STRATEGIC HEALTH POLICY INTERNATIONAL

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Donated Medicines: Covenant with the Global Community[1]

Suffering today is because people are hoarding, not giving, not sharing.[2]
—Mother Theresa

Recognizing Need

The world beyond our borders is a globe romanticized by television's Discovery Channel and National Geographic. It is a fantasy of Arabian Nights and jungle princes cartooned by Disney. It is a world of poetry and adventure tourism.

The developing world is altogether different, and since September 11, we in America have become more aware of its realities. It is a nightmare of child labor, child soldiers, starvation, death, slavery, and war. It is a world with few hospitals. Clinics are a thirty-mile walk from home. That is, if the person has a home: far too many people are refugees from wars, persecution, and natural disasters, living in unspeakable conditions. Parasites live in the drinking water. Most of the people do not have access to health care as we know it. Health care spending may be as low as $10 per person each year—or less—and millions die annually from diseases that could be treated with modern public health measures and medical care. People, especially children, die from pneumonia, malaria, diarrhea, tuberculosis, and vaccine-preventable diseases. If they do not die, they may be left orphaned when their parents or grandparents die—11 million are orphaned worldwide from AIDS alone.[3] Blood is not safe from HIV, hepatitis B and C, and syphilis contamination. Government corruption is common. Public health and disaster relief systems are stressed beyond capacity.

Some of these developing world diseases do not cross the oceans and continents easily to threaten the United States, but some do. Tuberculosis is one of those diseases, particularly as it becomes increasingly drug resistant. Declared a global health emergency by the World Health Organization (WHO), tuberculosis is spreading around the world at faster rates than public health experts anticipated and at much faster rates than they can control. Dubbed by the Institute of Tropical Medicine as "The Real Millennium Bug," it is spread easily by coughing. A passenger from the Ukraine recently infected 13 people on a flight from Paris to New York, and a child from the Marshall Islands living in North Dakota infected 56 people at home, school, and day care settings.[4] They join the growing number of cases in the United States that are caused by recent arrivals to this country.

Even in the presence of the emergency and global attention, fewer than 20% of people infected with tuberculosis are receiving even basic treatments. Public health experts today estimate that 1.9 billion people currently have active disease, and it spreads to 8 million new people each year. As a result 1.9 million people die annually. Even with newly recommended treatments in place, the next generation of public health experts is predicted to see between 171 million and 249 million new cases of tuberculosis and between 60 million and 90 million deaths from the disease during their careers.[5,6] Future scenarios for a disease so easily transmitted are horrifying.

Reaching Out and Responding

Clean water, sanitation, reliable supplies of food, economic development, and democracy would go a long way to improving the lives and preventing the diseases of most of the developing world's population. It would also protect those of us who live in privilege in the developed world.

That is not the only reason to reach out, however. An even better reason is that there are people in poor countries around the world in such need and we should live in covenant with them. They live at levels of poverty and disease unimaginable to even the poorest in this country. It is so shocking, in some cases, that even travelers to those places can become numbed from the immense needs and forgetful about what they have witnessed once they arrive home. As health care practitioners and healing enterprises in the United States, we have the technology, the insight and, occasionally, the personal and political will to assist in these ventures. Some healers in this country act within a covenant responsibility to care for others in these distant places. Clinicians spend their vacation time overseas doing surgery and treating patients; medical centers send their consultants, journals, and books to mission hospitals that can use them; churches sponsor exchange programs and summer trips abroad for teens to build sanitation systems and shelters to help families. Those in health care cannot do it alone, nor do we need to. Tackling immense problems such as these requires the efforts of more than just a few.

International aid from North American, European and Japanese governments supports development projects and makes contributions to the improvement of living conditions. Private firms, foundations, and service organizations also contribute. For example, The World Bank provides $800 million annually to HIV prevention programs.[7] Private non-health care firms doing business in the developing nations of the world contribute to the economy and to health care as well. ENI, an Italian firm, gave the World Health Organization $750,000 to fight malaria in Azerbaijan. BP Amoco financed child nutrition programs in Vietnam. De Beers contributed $2.7 million to the WHO to fund polio eradication and used its own employees to help in the immunization campaigns. Eskom contributed $5 million to develop a vaccine for AIDS.[8] The Bill and Melinda Gates Foundation contributed $50 million,[9] Ted Turner contributed $28 million,[10] and Rotary International committed $500 million to eradicate polio.[11] The Gates Foundation is also contributing $750 million over five years to other child vaccination programs and $50 million to prevent maternal mortality.[12] Kiwanis International has pledged $75 million for salt iodization programs sponsored by the United Nations International Children's

Emergency Fund (UNICEF) to prevent the iodine deficiency disorders that impair the mental health of children.[13] There is no tally of the total value of donations such as this, but it is large. Even in the face of expansive philanthropy, the need is still overwhelming—especially for pharmaceuticals.

The World Health Organization estimates that 30% to 50% of the world's population does not have access to needed medicines.[14] Recent litigation focused attention on the need for the sophisticated AIDS drugs in the developing world, and the outcome was predictable: regardless of the availability of the medicines, it is difficult to get them to the people in need. Another outcome was less obvious: the reality that even many of the basic vaccines and medicines are unavailable to many people around the world. Developing nations are too poor to purchase them on the world market, even when they are available at low prices. The professionals who can prescribe or dispense the products are not accessible in many countries, and the infrastructure to deliver the products to the clinic or hospital sites often does not exist. Roads are not passable. Trucks don't have fuel. Land and water barriers prevent easy passage. Refrigeration is not available for products requiring special handling. Wars and natural disasters interrupt the supply of necessary goods and services.

