What is wrong with the current system for funding R&D? What are the most important ideas for change?
(In two pages, prepared for OSF meeting on drug development)

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1. What is wrong with the current system for funding R&D?

The current system for funding R&D is so complex it is a challenge to describe its flaws in few words. At present there are a diverse set of funding mechanisms, including research grants and contracts from governments and charities, tax credits and other subsidies, and a variety of incentive mechanisms to induce private sector investments. The incentives include the grant of patents on new inventions plus a growing set of *sui generis* intellectual property rights and regulatory policies designed to create, broaden and/or extend the term of legal monopolies. The *sui generis rights* include exclusive rights associated with test data, paediatric testing market exclusivity extensions, orphan drug exclusivity, patent extensions for regulatory delays, and the new similar sets of exclusive rights associated with the 21st Century Cures and Dormant Therapy legislation.

The problem with the current system of **research grants and contracts** is that (a) the amount of funding is inadequate, (b) the amount of funding for certain medically important areas is particularly neglected, (c) the intellectual property rights associated with the public sector funding often vest with the researchers (rather than the funders) and end up being licensed as a monopoly to a company that prices products unreasonably (in several dimensions), (d) there is a lack of transparency over research outcomes and issues such as the costs of conducting clinical trials from publicly funding research, (e) inadequate funding of transitional and late stage research and development, (f) inadquate competition in the management of grants and contracts, and (g) there are no global mechanisms to address the free riding issue, resulting in underfunding.

Tax Credits are problematic because (a) there is no transparency regarding how much is claimed for tax credits for specific drugs or taxpayers, (b) tax credits often (i.e. US R&D or Orphan Drug Tax Credit) do not result in public interest obligations of the recipient of the subsidy (unlike grants), and (c) there is no global mechanism to share the cost of the tax credits.

The problem with the **patent system** is that (a) there is often little relationship between patentability criteria and the costs and risks of drug development, (b) the monopoly leads to excessive prices, (c) the amount of money invested in R&D is only a small fraction of the increased prices[1], (d) patents do not reward many socially important R&D activities, including in particular those that expand access to knowledge, (e) patents sometimes discourage investments by companies, some potential rivals, that cannot obtain affordable patents licenses, or where transaction costs of licensing are high, (f) there is inadequate transparency of patent landscapes and insight into which products the patents are relevant to, (g) the grant of a monopoly is not a useful incentive for inventions that address the needs of poor people living in poor countries, (h) it is very costly to resolve disputes over the standards for granting patents or determining if patents have been infringed, and the (i) the exclusive marketing rights induce excessive investment into products that merely match outcomes, and wasteful spending on marketing.

The problems with **test data** include many of those associated with the patent system, but also include conflicts of medical ethics, by inducing/requiring companies to replicate clinical tests on humans when results are known, and because in many legal systems there are **no exceptions** to the rights, unlike patents. For other sui generis rights, such as **orphan drug or paediatric exclusivity**, many of the problems of the patent system are also present, including excessive pricing, and there is no relationship between the amount of money for R&D the *sui generis* system induce, and the costs to consumer, and often the costs are not shared globally.

[1] See discussion in James Love, "Talking Drug Prices, Pt 4 Drug pricing is out of control, what should be done?", *PLOS Blogs*. October 19, 2015. http://blogs.plos.org/yoursay/2015/10/19/talking-drug-prices-pt-4-drug-pricing-is-out-of-control-what-should-be-done-by-james-love/

2. What is a better R&D funding system?

There are several areas where the global system for funding R&D needs to be improved. The current system of trade agreement obligations designed to expand intellectual property rights, and more generally promote higher prices, could be replaced with global agreements that focus on R&D funding, and which provide more flexibility on how to supply that funding. The 2002-2005 proposals for a large R&D treaty were about eliminating IPR obligations if a country could satisfy a different standard for R&D funding, using the TRIPS as a fallback mechanism only if a country failed to fund a sufficient amount of R&D through other means. There are also other approaches that can be explored, including the proposal for a WTO agreement on the supply of public goods, or including R&D funding in new agreements negotiated within the WHO or in various regional or bilateral negotiations, including the TTIP. The challenge for such international agreements is finding the best starting points and mixes of R&D targets that appeal to the countries that are currently most focused on the IPR agreements. In the present environment, this mix should include projects of more universal interest, for example, expanding the funding basis for projects like the UK's 100,000 Genomes Project, R&D for new antibiotic drugs, Ebola treatments and vaccines, or very large inducement prizes for new low cost and efficient point-of-care diagnostics.

The tax credit system should be reformed by requiring transparency of the amount of the credit earned (something done for tax credits in other areas[2]), attaching Bayh-Dole-like public interest provisions to the credit, and creating mechanisms to globalize the costs of the tax expenditures. This is actually potentially quite an important way to address the issue of funding clinical trials, without high drug prices. Tax credits for orphan products, now only provided by the United States, cover 50 percent of the costs of qualifying trials, and were available to 8 of 9 new cancer drugs approved in 2014.

The most important reform in funding R&D will be to de-link the incentives from high drug prices, through innovation inducement prizes. The first serious proposal on how this might be done was the 2005 Sanders Medical Innovation Prize Fund bill, which has been revised and improved, most recently in 2013 as S.627 (113th Congress) and S. 626 (113th): Prize Fund for HIV/AIDS Act. By delinking R&D incentives from prices, prescribing decisions become more rational and access is more fair. With delinkage, incentives can target important goals such as products that improve rather than match outcomes and address research priorities from a health perspective. Delinkage with evidence based rewards can reduce wasteful marketing spending, and IPR systems can be reformed without putting at risk R&D funding.

Prizes should be implemented in a three-part system: end product prizes, interim results prizes and open source dividends. Each has its own role to play, the most controversial but most important being the end product prize, which can be a replacement for the monopoly granted by patents and other IPR. The open source dividend would also be revolutionary. The least controversial and least transformative are the interim results prizes, including so called milestone prizes.

Without full delinkage, some of the benefits can be obtained through a pricing system that explicitly considers three factors: (1) the benefits of the product, (2) the risk adjusted costs of R&D and (3) the budget constraints of the health system. Any pricing system that does not consider (3) will lead to the rationing of access to medicines, and any system that addresses either (1) or (2) but not both is sub-optimal. In general, policy makers should seek rewards that maximize innovation benefits, without breaching budget constraints or inducing rationing of access (all of this easier with full delinkage).

Interim results innovation inducement prizes and grants for open source medical research can, and in some cases should, be managed through more decentralized systems, including the competitive intermediaries described in the more recent Sanders innovation inducement prize fund bills.

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[2] 2014. James Love, Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models, World Intellectual Property Organization, CDIP/14/INF/12, September 19.