

De-linking R&D costs from product prices

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1. Context:

- (a) There exist significant disparities in health outcomes based upon incomes. One important element of those disparities concerns the granting of exclusive rights to make, use and distribute products.
- (b) Health R&D needs are complex, and include all sorts of things that are not provided by patents or similar IPR mechanisms.
- (c) The world is facing an explosion of new restrictive international trade agreements that continue to ratchet upwards to the IPR obligations on developed and developing countries. The agreements are justified upon the need to provide sustainable and fair global norms for supporting R&D.
- (d) The exclusive rights regime can be very expensive, and inefficient relative to the amount of money the exclusive rights regimes impose on society, when compared to the paucity of the R&D investments that it induces.
- (e) Globally, it is reasonable to assume that the system of exclusive rights increases drug prices for prescription drugs and vaccines by more than a half trillion per year.
- (f) Less than 10 percent of global turn over of pharmaceutical sale is reinvested into R&D.
- (g) Most of the money now invested in R&D is spent on products of limited medical benefits, due to strong economic incentives to invest in similar products within a therapeutic class, and the tendency to use R&D budgets to generate information useful for marketing similar products, and maintaining ties with prescribing physicians.
- (h) There are well documented deficiencies in R&D investments relating to products
- (i) There is an appalling lack of transparency of the R&D system, given the amount of money involved, and the relevance of the information to policy making.

¹ Knowledge Ecology International (KEI) is a not for profit non governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI was created as an independent legal organization in 2006, assimilating the staff and work program of the Consumer Project on Technology (CPTech), while redefining the mission of the organization. KEI is focused on human rights and social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups.

- (j) New thinking about innovation stresses the importance of access to knowledge, transparency, collaboration and sharing of data, materials, technologies and other R&D inputs.
2. The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) has the opportunity to do something radically different that can accelerate the needed reforms in the way we manage innovation and access to new medical innovation. By embracing new policies that de-link R&D costs from product prices, it is possible to vastly expand access to new products, while more efficiently targeting R&D incentives, and providing a more balanced and effective global framework for funding every aspect of the value chain for R&D. De-linkage is a concept anchored in the WHO Global strategy and plan of action on public health, innovation and intellectual property² and embedded in resolution WHA63.28 establishing the CEWG³.
 3. The de-linkage approach is profoundly different than one that seeks to sustain R&D through legally enforced time-limited monopolies on new products. De-linkage eliminates monopolies on final products and permits a much more decentralized system of manufacturing, distributing and marketing. Incentives are designed to reward investments in products that have the greatest impact on health outcomes, and also to finance and reward R&D efforts that advance a wide range of science, engineering and product development activities, including basic research, pre-commercial and transitional product development, the supply of knowledge as a public good, and research that leads to more rationale and informed use of existing products.

4. Core Features of the De-linkage Paradigm

5. The details of a de-linkage approach to medical R&D can appear to be complex and nuanced, but in fact are considerably easier to design than a working system to support R&D that depends upon high product prices. Note that our current system of high prices is accompanied by a complex, controversial and error prone patent

2 WHA61.21, Paragraph 4 of the WHO Global strategy and plan of action on public health, innovation and intellectual property states: “Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.”

3 WHA 63.28, 'Recognizing the need to further “explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes”’.

system, a growing array of *sui generis* IPR regimes, increasingly complicated and sometimes contradictory multilateral, plural-lateral, regional and bilateral trade, investment and services agreements, complicated national tax provisions, and difficult to manage systems for reimbursement and price negotiations, all working alongside multi-billion dollar grant programs managed by federal governments and tax exempt foundations.