To assist in meeting the needs for medicines, some very inexpensive products are made available through loans and purchase programs of the WHO and other international agencies. A number of countries are attempting to develop their own local pharmaceutical industry to manufacture generic products and to make them available for export. Some medicines are donated by the research-intensive industry in the United States, Europe, and Japan in order to make the most modern medicines available to a wider group of people who need them. As in the case of the total health or economic assistance to the developing world, there is no precise estimate of the volume of this assistance, but it is substantial. Those who donate medicines provide the products and, frequently, the technical assistance to assure their correct usage. Working with not-for-profit agencies, donor companies arrange for shipments of large volumes of products overseas. In some cases they also provide the trucks, pay the import duties, and provide the healers in order to get the products to the people. Lately, they also combat the public relations fallout of their well-intentioned efforts.

Healing in the Absence of Explicit Covenants

Healing has always been a risky business. If not tampering with the power of the gods, the healer might have been viewed as bargaining with the devil. Fail to cure and the consequences could be great. Lose a patient in surgery and a doctor could be fined—or worse, could lose a hand. Attempting to provide healing services in the absence of an explicit covenant carries great risks as well. This was true of secular healers in the Middle Ages who practiced medicine without benefit of holy orders. It proved true as well for American pharmaceutical companies who donated products to private relief agencies whose mission it was to bring them to people in need around the world. One particular story is notable and provides a clear example of how the lack of an explicit covenant among all the players involved in the healing process can create problems. This is a story of "good deeds punished." It is a story of the unreasonable and

outrageous backlash that can befall a healer who acts in the absence of an explicit covenant with the patients and communities they seek to heal.

It required some hard work in 1994 for pharmaceutical company Eli Lilly to donate 25 million doses of Ceclor CD®, a potent antibiotic, to Rwanda to treat the wounds people suffered in that country's civil war.[15] The product was a newer, more potent version of an antibiotic already on the market, but it was not yet approved for sale in the United States; and, therefore, could not be donated to help the people of Rwanda, either. Lilly learned of the need for the drug and recognized that it would be of particular help in treating the machete wounds suffered in the war because the company's research showed it to be particularly well suited for treating skin wounds. The company approached Commissioner of the Food and Drug Administration David Kessler with a request to approve the medicine in order to release it to Rwanda. Dr. Kessler and his team worked nearly round the clock over a weekend to review the company's studies and to release the drug for the donation.[16] Rwandan agencies, hospitals, clinics, and ministries of health received the drug from the private relief agencies who partnered with the company in making donations such as this. The result should have been public acclaim for the company, kudos for the quick action of the FDA, and international thanks for the generosity of Americans. Instead anti-industry activists unleashed a public relations disaster on everyone involved.

What went wrong? Eli Lilly believed that since the product was needed and requested, it would be accepted when it arrived and used quickly to help the people in need. The company, which was not interested in public relations coverage, was unprepared for the public relations disaster that followed. It was interested in helping. Should Lilly have been prepared for the backlash? How could it have known that the attempt to do good would be punished in the press? What are the motivations for mounting public attacks on donors of products and services? Is there a way to structure the international relationships to accommodate the objectives of all the parties involved? Who speaks for the patients in poor countries who need but will not receive these medicines unless they are donated? What is the best way to help those patients? Can we come to peace with profit and allow those companies that discover and make these medicines—and make profits on some of them—to give them away without such public relations disasters? How can we encourage, rather than discourage, generosity from a nation and an industry that has produced such abundance? How, in the face of such international need, can we not support the efforts of those who are trying to assist? Could the existence of an explicit covenant have prevented the conflicts that ensued?

Dealing with Public Relations Disasters

In the case of the Lilly donation, the United Nations High Commission for Refugees (UNHCR) miscalculated the flow of Hutus back to Kigali, where the medicine was waiting for them. When Lilly and the relief organizations learned of this, they attempted to recover the drug supply from the warehouses where it was being stored and to redeploy it to other locations where it could be used. They also offered to provide the country with fresh supplies of medicine, since the first shipments were now close to expiration in the warehouses. Rwandan government authorities blocked those efforts, held the drug until the Ceclor CD® expired, and then made

claims that Lilly had donated expired drugs. The government's version of the story was published by *TIME* magazine, criticizing Lilly and leaving readers with the impression that expired, unnecessary drugs were "dumped" so that the company could enjoy a tax write-off for the donation. In its handling of the story, *TIME* blackened the eye of Eli Lilly and similar corporate efforts to assist people and nations in need.[17]

TIME magazine was trying to make a point. It was a point that needed making, because in the past there have been problems in donations of all types and from all donor sources. Unfortunately, the magazine selected the wrong example. In the witch-hunt to find and punish an errant healer, the magazine's reports oversimplified the complexity of donations and stimulated unproductive conflicts in the international health community. In doing so, it risked a substantial portion of the donations from the U.S. companies who were swept up in the wake of the Rwandan cause célèbre.

TIME assumed that only the pharmaceutical company could have been held accountable. It neglected the facts that drugs are donated from a variety of sources, for a variety of reasons and may pass through many hands on the way to the patient. Some donations come from pharmaceutical companies directly, but others come from physicians, hospitals, pharmacies, drug wholesalers, churches, and individuals. Many donations come from the United States, but they also come from other countries. The donations may come in shipments of drugs and medical supplies, or they may be consolidated with shipments of food, clothing, and materials to build homes. The shipments are rarely delivered directly by the groups making the donations. Rather, they are shipped and delivered "in-country" by private groups with experience in managing the complexity of delivering donated goods. Shipments also pass through the hands of local government officials at customs offices and other stops along the delivery route. These stops incur delays and risk diversion into the black market. The private relief agencies generally manage the problems of war-torn areas, the challenges of tribal conflicts, and the problems of transport where no roads exist or trucks can travel. They are familiar with these conditions because their local operatives are often native to the country, or are longstanding missionaries with credibility. They have influence in addition to years of experience. Having trouble with a customs official who will not clear a shipment, for example? Then perhaps this official's third-grade teacher, the nun in the religious order partnering to receive the goods, can place a call to him and expedite the clearance. Unable to land a plane in one country? Then arrange with your field operations to land in a neighboring country and truck the materials across the border, where the customs officials are more favorably inclined to let you pass through. Can't donate what the recipient needs, but something else instead? They'll take what you have and use it to barter for something else on the long wish lists they keep. Sometimes that's how it works.

