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Donation Policy Study

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Introduction

The objectives of the donation policy study are twofold: (1) to review, compare, and assess the policies of major US pharmaceutical companies and private voluntary organizations (PVOs) concerning pharmaceutical donations and (2) to identify ways in which the policies for and processes of drug donations could be improved. Our analysis assesses donation policies in terms of their content vis-à-vis established, suggested standards for the field, as well as the quality of their written explanation and degree to which they are publicly available. This exercise represents a first step in the iterative process of defining and identifying "best practices" in pharmaceutical donation policies. To our knowledge, the present study is the first to explore this topic in a systematic way.[1] This analysis may help inform the development and refinement of standards and initiatives designed both to facilitate the processes of drug donations and to improve the environment in which they take place.

Methods

For this analysis of pharmaceutical donation policies, a list of 36 PVOs and 31 companies in the United States involved in pharmaceutical donations was provided to the research team by the Joint Committee of Private Voluntary Organizations and Health Care Firms. All of the companies and PVOs on the list were contacted by mail, with a request for copies of their policies and procedures for pharmaceutical gifts-in-kind.

Organizations that did not respond to the first letter received a second letter to request a reply. Overall, 18 companies and 13 PVOs responded to the request, yielding a combined response rate of 46.3 percent.

The written materials received from 10 companies and 11 PVOs were carefully reviewed and analyzed. Subsequently, representatives of the companies and PVOs that provided documents were contacted by phone and asked to clarify the policy statements and to provide additional information not included in the written documents. Individuals from a total of 10 companies and 10 PVOs were interviewed.

Based on information from the written statements and follow-up interviews, PVO and company donation policies were then analyzed in two ways. The first assessment analyzes the content of the policies—the nature of specific provisions on six key dimensions of the donation process: (1) the type of donation program, (2) criteria and/or screening procedures for consignees, (3) criteria and/or screening procedures for donated products, (4) procedures for donor-consignee communication, (5) procedures governing logistics, and (6) provisions for the follow-up and tracking of donations. These criteria are based on selected provisions of the 1996 WHO *Guidelines for Drug Donations,* the July 1997 draft of "Statement of Principles in the Provision and Distribution of Donated Medicines and Medical Supplies" (PVO-Industry *Principles*), and additional factors that capture important dimensions of the donation process not specified in formal guidelines. The criteria were selected as those most likely to have bearing on the probability of appropriate donations and specific enough to be assessed with the limited information available for this study. For most of the categories, both PVOs and companies are discussed, although the applicability of the issues varies. Furthermore, while the WHO *Guidelines* do not specify a "division of responsibility" between the various actors in the donation process, each of the PVO-Industry *Principles* is directed specifically at either companies or PVOs. In a number of instances, this role division was used to guide the follow-up interviews in our study. For example, more emphasis was placed in the interviews on the respective policy components for which companies and PVOs are deemed "responsible" according to the PVO-Industry *Principles*.

The second assessment addresses the written quality and availability of company and PVO donation policies—that is, the existence of written policy statements, the quality of their written explanation, and the degree to which they are or can be shared with others. For those organizations

that provided written materials, the quality of policy statements was evaluated in terms of (1) the *completeness* of written policy statements as compared with unwritten policies (reported in the interviews); (2) *explicitness*—the extent to which written policy provisions are unambiguously stated; and (3) *presentation*—whether the provisions are part of explicit "policy statements" or "guidelines" or are embedded in transaction forms or internal procedures. To determine the public availability of donation policies, respondents were asked in follow-up interviews whether policies can and have been shared with outside parties.

This study has a number of limitations. The first concerns the generalizability of the findings. The list of PVOs and companies originally contacted was not exhaustive or random, and those that did reply may not be representative of the larger universe of actors. The second limitation relates to the scope of the study. The analysis is based on the stated policies of PVOs and companies and does not address the practical application of these policies or the actual behavior and compliance of the organizations. Therefore, the degree to which inferences can be made concerning the performance of PVOs and companies based on this information alone is limited. The operating assumption is that better practice follows from having more complete and transparent written policies that conform as much as possible to established standards, but it is possible that donation programs can be equally effective without them. A third caveat concerns the "instrument" used in follow-up interviews. The follow-up interviews were intended to clarify and expand on the written policy statements as needed, not to survey respondents exhaustively on all dimensions of the policy process. As a result, the questions posed to company and PVO representatives were not entirely uniform in scope or specificity. The fourth limitation, also methodological, relates to the quantitative assessment of the quality of written policies. Quantification of qualitative assessments is always problematic and open to debate. However, as with other components of this study, the objective is to provide a descriptive overview and identify "best practice."

Assessment of Contents

Below we present the rationale for and the results of the analyses of the donation policy statements for six dimensions of content: type of donation program; recipient selection; product selection; communication; logistics; and follow-up.

Type of donation program

Rationale

Although PVOs are engaged in a variety of donation programs (for emergency assistance, ongoing health programs, and/or periodic physician medical missions) this issue pertains primarily to the companies. Companies may be involved in drug donations in one or more of three ways: (1) as part of their inventory management, whereby short-dated or excess products are identified on a regular basis and offered to consignees; (2) on a by-request basis, for emergencies or ongoing health programs; and/or (3) in the context of planned production or "produce-to-give" programs, whereby pharmaceuticals are manufactured specifically for donation. The PVO-Industry *Principles* recommend that donor companies consider planned production programs "so as to improve the availability of these products on a reliable and expeditious basis." These programs can help ensure both that the specific products that are needed are available and that the remaining shelf life is more than sufficient. The WHO *Guidelines* include general statements discouraging unsolicited drug donations but do not make any specific recommendations regarding the types of donation programs. Inventory control programs do not necessarily imply unsolicited donations (PVOs may still request and approve products from the "excess" stock available, including short-dated products), but this kind of program is likely to be less recipient-driven than other approaches.

Results

Nine of the 10 companies donate drugs as part of their inventory management. The tenth company did so in the past, but discontinued this practice several years ago because of concerns that there was not enough follow-up to ensure that shorter-dated products would be distributed and used in time. For three of the 10 companies, the vast majority (or all) of their donations are made on the basis of inventory control, allowing them to "avoid unnecessary disposal" of "excess" products.

Eight of the 10 companies 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 PVOs associated with ongoing health programs. Drugs donated in this manner may come out of the regular inventory or requests may be kept on file in the event the needed products become available in surplus stock. For one company, request-based donations comprise the bulk of its giving program; the

donated drugs come out of the company's regular stock and are used for ongoing health programs.