6. R&D with de-linkage can be implemented with or without intellectual property protections, as long as intellectual property rights are not implemented as the exclusive rights to make, sell or distribute products. Patents can be used to establish claims on rewards that are implemented, outside the system of time limited legal monopolies. But sharing of knowledge, materials and technologies can also be rewarded through open source dividend reward programs, creating different and competing incentives for researchers and research firms.
7. The globalization of a de-linkage approach will eventually require the development of new norms to replace trade agreements that focus on higher prices and stronger product monopolies. The CEWG has been asked to consider a proposal that the WHO hold one or more meetings to discuss possible elements of a biomedical R&D treaty. This proposal, as modest as it is as regards the terms of reference, became controversial precisely because it was seen as step toward more radical changes in global trade agreements that would create the flexibility and the means to implement de-linkage approaches globally.
8. At present there are a number of different proposals and models for a biomedical R&D treaty, many of which were cited in the 2009 Bangladesh, Barbados, Bolivia and Suriname proposal for a meeting to discuss possible elements of such a treaty. Most of the proposals include some norms or mechanisms for identifying and funding priority research, and may also have other elements, such as norms on medical ethics or the transparency of research.
9. The 2006 CIPIH Report discussed the possible R&D treaty, but was unable to reach consensus on carrying this proposal forward. Since then, there has been a proliferation of proposals as to the possible elements and objectives of such a treaty.

10. In 2008, the WHO referred to a biomedical R&D treaty in paragraph 2.3c of WHA61.21, a resolution adopting the WHO Global Strategy for Public Health Innovation and Intellectual Property.

2.3 IMPROVING COOPERATION, PARTICIPATION AND COORDINATION OF HEALTH AND BIOMEDICAL RESEARCH AND DEVELOPMENT.

(c) Encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including *inter alia*, an essential health and biomedical r&d treaty

11. A number of NGOs and other stakeholders have created the 23c Committee, to explore the possible elements and implementation strategies for such a treaty.
12. In 2008, KEI also proposal an entirely different approach for funding R&D, within the WTO, modeled after the WTO General Agreement on Trade in Services (GATS). This involved a schedule in the WTO, that would allow nations to volunteer to make binding offers to fund public goods. KEI suggests the CEWG also consider this proposal as a mechanism to make pledges of R&D funding sustainable, without much organizational overhead (using an existing organization). The CEWG is encouraged to evaluate the WTO proposal as a possible mechanisms to increase sustainable funding for public goods projects. However, this is not suggested as a substitute for the more fundamental changes in trade policy that have been associated with some versions a WHO biomedical R&D treaty, and it is also not the best mechanism for dealing with other possible elements of a biomedical R&D treaty, such as those relating to priority setting, transparency, or medical ethics.
13. De-linkage approaches can be implemented with a large or a small role for private for-profit businesses, depending upon the preferences of policy makers and the relative advantages of both non-profit and for-profit institutions and business models. The current system of trade agreements to protect monopolies and high prices for new products are solely focused on incentives for private for-profit firms. These firms provide important services and skills, but a global trading system that focuses only on the privatization of knowledge leads to an unbalanced and inefficient R&D investment portfolio. To bring more balance to the global system for R&D, investments in knowledge as a public good must also become part of the trading system.

14. It is important to systematically recognize and respect the obligations of policy makers to promote access to medicines for all, not only via transfers of incomes from donors in high income countries to consumers in low income countries, but through the more sustainable approach of lower prices. By de-linking R&D costs and incentives from product prices, access and innovation are no longer competing objectives requiring trade-offs.
15. The de-linkage approach can accommodate a variety of funding and spending mechanisms, so long as they do not require high prices to drive R&D investments. A balanced R&D program will include both “push” and “pull” funding mechanisms.
16. The *push* funding of course includes research grants similar to those now provided by government affiliated institutions such as the United States' National Institutes of Health (NIH), the European Union Framework Program for Research and Technological Development, the India Science and Engineering Research Council (SERC), and private donors such as the Bill and Melinda Gates Foundation (BMGF) or the Wellcome Trust. By including such grants in the larger trade framework, there would be broader support for funding the type of things best supported through grants, including much of the basic science and pre-commercial product development that is so important for innovation.
17. **Innovation Inducement Prizes**
18. In a de-linkage approach, the mechanisms for pull funding would be reformed. Advanced Market Commitments (AMCs) and patent monopolies would be replaced with large cash “innovation inducement prize” awards, implemented in a variety of ways, depending upon the context and the objectives of the entities funding the rewards.
19. Economists are perhaps more comfortable with the terms like “innovation inducement prizes,” than others, but even for economists, there is wide spread confusion as to how prizes can be implemented.
20. The popular understanding of prizes is shaped by the popular literature and news reporting around the