Relief on a Massive Scale

Natural disasters and changes in political systems—such as those in the former Soviet Union, Eastern Europe, and Africa during the last decade—have escalated 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 players are independent, autonomous groups and individuals. They include domestic and international, private, not-for-profit relief agencies, foundations, churches, pharmaceutical companies, hospitals, medical schools, pharmacies, wholesalers, governments, shippers, private practitioners, and individual citizens. Some of these groups have decades of experience; others are entrepreneurial start-ups, particularly those serving regions of the former Soviet Republic. Some groups are large multi-million dollar operations, some are single individuals with not much more than a passion to save their homelands. This group of varied players has no commonly agreed-upon vision, no mission statement, no standard policies and operating procedures, no accountability structure, and no ongoing monitoring. They also have no explicit covenant, either with each other or with those they serve. 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 there have been problems.

In recent years, published reports indicated that problems have sometimes occurred with drug donations and that some donations have failed to serve the needs of the organizations and people receiving the products.[18,19,20,21] With increased scrutiny by the WHO and, more recently, the U.S. Congress, it would be no surprise if more major crises were to surface. Donors, frequently unfamiliar with local needs and circumstances, have created problems in areas they intended to assist. During the Armenian earthquake in 1988, 5,000 tons of drugs arrived, of which 22% were expired or damaged. In 1989, during the 30-year war for independence in Eritrea, seven truckloads of expired aspirin were received. It took six months to burn. One unsubstantiated report claims that half of the drugs entering Albania during the Kosovo refugee crisis were found to be unusable, probably because the products had less than twelve-month dating.[22] Between 1992 and 1996, over 17,000 metric tons of drugs donated to Bosnia and Herzegovina had to be destroyed, at a cost of $34 million.[23]

A number of different types of problems have been prevalent in donations: Shipments have included expired drugs and drugs that had not been requested by the relief agency. When this occurs, local medical teams, who are already stressed with patients and strapped for cash, must arrange for destruction of the products. Drugs not relevant to the diseases in the country have been sent, again creating destruction problems. Drugs have arrived unsorted, poorly labeled, or labeled in a language not understood in the country. This makes use of the drugs difficult in what are already difficult treatment situations in field clinics and hospitals. Drugs have been improperly packaged, exposing them to temperatures and moisture that degrade the products and expose the environment to contamination from the drugs.

These problems have occurred when those involved are well intentioned, but ill informed or ill prepared for the tasks of delivering and using the medicines. In some cases, the donors are local church and service groups, unfamiliar with pharmaceuticals, who purchase and collect medicines and treat them like other commodities, ignoring the needs of dating, refrigeration, and humidity controls. This also occurs in cases where medical missions are so desperate for any products that they accept whatever is given to maintain any supplies they can and to have pharmaceutical products to barter for other goods. It is also a problem when hospitals, clinics, and wholesalers send about-to-expire products in order to make their products available for

others in need. Finally, the problem is created by new relief organizations targeting particular war-torn or natural disaster areas of the world, reacting to the crisis needs of the nation but short-cutting the precautions needed for medicines. As a result, countries and clinics receiving the drugs have been left with problems of good intentions and bad operations. This further stresses their already stressful national situations.

Most pharmaceutical companies and relief agencies have policies and procedures that minimize the chance of ill-informed donations. Questionable donations have rarely been traced to particular companies in the past, but U.S.-based companies take the brunt of public outrage resulting from problems, as was the case for Eli Lilly. 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 is the name of the manufacturer emblazoned on the product. The others involved in supplying the products 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 can be forced to accept responsibility for the final disposition of products that have long since left their control. 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.

Seeking a Solution

It should have been no surprise, then, when in 1995, the WHO, along with a number of international organizations, drafted Guidelines for Drug Donations.[24] These guidelines were intended to facilitate the movement of scarce medical supplies to the most needy areas of the globe. The pharmaceutical industry was a significant target for the guidelines. It was also no surprise that the American companies were under the most scrutiny and took the most direct hit at that time.

In draft form the guidelines were widely circulated and adopted by a number of countries to improve the flow of donated medicines into their countries. The guidelines promote four core principles: maximum benefit to the recipient, respect for the wishes and authority of the recipient, uniform standards of drug quality, and effective communication between the donor and recipient.

In practice, the guidelines state that

- Donations should be based on need, relevant to the disease pattern of the country, and sent only with prior clearance from the recipient, except in emergencies.

- Products should be registered for sale in the recipient country, donated in the formulation and strength similar to those used in the originating country, and appear on the WHO Essential Drug List (EDL) or the drug list of the country.

- Products should be from a reliable and quality source, complete with labeling in the language of the country and in large quantities. Products should have at least one year of shelf life upon arrival in the country, unless the recipient knows shorter-dated product is arriving and can properly use it.

- No products should be donated if they have been issued to patients and then returned to the pharmacy (a common practice among European donors), nor if they have been given to doctors as free samples (formerly a common practice among U.S. donors, particularly those associated with physician groups).

