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Embargoed: Sunday, August 15, 1999, 4:00 p.m. EDT
Released in Boston, MA

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**U.S. Drug Donations Overseas Mostly Meet International Guidelines,
Harvard Study Suggests Ways to Improve Donations Processes**

Michael R. Reich, Ph.D., Takemi Professor of International Health Policy at the Harvard School of Public Health, is available for interviews in Boston on Friday, August 13, 1999. Please call (703) 820-2244 to schedule a time.

A Harvard University study of U.S. pharmaceutical donations to developing countries finds that a majority of the donated drugs meets local medical needs and a majority arrives well before their expiration date, according to an article published in the *Bulletin of the World Health Organization*.

The article is based on a 280-page study, **An Assessment of US Pharmaceutical Donations: Players, Processes, and Products**, directed by Michael R. Reich, Ph.D., Takemi Professor of International Health Policy at the Harvard School of Public Health. The study is the first comprehensive analysis of overseas donations by American pharmaceutical companies and U.S.-based private voluntary organizations (PVOs).

Dr. Reich undertook this extensive study for two reasons. First, pharmaceutical donations to developing countries are a major international health issue, in disaster situations and in development aid. Second, no studies have examined the full range of factors that affect the impacts of donations, considering both the positive and negative consequences. Previous

examinations, based mostly on disaster situations or single country experiences with limited data, reported that outdated and inappropriate drugs made up much of the contributions.

The Harvard study examined the drug products donated by two major U.S. PVOs to 129 developing countries over a 2-3 year time period, involving 16,566 individual shipment items, and proposed a system for classifying donated drugs. The researchers conducted in-country field surveys in Armenia, Haiti and Tanzania. The study also examined donation policies within pharmaceutical companies and private voluntary organizations.

The main findings of the study are:

- For the full data set of donations sent to 129 countries, the median time to expiration at the time of shipment was 599 days for PVO A and 550 days for PVO B. If shipment to the recipient countries were to take a month, these items would be delivered well within the standard period of a year to expiration on arrival, as recommended in the World Health Organization (WHO) Guidelines for Drug Donations. About 70 percent of the more than 16,000 different shipment items had more than one year before expiration at the time of shipment. However, about 30 percent had one year or less, which would not meet the WHO guideline, including 6% with less than 100 days to expiration at the time of shipment. The study did not find any shipments of already expired drugs.

- Between 37 and 65 percent of the donated drug products in the database sent to the three field countries were on the Essential Drugs List (EDL) of the recipient countries – those pharmaceuticals deemed most essential to meet the country's most common health problems – or were permissible therapeutic alternatives, according to the authors' classification. Between 10 and 42 percent were non-list drugs: not listed on either the country's EDL or the WHO's Model List, nor were they therapeutic alternatives for listed drugs.

“The strength of these donation programs is that the overwhelming proportion of different pharmaceuticals shipped had more than one year of expiration at the time of shipment, and a majority of them fit the needs of recipients,” says Dr. Reich. “The main weakness is that at times, the donated drugs were not requested by the recipient, creating logistical, management and disposal problems, as shown in our country surveys. In addition, the study found 6 percent of the

shipment items had less than 100 days of shelf-life at the time of shipment by the PVO. This short shelf-life significantly increases the risk of not being used before the expiration date.”

Overall, the study demonstrated that the drug donation process is extremely complex, involving several layers of different kinds of organizations – U.S. pharmaceutical companies, American voluntary groups, national governments, and national and local medical facilities. These groups must work together to enhance the benefits from donations.

Among the other findings of the study are:

- The majority of the donated drugs in the world-wide sample was composed of anti-infectives, analgesics, anti-fever drugs, anti-inflammatory agents, and various cold preparations.
- Medical personnel of the recipient countries interviewed in the field studies perceive drug donations to be important and having a positive impact on their delivery of health services, and also reported various problems with drug donations.
- U.S. pharmaceutical companies and PVOs have a great variation in the content and quality of their donation policies and in the public availability of their policies.

The study team recommends four main ways to improve the positive impacts of drug donations:

1. **Expiration:** the Harvard team recommends that pharmaceutical companies, PVOs and recipient countries seek ways to lengthen the shelf life of drug donations at shipment. The number of drugs with shelf life under one year should be reduced, and short-dated drugs should be shipped only after prior acceptance by recipients and careful logistic attention, to assure that they are used prior to the date of expiration.
2. **Drug selection:** the Harvard team recommends that efforts be made to improve the match between the drugs donated by external groups and the drugs requested by recipient groups. The various organizations participating in the donation process could use four categories in setting selection priorities: drugs listed on the recipient nation’s Essential Drugs List; permissible therapeutic alternatives for listed drugs; drugs listed on the WHO’s Model List of Essential Drugs; and non-listed drugs.

