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# 1960s economics and modern medicines—a fatal combination

*Philip Stevens*

SOMETIMES it's difficult to keep a bad idea down. Throughout the 1960s and 1970s, governments in Asia, Africa, and Latin America attempted to kick-start their economies by shielding their domestic industries from the forces of international competition. Where this was tried, it quickly resulted in inefficient companies, shoddy products (for example, India's ubiquitous Ambassador car), and a host of economic headaches. This doctrine was sensibly abandoned by the 1980s, but has now found a surprising new champion—the global public health community. This time, however, the focus is on a product whose quality can be a matter of life or death.

In recent years, the problem of disease in the poorest parts of the world has leapt up the international agenda. While much of Africa's health care crisis is now a matter of dysfunctional health care systems and chronic staff shortages (Reaney, 2006, July 21), the international community has come to the conclusion that much of the problem relates to the availability of pharmaceuticals, many of which have to be imported from overseas (CIPIH, 2006).

Cheered on by the health activist lobby, many countries are now actively building local domestic pharmaceutical industries in order, they hope, to become self-sufficient in drug production and to drive down drug prices. The African Union, for instance, has noted the need to “formulate a plan of action ... to facilitate increased drug manufacturing in the region and to bolster research and development [R&D]” (TCPMPA, 2007).

This process is being actively encouraged by the donor community. The Global Fund for Aids, Tuberculosis, and Malaria recommends the procurement of many drugs that are manufactured locally, and in May, the World Health Organization (2008) ratified a plan that will encourage donor investment into local industries.

While this all seems beautiful in its simplicity, the health community seems to have forgotten the lessons of the 1960s—primarily, that if there is no sound economic reason for an industry to exist in a particular region, a government will only create problems by trying to force it into existence.

## The cost of local production

THERE are good reasons why an internationally competitive pharmaceutical industry has not emerged spontaneously in Africa (with the obvious exception of South Africa). Building pharmaceutical plants to the highest standards of safety and hygiene requires large amounts of capital and expertise. Many of the components have to be imported from Europe and the United States, and then maintained by foreign contractors. All of this requires hard foreign currency, something that is in short supply in Africa.

The raw materials and active ingredients required often incur import taxes, driving up the final cost of a drug. One representative from a pharmaceutical company I visited in Lagos, Nigeria, told me of the extra financial burden imposed on the company by the city's highly erratic power supply, which is vital not only for manufacturing, but also for the refrigeration of the finished

product. The cost of expensive generating equipment and diesel fuel has to be factored into the final cost of the drug.

Consequently, even if the World Health Organization (WHO) manages to increase local manufacturing capacity, it may not necessarily result in cheaper drugs—even the World Bank has admitted that this is the case (Seiter, 2005).

For instance, in May 2007, the Clinton Foundation negotiated a procurement contract with Cipla, an Indian company, for a copy of a patented AIDS drug at \$695 per person per year. However, the company that invented it, Abbott, had been selling it to 69 poor countries (including every country in Africa) for only \$500 for the previous five years. In this case, the locally produced drug was 39% more expensive and came with no proof of quality or efficacy.

In its analysis of a hypothetical local production plant in Nigeria, the US National Academies of Science found that it would have initially cost 15% more to grow, extract, purify, and derive local artemisinin—a key ingredient in modern antimalarials—than to import them directly (NRC, 2007: 110).

It would make more sense to save money by importing drugs from places where they can be manufactured more efficiently. After all, the British do not waste money attempting to grow pineapples when the fruit can be imported easily from countries that specialize in producing them.

## Is feasibility possible?

THE feasibility of the local production plan rests on the new willingness of devel-

oping countries to take advantage of the flexibilities enshrined in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), particularly those which allow for "compulsory licensing" of patented pharmaceuticals (see WTO, 1994). This would allow local manufacturers to co-opt the intellectual property of rights holders in Western countries in order to make their products locally.

Compulsory licenses have great populist appeal. However, experience to date has shown that the production of drugs of known quality, safety, and efficacy is a costly undertaking, and that compulsory licensing is fraught with difficulties, as illustrated by a recent experience in Canada. In 2005, the Canadian government offered a \$100 million subsidy to its generic industry for the production of anti-retroviral drugs (for HIV/AIDS treatment) which would be made available to African countries through the Canadian Access to Medicines Regime. Doctors Without Borders (MSF) partnered with Apotex, a Canadian drug manufacturer, to produce a drug that combines three patented AIDS drugs into a single dose.

