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Unused Medicines: Perspectives from the Humanitarian Community
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James B. Russo
Senior Advisor
The Partnership for Quality Medical Donations¹

Good morning. I want to thank the tireless Dr. Steven Gressitt for sparking the interest of my organization — The Partnership for Quality Medical Donations — in finding solutions to the drug disposal problem, and I also thank Len Kaye for letting me attend this extraordinary gathering.

Let me begin by reviewing with you the problems unused medicines cause in the developing world, problems not many Americans understand. A few statistics should do the job:

- In war-torn Bosnia and Herzegovina between 1992 and 1996, 17,000 metric tons of inappropriate donations arrived. The cost of disposing of the resultant threat to the environment: \$34 million.
- In Rwanda in 1994, thousands of doses of a very sophisticated antibiotic were donated, but relief workers were not familiar with the drug, so the gift became a disposal problem.

¹ For more information: www.pqmd.org

- In 2004, 4,000 tons of drugs donated after the tsunami in Banda Aceh were expired, unapproved or otherwise useless to the victims of that awesome tragedy.

These examples, I regret to say, are not exceptions. They are more nearly the rule.

That is why the Partnership for Quality Medical Donations intends to take part in the search for solutions to the unused drugs problem. As it happens, we're in good company. Dr. Hans Hogerzeil, director of the World Health Organization Department of Medicines Policy and Standards, said in The Financial Times,

“It is just not acceptable when people empty their medicine cabinets of drugs for donations that could never be resold in their own countries. It creates a managerial nightmare.”

Dr. Hogerzeil is a world authority on drug policy, and he is entirely correct. But aside from the public health problem inappropriate drug donations cause, there is a secondary reason why this problem needs to be stopped: It has to do with the increasing concern pharmaceutical company CEOs have about their corporate responsibilities. When a package of expired medicine arrives in a disaster area, the maker's brand name is usually on the label. It's only human nature for relief workers and others to assume that the manufacturer made that bad donation, or knew about it, or should have known about it — even if the drug was donated by a well-meaning family, a local wholesaler or a government agency without the firm's knowledge.

There's a corollary to this scene. If the bad donation is covered in the media and the company receives negative publicity, the likely response of company management is predictable: “We don't want to expose our brands to needless risk; don't ask us for product donations again.

You understand of course that the upshot of this scenario is a lose-lose outcome. The companies stop giving, and victims of disaster pay in misery and pain and neglect.

That scenario is unacceptable and it's why PQMD was formed. Thousands of remarkably skillful people are involved in making prescription medicines, medical devices, biopharmaceuticals, vaccines, and nutritionals – from Abbott to Wyeth. Thousands more work in NGOs — non-governmental organizations with names ranging from AmeriCares to UNICEF, Catholic Medical Mission Board to Mercy Ships and Project HOPE.

The Partnership for Quality Medical Donations puts the two together. There's nothing quite like it, so far as we know.

PQMD's mission: to unite the concerns and competencies of leading humanitarian agencies with the unexcelled resources and managerial skills of major health care companies. It has been an exceptional experience for all of us, indeed a surprising one.

Corporate life — in any industry — is hard-driving and bottom-line driven, and deservedly so. But many of the people in corporations — health care companies in particular — see themselves as part of a different business, driven to a special standard. Their products, after all, can make the difference between disease and survival; psychosis and sanity; reliance on others and the dignity of making a living and supporting a family.

I've found — and it should not have been so surprising — that such people are receptive to calls of conscience. To the desire to seek the light, as my Quaker veterinarian wife might say.

I know this for a fact, because I am of that industry. I worked in Washington for “Big Pharma” for 18 years and for another 18 years for what is now GlaxoSmithKline, a fine old Philadelphia firm now headquartered in London.

In those 36 years, I saw ample evidence that the best leaders in the pharmaceutical industry know their work is a privilege. And with a little encouragement, they readily

embrace the dictum of Horace Mann, the father of public education, who said “be ashamed to die until you have won some victory for humanity.”

Which brings me back to PQMD. In half a decade we have transformed product donations — mounting projects and programs in about 100 nations, changing the outlook for millions in the developing world. In 2000, our members donated and delivered medicines worth about \$400 million. By 2004, they’d grown to \$3 billion.