3. **Donation policies:** the team recommends that efforts be made to develop performance standards on ‘best practices’ for pharmaceutical donations and to develop policies for drug donations, for all organizations involved. These performance standards and policy statements should be made available to the recipients of drug donations and to the general public.
4. **Logistics:** the team recommends that efforts be made to improve the communication among donor companies, PVOs, recipient governments, and recipient health facilities. Better communications could help improve the match between the supply of donated drugs and the requests of the recipients. PVOs could also improve their methods for management of drug donations and the information systems for tracking donated products.

The study was sponsored by the Partnership for Quality Medical Donations, a consortium of pharmaceutical companies and private voluntary organizations. The work was carried out independently of the sponsors. “Every effort was made to limit influence by the study’s sponsors,” Dr. Reich says.

Dr. Reich assembled a multidisciplinary team that used qualitative and quantitative research methods, and collected data from all involved organizations, including the WHO. In order to obtain accurate data and full cooperation, the team agreed not to identify any pharmaceutical company or PVO.

The study has a number of limitations, including the lack of a measure of quantity of donated drugs and the lack of quantitative assessments of the health consequences of donations in the recipient countries.

“This study is the first systematic effort to evaluate the entire process of drug donations, from policies within producers, to practices of PVOs, to the conditions and perceptions within recipient pharmacies and clinics,” says Dr. Reich. “We hope the study’s findings will promote a more informed discussion about strategies to enhance the benefits of drug donations for developing countries and disaster situations.”

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An Assessment of US Pharmaceutical Donations: Players, Processes, and Products

The study by the Harvard team, on which the WHO article is based, is composed of four independent investigations: a quantitative analysis of certain characteristics of donated drugs (Quantitative Study); field surveys of donation processes and results in three recipient countries (Field Survey Study); the development of a model to classify donated drugs and its application to drugs donated to the three field survey countries (Classification Study); and an analysis of donation policies of drug manufacturers and PVOs (Donation Policy Study). Some methods and results from the Quantitative and Classification Studies were presented above. Additional details on each area are provided below.

I. Quantitative Study – The Harvard team created and analyzed a database of all donated drugs received and shipped by two major U.S. PVOs to 129 countries over a 2-3 year time period. The analysis of 16,566 shipment items focused on two criteria – Essential Drug List (EDL) status and shelf-life. The team removed all non-pharmaceutical items from the PVO data base, used a computer program to construct a specific identifier for each product, and examined when the PVO shipped each item and how much time was left before expiration. In addition, the authors examined to which countries the PVOs most often sent shipments.

The researchers compared the list of all shipment items from the two PVOs to the WHO's Model List of Essential Drugs, to examine whether donated products represented therapies that were listed as essential drugs. For the full data base, about 15 percent of PVO A's shipment items and 26 percent of PVO B's shipment items were on the WHO Model List. Based on the WHO Model List, countries construct their own, country-specific lists of essential drugs. Those are thought to represent the drugs needed by the majority of the country's population. When comparing items shipped to a particular country with the drugs on the country's EDL, the proportion of donations on a national EDL can be significantly higher. In the case of Armenia, for PVO A, nearly 75 percent of all drug shipment items were found on the Armenian EDL; for PVO B, the similar estimate was 66 percent. These results suggest that the majority of donations to Armenia were appropriate, if appropriateness is defined by a product's presence on the country's EDL.

One important indicator of quality for drug donations is time to expiration. As noted above, the analysis found that more than half the shipment items in the PVO data base had more than 500 days before expiration at the time of shipment. If shipment to the recipient country takes one month, then these shipments would arrive well within the standard in the WHO Guidelines of one year on arrival in the country.

In the world-wide database, the leading recipient countries for PVO A were El Salvador, Nicaragua, Romania, Russia, and the Ukraine. The comparable recipient countries for PVO B were Croatia, El Salvador, Honduras, Lithuania, and the Ukraine.

“There is a great need for data about the quality of donations, to help formulate policies that could improve drug donations. This quantitative study is the first public analysis of all drug donations that two U.S. PVOs shipped over a two to three year time period. Although we analyzed only two aspects of drug donations, namely Essential Drug status and time to expiration, these are two key points in the public debate over donation practices,” said Dr. Reich.

II. Field Survey Study – According to Dr. Reich, “most published accounts of drug donations describe donations in disaster situations. We wanted to gain an understanding of how donation processes work under regular development conditions.” The Harvard team conducted three in-country field studies. Researchers interviewed practitioners and administrators at governmental and non-governmental health facilities in three recipient countries – Armenia, Tanzania and Haiti – to examine the processes of requesting and receiving donated drugs, from the perspectives of the different recipients.

“The field surveys demonstrated that medical personnel in health facilities in all three countries saw the benefits of donated drugs as real, multiple and desired,” Dr. Reich says. “They appreciated the benefits of drug donations for a variety of reasons: the additional supply of products on national Essential Drugs Lists; the supply of products not listed on the national Essential Drugs List, but still valuable medically; expanded financial flexibility through low-cost products; and drug access for poor patients.”