Only four companies are currently engaged in some form of planned production to give, and 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. Two additional companies reported that planned production programs were beginning to be considered. Three of the four companies currently manufacturing to make donations described a process whereby donation budgets are established and drugs are produced for donation based on the forecasted needs of the PVOs with which they work. The fourth reported an additional, complementary strategy whereby decisions to produce specific drugs for donation may be incorporated into regular business practice; surplus stock may be produced (with the intention to donate it), for example, as a way of maximizing human resources and machine utilization. The company with the most extensive "produce to give" program donates specific drugs that are manufactured primarily or exclusively for donation purposes. In addition, this company allows its PVO partners to order a capped value of drugs from its full product line on a quarterly basis.

Only three companies in the sample are currently involved to some degree in all three types of donation programs.

Consignee selection

Rationale

Neither the WHO *Guidelines* nor the PVO-Industry *Principles* provide any criteria or procedures for the selection of consignees. However, the type, number, and regularity of the recipients (both PVO consolidators and end-users), as well as the basis for choosing them, can have important implications for the probability of an appropriate donation program. The use of detailed written criteria or formal applications for selecting recipients can help to ensure standardized procedures and accountability.

Results

Companies. Seven of the 10 companies in our sample work exclusively with a small group of US PVOs, numbering from two to seven. In most cases, these are PVOs that were "checked out" a long time ago and with which the company now has "long-standing relationships." If other PVOs contact these companies requesting donations, they are usually referred to their regular partners. The remaining three companies also work pri-

marily with established PVO partners (between three and eight) but will, on occasion, donate to a new PVO if there is a specific need that the company feels it could best serve directly (rather than working through another PVO). Only one company in our sample donates directly to physicians for medical missions.

Three companies have specific, written requirements for selecting PVO consignees beyond criteria for maintaining nonprofit tax status (that is, donations must go to the ill, needy, or infants free of charge, must not be exchanged for money, and so forth). These criteria pertain, in varying degrees, to the presence and qualifications of medically trained staff and/or the PVO's capacities with regard to safety, storage, distribution, and tracking. Four other companies include in their policies general statements that they work with "qualified" PVOs that adhere to (nonspecific) company "standards" or that demonstrate "accountability," "integrity," or "reliability." The remaining three companies do not have any written statements regarding PVO qualifications. There is, however, some relationship between the breadth and detail of the criteria, on the one hand, and the practice of accepting new partners, on the other. For example, of the seven companies with no criteria or with nonspecific criteria for consignee selection, only two are working occasionally with new partners, and both report that they check with their regular partners or other companies to determine the reputation of prospective new consignees. Similarly, the company that reportedly works with the greatest number of regular PVOs (eight) and also accepts new consignees has the most extensive written criteria.

PVOs. The consignees of PVOs fall into two broad categories: (1) groups or facilities that are not affiliated with the donating PVO or that become affiliated for the purpose of receiving donations only; and (2) field offices, staff, or projects of the donating PVO that use the products themselves or act as facilitators between the PVO and local groups. (Only one PVO in our sample donates to both categories of recipients.) Six PVOs donate to the first category of consignees, and most of them, like the companies, work with regular partners but also accept new recipients. The number and type of these partners also varies a great deal: Some work with as few as seven or eight on an annual basis, others up to 100, and some donate primarily to other US PVOs, while others work exclusively with consignees overseas, such as mission groups. Three PVOs also offer regular or "pre-packaged" donations to individual physicians on medical missions.

The second category of PVO consignees applies to six PVOs in two ways. PVOs have field offices and may donate to their own projects (three) and/or donate to their local staff who, in turn, identify and distribute products to local service providers (five). Local staff are involved in the donation process in varying degrees, some merely "checking out" new partners and others providing ongoing needs assessment and oversight. For example, one PVO donates 75 percent of its drugs to its own in-country projects and the remainder goes to local partners originally identified by field-level staff, but with which the central office now deals directly. Another relies on local staff to coordinate all shipments and to validate the ultimate usage of the donations.

In general, PVOs consider recipients' overall abilities, experience, and reputation when deciding whether to establish new (and maintain existing) "partnerships." In addition, seven PVOs have, to some extent, specific requirements for selecting recipients beyond verification of tax status and/or religious affiliation. Like those of the companies, PVOs' selection criteria pertain to the recipients' capacities with regard to various aspects of the donation process, such as clearing Customs, storing and distributing drugs, and maintaining adequate security. These PVOs also seek assurances that qualified medical personnel will be involved in drug disbursement and that follow-up documentation on the use of donations will be provided. Six of the seven PVOs with specific requirements incorporate their selection criteria into some type of "consignee guidelines" or "eligibility questionnaire" that serves as a partnership agreement form or "contract." Three of these PVOs ask for references as part of the written application.

The other four PVOs do not employ specific criteria when deciding on new recipients.[2] However, all four of the PVOs without detailed requirements have field staff who either evaluate prospective new partners or are heavily involved in local oversight of all aspects of the donation process (as described above). One PVO relies on both specific criteria *and* national staff to determine the qualifications and "credibility" of local partners.

In addition to screening the recipient overall through applications and/or consultation with other groups, four PVOs also screen each specific donation request by requiring detailed "proposals" or "implementation plans" for how the drugs will be used. For example, one of the larger PVOs requires a general written application from all partners and a more detailed project description from recipients for each large volume order they place. The latter requests information on overall program goals and

emphases, populations served and their health problems, and the agency's logistic capabilities.

Product selection

Rationale

Both companies and PVOs utilize various criteria and screening procedures to identify the products they will donate and/or accept. These procedures and the consistency with which they are applied may have important implications for the appropriateness of the products donated. In addition to general statements regarding quality standards and appropriate formulation and dosage, the WHO *Guidelines* related to product selection contain three specific, key provisions: (1) Donated drugs should have a remaining shelf life of one year *after arrival in the recipient country*; (2) donated drugs should be on national essential drugs lists or the WHO Model List of Essential Drugs (WHO-ML); and (3) drugs should not be donated if they have been issued to patients and returned or if they have been distributed to health professionals as free samples. By comparison, the July 1997 draft PVO-Industry *Principles* recommended a minimum of six months dating remaining on products *when they are received by the PVO*.[3] The PVO-Industry *Principles* do not include criteria regarding essential drugs lists, but they do contain a provision recommending that PVOs maintain "written policies and procedures to evaluate potential pharmaceutical donations to ensure that they meet appropriate programmatic, medical, cultural, and ethical criteria." The *Principles* also discourage companies from donating free samples and returned products.

