, because 'big names don't play that game; what can they gain?' Instead, direct retailers, consumers, hospitals, and charities are the guilty ones."

It appears that no IRS action will come from the congressmen's request. Meanwhile, other actions continue on Capitol Hill. The House and Senate are considering a joint resolution, which Kucinich introduced, to adopt the WHO guidelines. The rationale for the resolution is based on a recitation of the type of anti-industry accounts that characterized the initial WHO guidelines document.

The *Scientific American* article in April 1998 added fuel to the fire that the *NEJM* article sparked. "Not What the Doctor Ordered" rehashed previously published negative stories and distorted the essence of the Notre Dame conference. In one reference to the historic meeting at Notre Dame, writer Sasha Nemecek reported, ". . . one industry spokesperson termed the practice [of drug donations] 'inventory purging.'"

That comment was taken out of context and incorrectly implied that the conference centered on industry wrongdoing and self-criticism. Just as in the case of the Lilly–*Time* story, Lilly was not contacted for comment.

POWER IMBALANCE

Donations of pharmaceutical products and medical supplies—whether surplus or manufactured specifically for donation—are laudable endeavors. They are consistent with an American impulse toward philanthropy. But they are also complicated by an interplay of international political agendas and activist incentives to erode the credibility of the industry and reconfigure global region economics. If companies plan to continue to make donations, they must address the management challenges that exist within the world's health care network.

An underlying imbalance of power and accountability hampers donations. Specifically, donor companies exercise the greatest and most independent power—they choose whether to donate. The relief agencies that deliver the goods are intermediaries between the companies and the recipients. They are dependent on the companies for products and at times feel obligated to take any product, regardless of need, to assure that the pipeline remains open.

On the other hand, relief agencies exercise power over the recipient governments and clinics that receive products and distribute them to other health care providers or patients. The recipients are wholly dependent on both the companies and relief agencies and likewise must work to maintain good relations with upstream suppliers. Products flow from the companies to the relief agencies, then to the recipient countries and to health providers, and finally to the patients. As a result, it appears that the companies exercise the greatest power in the transactions. They are therefore held to the highest level of accountability among all players.

In reality, donations advance the agendas of all players and should be managed within a set of interdependent relationships. Donors receive the satisfaction of meeting philanthropic objectives, improving corporate image, and seeding future markets. Relief agencies more efficiently meet their organizational missions. Recipi-

ents care for the needy with the benefits of free, first-world technologies.

Although the WHO draft guidelines theoretically distribute the power among the players, they have yet to create a true accountability and interdependence among them. For example, the guidelines fail to address the responsibility of the recipient countries to distribute the products efficiently to meet patient needs, and they require no accountability of the recipients back to the donor through reporting of treatment programs and their effects on health.

RIVERS TO CROSS

Properly constructed, the guidelines would form the basis for a discussion among equals in which each party would recognize the value of donations to the others and work toward mutually beneficial solutions to problems. Relief agencies and recipient countries would then be free to refuse unneeded product without fear of losing future donations. Companies could require information concerning the use and influence of their donated products.

Currently, the guidelines provide only one opportunity to "balance" the power—they give the recipient countries the "power" to refuse donations for downstream users. That has resulted in some unfortunate lost opportunities to provide care to needy people. In 1998, officials from Haiti, Kenya, and Egypt denied acceptance for entire shipments of requested medicines because a portion of the products had less than 12 months dating. As a result, the people of those countries failed to receive an estimated 200–400 cartons of antibiotics, pain relievers, and vitamins, among other basic products, because of strict interpretation of the guidelines, according to Sister Maura O'Donohue of the Catholic Medical Mission Board.

Guidelines as a tool. EDL, first developed in 1977, was initially intended to reflect a minimum list of medicines that should be available in every country of the world, regardless of how poor. In recent years, however, WHO has increasingly promoted EDL as a type of national restrictive formulary.

The current draft donation guidelines restrict donated drugs to EDL-listed products. In doing so, the draft further entrenches the notion of EDL as a normative formulary rather than a "minimum list" and legitimizes it. Applying EDL restrictions to donated products is a distortion of the list's intention. It unnecessarily limits the availability of products. Strict interpretation of EDL restricts U.S. philanthropy because the list includes only generic or early generation drugs. Companies must clear special hurdles to donate proprietary, state-of-the-art products. Specifically, government officials and ministries of health often exclude multivalent vaccines from donation because they are not specifically cited in the lists and guidelines, according to James C. Smith of Project HOPE.

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Underappreciated contributions. Pharmaceutical company donations to the developing world have never been quantified across the industry, and their full effect is unknown. The testament to the value of the products is largely anecdotal. It is also obvious. Few would disagree that the needs of poor nations and disaster areas exceed the abilities of local governments to meet them. Some companies have dedicated resources to the research and development of drugs to address diseases specifically in recipient countries, and many have manufactured products in certain combinations, strengths, and packaging solely with the intent to donate

More than tax breaks. The United States is the only government in the world that, as a matter of national policy, encourages private philanthropy through its tax code. The enactment of the first U.S. income tax in 1913 allowed for deductions for charitable contributions. Although through the years the U.S. government has imposed certain restrictions—related to certain tax-exempt organizations and record keeping—the support of individual and corporate philanthropy has been high.