PQMD’s membership at present is 27, about evenly divided between manufacturers and humanitarian agencies. I’m clearly biased, but in my view we have *all* the leaders. Chances are, if you’re on a medication for hypertension or depression, cholesterol or diabetes, your payment for them helps pay for what we’re talking about today. If you support humanitarian agencies, chances are you’ve made donations to one or more PQMD charities. It’s equally likely, if you attend a mainline church or donate to a mainline charity, you’ll find it on our member list.

We formed initially to raise the standards of medical donations. Published accounts in the late 1990s described tons of bad drug donations. Outdated drugs. Unneeded drugs. Drugs unknown in developing nations. Drugs not labeled in a language understood in the recipient country.

Our first major project was to benchmark the situation. Experts at the Harvard School of Public Health studied in several nations where disasters had occurred. They made two findings: One, drug donations are important in many nations – in some cases accounting for half the medicines *in* the nation. But secondly, up to forty percent of donated drugs were inappropriate. Our study made the papers, as bad news often does. It put the entire donations community under a cloud. But we sure had our benchmark.

Next, we set out to mend cumbersome World Health Organization guidelines on drug donations, first published in 1996 to clean up donations, but causing undue difficulties. We approached WHO with suggestions to make the guidelines more workable. To our

great relief, WHO accommodated nearly all our changes. When the revised guidelines were issued, we endorsed them.

As things turned out, we were the first signatory to the guidelines. What seemed to us a modest and small gesture in reality began an extremely constructive relationship with the WHO on a global scale.

For the next couple of years we held seminars on drug donations, at which members shared, in exquisite detail, policies, practices, failures and triumphs. There began to be a truly exceptional level of collegiality among our members. As one new member remarked, PQMD meetings feel like Woodstock. Everyone, she said, “seems to have left their competitive guns at the door.”

It’s true. Merck helped GSK improve its program, and Johnson & Johnson helped Genentech with theirs. The Catholic Medical Mission Board works side by side with Protestant groups like Heart to Heart and World Vision, and with non-sectarian organizations like UNICEF and Project HOPE.

But having great meetings doesn’t mean our efforts to do donations right were paying off. In 2001, we got the chance to put our work to the test.

The World Bank decided to fund a study to test whether the WHO donations guidelines were working. PQMD was invited to join teams from WHO and the Bank. They’d go to India, East Timor, Mozambique and El Salvador, where major disasters had occurred.

At first we were flattered to be invited to join the study. Then we realized we could be joining a search that might show no improvement in the quality of drug donations. Worse, somebody said, “How do we know we’re not tying our own noose?”

We decided to bite the bullet, or the noose, whatever, with one stipulation – that the teams trace the actual donors of bad donations. That increased the risk, certainly, but it

would tell if the years we'd spent working on our own standards had been well spent. In candor, we thought we'd become very good at getting the right drug to the right patient in the right amount, quickly. So, if the WHO/World Bank study could prove that donations from PQMD organizations met the highest standards, it would be a victory for us. If it uncovered more mistakes, well, we'd deal with it.

When the teams returned and reported their findings, they reported that thousands of bad donations had been exposed. Again. But for PQMD, it was a Fred Astaire and Ginger Rogers moment. To quote from the World Bank/WHO/PQMD report, "...no evidence was found of inappropriate donations attributable to major pharmaceutical companies or experienced NGO agencies."

So who dumped bad drugs on disaster victims? Quoting again from the report: "Smaller organizations with little or no field presence nor experience, governments and local in-country distributors."

And one of the principle recommendations was that:

"Only organizations with institutional memory, pharmaceutical experience, established relationships with government and other actors, and a strong field presence in the recipient country should be permitted to assist in drug donations."

In sum, the report gave us more than we'd hoped for. Dr. Hans Hogerzeil, director of the WHO office of essential drugs and medicines policy, put it simply and well at a PQMD meeting. He said we'd shown that "drug donations are not for amateurs."

Building these partnerships requires significant investment beyond the cost of the medicines. It requires a commitment to fund the networks, training and infrastructure needed to administer medical care and implement preventive measures, often under daunting conditions. Health workers trained for river blindness, lymphatic filariasis or

preventing mother-to-child transmission of AIDS are of course invaluable assets for future health interventions.