Product-dating guidelines seek to ensure a minimum standard practice that accommodates the often-lengthy transaction time both in the United States and the receiving country, as well as any unanticipated delays in shipment, clearance, and distribution. Recognizing to some extent the diversity of situations, both the WHO *Guidelines* and PVO-Industry *Principles* allow for exceptions to their respective shelf life minimums, mostly in the case where the recipient can guarantee utilization prior to the expiration date. Essential drugs list provisions are designed to prevent the donation of drugs that are either unnecessary, unknown, or inappropriate in the receiving country (see Chapter 2 in this report). Prohibitions on the donation of samples and returned goods are concerned primarily with quality assurance, although the donation of small sample packages also raises issues of packaging disposal and the increased possibility for diversion. There is an important distinction between returns and samples in that the latter might never leave the control of the producer prior to

donation and, if so, may be less at risk of being compromised compared to returned products.

Results

Tables 4.1 and 4.2 show the written policy provisions of companies and PVOs, respectively, concerning product dating and essential drugs list status.

Dating: Companies. Nine of the 10 companies' minimum dating requirements range from three to 12 months. Seven companies' policies are consistent with the industry guidelines' stipulation of a six-month minimum, but none of the companies' policies match the WHO criteria of 12

TABLE 4.1

Analysis of Donation Policies: Pharmaceutical Companies (Written Articles on the Product Dating and Essential Drugs List Status of Donated Products)

	Product Dating	Essential Drugs List Status
Company 1	Three months minimum.	None
Company 2	None.	None
Company 3	Seven months minimum. Cooperating consolidators must ship with a minimum of six months remaining.	None
Company 4	Six months minimum. Exceptions possible with approval of country recipient. Also possible to extend dating with proper testing and regulatory approval.	None
Company 5	Nine months or more preferred; six months minimum, with exceptions on a case-by-case basis.	None
Company 6	Where applicable, donations should have a minimum of six months remaining.	None
Company 7	Three months minimum; less on occasion if PVO can guarantee in writing that the product will be used prior to expiration.	None
Company 8	Six months minimum; practice is one year.	None
Company 9	Twelve months minimum. Cooperating consolidator must ensure that product is shipped within three weeks of receipt.	None
Company 10	Where applicable, donations should have a minimum of six months remaining.	None

months dating on arrival in the recipient country. One company has a policy that requires a minimum of 12 months at the time of donation and requires that the PVO must ensure that products are shipped within three weeks of receipt. One additional company's policy includes a specific stipulation regarding the remaining shelf life upon shipment from the PVO. Two others include explicit language dealing with exceptions to the minimum dating requirement. Only one company policy does not have a

TABLE 4.2

Analysis of Donation Policies: PVOs (Written Articles on the Product Dating and Essential Drugs List Status of Donated Drugs)

	Product Dating	Essential Drugs List Status
PVO 1	Six months at donation. Exceptions allowed when agreed to by final consignee.	None
PVO 2	Six months remaining when consolidator takes possession.	None
PVO 3	Expiration date is to be considered when donations offered; no specific criteria.	None
PVO 4	Request one year minimum. Exceptions handled on case-by-case basis and approved when specific recipient agrees.	None
PVO 5	One year upon arrival in recipient country. Exceptions allowed when recipient indicates.	Must be on WHO-ML or interchangeable. Exceptions possible when recipient indicates need for specific non-ML drug.
PVO 6	Prefer six months at donation; accept four months for "high demand medications." Require one-year minimum for DEA-controlled substances.	None
PVO 7	One year at donation. Exceptions must be approved by in-country staff and be assigned to a specific program before acceptance.	None
PVO 8	None.	None
PVO 9	One year at time of arrival in recipient country.	Seeks drugs on national EDL or WHO-ML.
PVO 10	One year minimum. Consideration given to special offers with six to 12 month dating.	None
PVO 11	Donations of products dating less than one year.	None

specific minimum dating requirement or guideline; instead, individual decisions about the appropriateness of product dating are made based on considerations of the type of drug (its overall importance and usability) and the probable destination.

Dating: PVOs. Two of the 11 PVOs in the sample do not have specific, written criteria concerning product dating. One of the two has a strong field presence and uses input from field offices to evaluate the dating and overall appropriateness of products offered. The other PVO purports to prefer one year dating, but does not insist on it; if they receive offers of short-dated products (which they consider to be under six months), they check with prospective recipients to ensure that the drugs can be used before expiration. Three PVOs require six months dating for donated drugs, but only one of them stipulates explicitly that this must be the dating when the donation is received by the PVO, as per the 1997 PVO-Industry *Principles*. Four PVOs require one year dating at the point of acceptance only and do not have written articles concerning the acceptable amount of time between receipt and shipment (nor do other PVOs). The remaining two PVOs' policies are consistent with the WHO *Guidelines* in that they include explicit statements that one year shelf life should be remaining upon arrival in the recipient country. Seven of the nine PVOs with written criteria on dating include provisions for allowing exceptions: either general requirements for case-by-case approval by PVO management and/or the end-recipient, or specific criteria requiring consideration of the priority-level of the drug or preplacement of the donation with a recipient before accepting it from the company.

Essential drugs list status. As shown in Tables 4.1 and 4.2, none of the companies' and only two of the PVOs' written policies include articles pertaining to the WHO-ML or national EDLs. Essential drugs lists are, however, incorporated into the donation process in varying ways by a number of PVOs. For example, one PVO requests from all its recipients a copy of their countries' essential drugs lists. Another uses the WHO-ML as a guide in determining the usefulness of products offered for donation by firms. And a third reported using the WHO-ML to recommend appropriate drugs to physicians who request products for medical missions but may not know what is needed in a particular country. In addition, a fourth PVO reported that an EDL article is not relevant to their operation, because it is rare that anything its recipients need is not on the WHO list or a national equivalent.

Samples/returns: Companies. None of the written policy statements of companies mention samples. One company reported donating samples on an occasional basis; another responded (in the follow-up telephone interview) that it expressly does not donate samples. The remaining companies either reported that the issue is not applicable (three) or did not mention samples as part of their product eligibility criteria and were not asked directly (five). Two company policy statements contain written articles concerning returned products, both allowing their donation. Neither company stipulates the source of the returned products. Two others reported that they will donate returned drugs if in their original, unopened packaging. An additional two companies prohibit the donation of any kind of returned products. Three others did not offer policy provisions regarding returns when asked (in a telephone interview) about product eligibility, and a fourth reported "not applicable."

