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Assessing Public Contributions to Drug Development: A Novel Framework

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Based on Darrow & Light, "*Beyond High Prices of Prescription Drugs: A Framework to Assess Costs, Resource Allocation, and Public Funding that Provides a Comprehensive Framework for Legislators and Scholars to Access the Total Costs of Prescription Drugs*,"
Health Affairs 2021 40 (2): 281-288.

Introduction:

- Not a physician, nor a medical researcher, but a medical & economic sociologist who tries to make sense of health care systems and health care policy.
- There's a lot I don't know, and I'll try my best to be informative. This talk reflects my personal interpretation, based on more than 25 years of research & experience.
- See my Bio-Profile in the Webinar materials

I. The larger context for Assessing Public Contributions

A. The national perspective on preventing & treating illness for resident population

1. – A public or non-profit responsibility? Or private?

2. – Public & voluntary organizations, institutions, providers? Or private, corporate, investor-owned?

3. Based on universal, often public, funding?

4. Eg in the USA: a non-system of various institutions for funding and providing, based on contrasting values & ethics. Since the 1960s, increasing dominance of for-profit corporations in all sectors and subsectors.
(See Starr, my history, and *Dead on Arrival*)

I. B. Second, The national perspective on the development of Medicines (or prescription drugs)

1. How dif are drugs or meds from medical care, hospitals, or clinics? Very dif? How do the public, private & corporate contributions to research & "innovation", development, testing & trialing differ for medicines compared to other major aspects of medicine?

2. Need a 50-100 yr perspective on current inst & laws.

a) I'm an historical, comparative sociologist

3. Need to study *roles of countervailing powers*

4. Key for drugs is which parties pay for how much of the costs of risk - - very high costs of failures in discovery, modest costs of failure in development, declining costs & risk of failure in clin trials. How much is borne by and paid by which parties?

5. How much of what kinds of risks are borne by for-profit companies – Big Pharma as well as Little Pharma?

I. C. Third, what is the National & historical perspective on patents?

1. Pharma patents are the privatization of public goods (that otherwise would be available to all), in order to create pri mkts at high prices. Called "intellectual property" only there is not property in the usual sense of that word. It's "intellectual rights" on a public good (knowledge).

2. Historically, have been major changes regarding patents. For the first half or more of the 20th century, patents on meds were prohibited in many European countries, because they were regarded as *public health goods*, not private goods.

3. Now, massive, global efforts by Big and Little Pharma to privatize scientific knowledge discovered & developed in publicly funded labs (a pure public good) into patents to make them privatized medical goods and sell them at patent-protected monopoly prices.

4. Patenting now drives much pharma research and has become a primary end in itself – to develop variations of existing drugs with minor clinical advantages that can be patented and promoted as "new" or "better" at monopoly prices.

(See Light & Lexchin 2012 BMJ: "Pharma R&D: What do we get for all that money?" and other articles by us, like our 2021 "lemons" article in SS&M.

5. Research for what are commonly called "orphan drugs", to help patients with rare diseases, has become a rising and dominant development, heavily subsidized by taxpayers, as patent-driven meds, often with little evidence of clinical benefit but with publicly funded monopoly prices and large profits. Companies love the public subsidies for so-called orphan drugs. They are happy to be their Daddy Warbucks.

II. **Net** R&D Costs: Public Direct & Indirect Funding

A. The Health Affairs article, led by Jonathan Darrow at Harvard, and me, began by gathering as much information as we could on taxpayer funding of corporate R&D expenditures, as well as **direct funding of research** in the US for the NIH (National Institutes of Health), a FDA (Food & Drug Administration) program for orphan drug research, drug research in some states, and drug research by some foundations and charitable institutes (which also benefit from indirect funding through tax breaks)

1. This study and framework is based on the United States, which is atypical but illustrative of how officials and policy researchers in other countries might investigate analogous funding in their respective countries.

