

To: The High-Level Panel on Access to Medicines

From: William Fisher

Re: The Social Responsibility Index (Contribution C-157) March 25, 2016

Thank you for the opportunity to discuss with the High-Level Panel the proposal that Talha Syed and I have submitted for the creation of a regulatory framework designed to help alleviate the global health crisis (C-157). Because of the time constraint, I was unable during our discussion in Johannesburg to address adequately the questions posed by Secretary Matsoso, Prof. Gönz, Prof. Abbott, and Dr. Balasegaram, so I will accept Chairman Kirby's invitation to offer some brief additional responses in writing. Set forth below are the principal outstanding issues and my suggestions with respect to each:

1. Why should pharmaceutical firms be permitted to buy and sell disability-adjusted life years (DALYs) in order to satisfy their obligations under our proposed system?

Response: Our principal goal is to alleviate as much human suffering as possible with the least expenditure of resources. Some pharmaceutical firms are well positioned either to adjust their pricing practices to increase the accessibility of essential medicines or to modify their R&D portfolios to develop new medicines aimed at neglected diseases; other firms are less well positioned to make such adjustments. Permitting the former to sell DALYs to the latter would provide the former with additional funds and incentives to pursue their projects and thus ensure that lives are saved most rapidly and efficiently. In this respect, the market for DALYs that would arise under our proposed system would resemble the market for emission permits that results from existing "cap-and-trade" regulatory systems for reducing greenhouse-gas emissions – and would be similarly socially beneficial.

2. Is accurate measurement of the health benefits reaped (annually) through the consumption or availability of particular drugs feasible?

Response: An affirmative answer to this question is critical to the implementation, not only of our own proposal, but also of the various proposals for prize systems that would supplement or replace intellectual-property laws as the principal stimuli for innovation in the pharmaceutical industry (see, for example, Contribution C-22) as well as proposals for increasing government funding for projects offering large public-health benefits. (See, for example, Contributions C-38, C-83, C-89).

Our confidence that reliable estimates are indeed practicable arises from two sources: First, techniques for measuring and comparing the health benefits of particular drugs have already been developed – and are constantly being refined – by government agencies in Australia, Canada, France, Germany, New Zealand, Sweden, and the United Kingdom. (Adler 2006, Cerri, Knapp, and Fernandez 2014, Sorenson and Chalkidou 2012, Walley 2010) As Professor Pogge suggests in his contribution to the Panel, a regulatory or prize regime aimed at alleviating the global health crisis could and should rely upon those techniques. (Contribution C-22) It must be conceded, however, that these existing methodologies are not optimized for assessing the long-term global impacts of specific pharmaceutical products. Precise implementation of our proposal (or of other, analogous proposals) would require refinement and adaptation of those methodologies.

This leads to the second dimension of our response: we propose the creation of a consortium of individuals and institutions that would develop and deploy suitable health metrics – in part by building

upon the work already done by the government agencies mentioned above. At the heart of this consortium would be a group of experts in pharmacoeconomics. This group would be assisted and advised by economists, philosophers, public-health experts, and legal scholars who can help address the complex practical and normative challenges associated with the measurement of health impacts.

Some of the public policies that would rely upon the work of this consortium could have substantial impacts on the fortunes of private firms and the welfare of many countries and social groups. Consequently, pressure of various sorts would be brought to bear on the consortium. It is thus imperative that its members be free of bias and resistant to such pressures. For this reason, the principal members of the consortium are likely to be established academic institutions and their faculty members. We have already begun enlisting universities on several continents interested in participating in such a consortium – and would be more than willing to continue to do so.

3. Are not government officials better able than the executives of pharmaceutical firms to determine which research projects would most effectively and efficiently reduce the burdens of disease in developing countries?