Samples/returns: PVOs. Four of the 11 PVOs' policies include specific statements concerning returned products and/or samples. Based on the interviews and written materials, three PVOs[4] appear to accept physician samples for donation with some kind of safety/quality stipulation. For example, one PVO requires that samples be pre-approved by field staff and be assigned to a specific country and program upon receipt. No PVO accepts returns of dispensed drugs, and only four PVOs accept returned products that were excess but not previously dispensed to patients. Three PVOs would not take any returned products. Only one of these PVOs' policies includes written statements concerning the donation of returned products of any kind.[5]

Other Criteria and Procedures for Product Selection. Four companies and six PVOs include in their policies some type of language regarding quality and safety standards (for example, products "must not be compromised" or should adhere to GMP standards) and/or regulatory approval (such as FDA acceptance). Several PVOs also employ additional, specific criteria in making product acceptance decisions. For example, a few stipulate that donated drugs must not require companion products and others, knowing generally what their recipients can handle, try to avoid "esoteric" drugs or those with multiple ingredients. One PVO also reported regularly drawing on outside professional expertise to evaluate potential donations.

In addition to precise selection criteria, most PVOs also use needs-based assessment procedures, with varying degrees of specificity, for both screening and soliciting drugs. We identified four types or "levels"[6] of

discrimination that in many respects reflect the extent to which drug solicitation is "recipient-driven." At the first, most general level, PVOs may categorize prospective drugs according to their overall usefulness and importance and then base solicitation and acceptance decisions on the priority level of the drug under consideration. One PVO uses its needs-based prioritization to screen donation offers and may be more lenient in dating requirements for "high-need" products. One of the larger-scale PVOs categorizes its existing inventory as to whether the drugs are "essential" according to the WHO-ML or are otherwise therapeutically important, then solicits donations of drugs in the category in short supply.

At the second level, PVOs may use historical request patterns and ongoing needs assessments from their regular recipients as "tools" for making acceptance and solicitation decisions. Six PVOs in our sample use this approach, either exclusively or in conjunction with another approach. For some PVOs, this consists of a very systematic, regular process of ascertaining specific program needs—in a few cases, with the in-country involvement of PVO staff. For others it is more of a general "sense" of recipient priorities, often as a result of ongoing, more informal communication.

At the third level, PVOs may accept products from companies only after placing the prospective donations with recipients. This is distinct from the (often-found) exceptions to dating requirements whereby specific donations require pre-approval from the end-user recipient because of short-dating. Two PVOs use this recipient-consultation approach when they receive offers of products that are not part of their regular inventory. However, an additional three PVOs accept unsolicited products from companies only after they have, in turn, placed the drugs with the end-recipient. (Companies were not asked about their policies for giving PVOs time to place prospective donations before accepting them. One PVO reported that many companies allow a few days for consideration, but others are "too impatient" to wait at all.)

At the fourth (and most directly recipient-driven) level, PVOs solicit donations of specific products on the basis of requests from their regular partners. Three PVOs acquire 50 to 100 percent of their donated drugs in this manner. Those PVOs that use exclusively either or both of the latter approaches (pre-acceptance approval or request-based solicitation) have, as a result, very little or no standing inventory.

The appropriateness of the "level" at which PVOs consider recipient needs in screening and soliciting drugs may depend on the scale of the program involved. PVOs with a large, diverse, and changing clientele

may tend (appropriately) to operate only at a more general level. Similarly, those with smaller operations and fewer, more closely affiliated recipients may be able to (or can only afford to) acquire drugs that are specifically and immediately needed by their partners.

Communication with consignees

Rationale

"Effective communication between donor and recipient" is one of four "core principles of a donation" specified in the WHO *Guidelines*. The intent of the principle, designed to apply to donations between companies and PVOs and between PVOs and end-recipients, is that donations should be needs-based and should not be sent without prior consent. The equivalent PVO-Industry principle is directed at PVOs and stipulates that no donated products should be shipped "without proper documentation indicating a specific need for it." Broadly defined, "effective communication" is relevant to all aspects of the donation process—from initial needs assessment to end-use follow-up—and therefore many of the dimensions of donor-recipient communication have been addressed elsewhere in this study. As a result, this section reviews briefly the aspects of communication in the donation process that have been addressed previously and focuses primarily on companies' and PVOs' policies and procedures for obtaining final approval from recipients for individual shipments of donated products.

Results

Communication between companies and PVOs is essential (and has been described above) with respect to three situations: (1) in the context of "demand-driven" (for example, produce-to-give) donation programs, companies communicate regularly with PVO partners to determine their ongoing needs and capacities; (2) companies that accept donation requests from PVOs for specific products have procedures to report on the status of the request and/or to refer the PVO to another agency; and (3) if a company honors a PVO's request to place offered products before accepting them, both parties may need to communicate several times regarding a specific donation. Similarly, as described above, PVOs and their recipients in turn must communicate regarding ongoing needs, the appropriateness and usability of donation offers, and specific recipient requests.

Companies. Based on the written policy statements and follow-up interviews, this survey found that none of the companies in our sample send

shipments of donated products to PVOs unannounced. Furthermore, as described above, specific company-PVO drug donations are "needs-based" to varying degrees, depending on the type of donation involved. However, only four companies have explicit procedural statements indicating that a specific donation shipment takes place only *after* the receiving party has agreed. None of the companies provided examples of forms used to obtain the recipient's approval in writing.

PVOs. Similarly, based on the written policies and interviews, the PVOs in our sample do not send donations to their recipients without prior notification. There is, however, some variation in the degree to which recipients are able to know and approve of exactly what is being sent to them at the end of an often lengthy back-and-forth process of submitting and amending donation offers or requests. All PVOs in the sample have some type of procedure for informing recipients regarding specific donations, but only three have relevant policy statements (and only one of these is explicit that individual shipments must be pre-approved by the recipient with regard to specific attributes). One of the three with policy statements and one other PVO provided sample pre-approval forms for recipients.

The issue of pre-approval is particularly important for PVOs that employ a policy of "first come, first served" in filling donation requests or that are otherwise regularly unable to fulfill requests as originally submitted. Five PVOs fall into the "first come, first served" category and are usually those with larger operations and some amount of standing inventory. Three of these PVOs reported in interviews that if the PVO cannot fulfill a donation request in any way (because of low inventory, unsuccessful solicitation, or competing requests), recipients are sent a revised packing list for final approval. The fourth PVO reported a process of communicating changes to donation requests on both the PVO and recipient ends, but no specific procedure for ensuring final approval from the recipient of what is eventually sent. The fifth PVO in this group reported both a systematic process for amending requests on both ends and a requirement that the final, amended shipment be approved by the recipient in writing.