- Recipient nations are to be informed of all donations, with transportation, port clearance, storage, and handling paid by the donor, and the declared value based on the wholesale world-market price.

Developing Covenants

The guidelines were an attempt to solve the problems associated with donations and have resulted in a covenant, of sorts. They could have resulted in a true covenant if all the players in the drug donation process had been involved in developing them. They were not. Neither the product donors nor many of the relief agencies were involved in the early drafting. Nor were patients involved. In fact, the guidelines, when they emerged in draft, came as a complete surprise to most of the American donor companies and relief agencies involved in making and facilitating donations.

It is not possible to craft a covenant without the full range of parties involved. Attempting to do so from the start would have required substantially more effort, and it would have been difficult. Defining the nature of a covenant in global ventures will never be easy, but in fact, doing so is essential. The complexity of managing operations such as those embodied in donations across different cultures, languages, medical systems, political boundaries, infrastructures, and players makes defining the covenant all the more critical.

The guidelines also could have been more covenant-like if the value of the healing efforts of donations had been acknowledged and if the guidelines had not been used as a weapon to attack the donors. Instead, the international dialogue required to achieve the resolution was conducted against a backdrop of controversy. After several years of contentious debates, accusations, and counteraccusations punctuated by the *TIME* story, the guidelines were finalized in 1999 and are now supported by significant parties to the discussions. At long last, the covenant discussions were initiated.

Significant in this resolution was a meeting held at Notre Dame University in 1997, which should stand as a model for covenant development ventures. The Notre Dame meeting was the occasion of the first global, comprehensive, and candid public discussion of the issues involved in donations. Recipient countries described the loss of national pride from having to provide care for their countrymen with donated goods and expertise. The WHO noted the

problems of donations that did not fit the profile of planned health care needs of the developing world.

The Notre Dame meeting was also the first forum in which pharmaceutical companies disclosed the challenges of dealing with negative publicity. Saddled with the burden of proving 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. It was in this context that some drug company representatives admitted that under continued, burdensome threats to company operations and image they might consider terminating product donation programs. Workers in the medical mission field acknowledged that would present a crisis of unimaginable proportions.

The dialogue that took place at Notre Dame changed the landscape of the debate and began the first, tentative steps toward reaching a compromise that would create a true covenant. It was the first time in anyone's recollection that donors, relief agencies, missionaries, and recipient countries discussed their common interests. It was the beginning of fruitful discussions about the best methods to manage a global, multiorganizational, multicultural effort in easing suffering and saving lives with donated pharmaceuticals. It was also the catalyst for donor companies and relief agencies to form relationships that improved each of their separate and joint donation operations with refined policies and procedures. But all parties did not yet agree to a covenant, and so, to political observers, the response was predictable. Attacks against industry continued, taking 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 wrong.

Managing the Domestic Spin

Those who deal in global healing must be prepared for domestic consequences. In the midst of the international debates, claims concerning irresponsible international donations reached the readership of the *New England Journal of Medicine* in a December 1997 Sounding Board article on problems in Bosnia and Herzegovina. The article reported that as much as 50% to 60% 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 a common view among some groups that the relief effort may have been used to dump outdated supplies.[25]

This article sparked Congressional reaction in January 1998, when Representatives Dennis J. Kucinich (D-OH) and Fortney H. "Pete" Stark (D-CA) 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. The IRS did not immediately respond to the Stark and Kucinich request for an

investigation, but the major U.S. pharmaceutical companies were eventually exonerated. Dr. Philippe Autier, a researcher who examined the drug donation records on site, confirmed that at least the large U.S. pharmaceuticals could not be blamed for the donations. He did eliminate the big companies, such as Eli Lilly, because "big names don't play that game; what can they gain?" Instead, he named direct retailers, consumers, hospitals, and charities as the guilty ones.[26]

This wake-up call was not entirely a false alarm, however. Although it appears that no IRS response will come, other actions may result from Capitol Hill initiatives. The House and Senate considered a Joint Resolution, introduced by Kucinich, 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.

Obligations to the World's Needy Patients

Donations of pharmaceutical products and medical supplies—whether they are shipped from surplus inventory or manufactured specifically for donation—are laudable endeavors that are consistent with an American impulse toward philanthropy. But they are also complicated by interplay of international political and activist agendas. In the wake of anti-pharmaceutical industry activity at the World Trade Organization meetings, beginning in Seattle in late 1999 and continuing through 2001 in Doha, these activities are likely to intensify. Unfavorable press concerning donations is an international health activist tool to erode the image of the pharmaceutical industry and limit its participation in public policy discussions. The activists condemn Americans and the industry for their donation policies and interests at a time when the industry is also vulnerable to criticism on other fronts at home. This adds to the risks that companies will consider limiting donations altogether, a most unfortunate necessity, should the controversies not be resolved. If donations are to continue, three challenges within the world's health care network must be addressed: (1) marrying donations policy with other international drug policies, (2) balancing power among the players, and (3) limiting international activist incursions into U.S. tax policy. Covenants can be helpful in this regard because they can encourage each of the parties to move beyond limited, self-interest agendas.

The first challenge of linking donation policy with other international drug policies is related to the two-fold strategy to make drugs available to more people on the globe. The first component of the strategy is to eliminate, or at least severely limit, intellectual property rights for drug developers. The second is to entrench the WHO Essential Drug List (EDL), which forms the basis for acceptable donated products in the guidelines.

It is well established in the developed world that patents provide the opportunity for drug companies to gain returns from the risks of pharmaceutical research and development. Without the ability to gain a return on investments made to discover a medicine, no private firm would be able to engage in drug development. Those nations with the best patent protection have been the sources of the most innovations for precisely that reason.

