

Appendix H

Dumping old or unsuitable drugs onto poor countries as aid and charity

Shah, Anup. Global Issues: Social, Political, Economic, Environmental Issues that Affect Us All. <http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research#Testingonhumanswithoutpermission> (23, August, 2011)

While pharmaceutical companies have no doubt created life-saving drugs that have saved millions of lives, they have also participated in practices around the world that have come under a growing amount of criticism. John Madeley is worth quoting at length:

[NGOs] allege that the corporations:

- sell products in developing countries that are withdrawn in the West;
- sell their products by persuasive and misleading advertising and promotion;
- cause the poor to divert money away from essential items, such as foodstuffs, to paying for expensive, patented medicines, thereby adding to problems of malnutrition;
- sell products such as appetite stimulants which are totally inappropriate;
- promote antibiotics for relatively trivial illnesses;
- charge more for products in developing countries than they do in the West;
- fail to give instructions on packets in local languages;
- resist measures that would help governments of developing countries to promote generic drugs at low cost;
- use their influence to try to prevent national drug policies;
- give donations of drugs in emergencies which benefit the company rather than the needy;
- use their home government to support their operation with threats if necessary, such as withdrawing aid, if a host government does anything to threaten their interests.

— John Madeley, *Big Business Poor Peoples; The Impact of Transnational Corporations on the World's Poor*, (Zed Books, 1999) pp. 145-146,

Madeley goes on to provide an example (amongst many others) where US-based drug company Eli Lilly made the largest one-time pharmaceutical donation at that time, to provide an antibiotic to Rwanda during their refugee crisis in 1994. They donated enough for 1.3 million people. However, the World Health Organization didn't list this drug on their list of essential drugs for treating refugees. He also pointed out that "Médicins sans Frontières (Doctors without Borders) ... said 'it would never prescribe such medicines in the camps'."

Many of the pills were past their expiry date, which added additional resource burdens to a country already suffering from the aftermath of a civil conflict. Madeley also shows some additional reasons to this apparent generosity that:

[w]hile Eli Lilly conceded that the tablets donated were excess stock nearing expiry date, they "felt it was the right thing to do." ... although drug donations may seem pure altruism, they can sometimes harm rather than help the victims of emergencies. However, they nearly always help a company's balance sheet. European and USA-based TNCs receive substantial tax benefits when they give donations. For gifts to the needy, US tax regulations allow a write-off for tax purposes of up to twice the production costs.

— John Madeley, *Big Business Poor Peoples; The Impact of Transnational Corporations on the World's Poor*, (Zed Books, 1999) p. 153

Madeley wrote the above in 1999. A decade later, Elizabeth Sukkar notes a similar pattern in the *British Medical Journal*, "International Aid; The cost of donated drugs", October 10, 2009 (p. 832):

One example: the 4000 tonnes of medicines donated to people in the Aceh region of Indonesia after the December 2004 Tsunami; 600 tonnes were out of date or about to expire and cost an estimated \$2.4m (£1.5m; €1.6m) to destroy.

To help prepare [for new and updated guidelines on drug donations], WHO [World Health Organization] did a systematic review of drug donations during 1998 to 2008. It found that only 56% of donations were appropriate given the characteristics of the event and what the recipient needed, and only 12.5% of drugs requested by recipient countries were received.

Of the inappropriate donations, 57% had improper labels ... and 40% had expiry dates of less than one year. Up to 80% of appropriate donations were surplus to requirement. "The ensuing cost of drug destruction, where documented, was significant," says Dr Moller, one of the authors of the review.

— Elizabeth Sukkar, *International Aid; The cost of donated drugs*, *British Medical Journal*, October 10, p. 832

Sukkar adds that the current WHO guidelines were written for emergencies, but the new ones are to include other scenarios such as protracted emergencies, donations targeting specific diseases, and other forms of donations.

Noting that drug companies are one of the key donors for long term programs, she lists why they are so:

- Tax incentives
- Good public relations
- Cost saving (it is cheaper to donate a drug than destroy it)
- Surpluses in the market, and
- A genuine desire to help

She also notes that the industry has improved over the past 2 decades, suggesting it may partly be because there is more scrutiny over what drug companies do, these days.

More fundamentally, however, UNICEF and others feel that after the acute phase of an emergency is over, cash donations may be better than drug donations as that can be better targeted as needed. (Many humanitarian organizations find that in emergencies they sometimes receive many items in excess, where cash donations may be better for it can help mobilize local resources as needed). Of course, the problem of cash donations is corruption and misuse of such funds as well. These and more are discussed in more depth on this site's section on [foreign aid](#).

Successful human trials, but drugs priced beyond the reach of many patients

Shah, Anup. Global Issues: Social, Political, Economic, Environmental Issues that Affect Us All.