Three other PVOs are, at times, unable to fill requests as originally submitted: Two have explicit policies to inform recipients and the third reports regular "communication" with recipients about specific donations but no specific procedures. The remaining two reported that they are usually able to fill donation requests without amendments.[7]

Logistics—packaging, labeling, and payment procedures

Rationale

The WHO *Guidelines* include provisions concerning the packaging and labeling of donations and the coverage of various costs associated with sending and receiving donations. Specifically, the *Guidelines* recommend that donations be packaged in larger-quantity units (to decrease bulk and cost) and labeled in the appropriate language with, at a minimum, the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, manufacturer name, quantity, storage conditions, and expiration date (to help ensure proper usage). The *Guidelines* stipulate that shipping, storage, and handling charges (including port clearance) be covered by "the donor agency" unless otherwise agreed. The PVO-Industry *Principles* similarly call for companies to donate in larger packaging, when possible, and to ensure proper and detailed labeling. They also recommend that PVOs should decide in advance (with their recipients) how transportation and other transaction costs will be handled.

There are a number of other important logistical components of the donation process—for example, physical storage and inventory management—which have direct implications for program quality and accountability and for which many PVOs have detailed policies and procedures. The focus in this section, however, is on those logistical issues most likely to affect directly (either impede or facilitate) the *end-use recipients*' ability to manage and utilize drug donations successfully.

Results

Companies. Three of the ten companies include in policy statements or reported in interviews at least one specific provision regarding packaging or labeling. One company seeks to donate in large quantities and requires "correct labeling" on donation shipments. The second requires (in its written policy) detailed labeling of the kind called for by the WHO *Guidelines* and PVO-Industry *Principles*. The third stipulates that special handling instructions be included with shipments as necessary.

Two other companies that do not have relevant written provisions reported that packaging and labeling requirements are not included in "donation policies," per se, but rather are the responsibility of other corporate divisions. The remaining five companies do not have explicit, specific labeling and packaging guidelines.[8] In addition, three companies have written policy provisions concerning shipping costs; two require the receiving PVO to cover all expenses (one may, in special circumstances,

provide shipping support). The third covers domestic shipping costs but requires the recipient to pay for overseas shipping.

PVOs. Very few PVOs have explicit (much less, written) policies concerning donation packaging.[9] A total of six PVOs have some form of packaging guidelines, most of which are general and are designed to protect shipments from damage or tampering. Only two of the six PVOs specify that they attempt to package drugs in larger quantities. In contrast, six PVOs have as part of their formal policies or procedures requirements for the kind of detailed labeling of drugs recommended by the WHO *Guidelines* and PVO-Industry *Principles.* Two of these PVOs also specify in policy statements that the labeling (packing inserts) be provided in languages appropriate for the end-user.

All PVOs (except one) were asked in follow-up interviews about their policies for covering donation expenses. Eight of the PVOs have written articles on this issue. Five PVOs require that their recipients pay all related expenses; four of these allow exceptions when, for example, USAID ocean freight reimbursement funds are needed and available. Only two PVOs take responsibility for paying all donation expenses, and one of the two (which donates primarily to its in-country offices) first attempts to secure funding for these costs from the donating company. The remaining three PVOs[10] "split" the expenses in the following way: The PVO covers all external shipping costs to the recipient country port of entry, and the recipient pays for all expenses related to customs clearance and local transport. One of the three will, if necessary, try to provide financial aid to the recipient for in-country costs.

Follow-up

Rationale

The WHO *Guidelines* do not include specific provisions concerning the follow-up or tracking of pharmaceutical donations. In contrast, the PVO-Industry *Principles* statement highlights "accountability" as a program goal and includes specific provisions related to PVOs' responsibilities for ensuring the proper distribution of donations and the destruction of products when necessary. The industry guidelines also stipulate that PVOs will document "the utilization of donations and their humanitarian impact." Most companies and PVOs require at least the most basic documentation in order to verify a donation for tax purposes. As the industry statement suggests, however, detailed follow-up and documentation is

important both for accountability and for ongoing improvement in the quality of donation programs.

Results

Companies. Because the issue of substantive follow-up (that is, follow-up pertaining to more than tax-related verification) is designated by the PVO-Industry *Principles* as the responsibility primarily of PVOs, companies were not asked in follow-up interviews to elaborate on their relevant procedures. However, a review of the written company policy statements provided shows that several do include some type of provision for follow-up and tracking. For example, five companies (according to the written statements alone) require from the PVO written confirmation of receipt of donated products. Three of these companies referred to (in their statements) or provided copies of form letters that are sent to the recipient to be returned with acknowledgment of the type, quantity, and so forth of the donation made. One company policy also specifically requires notification in the event that donated products are transferred to another organization. Only three companies require reports ("periodically" or "quarterly") from PVOs providing more detailed information on the end-use of the donations. One company statement referred to a formal tracking system for donations, and one other stipulates that PVOs must provide written documentation in the event of product destruction.

PVOs. According to written PVO policies and follow-up interviews, five PVOs in the sample require, at a minimum, written confirmation of the receipt of donation shipments. Ten of the 11 PVOs require some type of "end-use" reporting from recipients, detailing in various degrees where, how, when, and/or for whom the donated products were used. In two cases, this reporting is requested in the form of a detailed thank you letter to the donor company. One of these PVOs sends with its shipments an "assessment survey" that asks for details concerning the quality of the products donated (including their labeling), any problems or delays encountered, and the tangible benefits of the specific donation. The assessment also explicitly requests feedback on the services of the PVO. Of those policies we reviewed, this example represents the most explicit strategy for gathering the type of information useful for program improvement. Only two of the PVOs requiring end-use reports specify the date by which the documentation must be received (one year for one, 30 days for another). The one PVO that does not specify in its written policy statement that end-use reporting is required[11] relies on the oversight of its

in-country staff to ensure "product accountability" and to validate ultimate product delivery and usage.

In addition, one PVO expressly requires documentation of donation transfers, three PVOs have written articles dealing with the follow-up and oversight of product destruction, and two PVOs make use of a computerized inventory system to track donations from the PVO warehouse to their final destination.

Assessment of Written Quality and Availability

Overall policy availability

Figure 4.1 shows the distribution of company and PVO responses to requests for their written policies and procedures. Ten of the 18 companies that responded (56 percent) provided written policy statements, but two of these statements were prepared in response to the study's request. The remaining eight companies reported that they did not have a formal policy (five), that they could not participate for unstated reasons (two), or that they could not participate because their policies are confidential (one).

In contrast, many more of the PVOs that responded provided policies (11 out of 13 PVOs, or 85 percent). Furthermore, to our knowledge, all 11 of the PVOs that provided policies submitted pre-existing written statements. Of the remaining two PVOs, one reported that there is no official policy, and the other reported that the policy is currently under review.

Quality of written policies and procedures

Tables 4.3 and 4.4 provide a numerical assessment of the quality of the written policy statements received. Only those policy components most relevant to companies and PVOs, respectively (as indicated above), are analyzed. Individual policy components are ranked "low," "medium," or "high" on a three-point (one to three) scale for each criterion (completeness, explicitness, and presentation). The numbers in the columns represent the averages of these rankings. The averaged "scores" are then summed across the policy categories, creating an overall possible score ranging from four to 12 for companies and from five to 15 for PVOs. The PVO that was not interviewed is excluded from this assessment.