While eliminating or limiting patent life—either directly through law or indirectly by allowing parallel trade—might seem a reasonable short-term solution to the problem of the availability of medicines, it is unwise from several perspectives. First, it will rather quickly limit the supply of new drugs for the entire world coming from research pipelines because companies could no longer realize the returns that draw inventor risk-capital and would therefor be unable to sustain research costs. Second, it ignores the reality that many of the disease problems of the developing world will not be treated with current medicines. The companies whose research resources would be lost to patent infringement are today exploring those developing world diseases most in need of cures. Third, companies have demonstrated in the past several years that, informed of the need for drugs, they will manufacture medicines for the specific needs of the relief agencies.

A much older issue is that of the EDL. First developed in 1977, the EDL was initially intended to reflect a minimum list of medicines that should be available in every country of the world, regardless of the level of poverty. It provided guidance to assist poor countries in purchasing the most cost-effective products. In recent years, however, the EDL has increasingly been promoted as a restrictive formulary and now is used to regulate the movement of donated drugs. Since the guidelines restrict donated drugs to EDL-listed products, the EDL is further entrenched as a normative formulary rather than a "minimum list." Applying EDL restrictions to donated products is a distortion of the intention of EDL that unnecessarily limits the availability of products to people who may need them. Strict interpretation of the EDL also restricts U.S. philanthropy, since the list includes only older, generic drugs which, by-and-large, are no longer manufactured by American companies.

If a company wishes to exercise its philanthropic intentions—and many do—they, their partners, and recipients in the donations must clear special hurdles to send the proprietary, state-of-the-art products that companies produce today. When these hurdles become barriers, they defeat the purpose of the covenant relationships that should be the foundation of the guidelines. Working together to make these guidelines support, rather than prevent, the movement of necessary medical goods, is the goal of a new coalition of companies and relief organizations, The Partnership for Quality Medical Donations.[27]

The second donation challenge relates to the fact that donation policy discussions are hampered by an underlying imbalance of power and accountability. This is a covenant issue as well. It is important to resolve the issue of power among the players. Unfortunately for people in need, and wholly inconsistent with a covenant, the guidelines, as they have been implemented, provide a mechanism to "balance" the power. They give the recipient countries the "power" to refuse donations for downstream users. This has resulted in some unfortunate lost opportunities to provide care to needy people. Medical missions of surgeons, on one-week trips overseas, have been denied entrance at the border because the drugs they were carrying and would use in surgery in the coming week lacked twelve-month dating. In 1998, entire shipments of requested medicines to Haiti, Kenya, and Egypt were denied acceptance because a portion of the products had less than twelve-month dating. As a result of the strict interpretation of the guidelines, the

people in these countries were denied access to an estimated 200 to 400 cartons of antibiotics, pain relievers, and vitamins, among other basic products.[28]

Additionally, donor companies—usually large pharmaceutical firms in the case of medical supplies—exercise great and independent power, because they choose whether or not to donate. Some relief agencies and others purchase the products they donate in the United States or in other markets, but the bulk of the donated products comes directly from the manufacturer. The relief agencies that deliver the goods are intermediaries between the companies and the recipient nations. Since the relief agencies are dependent on the companies for products, some of them, particularly the smaller operations, at times feel obligated to take any product, regardless of need, in order to ensure that the pipeline of donations remains open.

On the other hand, some 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 they must work to maintain good relations with upstream suppliers. Products flow from the companies out to the relief agencies, then to the recipient countries and to health providers, and finally to the patients. The companies appear to exercise the greatest power in the transactions, and they operate within a covenant of grant. They are, therefore, held to the highest level of accountability among all other players and are frequently held accountable for actions over which they have no control. Many donors today, however, are calling for relationships of mutual responsibility and accountability—a covenant of obligation, though they do not use that specific term. In so doing, all parties would work more cooperatively to ensure the desired goal. In the course of refining donation operations in recent years, this is beginning to happen. Many of the donors and larger relief agencies have worked to ensure that communications are improved and good records of transactions are kept. As a result, donations have actually increased, even in the face of negative publicity. These policy and procedural changes enhance and operationalize the growing covenantal relationships among the involved groups.

In reality, since donations advance the agendas of all the players, donations should be managed within a set of interdependent relationships bound in healing covenants. It is an optimistic trend that, increasingly, they are. Donors receive the satisfaction of meeting philanthropic objectives, improving corporate image, and seeding future markets. Relief agencies meet their organizational missions more efficiently. Recipients care for the needy with the benefits of free, developed-world technologies.

The WHO guidelines take some steps in distributing power among the players, but they could do more to create true accountability and interdependence among them. For example, the guidelines briefly address the responsibility of recipient countries to distribute the products efficiently to meet patient needs, but they do not yet require any substantial accountability of the recipients to the donor through reporting of treatment programs and their impact on health. As these final guidelines are implemented, and in subsequent revisions, new discussions can create a forum among equals in which each party would recognize the value of donations to the others and reach toward mutually beneficial solutions to problems. More relief agencies and recipient

countries would then be free to follow the lead of most responsible groups today, who refuse unneeded products without fear that they will lose future donations. Companies, in turn, could require information concerning the use and impact of their donated products and could be better prepared to deal with any negative consequences of the donations.

The third donation challenge relates to the fact that international activists are critical of American tax policy that rewards personal and corporate philanthropy with deductions. As a result of their disagreement with our national policy, they intend to lobby for the elimination of tax benefits for donations—at least for pharmaceutical donations. Non-U.S. players and activists view donations as mere tax strategies, since ours is the only country in the world that encourages private philanthropy through its tax code.

