WORKING DOCUMENT - BARBADOS AND BOLIVIA

PROPOSAL 6

Clinical Trials on Medicines as Global Public Goods

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Issue to Discuss for Meeting on Biomedical R&D Treaty

The WHO/PHI/IGWG has agreed there will be further discussions about a possible biomedical R&D Treaty. One issue that should be discussed concerns global cooperation to fund independent clinical trials on medicines, as global public goods.

The Problem

Clinical trials reveal evidence of the safety and efficacy of medicines, including also the relative efficacy of different products used treat the same illness. A growing number of experts say the system of relying upon trials performed by the owners/manufacturers of products is plagued with controversy and ethical lapses, and the high cost of undertaking clinical trials is both a barrier to innovation and a rationale for high drug prices.[1]

1 For discussions of the rationale for and the possibility of funding clinical trials as public goods, see: I. Chalmers, "Underreporting research is scientific misconduct," *JAMA,* 1990, 263:1405-1408.; T. Bodenheimer, "Uneasy alliance: Clinical investigators and the pharmaceutical industry," *N Engl J Med,* 2000, 342:1539-1544; Rich McManus, "'Abolitionist' Angell Calls for Clinical Trial Reform," *The NIH Record*, July 24, 2001, Vol. LIII, No. 15; John Yaphe, Richard Edman, Barry Knishkowy, and Joseph Herman, "The association between funding by commercial interests and study outcome in randomized controlled drug trials," *Family Practice,* Vol. 18, No. 6, 2001: 565-568; Sameer S. Chopra, "Industry Funding of Clinical Trials: Benefit or Bias?" *JAMA*, 2003, 290:113-114; Joel Lexchin, Lisa A Bero, Benjamin Djulbegovic, "Pharmaceutical industry sponsorship and research outcome and quality: systematic review," *BMJ,* May 31, 2003, 326:1167-1170; Samuel O. Thier, Hamilton Moses III, MD, E. Ray Dorsey, MD, MBA; David H. M. Matheson, JD, "Financial Anatomy of Biomedical Research," *JAMA,* 2005, 294:1333-1342; Marcia Angell, *The Truth About The Drug Companies: How They Deceive Us And What To Do About It*, Random House, 2005; Thomas Alured Faunce, "Intellectual Monopoly Privileges, Cost-Effectiveness Evaluation and the Knowledge Commons-New Political Paradigms for Wisdom in the Age of Corporate Globalisation," Presentation at TACD meeting on the politics and ideology of intellectual property rights, March 2006; Thomas Faunce, "Toward a Multilateral Treaty on Safety and Cost-effectiveness of Medicines and Medical Devices," WHO Public Hearing on Public Health, Innovation and Intellectual Property, 14 November 2006; Tracy R. Lewis, Jerome H. Reichman, and Anthony D. So, "The Case for Public Funding and Public Oversight of Clinical Trials," *The Economists' Voice*, 2007, Vol. 4, Issue. 1, Article 3; Dean Baker, *The Benefits and Savings from Publicly-Funded Clinical Trials of Prescription Drugs*, the Center for Economic and Policy Research, March 2008; Djulbegovic B, et al., "Treatment success in cancer: New cancer treatment successes identified in phase 3 randomized controlled trials conducted by the national cancer institute-sponsored cooperative oncology groups, 1955 to 2006," *Arch*

Clinical trials are first and foremost methods of generating information. Once findings of a clinical trial are published and known, the benefits of the trials can be used everywhere.

Some governments have tried to assign exclusive rights in pharmaceutical test data as a method of appropriating the value of the test and protecting the investments associated with the trials. However, the potential negative impact of doing so is large. By creating a monopoly in the evidence that a drug is safe and effective, as a barrier to competitive entry against manufacturers offering the same molecule, governments encourage very high prices. The exclusive rights system also requires competitors to replicate known experiments on humans, a process that is not only time consuming, expensive and wasteful, but which violates ethical restrictions regarding experiments involving humans.

Direct funding of independently managed clinical trials reduces the costs of product development and evaluation, increases the utility of the trials as a source of unbiased information, and avoids unethical experiments involving humans.

Governments can and do fund clinical trials, but not to the degree that is needed, largely because clinical trials have the characteristics of global public goods. No one government has the incentive to subsidize such trials. Therefore, governments need to undertake greater cooperation in the funding of such trials, and to address other concerns regarding the management of clinical trials as global public goods.

Multilateral Agreement on Independently Managed Clinical Trials

The WHO should hold a meeting, in the context of a possible biomedical R&D treaty, to consider an agreement among governments to share the costs of independently managed clinical trials for medicines and vaccines.

The meeting should consider the following issues.

1) Identification of the amount of money that is currently invested annually in clinical trials, disaggregated by the stage of the trial and the area of research, and whether the source of funding is public or private,
2) Identification of areas where governments benefit from independently managed clinical trials,
3) Analysis of the benefits of global clinical trial registries and other transparency issues,
4) Alternatives to exclusive rights on pharmaceutical test data,
5) Priority-setting in terms of clinical trial testing, including:
   a) New drug and vaccine development, and
   b) The evaluation of safety and cost-effectiveness of existing products.

Intern Med, 2008, 168: 632-642; Crystal Phend, "NCI-Sponsored Cancer Trials Offer Decent Clinical Return on Investment," *MedPage Today*, March 24, 2008.