<http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research#Testingonhumanswithoutpermission> (23, August, 2011)

In the next example, the documentary highlighted how after successful trials, high pricing of drugs meant they were sometimes beyond the means of the very same patients in the trials who depended on those drugs. The case in question involved an innovative drug for a form of Lukemia, developed by Novartis, trialled successfully in South Korea, but the issue highlighted deeper political and economic problems.

Even though the trials were very successful (the drug was approved in record time, for example), the eventual price of the drug was out of the reach for many, who ended up protesting on the streets. This drug was going to be priced by Novartis at around \$55K a year, 19 dollars a tablet, 8 a day. Yet, even with the Korean government helping with costs, many patients said they could not afford the drug.

As Jamie Love commented, “Products are priced according to what it is worth someone to get access to the drug. If it saves your life, it is worth quite a bit. It is certainly worth everything you have. What the companies want to do is they want to say is ‘this is how much a human life is worth and this is what our company wants to keep that life on.’”

Commenting on why this was more than merely economic issues, Dr Drummond Rennie pointed out, “Pharmaceuticals, they are a commodity. But they are not just a commodity. There is an ethical side to this, because they are a commodity that you may be forced to take to save your life. And that gives them altogether a deeper significance. But they [the pharmaceutical companies] have to realize that they’re not just pushing pills, they’re pushing life or death. And I believe that they don’t always remember that. Indeed I believe that they often forget it completely.”

But high pricing for drugs are often controversial. As the documentary noted, “Big pharma generally defends high prices for new drugs saying they have to cover costs for researching and developing new drugs. But in fact, most new drugs launched are just slight variations of existing medicines. So called Me Toos.”

Commenting on this Nathan Ford, of Médecins Sans Frontières said, “At the moment we are getting more and more drugs of less and less use. Me Too drugs; the tenth headache pills; the 15th Viagra. There are currently eight drugs in development at the moment for erectile dysfunction. Do we need 8 more drugs for erectile dysfunction? I don’t think we do. Meanwhile diseases like Malaria, TB that kill 6 million people every a year, are neglected—no new medicines are coming out and we are left treating people with old drugs that increasingly don’t work.”

Ben Goldacre, in his book, *Bad Science*, (Harper Perennial, 2009), also adds that “the number of ‘me-too’ drugs has risen, making up to half of all new drugs.” And yet, “for all the hard work they involve, they don’t generally represent a significant breakthrough in human health. They are merely *a breakthrough in making money.*” (p.202, emphasis added)

As noted earlier on this page, this is related to how markets for pharmaceutical companies are not just about finding people to target, but people with money. Dr. Jonathan Quick of the World Health Organization (WHO) added that the majority of the market for some of the tropical diseases is in developing countries but, “it’s a market in terms of numbers of people but the purchasing power is not there. And if the purchasing power is not there then the normal dynamics of the research and development industry just don’t address those problems.”

The drug’s price from Novartis was justified due to the research and development costs, yet, as Jamie Love pointed out, the price was still too high:

- A lot of important development was paid for by U.S. government.
- The speed to approval and get to market was quick.
- Short, small trials and short development period implies a relatively inexpensive product to bring to market.

...Big pharmaceutical companies consider the generics companies as pirates, because of the threat to profits, and because they create the same end product without the amount of research and development effort that the big pharmaceuticals supposedly invest. Yet, as detailed above, often, a lot of initial research and development has come from the public sector, and so some have considered the big pharmaceuticals to also be guilty of the accusations that they levy against generics companies.

Under pressure from the large pharmaceutical companies, the WTO has decided that from end of next year, India must bring in full patent protection. India is one of the world's main sources of cheap drugs, and this is now under threat. By destroying such competition, big pharmaceuticals, Dr. Rennie adds, will be able to charge anything. After 30 years of having drug prices undercut by India, they will once again have total control of supply. Just a handful of manufacturers will have a lot of control. "What worries me is the monolithic, overuse of power to push pills. That's terribly worrying to me. That is not a future we should encourage. It is the worst possible future."

The documentary then moved on to show how these prices directly caused the death of a child in Honduras, suffering from AIDS, while activists resorted to breaking the law and attempted to smuggle cheaper drugs from across the border, where generic ones were being sold.

Killer prices and breaking the law to save lives

Shah, Anup. Global Issues: Social, Political, Economic, Environmental Issues that Affect Us All. <http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research#Testingonhumanswithoutpermission> (23, August, 2011)

Even before rule changes, mentioned above, the power of big pharmaceuticals is already pervasive. The documentary followed a woman in Honduras forced to break the law by smuggling cheaper generic drugs across the Guatemalan border, in order to try and save lives. This just highlights how inequality and injustice is structured into law itself, to have to break it.

In Honduras, there is some degree of free health care. However, there are some 14,000 AIDS orphans and 60,000 people with HIV infection. A poor country, it desperately needs cheap AIDS drugs, like those made by CIPLA.