It is unlikely that their efforts will be successful, though any debate could be damaging to the climate for pharmaceutical donations. The U.S. Tax Code has supported the deductibility of donations of all sorts since the enactment of the first U.S. Income Tax in 1913, which allowed for deductions for charitable contributions. Through donations, major educational, artistic, and charitable ventures have provided services to millions here and abroad. Public support for individual and corporate philanthropy remains high in this country. Not only is there a support for the policy, but there is action as well. More than three-quarters of all U.S. households donate to charities and, in the past 25 years, the not-for-profit sector in the United States has grown at 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. companies' motives.[29]

The resolution of this debate will be particularly important given that, in reality, pharmaceutical companies receive tax deductions 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 do not drive the decision to donate. In fact, although the calculation has never been made, it is probably the case that if the total costs of donations were tallied, in some cases companies would find that their donations are actually more costly than destruction of the products. This is because companies pay for much of the costs associated with making most of the donations—not only those in their internal operations and recordkeeping, but also those external costs associated with shipping and handling and import duties on donated products. In the final analysis, for some companies the tax deductions may be an incentive to donate, while for most others, deductions merely remove some of the disincentives to becoming involved in this type of philanthropy.

Sustaining the New Covenant

The Notre Dame conference, the guidelines, and all the other communications among the participants in the donation of medical products and services are important steps toward developing a global covenant of obligation to care for those in need. Other steps will be necessary to refine the covenant, to further develop the systems to support the caring, and to

bring other donors to the table. It is critical for the health of people around the world that we continue to reach out to each other to ensure that the flow of developed-world technology not only continues, but becomes a torrent of giving. It is critical not only for health, but for peace and prosperity globally.

To that end, donations of all types are important and greatly underappreciated for the contributions they make to the lives of the people in developing nations. This is especially true for the pharmaceutical products that reach the most remote places and the neediest people. Aside from the safe water and environments and the food and housing that the developed world can lend, there is no more important, cost-effective donation than that of a medicine to prevent and treat disease.

Working cooperatively with the industry can result in new programs to create solutions to tropical diseases, as recent experience has demonstrated. Merck developed and now donates Mectizan®, which prevents river blindness with only one tablet per patient per year. Over 250 million tablets have been provided to 31 countries in Africa, Latin America, and the Middle East.[30] SmithKline Beecham pledged to donate albendazole for lymphatic filariasis, to treat the 120 million people in 73 countries who suffer from that intestinal parasite.[31] The company has committed to continue the donations until this public health problem is solved. GlaxoWellcome committed to one million courses of treatment with its drug Malarone®, which will cure over 98% of the patients who receive it and will assist in reducing the suffering and death from malaria.[32] Bristol-Myers Squibb has committed $100 million over the next five years in its Secure the Future™ program to find sustainable solutions to HIV/AIDS for women, children, and communities in sub-Saharan Africa.[33] In all, ten major disease conditions are the subject of global philanthropy: African trypanosomiasis, HIV/ AIDS, leprosy, lymphatic filariasis, malaria, onchocerciasis, polio, trachoma, and vitamin A deficiency disorders.[34]

The impact of some of these programs is still too new to quantify, but the size of donations from major donors overall has recently been calculated at nearly $2 billion between 1998-2001.[35] This figure does not fully capture the contributions of smaller donors, who are numerous and make substantial efforts to relieve suffering through their programs. The types and numbers of donors and relief agencies are so varied that a complete list would be difficult to compile. The evidence of the value of the products is largely anecdotal. A recent study by Harvard University Professor Michael Reich is a testament to the complexity and value of even a limited sector of the donation community's effort to get products to people. Even after years of study, this expert in international public health could not quantify the impact of more than a small segment of the donated products.[36] But we do not need to fully quantify the value of the donations to know that philanthropy from the developed world has value.

Few would disagree with the statement that poor nations and disaster areas have needs that exceed the capacity of local governments and international health agencies, such as the World Health Organization. We know that there are people in need and there are people who are willing to help. The most crucial thing we can do to address these needs now is to return to our values as healers and Americans. Will we isolate ourselves and refuse to see the needs beyond

our own shores? Will we support or hamper the efforts of those who are the donors? Can the philanthropic intentions of companies prevail in the face of international condemnation? If a resurgence of attacks were to occur, would donors decide that destroying products is a better alternative than donating them? Will the public, once it learns that companies are making international donations, force them to redirect drug supplies to the needy population within this country?

Robert Davies, head of the Prince of Wales Foundation, notes that in workshops to teach WHO and other UN officials to work with the private sector, the tensions mount as the teaching proceeds. Frequently, shouting erupts on both sides. Government officials view the private sector with suspicion and see it as corrupt and immoral. Business people view governments as corrupt and inefficient. In fact, the only thing they agree about is each other's corruption.[37] Coming to peace across the public-private table will not be easy, but it must be done. Coming to peace with the presence of a for-profit sector within the global health care enterprise, likewise, will be fraught with challenge. Lives are at stake as we debate. Coming to peace will involve engaging new partners and learning new skills. Coming to peace will require developing new operations and elevating the concerns for health care in the developing world at a time when America is struggling with its own health care crises. The most recent set of revised guidelines is a start, but more steps must be taken by all parties in order to secure even more comprehensive standards.

One of those steps was taken recently in a milestone effort. A number of organizations, including the World Bank, the World Health Organization, Agence Européenne pour le Développement et la Santé (AEDES), and The Partnership for Quality Medical Donations, jointly conducted a study of drug donations in four national emergency situations. This joint effort represented an unprecedented collaboration between formerly hostile players in the donations arena. The results of the study produced helpful relationships, and data, for future endeavors. The critical need for drugs in emergency situations, the value of the donation guidelines, the need for effective coordination, and the role of the media in alerting the world to needs were evident. In addition, however, it also became clear that no major U.S. pharmaceutical manufacturer or donor partners had made inappropriate donations. Aware of the guidelines, they operated within them, unlike some of the smaller, less-experienced governments and organizations that now must be educated in their value and application.[38] The organizations are working cooperatively to acquaint the small, well-intentioned but unknowledgeable, donors about the importance of the guidelines to assure their donations are in compliance. They will also offer small donors effective and efficient alternative pathways for the donations they wish to make.