Three years into the partnership, however, Apotex ran into two problems. First, it couldn't produce the combination therapy to Canadian generic standards at a cost that would yield a profit—even with a subsidy. Second, by the end of 2007, Apotex and MSF concluded that the legislation to support this partnership "appears to have disappeared into the Canadian Ministry of Industry's office, with no sign that it will see the light of day in the near future" (Davis, 2007, Dec. 5). They both agreed that regulatory hurdles were more complex than previously envisioned. Accordingly, on December 5, 2007, MSF announced that since not one pill had been produced and the legislation was bottled up, it would abandon all future efforts and turn to India for ARVs.

## Drug manufacturing standards

THE success of local production also relies on the ability of African companies to manufacture precise copies of brand name drugs that are currently made in the West and India. This is not as simple as creating a copy of a DVD, for example. Unless the copies are exact molecular replicas of the originals ("bioequivalent"), there is no guarantee that they will work on the patient in exactly the same way.

If the levels of active ingredients in the copy were too low in AIDS drugs, for instance, it would encourage mutations of the virus and create drug resistance. Patients would then have to begin expensive and complex "salvage therapies." Similarly, incorrect levels of active ingredients in malaria drugs would result in the malarial parasite becoming resistant, making current drugs useless. This would be a disaster for the 35% of the world's population at risk of contracting the disease. Imprecise copies of other drugs would certainly result in an increased risk of clinical failure—in the extreme, it may result in death.

As clinical pharmacologists and physicians from Stanford Medical School and Trinity College, Dublin, have stated, "Manufacturing standards must be monitored. Drug concentrations that are too low can cause the therapy to fail and, equally important, promote the emergence of resistant forms of the infectious agent ... this failure can compromise the response of the patient to other medicines in the future" (Blaschke and Merry, 2003, Oct. 6).

Ensuring good manufacturing standards is difficult in much of Africa. According to the WHO, less than 70% of African countries have a properly functioning drug regulatory system (WHO, undated). In West Africa, there are no laboratories capable of testing for bioequivalence. This means that all the drugs produced in the region are

"experimental" drugs, with no proof of their quality or efficacy. No Canadian doctor would risk such drugs on his patients. That the WHO should be recommending these drugs to African patients demonstrates deplorable double standards.

Not only is the promotion of local drug production economically illiterate, it also jeopardizes the health of patients on a grand scale. If the concern is high drug prices, it should be noted that most developing countries massively inflate the cost of imported drugs with unnecessary taxes and tariffs. For instance, the government of the Democratic Republic of Congo increases the price of imported drugs by 39% through taxes and tariffs (Bate *et al.*, 2005), even though the country is suffering from a severe health crisis.

The international health community, and especially the WHO, should focus on the issues that really matter—for example, building African health infrastructure and recruiting doctors and nurses. Without these things, even free drugs would be of no benefit to patients.

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# Canada's mismanaged SIN system

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CANADA'S Social Insurance Number (SIN) system has again come under scrutiny. A recent RCMP and Ontario Provincial Police investigation revealed that two Canadians, one of whom was a former federal government employee, had forged 400 social insurance cards and used them to commit \$7 million worth of fraud (*CBC News*, 2008, Feb. 21).

While the two individuals were arrested and charged, Canadians should not feel at ease with respect to the security of Canada's social insurance system. The fact is that Canada's system of managing SINs remains open to fraud, misuse, and overpayment, costing Canadians billions of dollars. An airtight SIN system is critical for Canada, and the time has come for the federal government to develop a measurable plan for reform.

Social Insurance Numbers (SINs) serve as a de facto source of national identification and are the backbone of virtually every federal and provincial income support program including the Canada Pension Plan, Employment Insurance, welfare, and workers' compensation.<sup>1</sup> In total, approximately \$120 billion of government spending (federal and provincial) is allocated by programs that rely on the SIN system (Statistics

Canada, 2007). In addition, the SIN is widely used in the private sector as a personal identifier.

Despite the importance of SINs, the federal government's management of the SIN system has repeatedly come under the scrutiny of the Office of the Auditor General of Canada (Auditor General). In fact, on four separate occasions spanning nearly a decade (1998 to 2007), the Auditor General has reviewed Canada's SIN system and repeatedly criticized the federal government for failing to improve the problem.

In its first major review in 1998, the Auditor General raised a number of concerns about the gap between the number of SINs and the actual number of Canadians. Specifically, the Auditor General found that there were 3.8 million more SINs than there were Canadians. Equally alarming was the finding that some 16.8 million SIN entries, representing 51% of SINs issued, had not been supported with identification documents. Not surprisingly, the Auditor General commented that the number of uncertain records created the potential for "error, misuse, and abuse" (Auditor General, 1998: s. 16.36). As a result, the Auditor General recommended that the federal government dramatically decrease the number of excess SINs and unverified SINs by putting corrective measures in place.

## FURTHER READING:

*Mismanagement of Canadians' Social Insurance Numbers*  
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