Type of program. The assessment shown in Table 4.3 indicates that the quality of companies' written policy statements regarding the type(s) of donation programs is, on average, fair to good. All but two were com-

FIGURE 4.1

Distribution of Company and PVO Responses to Requests for Donation Policies

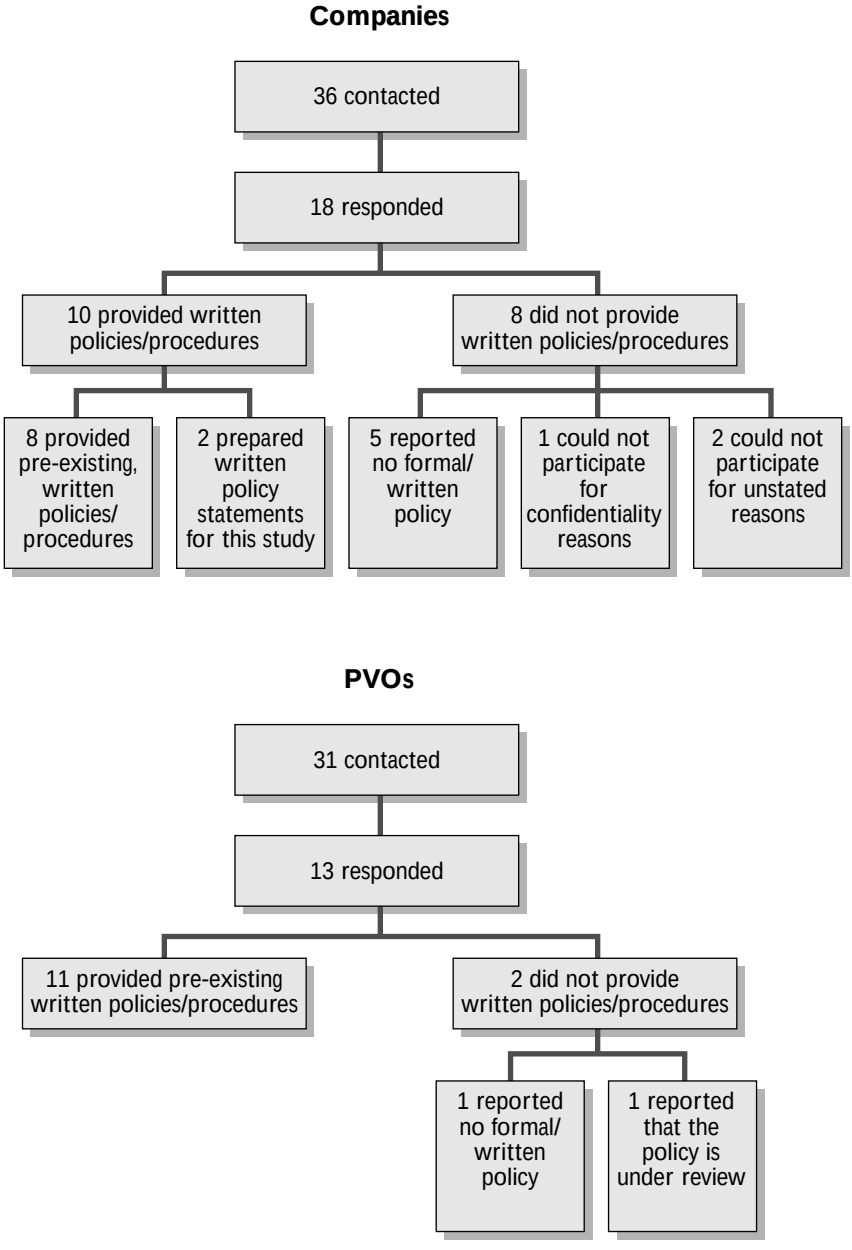

TABLE 4.3

Analysis of Donation Policies: Pharmaceutical Companies (Quality of Written Explanation of Selected Provisions)

	Type of Program	Recipient Selection	Product Selection	Logistics	Total
Company 1	2.7	1.7	3.0	1.0	8.3
Company 2	2.0	3.0	2.3	2.0	9.3
Company 3*	2.0	2.3	2.3	1.0	7.7
Company 4	1.0	3.0	3.0	1.0	8.0
Company 5	1.7	2.3	3.0	3.0	10.0
Company 6	3.0	3.0	2.7	2.7	11.3
Company 7*	2.0	2.0	2.3	1.3	7.7
Company 8	2.0	2.7	2.7	1.0	8.3
Company 9	2.7	3.0	3.0	2.3	11.0
Company 10	3.0	2.7	2.7	1.0	9.3

* Policy statements that were produced for the present study.

1 = written explanation is absent or poorly stated; 2 = written explanation is fair; and 3 = written explanation is good to excellent. Numbers in the cells represent averages of ratings on completeness, explicitness, and presentation.

TABLE 4.4

Analysis of Donation Policies: PVOs (Quality of Written Explanation of Selected Provisions)

	Recipient Selection	Product Selection	Communi-cation/Final Approval	Logistics	Follow-up	Total
PVO 1	2.3	3.0	3.0	3.0	3.0	14.3
PVO 2	2.3	2.7	1.7	2.7	1.0	10.3
PVO 3	1.7	2.7	1.7	2.0	1.7	9.7
PVO 4	2.7	1.7	2.3	2.7	1.0	10.4
PVO 5	2.7	3.0	3.0	2.7	3.0	14.4
PVO 6	2.3	3.0	1.0	2.7	2.3	11.3
PVO 7	2.3	2.7	1.0	2.3	2.7	11.0
PVO 8	1.3	2.7	3.0	2.7	3.0	12.6
PVO 9	1.7	3.0	1.0	1.0	2.7	9.4
PVO 10	1.0	3.0	1.0	3.0	1.0	9.0

1 = written explanation is absent or poorly stated; 2 = written explanation is fair; and 3 = written explanation is good to excellent. Numbers in the cells represent averages of ratings on completeness, explicitness, and presentation.

plete, and most described (or referred to) their programs as part of formal policy statements. However, many company statements on this issue were rather vague, and it was necessary to infer (with varying degrees of certainty) whether companies donate primarily as a form of inventory control, produce to give, or for other reasons. For type of program, the two "best practice" examples are Companies No. 6 and No. 10 in Table 4.3. Both clearly describe, sequentially and in detail, the different components of their donation programs as part of official policy documents.