Response: Neither of these two groups has a monopoly on good judgment. Generally speaking, government officials (with appropriate training and experience) are better able to gather and evaluate data concerning the incidence and impact of diseases and thus are better positioned to ascertain the welfare gains that could be reaped by developing and distributing vaccines or treatments for each ailment. By contrast, generally speaking government officials have knowledge inferior to that of private firms concerning the relative merits of potential lines of innovation – which drugs aimed at particular diseases would work best, which of the possible ways of developing such drugs are most promising, and the cost of each of those routes. (Kremer 2000, Nelson and Winter 1982, Wright 1983). However, there are many exceptions to these generalizations. For example, the decision by the National Institutes of Health not to devote substantial funds to the development of an Ebola vaccine prior to the recent West African outbreak of the disease casts doubt on the prescience of government officials with respect to the relative importance of public-health needs. (Fisher and Geddes 2016) On the other side of the ledger, pressure from investors and the partial path dependency of pharmaceutical research sometimes distort evaluations by private firms of R&D options. In short, there is no simple answer to the question.

Our proposed regulatory system would improve the capacity of the legal system as a whole to harness the respects in which the knowledge and judgment of the private firms is superior – by increasing the firms' incentives to identify and pursue projects with major-public benefits. However, our system is not a panacea. As we suggest in the book from which our proposal to the Panel has been drawn, the regulatory system we advocate would function best if combined with an optional prize regime -- which would vest more decision-making authority in the hands of government officials. (Fisher and Syed forthcoming, Chapter 5)

A related issue: Decision-making by both government officials and the executives of private pharmaceutical firms is impaired by the absence of a global coordinating mechanism for identifying emerging public-health challenges and the most effective ways of meeting those challenges. In the near future, this problem is likely to worsen, as the ecosystem of private and public institutions that either conduct or fund pharmaceutical R&D becomes increasingly complex. As I suggested in the Global Dialogue in Johannesburg, the High-Level Panel could help address this growing problem – specifically, by facilitating the creation of a global coordinating mechanism that would mitigate the risk that some

health challenges will receive insufficient attention, while others receive too much. (Fisher and Geddes 2016) This might be achieved through enhancement of the powers and responsibilities of the World Health Organization. Alternatively, it might be achieved through the creation of a separate institution that would draw upon the expertise of both public and private actors.

4. The engagement of which stakeholders is necessary to the implementation of the proposed regulatory system?

Response: The active participation of at least three groups would be essential: public-health advocates; major pharmaceutical firms; and lawmakers in the governments of both developing and developed countries. All three groups could help refine the design of the system. Perhaps more importantly, adoption of such a system is unlikely without the endorsement of all three groups.

In our view, however, the members of all three groups have good reason to lend it their support. Public-health advocates should find attractive capacity of the system to save many lives. Pharmaceutical firms should find attractive its efficiency, flexibility, and relatively non-intrusive mechanism. Government officials should find attractive the fact that, in contrast to most other major reform proposals, adoption of our proposal would not require substantial expenditures of public funds.

## References

- Adler, Matthew D. 2006. "QALYs and Policy Evaluation: A New Perspective." *Yale Journal of Health Policy, Law and Ethics* 6:1.
- Cerri, Karin H., Martin Knapp, and Jose-Luis Fernandez. 2014. "Decision making by NICE: examining the influences of evidence, process and context." *Health Economics, Policy and Law* 9:119-141.
- Fisher, William, and Katrina Geddes. 2016. *Learning from Ebola: How Drug-Development Policy Could Help Stop Outbreaks of Infectious Diseases*.
- Fisher, William W., III, and Talha Syed. forthcoming. *Infection: The Health Crisis in the Developing World and What We Should Do About It* (Stanford University Press 2017).
- Kremer, Michael R. 2000. "Creating Markets for New Vaccines, Part I: Rationale." NBER Working Paper #7716.
- Nelson, Richard R., and Sidney Winter. 1982. *An Evolutionary Theory of Economic Change*. Cambridge, MA: (Harvard University Press).
- Sorenson, Corinna, and Kalipso Chalkidou. 2012. "Reflections on the evolution of health technology assessment in Europe." *Health Economics, Policy and Law* 7:25-45.
- Walley, Tom. 2010. "Drugs, Money and Society." *Journal of Clinical Pharmacology* 70 (3):342-45.
- Wright, Brian D. 1983. "The Economics of Invention Incentives: Patents, Prizes, and Research Contracts." *American Economic Review* 73 (4):691-707.