The field studies also showed that real problems exist in the following areas:

- Donations are not cost-free for health facilities, and the monetary and time costs vary by facility, source and country;
- Shipments do not always match the needs or requests of recipients;
- Local health facilities often have to pay for customs or in-country transportation costs;

III. Classification Study – “A difficult question to answer is: which drugs should be donated?” Dr. Reich said. “We tried to design a system of classifying donated drugs according to how closely they meet the drug needs in a particular country, based on the essential drugs concept developed by the WHO.”

Essential drugs are those that satisfy the health care needs of the majority of the population of a country and that therefore should be available at all times in adequate amounts and in appropriate dosage forms.

The WHO Model List guides individual countries in the development of their essential drugs programs. The Tenth WHO Model List (December 1997) organizes 306 drugs into 27 therapeutic sections. According to WHO, more than 140 countries have developed EDLs as one component of a national essential drugs program.

The authors propose four categories of donated drugs:

1. A *country EDL drug* is a donated drug that is listed on the recipient country’s national EDL.
2. A *therapeutic alternative for country EDL drug* is a donated drug that is not listed on the recipient country’s national EDL but belongs to the same therapeutic class of such a drug, and belongs to a therapeutic class for which the WHO Model List allows the use of alternatives.
3. A *WHO-ML drug* is a donated drug that is neither listed on the recipient country’s national EDL nor is a therapeutic alternative, but is listed on the WHO Model List.
4. A *non-list drug* is a donated drug that is neither listed on the recipient country’s national EDL nor is a therapeutic alternative for a drug on the country’s EDL, and is NOT listed on the WHO-Model List.

The study used this classification system to analyze donated drugs in the PVO data base for the three field countries. The analysis found that a significant proportion (from 50 to 80 percent)

were either on the country's EDL or were therapeutic alternatives for the country's EDL drugs. If these categories are used to define the "relevance" of donations to local disease patterns and national pharmaceutical priorities, then these results suggest that the majority of drugs in this sample were relevant.

IV. Donation Policy Study – "A particular challenge to all participants in the drug donation process is the variability of donation procedures. We wanted to get an understanding of why and how companies and PVOs donate drugs," said Dr. Reich. To examine pharmaceutical donation policies, the study team conducted a survey of 31 U.S.-based PVOs and 36 companies in the United States involved in pharmaceutical donations. Responses were received from 13 of 31 PVOs and 18 of 36 companies, yielding a combined response rate of 46 percent. Among the respondents, 10 firms provided the company's donation policy, and 11 PVOs provided the organization's policy.

The Harvard team studied 10 pharmaceutical companies in depth. According to internal donation policies, nine of these firms donate drugs as part of inventory management. A tenth company did so in the past, but discontinued the practice several years ago due to concerns that there was not enough follow-up to ensure that shorter-dated products would be distributed and used in time. For three companies, the vast majority or all of their donations are made on the basis of inventory control.

Eight of the 10 companies also donate drugs on a request basis in varying degrees, primarily for emergency situations. Requests are made by individual physicians on medical missions as well as by PVOs associated with ongoing health programs. Drugs donated in this manner may come from the regular inventory, or requests may be kept on file until the products become available in surplus stocks.

Only four of the 10 companies are currently engaged in some form of planned production to give. One of these companies is involved only minimally – it occasionally increases manufacturing of a few core products based on the anticipated needs of its consignees.

The recipients of PVO drug donations fall into two broad categories: groups or facilities that are not affiliated with the donating PVO or that become affiliated for the purpose of receiving

donations only; and the PVO's own field offices, staff or projects, which use the products themselves or act as facilitators between the PVO and local groups.

For example, one PVO donates 75 percent of its drugs to its own in-country projects and the remainder goes to local partners that were originally identified by field-staff . In general, PVOs consider the recipient's overall abilities, experience and reputation when deciding whether to establish new or maintain existing partnerships.

“The drug donation processes are extraordinarily complex, involving a multitude of different players, with different bases of information, different constituencies, and in part different goals. Improved communication seems the key to improving drug donations. We hope that pharmaceutical companies, private voluntary groups, medical professionals and the WHO will use our report as a basis for discussing and improving their policies and activities related to drug donations,” says Dr. Reich.

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The full study is available on the Web at <http://www.hsph.harvard.edu/faculty/reich/donations/>.

The published article is: M. R. Reich, A. K. Wagner, T. J. McLaughlin, K. A. Dumbaugh, and M. Derai-Cochin, “Pharmaceutical Donations by the USA: An Assessment of Relevance and Time-to-Expiry,” *Bulletin of the World Health Organization*, 1999, 77 (8). The published article is available on the Web at <http://www.who.int/bulletin/bu0030.htm>.