Recipient selection. Regarding the quality of written policy statements on recipient selection, Tables 4.3 and 4.4 show a notable difference between companies and PVOs. Four companies' statements achieved a rating of "good to excellent" in this category, while none of the PVOs' did. Many of the company statements with lower ratings were partially incomplete in that they did not note the use of regular partners and/or they were presented poorly (many of the selection criteria were embedded in correspondence or contract forms rather than spelled out in policy statements or guidelines). PVO policy provisions on recipient selection were, on average, similarly incomplete or embedded, but they were also in many cases vague and unclear. Only two PVO statements on this issue were articulated with a high degree of clarity.

Product selection. Both company and PVO written policy statements on product selection rate, on average, from good to excellent. Almost all companies' and PVOs' written criteria are clearly articulated and included as part of formal policy statements. Two of the PVOs (No. 1 and No. 4), for example, state their criteria and/or procedures for selecting products as part of explicit product "acceptance" guidelines or policies. A number of companies and PVOs, however, were found (in follow-up interviews) to have product selection criteria that were not included as part of written statements.

Communication. Communication with recipients regarding specific shipments of donated products is the lowest-rated category of PVO written policy provisions (Table 4.4). Many of the written policies are incomplete regarding procedures for communicating and obtaining final approval and, in a number of cases, policy statements are complete but still minimal because there is also very little in the way of *unwritten* policies on this issue. A notable exception and "best practice" example is PVO No. 1 which, as part of its general policy statement and consignee guidelines, emphasizes the importance of "proper communication" and specifies a

number of procedures for ensuring regular contact with its recipients and for obtaining their approval for individual shipments.

Logistics.[12] Concerning written provisions on packaging, labeling, and shipping costs, there is again a disparity between companies and PVOs. PVOs' statements are, on average, more detailed and clearer than the company equivalents. For example, the statement for Company No. 7 notes that labeling and packaging must be "proper" for use by PVOs. In contrast, PVO No. 1 specifies in its policy statement the exact labeling requirements. For both companies and PVOs, policy statements concerning shipping costs are more common than those regarding other logistical issues, and packaging requirements are mentioned the least frequently. Where they exist, provisions concerning logistics are usually part of formal statements.

Follow-up. On average, PVO policy provisions concerning follow-up rate as fair. Most are complete, and those that are stated are reasonably clear and well-presented. However, a number of PVOs specify their requirements for follow-up in the context of letters and contracts for recipients rather than as part of a formal policy statement.

In addition to the range of quality found across categories of policy statements, there is also significant variation across and within the companies and PVOs themselves. Total ratings for companies range from 7.7 to 11.3, and those for PVOs range from 9.0 to 14.4.[13] The highest-scoring PVO policy statements (numbers 1 and 5), are similarly comprehensive and clear; both contain several pages of explicit policies and guidelines, along with a number of separate procedural/information forms for recipients. In contrast, the highest-scoring company statements (numbers 6 and 9) are quite different from each other. The statement of Company No. 6 includes five pages of detailed policies and program description, while the statement of Company No. 9 is only two pages long and far less detailed. Both, however, indicate explicitly the company policies on the various dimensions of the donation process under consideration.

Tables 4.3 and 4.4 also show the variation in the quality of the written explanation of policy provisions *within* individual companies and PVOs. A few policy statements, such as those of PVO No. 1 and No. 5 and Companies No. 6 and No. 9, are fairly consistent in quality across the policy categories. However, the ratings of PVO statements numbers 9 and 10 and company statement number 4 are highly varied, in some cases alternating between the highest and lowest extremes.

Public availability of policies and procedures

For the most part, both companies and PVOs report that they are "open" and "willing" to share their policies and procedures with others in the industry.[14] However, none of the companies or PVOs interviewed appear to have an official policy or procedure governing the availability of their policies to outside parties. By default, most handle such requests on a case-by-case basis.

Three companies reported that they maintain, in addition to formal policies for internal use, separate, more general written materials for public consumption. Five companies are willing to share their internal policies with other companies or PVOs on an individual case-by-case basis, with the assurance that they will remain confidential. Three company representatives reported that they would have to check with their legal departments or headquarters before responding to an outside request for their donation policies.

PVOs' policies on "willingness to share" are similarly varied. Two of the PVO representatives interviewed had not had any experience with outside requests and did not know their organization's policies on public availability. The remaining eight PVOs interviewed are willing in principle to share their internal policies (and/or have done so) with others in the industry on a case-by-case basis. None of the PVOs reported keeping separate policy statements for external dissemination.

Much of the reported experience of companies and PVOs with sharing internal policies with other organizations involved in drug donations is very recent and has come about as a result of the efforts of the joint PVO-company committee to develop industry standards. A few respondents gave examples of providing their policies to other companies or PVOs that were in the process of developing their own donation programs.

Conclusions and Recommendations

This review highlights a high degree of diversity in the substantive content and written quality of the pharmaceutical donation policies of US companies and PVOs—diversity that may simply reflect the diversity that exists in the donation programs themselves. The review also indicates that there has been considerable improvement in recent years in the development of donation policies. Although the written quality and public availability of donation policies is mixed, a comparison of the findings of the current study with those of Arnold and Reich (1990) suggests that substantial progress has been made. At that time, only five of eight PVOs

contacted reported having informal policies, and none reported having formal, written guidelines for accepting and distributing donations. In contrast, 31 percent of the PVOs contacted for the present study provided some form of written policy statement. Furthermore, in addition to developing their own internal policies, PVOs and companies have also begun to work collectively to strengthen the field overall by, for example, collaborating in the development of industry-wide policy guidelines. Specific key findings from these assessments include the following:

- *Type of donation program:* The majority of the donation programs of pharmaceutical companies reviewed in this study consist of some form of inventory management. Planned production or "produce-to-give" programs have the potential to be highly responsive to recipient needs and may be able to avoid problems of insufficient dating, yet they are the least common type of donation program among the companies in our sample.

- *Recipient selection:* Most companies and PVOs are donating pharmaceuticals in the context of ongoing relationships with established partners. This approach increases the probability of good oversight, effective communication, and responsiveness to recipient needs, yet it does not preclude the need for specific guidelines and criteria. This study found that, on average, the written policies of PVOs for screening recipients were not as well developed or clearly articulated as those of the companies. This observed difference in the quality of written explanation of policies for consignee selection may, in part, reflect the differences in the makeup of their recipient base. PVOs work with a wider range of recipient types. This diversity of recipients may make it more difficult to articulate in writing the criteria and procedures for screening potential consignees, but it also makes the development of clear policies more important. Similarly, many PVOs, unlike companies, also work with affiliated partners, and in these circumstances they may not feel that written criteria are essential. However, written guidelines are important not only for selecting recipients but also for ensuring the recipients' accountability by having established standards against which to judge performance.

