

# Drug Dumping: The Hidden Costs of Corporate Pharmaceutical Donations

Emily Clark

The hesitancy with which we approach a critique of international aid is understandable. It seems that with too much scrutiny, and without constant encouragement and prodding from the Western world, the flow of cash, goods and services to needy places in the world might just dry up. This, however, is a sentiment that must be checked if we are to make sure that those in need tangibly feel the benevolence of the developed world. If indeed we are serious about global health equity, then we will realize the necessity of holding foreign aid to account in all of its manifestations. After nearly every major humanitarian emergency, the press catches hold of instances in which drug donations coming from Western countries have done more harm than good overall. From the African food crisis in the 1980's to Haiti's 2010 earthquake, it has been repeatedly clarified that in a disaster situation giving away things is not always better than giving nothing at all. Drug donations are a critical problem, and when not done in a highly regulated fashion, giving away medicines can produce more problems than we started with.

Let's examine a case study of the crisis that occurred in the former Yugoslavia in the mid-1990's. When civil war broke out between Bosnian Serbs and Croats in 1993, the UN declared several "safe areas" which were then cut off from all assistance by the Bosnian president Radovan Karadzic.<sup>1</sup> In the subsequent years, from 1992-1996, international aid centered on the region as NATO air strikes targeted the Bosnian Serb army.<sup>1</sup> In 1997, a ground study was conducted to determine the effects of over 30,000 tons of donated pharmaceuticals.<sup>2</sup> What these researchers discovered was that nearly two-thirds of those materials could not be used, and not only were they not helpful in the aftermath of the crisis but something had to be done with the 17,000 metric tons of waste. Among the non-useful drugs, hazardous waste specialists found weight-loss drugs from the UK, toxic chemicals from the former East Germany, and expired medicines whose labels had been deliberately covered up.<sup>3</sup> After resources were deployed to figure out which of these drugs were useful, the rest had to be destroyed. Since pharmaceutical products constitute hazardous materials, certain classes require special incinerators and because war-ravaged Bosnia did not have the appropriate facilities, the WHO had to consider building facilities from scratch. In the end, the cost of safely dealing with these unusable drug donations was an incredible \$34 million US dollars.<sup>2</sup>

What exactly constitutes "drug dumping"? According to the authors of the previously discussed study, there are several reasons why donated pharmaceuticals are potentially not useful or unusable. The donations come from private individuals, corporations, non-governmental organizations

or from foreign governments, and they could be unhelpful if they arrive in poor quantity or quality, or are for other reasons inappropriate.<sup>3</sup> This could include being useless, for example when weight-loss agents arrived in Bosnia, and clearly were not what was needed in this situation. It has also been well documented that the majority of drugs produced in the developed world, which often have to do with chronic disease and impotence, do not fit the epidemiological profile of most disaster situations.<sup>2</sup> WHO publishes a list of roughly 300 essential medicines that reflect global needs, and anything not on this list is generally not useful in the context of a humanitarian crisis.<sup>4</sup> The donated drugs are also frequently unusable, which means they are a useful kind of medicine but the actual supplies cannot be used safely. Most commonly, this means that the drugs are expired.<sup>3</sup> The FDA stipulates that expired drugs cannot be sold in the US, therefore when surplus stocks exist there is an incentive to donate them abroad rather than to deal with the costs of disposal. Bosnia received packages of supplies left over from WWII armies, and a batch of plaster tape from 1961.<sup>3</sup> Drugs may also not be usable if they are not labeled and sorted properly.<sup>3</sup> If they are labeled in an unknown language or with a trade name that isn't an international standard, or if they don't arrive sorted properly in correctly labeled boxes, it often isn't possible to use them. In Bosnia many donations came in the form of unsorted free samples, of which 90% were unusable. Finally, certain classes of drugs are easily damaged in the transport process and if they are stored improperly. Insulin, for example is a commonly donated drug even though there is relatively little need for diabetes treatment in crisis situations compared to how often it is donated, and it needs to be refrigerated or is ineffective.<sup>3</sup>

It has already been shown that improper drug donations can cause an unnecessary burden on an already strained infrastructure during humanitarian crises. The costs of sorting through donations and disposing of waste are substantial. Yet there are also other serious consequences to consider. One of the gravest concerns is that use of improperly donated drugs will result in health problems for those that use them. The most well known example of this phenomenon is when in Lithuania, women were temporarily blinded by using a de-worming medication which was actually meant for veterinary use, but was donated for humans.<sup>3</sup> In 1994 in Zaire, a company chartered a plane to deliver cases of a soft drink meant for athletes, claiming that they would help address malaria. Yet if given to children, this product could have been extremely dangerous.<sup>5</sup> Related to this is the concern

that individuals may want to donate partially used bottles of medication, which opens up the dangers of a drug being handled by multiple parties between its distribution and donation.<sup>7</sup>