Similar steps must continue if the donation effort a decade from now is to be even more substantial than it is today. To help, national policymakers should allocate some time to engaging in the substantial additional dialogue that will be required among the WHO staff, U.S. Congressional staff and members, pharmaceutical companies, recipient agencies, nations, and activists. Some of these discussions might address questions such as:

- Who should take the lead in ensuring the quality of donations? Should it be pharmaceutical companies themselves, who have so far borne the burden of bad press? To keep the pipeline of donated medicines open to developing nations, companies should maintain impeccable donation operations, select relief agencies carefully, and respond to the political backlash that some donations will likely create. Whether for commercial, philanthropic, or image objectives, no company donating medicines today can ignore either its own operations or those of others who may be handling, receiving, and even donating their products. Goodwill can be generated through targeted and controlled donations; disasters can be created out of unmanaged philanthropy. The reality is that when donations go bad, it is the company that takes the heat. Should that be the case, or is the donation effort ready for shared responsibility and should others also be accountable on the world stage?

- Who should develop and manage the complex infrastructure required to ensure the quality of shipments under these most extreme circumstances? With a worldwide enterprise at least as large as any Fortune 100 corporation (in terms of transactions, international regulation, staffing, budgets, and volume), it is unwise to assume that donations can be managed with anything less than a common mission statement, operating procedures, extensive communications, and accountability. Perhaps common sets of forms, policies, and procedures should be developed across the entire supply chain, modeled after those used by large, sophisticated, and accountable relief agencies today.

- How should the responsible donors, recipient countries, and agencies make the effort to eliminate the (usually) smaller, local, irresponsible players in donations, who through their efforts disrupt the internal health care operations of the recipients? Though well meaning, they are often uninformed and uneducated in the policies and procedures that guide good donation practices. Their misadventures threaten the entire legitimate donation effort of the responsible players.

- How can non-health care players be brought into the discussions of health care needs to support infrastructure development? As companies like IBM, Dell, AT&T, and Microsoft enter the American health care market, should they be invited into the global donation effort? How can those in the fields of education, communications, and economic development be engaged for the good of people's health? Where can their resources be spent to improve the living and working conditions of local employees? What are the best incentives local governments can provide to increase their involvement?

- Can we bring an end to demonizing profit in the health care sector? Is the greed we perceive just a misunderstanding of the commercial imperatives of businesses that rely on private sources of capital? Is there an alternative to current revenues that will pay for research, or can we come to terms with the need for profit? Do governments want to increase their own levels of research effort to discover the drugs for the

developing world, or should companies be allowed to proceed? How can local generic industries be developed to expand the availability of important products without harming progress toward innovation worldwide? How can we recognize that differential pricing of products actually supports access to medicines and that a single worldwide price would spell disaster for all nations?

- Can we stop demonizing government regulators and bureaucrats? Is the inefficiency we perceive just a misunderstanding of their operating constraints? How can those in the for-profit sector support the imperatives of governments? How can the public and private sectors work together to meet their mutual goals of providing care to the needy?

- How can the parties to this debate best understand each other's separate agendas? Can we develop a global research agenda that, coupled with incentives for public and private sectors, could result in new solutions to tropical diseases? Can we find our way through issues as complex as this in a nation (the U.S.) which until recently had been isolationist in the perceived safety of the post-Cold War era?

In the end, the enemy is disease, not the parties to the debate. The weapons will be cures, not rhetoric. Maintaining the covenants that supply donated products and services and creating new covenants of obligation will require that the most powerful player in the process of drug donations—the American pharmaceutical industry—bear the lion's share of the effort. It will require that the industry work to ensure quality donations through its own donation channels and through the contacts of others, that it weather the storms of public image attacks, and that it continue to offer a wealth of products and talent to the developing world. It will not be easy. But it will, in the end, be the single best way for the industry, and this country, to reach out to others on the planet, demonstrate leadership, protect health at home, and avoid health isolationist policies that are unworthy of a nation so rich in resources.

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[1] This appeared originally in 2001 in *Covenants: Inspiring the Soul of Healing*. Readers interested in exploring covenants in greater depth can find background in *The Origins of Healing as Divine Gift* and *History and Modern Applications of Covenant Healing Traditions* which appear in this series.

In summary, healing traditions are based on ancient views that healing skill came from the divine. Healers were aligned with divine forces against the terrible, unknowable and sometimes evil forces of illness. As a result, healer-patient relationships were structured as covenants. Covenants differ from contracts. Contracts have a defined beginning and end and specify the duties of the parties in detail. Covenants do not end and do not detail the duties of the parties.

There are two types of covenants, both are relevant in health care and are expressed in oaths taken by clinicians and others in health care. The first type – a covenant of *grant* – defines what one party does for another, without conditions or expectations. Parents have covenants of this type with their children, providing them food, shelter, clothing and protection. The second type – a covenant *of obligation* – involves mutual promises between the parties. Spouses enter into this type of covenant '…for better or for worse.'

The *Oath of Hippocrates*, a classic covenant statement, contains both types. It creates a covenant of *obligation* with other healers, calling for the oath-taker to "…study, learn and teach my fellows…and to treat his sons as my sons."