contests like the 18th century longitude prizes for navigation, or the various X-Prize rewards for novel technical innovation in such areas as personalized space travel. More recently, the medical profession has become aware of the use of prizes to address specific technical challenges by firms like InnoCentive. Both MSF and the Gates Foundation are examining possible ways to use prizes to develop new biomarkers for TB diagnostic devices. These type of prizes present challenges regarding good technical specifications of the prizes, and the rules and management tasks associated with choosing the winners. The most widely advertised benefits of such prizes are to crowd source innovation, and bring in a more diverse and entrepreneurial set of researchers to address research questions.

21. The more important and controversial proposals for prizes are those to replace product monopolies as the inducement to develop new products. For large end product prizes, there are of course, a plethora of possible methods of designing the prizes rewards. Beginning in 2002, James Love and Tim Hubbard began work on new approaches to medical innovation prizes. The Love and Hubbard approach was to create a large prize fund that would potentially reward several successful developers of new products. There would be a fairly low threshold to qualify for a prize, but the several “winners” would then compete against each other for shares of the overall prize fund resources. In this design, the amount of money that any contestant won would be determined by this competition, eliminating or reducing the need for the administrators of the prize fund to anticipate the optimal size of a particular prize reward. The advantages of this approach were many, elaborated in some detail in the paper: “The Big Idea: Prizes to Stimulate R&D for New Medicines.”⁴ Several proposals for large medical prize funds now follow this approach, including the U.S. Medical Innovation Prize Fund, the Bangladesh, Bolivia, Barbados and Suriname donor, Chagas, and priority medicines prize fund proposals, the Bangladesh Bolivia and Suriname cancer prize,⁵ the Hollis/Pogge Health Impact Fund, and the proposal for a European cancer prize fund.
22. Among proponents of innovation prizes, there are large differences regarding the treatment of intellectual property rights. Generally, KEI and many public health groups and some political leaders prefer to present prizes as an alternative to a patent monopoly – through either voluntary (the Donor, Chagas, Priority medicines prize fund, the end product TB diagnostic prize and some InnoCentive prizes) or non-voluntary licensing of patents (the US medical innovation prize fund or the various cancer prize funds). Others propose that the prizes be

4 *Chicago-Kent Law Review*, Volume 82, Number 3 (2007).

5 The TB Diagnostics prize fund proposal is a different design, for a discrete technology.

complementary and allow the winner to maintain a patent monopoly (Health Impact Fund, X-Prize Foundation and *some* InnoCentive prizes), subject possibly to requirements for concessionary pricing (Health Impact Fund).

23. Decisions about licensing of patents are influenced by judgments about bargaining power, legal options, and ideology and the disposition to help or undermine the development of low cost generic suppliers.

24. The Health Impact Fund, in a manner similar to Advanced Marketing Commitment (AMC) models, has proposed that a prize fund type mechanism be implemented without open licenses of patents, effectively creating an anti-competitive subsidy for suppliers that will predictably undermine generic competition. Given the challenges of finding generic suppliers of essential medicines in a post TRIPS world, this is a major difference among the various proposals.

25. Open Source Dividends

26. The large end product innovation prizes do not by themselves address the tendency of pull incentives to use restrictive licensing or trade secrets, with consequent disincentives to share knowledge, materials and technologies

27. In 2008, several de-linkage prize fund proposals were designed to include new “Incentives for Collaboration and Access to Knowledge.” The basic idea was to share part of the final end product prize with persons or firms that were “unaffiliated and uncompensated by the winning entrant,” and that “openly published and shared research, data materials and technology.” Sometimes referred to as the “open source dividend,” the money would be allowed on the basis the usefulness of external contributions in achieving the end result. This would include research, data, materials and technology that were either placed in the public domain, or subject to open, non-remunerated licenses. One possible mechanism for allocating the open source dividend would be through a jury system.

28. An additional area of research regarding funding of knowledge as a public good through a system of competitive intermediaries, each competing against each other for resources that particular entities, such as

employer or insurance companies, would be required to make available.

Annotated References will be made available.