



The Case for Public Funding and Public Oversight of Clinical Trials

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Recent revelations that pharmaceutical companies have suppressed adverse findings in the clinical testing of new medicines have led many medical groups and health care specialists to call for mandatory disclosure of all clinical trial results.¹ But lack of disclosure is far from the only problem here: study design biases and other questionable practices² also taint drug company findings, and companies have an incentive to simply avoid research programs that could reveal unfavorable outcomes.

There is a fundamental structural problem causing all these problems: as long as drug

companies retain primary responsibility for conducting or funding clinical trials, the trials will be sub-optimal from the standpoint of public health and safety. Calling for mandatory disclosure, then, is not enough: we must recognize that clinical trials are a public good and treat them as such. This means public funding and public administration.

The federal government should oversee and manage both the process of drug testing, and the dissemination of test results. This would, of course, remove the direct link between the clinical trial sponsor and the drug tester, which causes serious conflicts of interest.

One approach would be to establish an independent testing agency to conduct clinical trials at a national testing facility, under specified conditions of transparency. Drug companies would no longer directly compensate scientists for evaluating their own products; instead,

scientists would work for the testing agency, which would be supported by funds collected from taxes upon the pharmaceutical industry and/or from general tax revenue.

This solution would address the conflict of interest issue, and would ensure that all drug tests that are important to the public will be conducted, and the results fully disclosed.

BENEFITS FROM TREATING CLINICAL TRIALS AS A PUBLIC GOOD

Information gleaned from the clinical testing of drugs and therapies is a public good, in the sense that each individual citizen can benefit from such information, without thereby reducing the information's value to others. At the same time, the results of the testing process reveal information that improves the conduct of research and development (R&D) in the industry as a whole, without disturbing the validity

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of the underlying patent rights protecting individual firms' innovations.

Peer-reviewed basic research results have always been recognized as a public good; peer-reviewed clinical trial results should be, too. Such results can promote a higher quality of decision making about the safety and therapeutic value of both single products and product groups, while also stimulating follow-on innovation and providing guidance for better clinical practice.

By contrast, our current system renders results artificially scarce, and allows companies to easily exclude others from access to results. Economic principles teach that privately-supplied public goods will inevitably be underprovided, and in this context, that can cost a great deal in terms of life and health—if, for instance, a head-to-head comparison between therapeutically-equivalent drugs is never studied; an adverse drug reaction is never explored; a specified clinical indication is never appropriately narrowed; or the possibility of a drug's use for another disease is never investigated.

Under our proposed system—of public funding, oversight, and full disclosure of clinical trial results, especially unfavorable or negative results—the total direct cost of drug testing

in the United States should fall, for investigators could exploit economies of scale and scope in testing, minimize unnecessary redundancies, and more easily interpret and compare the results of different tests. In addition, our system would reduce R&D costs, as drug companies learn earlier which candidate medicines are therapeutic, and which are not.

The global public health system would be benefited as well—for our system would create additional opportunities for development aid organizations and public-private partnerships to make essential drugs accessible. Currently, drug companies have little incentive to conduct R&D on drugs that would primarily benefit the uninsured poor, but the United States government can close that gap, not just domestically, but globally too. Moreover, state subsidies of clinical trials, and reductions in the cost of drug development, could complement private initiatives that research and deliver beneficial drugs to developing countries.

WHO SHOULD PAY FOR EXPANDED CLINICAL TRIALS?

Some may object to having the public pay the cost of clinical drug testing. One possibility is to fund our system by a tax on

pharmaceutical companies. But even if testing is funded from general tax revenue, that would still make much more sense than the current system.

The incentives for companies to discover new drugs decline, as their costs of testing and developing drugs for the market increase. Year after year, the cost of conducting clinical trials outstrips the medical component of the consumer price index. Recent studies show the growing importance of these costs in determining the aggregate expenses of bringing new drugs to market³ in a lottery-like environment where “most drug candidates taken into testing fail.” Public disclosure of clinical trials, in contrast, would increase the social value of testing, ultimately leading to a greater demand for clinical trials than currently exists.

Public funding of clinical trials has another important advantage, too: in health sector markets today, health care providers pressure drug companies to reduce prescription prices. This downward pressure on price is constrained, however, by the need for companies to earn sufficient profits from successful drugs to induce further investment in new drug therapies. With public support to reduce drug company testing

costs, the companies' cost of bringing new drugs to market would decline, as would the revenues drug companies require to offset their cost of new drug development. Health care providers could press for lower drug prices on current drugs without necessarily causing a reduction in investment for new drug therapies. Providers of health services, including federal and state governments, would benefit from these lower prices, as would low-income and uninsured drug patients who would have greater access to prescription drugs. The well-known allocation distortions that arise from patent-protected medicines would also be reduced, to the extent that public support of clinical testing would cause negotiated prices to decline.