B. **Indirect public funding of corporate R&D**, which means taxpayers bear their portion of the risks of failures, includes a longer, growing list of public contributions by taxpayers:

– tax deductions for research by foundations and charitable institutions;

– tax-based subsidies for graduate training for nearly all researchers;

– full same-year deductions ("expensing") for research costs (which companies rightly regard as a long-term capital investment);

– a 20% research tax credit;

– a 25% research tax credit on rare diseases;

– a waiver of the FDA application fee on orphan drug applications; ($2.88 million in 2021)

– Various state and local tax incentives to encourage companies to do pharmaceutical research

1. The main point is that *neither Congress nor state legislatures have tracked how much most of these authorizations have cost taxpayers, or how much they have saved drug companies* so that prices could be aligned with net costs.
2. The accountants of given companies must know; but no one else knows.
3. The self-reported gross expenditures for R&D by companies reported to their US trade association was $91 billion in 2020; but how much was paid for by taxpayers? What is the NET cost of corporate R&D? Half that amount?
4. A fair pricing of medicines and vaccines should be based on net costs plus a mark-up for profit.

   VS "value-based pricing." A policy trap one cannot get out of. (Discuss)

III. Public Provisions that increase drug revenues, which the public pays for anyway.

This is the most novel part of our framework, led by Jonathan Darrow, for assessing public funding for R&D.

A. Statutory "Pull" Incentives that increase revenues more than in regular competitive markets, like markets for post-patent generic drugs. Companies emphasize that these "pull" incentives are a critical source for corporate R&D budgets:

1. Exclusions of competitors to enable patent-protected higher prices, largely paid by taxpayers through insurance premiums and cash co-payments:

– *the patent system*. 13.6 years of protection from competitors and monopoly pricing on average.

(In the US, no limits on what companies can charge, versus other countries. Eg the German AMNOG drug pricing law and the Institute for Quality and Efficiency in Health Care (IGWiG) assess independently the added clinical benefits or harms of new drugs compared to existing drugs that treat the same disease so that prices based on added net clinical value.)
– additional 7 years of exclusivity in the 1980 Orphan Drug Act;
– additional 3-5 yr patent exclusivity periods in the 1984 Hatch-Waxman Act;
– 6 month additional patent extension to reward companies to do studies on pediatric patients;
– an additional 5-yr patent exclusivity for "qualified infectious disease products";
– a 12-yr patent exclusivity period for biological drugs;
– a priority review voucher for research on selected diseases that can be sold to another company for an unrelated drug, to shorten review time so that it can charge patent-protected prices sooner, largely to taxpayers;

C. Finally, a Non-statutory "Pull" mechanism: Insurance (Private, US)

1. Drug insurance pays for more than 86% of all drug expenditures. Cushions or protects patients from the impact of higher prices.

2. The layering of drug insurance over patent rights and extensions "has led to dramatic price increases in the U.S."

IV. Discussion

A. Governments "must have an accounting" of all revenues and all direct and indirect, "push" and "pull" mechanisms that increase the total costs of drugs for the public and decrease the R&D costs for drug companies.
   1. Require companies to develop an accounting system.
   2. Commission detailed studies of selected medicines by an independent organization.
   3. This framework provides a more comprehensive, realistic account of public, taxpayer contributions to corporate drug research.

B. Finally, a case in point are the estimated net costs to companies for research, development, clinical trials, approval, and manufacturing of COVID-19 vaccines published by Joel Lexchin and me last month in the *Journal of the Royal Society of Medicine*. (See https://www.rsm.ac.uk/media-releases/2021/covid-19-governments-must-stop-vaccine-cost-secrecy

   1. Because public direct and indirect subsidies for these public health goods have been so extensive, including capital costs, we and others estimate the net corporate costs based on a vol of 100 million doses a yr range from $0.54 to $0.98 a dose. Other detailed studies, which take into account only some taxpayer subsidies, estimate costs of about $1.18 - $2.85 a dose. Therefore, fair prices that include a 20% mark-up for profits could be much lower than the current "pandemic-discounted" prices that governments are agreeing to pay.

      For example, Kis and his team in London estimated the net cost of Pfizer's mRNA COVID vaccine is $1.18 a dose. Adding 20% profit results in a price of $1.42, a price that most of the countries where the pandemic still take a heavy human & economic toll could afford to vaccinate their populations. In my opinion, governments as buyers need to insist on transparent, verifiable

evidence that net costs are higher and then contract for large volume on this basis.

Thank you for your interest, and I look forward to your discussion.