- *Product selections:* Adherence to selected current normative standards for donated products by companies and PVOs in our sample is mixed. Only two of the PVOs' and none of the companies' policies are consistent with the 12 months minimum dating called for by the WHO

Guidelines (although the majority of both meet the six months minimum suggested by the 1997 PVO-Industry *Principles*); strict adherence to EDL requirements is minimal; and, while formal statements on samples and returns are uncommon, interviews suggest that most companies' and PVOs' policies are in line with current standards. In addition to established, specific standards, there is also extensive use by PVOs of needs-based criteria for screening and soliciting drug donations. There may be a relationship between the specificity and rigidity of product selection criteria and the degree of consultation with recipients about what is needed and can be handled, but this survey could not reliably assess that relationship. Overall, provisions in company and PVO policy statements concerning product selection were among the most complete and clear.

- *Communication:* Most companies and PVOs have established procedures for communicating with recipients and obtaining their approval of specific donation shipments before products are sent. The written and reported policies and procedures reviewed in the present study suggest that companies and PVOs are sending pharmaceutical donations with the prior awareness and consent of recipients. Furthermore, a number of PVOs—particularly those operating (explicitly or implicitly) on a "first come, first served basis"—have detailed procedures for communicating with recipients regarding the status of and amendments to donation requests. However, written policy statements on this issue are uncommon, and those that do exist are often vague and incomplete.

- *Logistics:* In practice, all companies and PVOs have some form of established or ad hoc procedures for handling logistical issues such as packaging, labeling, and payment of shipping charges. However, a minority of companies and PVOs in our sample include most of these procedures in formal policy statements, and very few do so in any detail. Several companies and PVOs reported that this information is not part of their "donation policy" and that such matters are the responsibility of other departments of the organization. Although such a division of labor may make sense practically, it is important that the functions of setting policy and receiving feedback from recipients are not divorced from the details of implementation.

- *Follow-up and tracking:* Most companies and PVOs in our sample have a standardized procedure for obtaining (at a minimum) written ac-

knowledgment of the receipt of donations and (particularly among the PVOs) written documentation of their end-use. These procedures appear (from written and reported policies) to be applied rather uniformly regardless of the destination, type of recipient, product dating, and so forth. Less common are procedures for obtaining the type of extensive, detailed feedback on the overall donation process that can be used to improve programs on an ongoing basis.

- *Public availability of policies:* Formal policies governing the public availability of company and PVO donation policies and procedures are uncommon in this sample of organizations. In practice, policies are reportedly shared with other organizations involved in pharmaceutical donations on a case-by-case basis. Although the practice of sharing internal policies and information has increased recently, largely as a result of organized PVO-industry efforts, there is still a significant lack of knowledge and awareness among those involved in donations (as well as in the general public) about the policies, practices, and experiences of others in the field.

The diversity of donation programs and policies reflected in this report is both an asset and a challenge. The range of actors, relationships, and approaches involved ensures that there are multiple and varied means through which drug donations can be channeled. But this same diversity can also hinder the effective application of industry-wide standards and guidelines. The findings of this report have demonstrated the importance of considering the various contextual factors that determine, for example, the appropriateness of strict recipient and product selection criteria. The diversity in the field may therefore be better addressed—in future analyses and development of policies and guidelines—by incorporating a more explicit focus on the *process* of creating drug donation policies and initiatives to improve policy implementation.

Specific recommendations that reflect this emphasis on process are first, that WHO should give more attention to process and flexibility in its *Guidelines* by incorporating the exceptional clauses into the main text. Presently it is too easy to ignore or dismiss the "exceptions" even though, in many cases, they may be more the norm than the formal guidelines. Similarly, WHO should accompany dissemination of the *Guidelines* with efforts to educate national governments and local practitioners on how to adapt the *Guidelines* to local realities and how to assess their impact.

Second, companies should consider developing produce-to-give programs as a means of ensuring the appropriateness of drug donations. At a

minimum, companies could improve their ability to forecast stock surpluses and make them available for donation earlier. To the extent that inventory control remains the primary basis for drug donations, companies need to increase their vigilance through enhanced follow-up for donations of short-dated material.

Third, PVOs should sustain and strengthen their efforts to ensure effective communication with donor companies and various recipients regarding product availability, needs, capacities, and problems. PVO consolidators are conduits of important information and feedback that can be used to improve the donation process.

And, finally, both companies and PVOs need to strive to develop formal written policies that are clear, complete, and accessible and that conform as much as possible to evolving normative criteria (such as the WHO *Guidelines* and PVO-Industry *Principles*). Deviations from such standards should be explained and justified as part of written policy statements. Although it is possible to have good practice with bad policy (and bad practice with good policy), the development, articulation, and review of formal policies can help strengthen donation programs and ensure their accountability. This process can contribute to a more proactive transparency, whereby donation policies are accessible to a wide audience as part of an overall education effort about pharmaceutical donations.

Endnotes

1 Arnold and Reich (1990) note the dearth of available information and knowledge of in-kind pharmaceutical donation flows and policies.

2 One of these four PVOs was not interviewed. The assessment of its recipient criteria is therefore based only on what was submitted in writing.

3 This criterion of time to expiration was changed to 12 months in the final version of the *Principles* (see Appendix 2).

4 Only nine of the 11 PVOs were asked specifically about their policies on samples *or* had explicit written articles concerning the issue.

5 Only eight of the PVOs were asked specifically about their policies on returns *or* had relevant written articles.

6 These categories are not mutually exclusive; several PVOs employ more than one approach.

7 One PVO was not interviewed and therefore no information is available on its needs and procedures for amending donation requests. It does, however, have a product pre-approval form for recipients.

8 Note, however, that three of these companies were not asked in interviews to provide this information.

9 And not all were asked specifically about them.

10 The PVO that was not interviewed does not address payment issues in its policy statements. Therefore no information is available on this PVO's policies for covering donation expenses.

11 This PVO was not interviewed.

12 As noted above, many companies and PVOs do not include as part of their formal policy statements provisions concerning packaging, labeling, and shipping costs. In follow-up interviews, many of the respondents were not familiar with some of the logistical procedures because the latter are the responsibility of other divisions, or they are contracted outside of the organization. Because of the inconsistency of information obtained in the interviews, the assessment of the completeness of the written statements on this issue is based solely on whether they include any mention of packaging, labeling, and shipping costs.

13 Note that the overall ratings of companies and PVOs are not comparable because of the different number of policy categories assessed for the two groups.

14 The "openness" is limited to requests from within the industry; PVOs and particularly companies were much more reluctant to make their policies available to the general public.

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