A second concern is that drug donations will undermine national production of pharmaceuticals. With drugs being given away at sub-market prices, any national plants will not be able to sustain themselves. Eritrea is a good example of this because they were actually able to build capacity for the specific drugs needed in their country during the crisis. Domestic plants were used during the war for independence and became the foundation for the nation to supply the majority of its need for IV fluids and tablets after the war.<sup>5</sup> East Timor has focused on government procurement of drugs to ensure an adequate and affordable supply without undermining the market by accepting international donations.<sup>5</sup> Some argue that drugs in situations of need should always be provided through government procurement.<sup>6</sup> Import taxes from the receiving country often require the domestic Ministry of Health or another receiving entity to spend money on the donations, which may or may not end up being usable.<sup>3</sup> The lack of means of accountability from private voluntary organizations who act as the intermediary, accepting corporate donations and distributing them abroad, means that the donor has no further responsibility after handing the medical supplies over to the private organization, whether or not the drugs actually make it to their destination. In addition, this practice can result in problems by changing the pattern of prescription by health care providers in the receiving country if, for example, they come to rely on trade name drugs from Western countries rather than generics.<sup>8</sup>

Finally, the relative cost to the public of relying on corporate donation rather than on selling medicines at tiered prices internationally, because of the impact of taxes that subsidize charitable donations, is significant.<sup>3</sup> Current US tax law is problematic for this reason. Corporations can claim donations of “in kind” charitable gifts against tax in the form of an enhanced deduction.<sup>3</sup> This means that they can claim the value of donated goods at either twice their base cost or at their base cost plus half of their “fair market value”, whichever is lesser. This is a strong incentive for companies to donate drugs that they would otherwise not be allowed to sell domestically. The double standard of drug quality for sale in the US, which is strictly regulated by the FDA, compared to the lack of regulations about what drugs can be donated abroad, allows companies to get rid of drugs without bearing the costs of their disposal. We have already seen that in the case of Bosnia and Herzegovina, the cost of safe disposal can be monumental.<sup>2</sup> Such a double standard distorts the impact of drugs as an environmentally hazardous waste, and represents an institutionalized inequality between populations.

This long list of issues that result from current drug donation practices makes it abundantly clear that a new set of policies is needed. Under the present system, the dual loyalty of pharmaceutical companies to their shareholders and to the general good of society is not well balanced.<sup>9</sup> Combined with the desire people have to donate material things rather than cash, drugs continue to be donated abroad in a relatively

unregulated manner. This practice has not escaped international attention though. The World Health Organization has issued two sets of guidelines, one about drug donation and one about the safe disposal of drugs, which should lead countries toward better drug donation policy.<sup>10, 11</sup> The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, which entered into force in 1992, makes it illegal to engage in dumping practices of materials that are dangerous to environmental and public health.<sup>12</sup> The WHO guidelines, which were drafted in 1996 and revised in 1999, establish four principles upon which drug donation should be based. The first is of “maximum benefit to the recipient”, which should take into account the needs of individual patients as well as the receiving community and nation. The second principle, “respect for wishes and authority of the recipient”, means that drugs should not be donated unless they are requested and match the epidemiological need of the crisis. Thirdly, “no double standards quality” means that expired or spoiled medications are not fit for anyone to be given. Finally, “effective communication between donor and recipient” is emphasized, and means that there should be an opportunity for the receiving country to indicate their wishes.

It is obvious that there needs to be a revision of drug donation policy, both on the part of individual donor entities and donor governments. There has been evidence that simply being aware of the WHO guidelines does not necessarily lead to appropriate practices.<sup>13</sup> Therefore the most effective remedy would probably be to change the regulations about corporate donations in developed country governments. For example in the United States, it would be possible to make compliance with the guidelines a prerequisite for companies to benefit from enhanced tax deductions.<sup>3</sup> There should not be a double standard between the quality of drugs meant for domestic markets versus in crisis situations; it is unjust if we allow medicines that don't meet FDA standards for American consumers to be sent abroad. Other suggestions to address this problem encourage what should be donated more often. It is much more beneficial to donate medicines that are on the WHO essential medicines list as well as pre-packaged emergency drug kits that are put together based on established epidemiological needs, and less room for these donations to become a burden to the receiving community.<sup>6</sup> Finally, cash donations are almost always more useful than in-kind gifts simply because they can be tailored to the specific situation. By following these recommendations and guidelines, medical assistance in the wake of humanitarian emergencies can be made into a much more valuable contribution.

**References for this editorial can be found at  
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