More than 75 percent of all U.S. households donate to charities and, in the past 25 years, the U.S. not-for-profit sector has grown approximately four times the rate of the economy as a whole. That makes the United States unique in its private approach to giving. Other countries promote care of the poor through direct taxation of corporations and individuals. This difference in national cultures and policies creates suspicion of U.S. company motives.

In reality, companies will receive some tax-deduction benefits whether they donate or destroy products in inventory. The exact calculation depends on a number of factors, and each situation is unique. But it is fair to say that deductions fail to drive the decision. In fact, although no one has ever made the calculation, it is probably the case that if companies tallied the total costs of donations, they would find that in some cases product donations were more costly than product destruction. That is because companies pay for all the costs associated with managing donations—not only those in their internal operations and record-keeping but for those external costs associated with shipping and handling and import duties on donated products. In the final analysis, for some companies the tax deductions are an incentive to donate. For others, they merely remove some of the disincentive.

TAKING ACTION

No public policy issue that has achieved this level of notoriety dies a quiet, unnoticed death. It is likely that pharmaceutical donations will continue to receive the attention of anti-industry forces, journalists, and legislators—it is too easy a target. Every knowledgeable observer of donations will admit that there have been problems with some donations.

Unbiased observers will note that the problems have been relatively few given the large numbers of donations made and the complexity of the cultural and transactional elements required. They will call for change, but not for such restrictive change implied by strict interpretations of the WHO guidelines. They will encourage global cooperation among companies, relief agencies, and recipients. In that context, the industry will have a number of opportunities to craft positive responses to address their philanthropic, commercial, and image objectives.

The reality, however, is that if the industry is to address its interests in donations, it must also deal with anti-industry forces that are also involved in the debates. Company management, which is focused only on the United States, is generally unaware of international anti-industry sentiment. It is incumbent upon industry to understand that the United States is likely to become a battleground for the political and economic agenda of the international activists. Anti-industry activists are interested in promoting the development of local pharmaceutical industries in the developing world, particularly in India and China, redistributing economic and political power on the globe, promoting EDL, replacing donations with cash, and weakening U.S. corporate access to new markets.

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Companies making donations outside the United States face a number of imperatives as they manage their donation operations now and in the future. Several are company-specific. Essentially, companies should do the following:

- Assess all aspects of their internal donation operations to assure that each of the responsible departments is fully conversant with the issues, controversies, company policies, and procedures related to donations. If the company has no defined policies and procedures, it should develop them and communicate the new policies to responsible divisions and departments. That applies especially to tax operations.

Industry consultant Elise Van Allen of Lodestar International has observed that even when companies act totally within the spirit of U.S. tax law, they frequently lack the documentation to demonstrate that they have made the donations appropriately. Staff turnover in key positions creates company vulnerabilities if companies are audited by the IRS, particularly if inadequate paper trails exist and key personnel keep the corporate memory.

- Assess all aspects of a relief agency's donation operations before giving product donations. Although an unpopular decision, companies should restrict their donations to those organizations that can verify that products reach the intended recipient population. That may mean that only a few organizations receive donations.
- Develop and execute strategies to protect themselves from claims of inappropriate donations. This recommendation goes beyond having good policies and procedures, as noted above, and recommends additional caution about donations that are accompanied by political pressure and high-profile disasters.
- Demand supply chain data and verification and keep those records current and accessible.

Several other strategies that formal or informal industry groups can undertake are industry association-specific. Those strategies are based on the belief that industry should do the following:

- Initiate a Washington-based and press relations strategy to inform key members of Congress and reporters about the need for and value of donations. Doing so will fill the vacuum of information that currently provides anti-industry activists with fertile ground for further eroding industry image.
- Assure that the debate is not broadened to include a renewal of attacks against domestic donation—indigent care—programs.
- Initiate an educational program for other U.S.-based donors, including churches, wholesalers, and hospitals, to inform them of the WHO Guidelines and acquaint them with best practices. Those groups are still largely outside the channels of information that would alert them to problems some donations have caused.
- Closely monitor WHO-based activities, maintain close contact with relief agencies and FDA, and establish a dialogue with the Department of State and the White House as a protective strategy against further international action. In particular, the industry must dislodge the use of EDL in donations because it represents a step toward crafting a global formulary that will inhibit the adoption of new, innovative medicines.

It is past the time on this issue where the philanthropic intentions of companies will be sufficient to prevail in international regulation. To keep the donated medicines pipeline open to developing nations, companies must maintain impeccable donation operations, select relief agencies carefully, and respond to the political backlash that some donations create.

Whether for commercial, philanthropic, or image objectives, no company donating medicines today can ignore its own operations or those of others who may be handling, receiving, and even donating their products. Targeted and controlled donations can generate goodwill; unmanaged philanthropy can create disasters. ▌

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