A THREE-PART PLAN FOR IMPLEMENTING A PUBLIC CLINICAL TRIALS PROGRAM

1. Awarding Clinical Tests to the Most Qualified Scientists

Our proposal does not require the government to physically conduct the tests under the aegis of a specialized agency, although this remains a possibility; the government could hire qualified, experienced scientists who had previously conducted clinical tests for drug companies. Instead, the government could simply oversee competitive

awards of testing contracts to worthy testing organizations—either public or private, but not affiliated in any way with drug companies—in accordance with public health priorities.

This approach would build on proven strengths of the federal government to administer extramural research grants, much like those awarded by the National Institutes of Health (NIH). As occurs in that process already, scientific review panels would identify potential biases in study design and, with input from the drug regulatory authority, would insist on appropriate treatment comparisons by designated clinical trial units.

2. Coverage and Funding of Public Clinical Trials

The category of products subject to this proposal should be broad enough to include drug treatments, vaccines, medical devices, and diagnostic or monitoring tests. By clinical trials, we mean Phases I through IV, in current terminology. (Phase I utilizes small groups to evaluate overall safety, appropriate dosage and side effects; Phases II and III enlarge the size of the testing group to examine effectiveness, safety, and the right dose; Phase IV follows after the drug is approved and marketed to gather information about its effects

on different populations and any side effects associated with long-term use.⁴)

We advocate that the government funding of clinical tests be revenue-neutral. Public support of clinical testing could be financed directly from the reduction in government drug reimbursement payments that would result, as negotiated drug prices fall. Drug companies should continue to bear a significant portion of clinical trials costs, in order to discourage the wholesale testing of marginal drugs with little therapeutic value, or candidate medicines with little chance of clinical adoption.

A process that reimburses a progressively larger share of testing for those medicines that display the greatest potential benefits, would encourage companies to select only the most promising medicines for clinical review at public expense. Selective funding of clinical trials would also afford the government some discretion in supporting the development of drugs with greatest potential social value that might otherwise be overlooked by a totally market-driven approach.

3. Phased Implementation

Transforming clinical trials from an *excluded* to a *non-excluded* public good is an ambitious undertaking, and one that should be implemented

gradually. We envision the first step would be to decouple drug company sponsorship from management of clinical trials, by requiring the federal government to oversee the trials and dissemination of results under the aegis of a national testing program.

Second, the program would conduct pilot projects targeting drug candidates that promise the greatest social benefit from public testing. Drugs that offer innovative therapeutic benefits, or significant gains over existing treatments, would be preferred candidates. As the program grows, public testing would expand to drugs that offer therapeutic alternatives in treatment areas where there are none.

Finally, after a set period, the pilot projects would be evaluated to identify the costs and benefits of public testing and dissemination for chosen drug groups, and to indicate other drug groups the program might include. Ideally, a successful program could be expanded to cover all prescription drugs and therapies.

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NOTES

1. See “AMA Recommends that DHHS Establish a Registry for All US Clinical Trials,” *AMA Press Release*, 15 June 2004, available at: <http://www.ama-assn.org/ama/pub/category/13934.html>; “Leading Medical Groups Endorse Public Clinical Trials Registry,” *American Academy of Child and Adolescent Psychiatry and American Psychiatric Association News Advisory*, 9 September 2004, available at: <http://www.aacap.org/page.ww?section=2004+Press+Releases&name=Leading+Medical+Groups+Endorse+Public+Clinical+Trials+Registry>. See also “Reps. Waxman, Markey Introduce Legislation to Establish Mandatory Online Database of Clinical Trials,” *MediLexicon*, 7 July 2005, available at: <http://www.medicalnewstoday.com/medicalnews.php?newsid=27062>; “Medical Journals to Require Clinical Trial Registration,” *NewScientist.com* news service, 9 September 2004, available at: <http://www.newscientist.com/article.ns?id=dn6378>.
2. See “Spitzer Sues a Drug Maker, Saying It Hid Negative Data,” *New York Times*, 3 June 2004, p. A-1; Peter Juni et al., “Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty,” *JAMA*, 16 April 1997, 277(15): 1224–28 (noting efforts to slow dissemination of undesired results).
3. On the increasing costs of clinical trials, see Henry Grabowski, Joseph DiMasi and John Vernon, “R&D Costs and Returns by Therapeutic Category,” *Drug Information Journal*, 2004, 38(3): 211–23.
4. To read more about this, see the NIH resource information on clinical trials at <http://www.nlm.nih.gov/services/ctphases.html>.