The documentary followed an activist trying to help a child dying of AIDS because the price of drugs was beyond the reach of the family. The child, a 12 year old boy, was called Jairo. The pictures were quite disturbing, showing the child near the end of his life. The situation was so urgent that the documentary crew offered to pay for some of the medicine that was needed and got a local specialist doctor in quickly.

The doctor pointed out that the child was suffering from various illnesses that could be addressed using readily available (though expensive) drugs. The few drugs that the family could afford was having distressing side-effects. One drug that the doctor suggested was owned by Pfizer and cost 27 dollars for just one tablet. Jairo's uncle earned just 19 dollars a week. The doctor highlighted that many of his patients are dying because of the high price of the drugs from Pfizer and others. For over two years, he and others had been campaigning to get prices lowered, but to no avail.

The documentary crew accompanied the activist to Guatemala, to smuggle in affordable drugs, even though this goes against trade laws.

The generic version of that drug was just 30 cents, just over 1 percent of the Pfizer version. But the company making this in Guatemala has no license to make or sell it in Honduras.

By the time it took to get the drug, Jairo was getting a lot weaker. The crew was told to continue filming as they rushed him to hospital. On the way, Jairo died.

As the documentary concluded, "If Jairo's family had been able to buy generic AIDS drugs at Indian prices, he would never have needed dyflocam [the drug from Pfizer] because he would never have succumbed to the infection in his throat. It's not only Pfizer that has played a part in his illness but every big pharma company that has AIDS drugs but refuses to sell them at affordable prices."

The documentary thus hinted at the use of political and economic power and how it has a direct bearing on people's lives with little accountability. The documentary's transcript or video is not available on line, but [accompanying material](#) can be seen at Channel 4's web site.

Perhaps almost predictably, Pfizer issued a statement soon after the documentary aired saying that the documentary was biased and that it was intending to sue. Jeremy Brecher, in a foreword to the book *Panic Rules: Everything you want to know about the Global Economy*, by Robin Hahnel (South End Press, 1999) pointed out that "Oxfam International Estimates that, in the Philippines alone, IMF-imposed cuts in preventative medicine will result in 29,000 deaths from malaria and an increase of 90,000 in the number of untreated tuberculosis cases. Tribunals investigating 'crimes against humanity' take note!" Yet, this would be unlikely to happen, unless it was clearly war and physical brutality that caused mass deaths. Economic and political causes of death, especially when coming from the dominant ideology are not registered in mainstream discourse as mass deaths.

Pricing

Shah, Anup. Global Issues: Social, Political, Economic, Environmental Issues that Affect Us All.
<http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research#Testingonhumanswithoutpermission> (23, August, 2011)

Grim lottery for people living with AIDS in Guatemala:

The Luis Angel Garcia Clinic in the San Juan de Dios hospital does not have the resources to supply medicine to the 90 people living with AIDS it cares for. The medicines bank of the clinic has anti-retroviral medications for only four people. These four were selected through a lottery. On 29 June 1999, in the waiting area of the clinic, 90 people living with AIDS gathered to see who would be the winners. The prize: a year's supply of life-saving anti-retroviral medications. "It was the most depressing lottery I have ever seen", commented Richard Stein, Director of the Asociacion Agua Buena in San Jose, Costa Rica.

— Ellen't Hoen, [*Globalisation and equitable access to essential drugs*](#), *Third World Network*, Aug-Sep 2000

Another concerning trend is the [extortionately high prices for prescription drugs](#) that people have to pay in the United States, home of most of the pharmaceutical companies. Just across the border in Canada, people can pay up to 80 percent less for prescription drugs. In some European countries, people can pay even less. As a result, Vermont Congressman Sanders organized bus trips for people to buy drugs across the border. The pharmaceutical companies' reaction? They claimed that in Canada this reeked of government interference. For whom? It is perhaps interference on corporate profits. What if the word used instead is something like government "support" for its people?

If in the wealthiest nation on earth there are pricing issues and corporations are able to push forth policies that will benefit them, imagine the impact on poorer countries, where most would not be even able to afford drugs for easily curable problems.

Few have challenged or even recognized the unfair tax upon the unfortunate created by vastly overpriced products and services. There is a consistent pattern; the greater the need, the greater the overcharge. Though the need of those with physical disabilities is great, they have limited power to defend themselves. The first efforts to develop mechanical aids for people with physical problems were undoubtedly undertaken with noble intentions. Typically no profit was involved and much labor and time was donated as generous people tried to help the unfortunate. However, those who knew the value of these aids when monopolized claimed patent rights, and those with disabilities now must pay those monopolists. Witness the hearing aids... Each is only a tiny amplifier, yet costs ten to twenty times as much as a radio, which is hundreds of times larger and much more complicated.