Since 1999, through Temple University's Center for Pharmaceutical Economics and Policy, we've tracked the dollar value of our members' donations. From 1999 to 2003, they grew from \$400 million to \$1.4 billion in 2003. In 2004, due largely to the tsunami, they more than doubled, to \$3.2 billion. We have only tentative data for 2005, but we're confident that 2005 donations from PQMD members will exceed \$3 billion again – partly, of course, in response to Hurricanes Katrina and Rita. But even so, it's a source of comfort to know that when extraordinary needs arise, the donations to meet them are made, atop our long-standing commitments to sustainable development. Since PQMD's inception, our donations have reached \$6.7 billion.

I hope you'll agree that those are serious numbers, but they vastly understate the value of the work, because they do not count the value of the several thousand physicians, pharmacists, nurses and other health care providers whose services are given free. Nor do they include the expertise in logistics, management, IT, inventory management, and so on that are also provided *gratis*.

As you may know, it is reliably estimated that at least 35% of the health care reaching the developing world comes from humanitarian agencies.

How important is all this? Well, PQMD members' donations used to match the global budget for health of the US Agency for International Development (\$1.473 billion).

That's no longer true.

For 2004 and 2005, PQMD member donations were double the AID global health budget. And again, that includes only the value of the medicines and medical supplies. USAID's figure necessarily includes salaries we haven't even begun to count.

Documenting the donation community's achievements is one of PQMD's objectives. Until fairly recently, even though our partnerships were making a difference in millions of lives, very little measuring was done.

The good evidence is mounting. In recent years, NGOs have developed indicators to measure progress, and we've begun to fund studies to capture the data. I'll mention two examples we've sponsored.

First is a model partnership in Uzbekistan, where six NGOs, using donated products from about a dozen firms, took part a program coordinated by the US Department of State, dubbed "Operation Provide Hope." The idea was to stabilize the precarious health care system in that newly independent state, with particular emphasis on cardiovascular, respiratory and digestive diseases and measuring any impact on the Uzbek GDP. Some \$50 million worth of drugs were donated. The services of the people from the six NGOs were valued at \$629 million.

The outcome: For every \$1 in program cost, productivity rose \$12. We think we're on to something here. What if governments, in partnership with the industry and the NGO community, made such programs instruments of our foreign policy?

Finally, I'd like to cite a few examples of the achievements of these partnerships in addressing specific diseases.

Leprosy may be eliminated in this decade. Multi-drug therapy donated by Novartis has cured four million people. By 2010, leprosy may well be found only in textbooks.

Elephantiasis (lymphatic filariasis): GlaxoSmithKline makes albendazole, a drug widely used in animal husbandry. But it is capable of stopping elephantiasis, a disfiguring disease whose victims at risk number in the hundreds of millions. GSK decided ten years ago to use its drug to eliminate this hideous affliction — no matter the cost or time required. So far it has given 440 million treatments in 40 nations. An entire

factory had to be built to meet the need. Victory is still a long way off; there are 400 million people at risk in India alone. But GSK will announce one day that one of the most appalling afflictions known to man is no longer.

River Blindness: Merck, the gold standard in donations for many decades, has for nearly 20 years regarded river blindness as its personal enemy. Its drug ivermectin, known primarily for its use in veterinary medicine, happens also to be capable of stopping river blindness in a single dose or two, once a year. Again, the disease seems to be everywhere in the tropics, and its victims are uniformly poor. So far, Merck and its NGO partners have given away more than 500 million treatments of ivermectin (as Mectizan) in Africa and Latin America. The disease is close to extinction in Colombia and Ecuador.

Well. I've bombarded you with a lot of data, and I apologize for that. Especially if in doing so I have missed the most important reason for doing these things: to show how important corporations and NGOs have become as agents for progress in global health.

If viewed at the macro level, the task may seem beyond impossible. Indeed, the pharmaceutical industry cannot meet this challenge alone. Success requires government to do its parts, with sustainable financing, political stability and most of all by quickening the pace of change.

But my point is that corporations, working with professional aid organizations, are capable of enormous good in a hurting world. They cannot feel content to leave the task to governments alone.

That's my story. It's my way of saying we're serious, and we're worried. The sooner we resolve the issue of aberrant drug donations — one cause being the paucity of alternatives to donating leftovers — the sooner we can more fully realize a mission every one of us supports: the use of medicine as an instrument of American foreign policy. I can't think of a more authentic goal.

Thank you for your patience and for letting me speak with you this morning. I look forward to your questions and suggestions.