Then, the oath "…grants health…" to the patient. The *Prayer of Maimonides*, an oath created later, contains the same covenant of *obligation* among healers and calls patients into a covenant of *obligation* as well, asking that patients follow medical advice, take prescriptions and avoid the advice of meddlesome friends and relatives uninformed about health and disease.

The book suggests that everyone in health care – not just clinical experts but those in any role in research, management, insurance, health reporting and even policy – are the sophisticated extension of ancient tribal healers. Our societies are more complex, as is our knowledge, our data and information, our technology and our systems of providing care. As a result, as healers we have entered healing streams of an ancient origin. Our patients and communities expect us to ascribe to these covenant values.

In my view – and I am not alone in this – health required the integral relationship among healers, patients and communities. I therefore proposed three steps to transform health: first, a covenant of obligation among all healers, as I broadly defined them; second, a covenant of obligation with patients; and third, a covenant of obligation with communities, as well.

This is an application of those ideas to the policy issues addressed here.

[2] Information at http://www.drini.com/mothertheresa/own_words/. Accessed March 18, 2000.

[3] Lawrence Altman, "U.N. issues grim report on the 11 million children orphaned by AIDS," New York Times, December 2, 1999, p. A12. See also United Nations Press Release PI/1205, "World AIDS Day held at headquarters, Focus on children orphaned by AIDS," December 1, 1999.

[4] Marilyn Chase, "New, virulent forms of tuberculosis spur concerns world-wide," Wall Street Journal, December 17, 1999, p. B1.

[5] David Satcher, "Tuberculosis—Battling an ancient scourge," JAMA, 1999, 282(21):1996.

[6] Judith Miller, "Study says new TB strains need an intensive strategy," New York Times, October 28, 1999, p. A6.

[7] Information available at http://www.worldbank.org. Accessed December 14, 1999.

[8] "Corporate hospitality," Economist, November 27, 1999, p. 71.

[9] Information available at http://www.gatesfoundation.org. Accessed December 14, 1999.

[10] Information available at http://www.capitalresearch.org. Accessed December 14, 1999.

[11] Information available at http://www.rotary.org. Accessed December 14, 1999.

[12] Information available at http://www.gatesfoundation.org. Accessed December 14, 1999.

[13] Information available at http://www.fdncenter.org. Accessed December 14, 1999.

[14] Gro Harlem Brundtland, "International Trade Agreements and Public Health: WHO's Role," presented by video at the Conference on Increasing Access to Essential Drugs in Globalized Economy, Amsterdam, November 25-26, 1999.

[15] "Lilly rushes antibiotic aid to more than one million Rwandan refugees," Lilly Press Release, July 27, 1994.

[16] "Lilly speeds needed drugs to Rwandan refugees," FDA Today, October 1994, pp. 4-5.

[17] "The goodwill pill mess," Time, 1996, 147(18):64.

[18] J.L. Zeballos, "Health aspects of the Mexico earthquake—19 September, 1985," Disasters, 1986, 10:141-149.

[19] P. Autier, M.C. Ferir and A. Hairapetiien, "Drug supply in the aftermath of the 1988 Armenian earthquake," Lancet, 1990; 335:1388-1390.

[20] H.M. Ali, M.M. Homeida and M.A. Abdeen, "'Drug Dumping' in donations to the Sudan" (letter), Lancet, 1990, 336:745.

[21] L. Offerhaus, "Russia: Emergency drug goes awry," Lancet, 1990, 339:607.

[22] Personal communication, Hans Hogerziel, World Health Organization.

[23] Frank Greve, "Drug donations: A bitter pill?", *Philadelphia Inquirer*, June 16, 1999, p. 1.

[24] Department of Essential Drugs and Other Medicines, *Guidelines for Drug Donations*, Geneva: World Health Organization, 1999.

[25] Patrick Berckmans, Veronique Dawans, Gerard Schmets, Daniel Vandenbergh and Philippe Autier, "Inappropriate drug-donation practices in Bosnia and Herzegovina, 1992 to 1996," *New Engl J Med*, 337(25):1842-1845.

[26] Jacqueline Rieschick, "Drug donors get deductions for not-so-charitable contributions," *Tax Notes International*, January 13, 1999, 16:174-176.

[27] The Partnership for Quality Medical Donations (PQMD) is an alliance of 19 pharmaceutical companies and private voluntary organizations working to improve the quality of medicine donations around the world. Their domestic and international activities to facilitate the flow of medicines to the developing world have been significant, and they have emerged as the key voice representing the interests of their membership in continuing to donate medical products. Further information is available at http://www.pqmd.org.

[28] Personal communication, Sister Maura O'Donohue, M.D., Catholic Medical Mission Board.

[29] "Charitable giving: Will Americans be generous in the '90s?" *CQ Researcher*, 1993, 3(42):985-1008.

[30] Information available at http://www.merck.com. Accessed December 27, 1999.

[31] Information available at http://www.sb.com. Accessed December 27, 1999.

[32] Information available of http://www.glaxowellcome.com. Accessed December 27, 1999.

[33] Information available at http://www.iclinic.co.za/sept99/healthaid3.htm. Accessed December 29, 1999.

[34] Information available at http://inpma.org/ifpmaselectedprograms.htm. Accessed November 21, 2001.

[35] Personal communication, James Russo, Executive Director, PQMD.

[36] Michael R. Reich, ed., *An Assessment of U.S. Pharmaceutical Donations: Players, Processes and Products*, Boston: Harvard School of Public Health, 1999.

[37] "Corporate hospitality," *Economist*, November 17, 1999, p. 71.

[38] Personal communication, James Russo, Executive Director, PQMD. A final report of this joint study will be available in 2002. Additional information can be obtained through PQMD, which can be contacted at www.pqmd.org.