— J.W. Smith, *The World's Wasted Wealth 2*, ([*Institute for Economic Democracy*](#), 1994), p. 78.

The *British Medical Journal* reported in November 2005 (Volume 331, p.1103), that a fictional book about terrorists, and poisoned Canadian pills "was commissioned as part of an effort to cause US citizens to worry about the safety of Canadian drugs." Apparently, the Vice President of PhRMA and a consultant for that pharmaceutical lobby group had been involved in the deal for the book. The *BMJ* did not report that the VP denied her own own involvement, only that PhRMA did not "directly" commission the book. The US ban on importing Canadian drugs combined with the exorbitant prices of US drugs means that many patients resort to Internet purchases from Canada and elsewhere, the *BMJ* also noted.

Testing on humans without permission

Shah, Anup. Global Issues: Social, Political, Economic, Environmental Issues that Affect Us All. <http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research#Testingonhumanswithoutpermission> (23, August, 2011)

Increasingly, the documentary highlighted, human trials without permission are taking place in the developing world, far away from scrutiny of European or American authorities.

The documentary focused in on a case in 1996 in a northern Nigerian town of Kano, already suffering from severe cholera and measles outbreaks. At that time, a third problem occurred: meningitis, where some 150,000 people were affected, and some 15,000 dies, many of which were children.

While this was mostly unreported in the West, it was noticed by the world's biggest and richest drug company, Pfizer. They moved fast and flew to Nigeria with a new drug, a "potential life-saver and a potential billion dollar money spinner", Trovan.

Trovan had never been tested on children before, and Médecins Sans Frontières (Doctors Without Borders, or MSF) had been at the hospital that Pfizer came to, and had for a number of weeks been offering free life-saving treatments, successfully treating thousands of people.

Yet it turned out that Pfizer were doing human testing or experiments without the voluntary consent of patients, a violation of basic human rights:

- From standards set at Nuremberg trials after WWII, there are strict rules on the conduct of experiments on humans.
- The first rule (and sentence of the Nuremberg Code) is that voluntary consent of the human subject is absolutely essential.
- This basic right was ignored, the documentary pointed out.
- Consent and risk explanation is normally recorded.
- Yet Pfizer had "never produced a single consent form from the 200 odd children treated in the ... experiment." Pfizer claimed this was because parents were illiterate, so was explained verbally.
- But interviews with some 100 sets of parents highlight that they too were not asked for consent, and that many could read and write.
- A lawyer trying to sue Pfizer on behalf of some of the parents says that if they were told that this was experiment and there was option for actual alternative treatment (which groups like MSF were offering) then they would have gone with them.

But there was also apparent outright lying as well. Not telling your test subjects what you are doing is a fundamental breach of medical ethics, but that was not the only charge.

- Trials like this must be approved in advance by an ethics committee.
- Pfizer claimed an ethics committee approved Pfizer's actions.
- Their ethics committee approval letter was shown to be a backdated later, because when dated, the committee didn't exist at the time.
- A Pfizer doctor later admitted to doing this.

Unfortunately, as the documentary also noted, this is "sadly far from unique. Several leading drug companies have also conducted questionable trials. Increasingly, in the poorer countries of the world."

One explanation given by James Love (also mentioned above on this page), Health Economist with the Consumer Project on Technology was due to lack of accountability. "This is a problem," he said, "because you are operating in an environment where there is really very few people around to protect the patient."

The United States had refused to license Trovan for use on children because of known side effects it caused.

- Some children in Nigeria died when on this treatment.
- It is not known if they could have been saved had they been on the other more standard treatment that organizations like MSF were already helping with, but it is standard practice to change treatment if a patient is not responding to one treatment when their life is on the line. Pfizer doctors did not do this.
- A doctor in the Nigerian hospital said that “I think they [Pfizer] played with that baby”, referring to a baby that died when under such treatment and had not been switched to an alternative.
- One of the most damning pieces of evidence was a letter sent to the Pfizer chairman, by the company’s own childhood disease specialist, Dr Walterspiel, protesting in the strongest possible terms about the trial.
 - The letter detailed 8 major objections, including that the drug was not tested against this particular form of meningitis.
 - The letter also referred to the lack of consent forms.
 - As a result of this letter, the company sacked him.

As well as the issue of human experimenting without permission, the actions of Pfizer highlighted the various ways power could be exercised to deal with the controversy. For example:

- Sacking the doctor who sent a message about the challenges to research scientists.
- Lawyers in New York took this case, but Pfizer succeeded in getting the NY courts to agree that this trial should be held in Nigeria, which as the documentary pointed out, was rated the second most corrupt nation according to Transparency International, implying that Pfizer would be able to take advantage of that.

But even where trials were going well but doctors had concerns about side-effects, pharmaceutical companies have used their power to try and stifle concerns and criticisms.