

Should western governments allow their pharmaceutical corporations to relocate medicine tests to resource-poor countries?

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Summary

One of the more recent trends in globalization is the increase of medicine testing abroad. Western pharmaceutical companies relocate risky medicine tests to resource-poor countries. Most of us will have the intuition that this relocation is not unproblematic, without immediately knowing what is wrong or why. I argue that *ipso facto* relocating medicine tests to developing countries is not intrinsically wrong; even more, it can even have beneficial effects for resource-poor countries. The problem, however, is the difficulty of distinguishing beneficial from harmful (or even exploitative) forms of medicine testing. The aim of the paper is to map the institutional context in which this practice of relocating medicine tests abroad has emerged and discussing the role of western governments in regulating this practice. The argument proceeds in three steps. I start by discussing the various reasons why it is attractive for western pharmaceutical companies to relocate these medicine tests, and separate ethically-unproblematic from ethically-problematic reasons. Secondly, I present a preliminary formulation of a principle of justice determining a fair distribution of burdens and benefits of border-crossing medicine tests. Finally, I show how this principle of justice for border-crossing medicine tests and the separation between ethically-unproblematic and ethically-problematic reasons for relocating medicine tests can be useful in determining western policies towards the relocation of medicine tests of western pharmaceuticals to resource-poor countries.

Introduction

In 2001 the US based corporation *Discovery Labs* sought approval of the *Food and Drugs Administration* (FDA) for a study of Surfaxin.¹ This is a drug for the prevention and treatment of IRDS, a lung-related disorder and common cause of death in prematurely born infants.² The experiment was contested for two reasons. Firstly, although the purpose of the test was to gain approval for the U.S. market, it was planned in Mexico, Bolivia, Peru, and Ecuador. Secondly, it was designed as a placebo test. All the infants in the test would undergo an uncomfortable intubation procedure, while only half of them would receive the medicine, the rest “sham air.”³ Another well-documented and notorious example is the testing of Trovan, an antibiotic developed by the American company Pfizer. This medicine was tested in Kano, Nigeria, during an outbreak of meningitis, while the NGO *Doctors Without Borders* was already present, dispensing approved antibiotics at the same hospital for free. In the Pfizer experiment, the unproven drug was given to nearly 100 children of which 11 died, at least one of them under suspicious circumstances. In an ex-post evaluation, Nigerian medical experts concluded that Pfizer never obtained authorization from the Nigerian government (Cf. Flaherty, Nelson, and Stephens 2000; Stephens 2000; 2001; 2006).

These are just two examples of an emerging practice in which western commercial enterprises relocate risky tests to resource-poor countries.⁴ They have many reasons to do so: to drive down costs and red tape, to escape rigorous government regulation and control, or to perform placebo tests in situations where they would be strictly prohibited in affluent societies. This practice has received much negative attention in recent years, some of these tests are even disapprovingly denominated as “safari research,” in which pharmaceutical teams fly in, only interested in the results of their experiments and leave as soon the tests are over and done with, lacking any interests in the long-term recovery of their test-subjects (Macklin 2004: 12).⁵

¹ Discovery Labs is a *contract research organization*, a for profit organization set up to organize and carry out medicine tests for pharmaceutical companies.

² IRDS stands for *idiopathic respiratory distress syndrome*. Surfactants are drugs that make it easier to inflate poorly functioning lungs of newborn infants.

³ In the end this design of the test encountered so much resistance that it was not actually carried out. The test was conducted (actively-controlled) in medical facilities in the U.S and Europe.

⁴ I use the term ‘resource-poor countries’ for counties that lack to financial resources to sustain basic health care provisions that provide their citizens with basic health care. I use this term this to avoid more controversial ones like ‘developing countries’ or ‘third-world countries’ (cf. Macklin 2004: 9-11).

⁵ “Pfizer’s Nigerian clinic opened and closed in a relative eye blink: About three weeks after the company’s team roared in with a chartered DC-9, the team roared out. Pfizer’s doctors returned once to examine the patients but did not track their long-term recovery” (Stephens 2000). This safari-like research is penetratingly exposed in the Oscar-winning movie *The Constant Gardener* (2005).

It is not the case that people in the developing world are not in need of new medicines. On the contrary, they urgently need effective medicines against *poor man's diseases* like malaria, sleeping sickness, and tuberculosis, but only 0.3% of the research and development of pharmaceutical companies is spend on such medicines.⁶ Indeed, most of these tests concern medicines targeted at Western markets, since they are too expensive for citizens of resource-poor countries, especially those targeted for such tests.⁷ Once such medicines are approved on western markets, they usually become *blockbusters*, generating millions of dollars for the pharmaceutical company that has patented them.⁸

Most people will have the intuition that this practice of relocating medicine tests is not unproblematic, without immediately knowing why. Does it harm individuals, exploit them, or violate their human rights? I should make clear straightaway that I cannot provide any determinate answer to these questions. The aim of this paper is much more modest. It firstly seeks to map the institutional context in which the practice of relocating medicine tests to resource-poor countries has emerged. Ultimately pharmaceutical corporations make the decision to relocate medicine tests or not. And, being commercial enterprises, their main consideration in developing new medicines is the return of investment. Pharmaceutical companies are not looking for patients per sé, they are looking for patients with purchasing power. However, western liberal-democratic governments shape the context in which these choices are made and can thus affect these decisions. So the second question is whether liberal-democratic governments have a regulating role. Should they allow the relocation of tests to resource-poor countries and, if so, under which conditions. The third question is, given the axiom of *ought implies can*, whether there liberal-democratic governments are able to enforce regulations upon pharmaceutical companies, given the emerging globalization and the accompanying *race to the bottom* it has generated.

The paper is organized as follows. *Section 1* provides a general background for the discussion by describing the role of medicine tests in the process of developing new medicines. *Section 2* explains how globalization has changed the practice of medicine tests. It gives an overview of the incentives for pharmaceutical companies to relocate their medicine tests to resource-poor countries. Moreover, it shows why globalization has weakened the ability of national governments to regulate the practice. *Section 3* discusses the role western

⁶ Of the 1393 new drugs approved between 1975 and 1999, only 16 were targeted at tropical diseases and tuberculosis (Trouiller et al. 2002: 2189). Cynically enough, 5 out of these 13 discoveries actually emerged from veterinary research (Trouiller et al. 2001).

⁷ For example, research of the NGO *Public Citizen* shows that a surfactant treatment for a premature infant costs between US\$ 1079 and 2440. (<http://www.citizen.org/publications/release.cfm?ID=6761>, assessed Jun 12, 2005).

⁸ Blockbusters are medicines with annual sales of 1 billion US\$ or more.

regulations can play in the decisions of pharmaceutical companies to relocate medicine tests. I argue that the interests of several groups must be balanced – patients and pharmaceutical companies in western countries and resource-poor countries and their citizens. Moreover, I present a consequentialist argument on how these interests must be balanced. *Section 4* discusses a central issue in current political debates – double standards in medical research – and shows how my approach, as developed in section 4, can be helpful in discussing this example. *Section 5* concludes.

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