Lethal Substandard Drugs: An Increasing Danger In Emerging Markets

From fake Avastin to contaminated generic Lipitor, every month Americans are becoming more aware about the dangers of lethal products they might be unlucky enough to take. With attentive regulators and competent companies, most incidents of dangerous drugs in US pass without significant harm, but when tainted steroid injections were recently distributed to thousands of patients, 36 died and over 500 suffered painful conditions.

The tragedy for those Americans harmed is multiplied at least a thousand fold in the carnage wreaked in developing countries. Perhaps 100,000 people die every year from dangerous medicines and by most estimates the situation is deteriorating. To put it simply we are losing the global fight against bad medicines.

Efforts are being made by law enforcement officials. Eighty-two million doses of counterfeit drugs in Africa were seized by numerous national authorities, comprising about $40 million worth of antimalarials, antibiotics, cough medicines, contraceptive pills, and fertility treatments.

Why Substandard Drugs Are Even Worse Than Counterfeits

The problem is that such crackdowns tend to focus on counterfeit drugs, deliberately falsified by criminal networks. Such efforts are obviously warranted, but probably a much greater public health threat, as the tainted steroid injections demonstrated, is substandard drugs that are the result of shoddy manufacturing and handling – or perhaps worse, deliberate corner-cutting.

In poor countries, an astonishing number of bad drugs reach patients through legitimate supply chains and even donor programs underwritten

by U.S. and European taxpayers. Substandard drugs tend to have a suboptimal — but non-zero — dose of active pharmaceutical ingredient. Such low-dose products do not effectively treat individual patients, yet they are more likely to rapidly increase population-level resistance than fake drugs with no real ingredients. Resistance can even be spread to effective drugs, undermining entire product categories. As a result substandards may well be worse than deliberately counterfeited drugs containing no active ingredient.

Donor governments and U.N. agencies do take measures to ensure the quality of medicine they procure. Most governments or multilateral donors, for example, will only purchase for aid programs medicines that have been approved by a stringent regulatory authority — such as the U.S. Food and Drug Administration or its European equivalent — or by the World Health Organization (WHO). But this isn't enough to safeguard patients against poor quality drugs.

As I've demonstrated through previous research, off-the-shelf drugs made by Chinese and, to a lesser extent, Indian manufacturers tend to perform inconsistently on quality tests. In one study, more than 15 percent of the Chinese drugs we collected that were approved by the WHO failed to include adequate amounts of active pharmaceutical ingredient.

Our latest paper, in Malaria World Journal, reinforces these findings. Over 97 per cent of products made by manufacturers approved by the WHO had the correct active pharmaceutical ingredient. Among manufacturers not approved by the WHO, the percentage drops to about 87 per cent.

Worse still, some of the drugs we tested had been bought through Western donor programs, funded by taxpayers, and steered through aid programs to African markets. Some of these drugs may have degraded through bad storage, but many were just badly manufactured, perhaps to cut corners to lower costs and increase profits. After all, once a manufacturer has obtained quality certification, it is relatively easy to sell the drug at a lower quality in countries with weak regulations.

The President's Malaria Initiative: An Example Worth Following

If a donor procures millions of treatments, even if only a few percent of those products fail – such as the three percent of WHO-certified drugs that failed our quality testing — it means that hundreds, maybe thousands of patients are treated with poor quality medicines. In our research of donors' regulatory practices, we discovered that the U.S. President's Malaria Initiative (PMI) is the only donor program that effectively self-polices when it comes to drug quality. According to PMI, it "subjects every batch of every drug…procured with malaria funds to various analytical quality testing…" As a result it finds occasional poor quality products and has periodically returned products with quality issues to the manufacturer based on this testing.

That's a sharp contrast with other governments and multilateral donors like the Global Fund to Fight AIDS, TB and Malaria, which outsources the job of assuring drug quality throughout the supply chain to the principal recipients of its grants. This is usually a government agency in the target country. This simply doesn't do enough to ensure that only good quality medicines are being procured and distributed with Global Fund resources. It is unclear, for example, how often quality control testing is actually being performed by donors. It should be a priority for the incoming Executive Director of the Global Fund, Mark Dybul, to improve oversight of procured medicine quality.

Indeed, if we're going to make progress, donors need to copy the PMI and conduct pre-shipment testing of every batch of drugs provided to poor countries. If the US Government's flagship malaria program insists on such quality control measures, should not all donor agencies receiving taxpayer dollars do likewise? In our research we suggest implementing the following policy: Any manufacturer found with failing batches of drugs on more than three occasions in a year, will not be eligible for tendering in the following year.

The U.S. should also make pre-shipment batch testing and post-market surveillance a condition of all drug-related aid, especially for the Global

Fund. While the 2013 budget for PMI is the same as in previous years, the Global Fund will see its budget increase, whereas on performance the reverse should be the case. Because the U.S. is the leading donor to the Global Fund by far, demanding better drug surveillance would send a clear message both to the organization's new management and to other donor governments: it is time to take the global fight against substandard medicines seriously.