The Genetics Revolution Challenge and How to Incentivize Biomedical Research

By Arnold Kling
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The genetics revolution poses challenges to the way that the FDA and patent system influence medical research. Prize- sort of research becoming valuable.

One-size-fits-all blockbuster drugs are giving way to treatments tailored to individuals' genetic makeups and aim

> "It's a new world," said Wendy Selig, president of the Melanoma Research Alliance, the largest private f expected to kill nearly 10,000 Americans. "We're segmenting what we thought of as large diseases into s distinctions. ... The goal is to match the right therapy to the right patient, and to do it with minimal collate
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> — "Drugmakers Find Breakthroughs in Medicine Tailored to Individuals' Genetic Makeups," Washingto

Indeed, medical research has entered a new world, created by the genomics revolution. However, as Peter Huber protecting property rights has not kept up.[1] Drug developers can now use genetic information to identify individ makes standard testing protocols, which call for broad-based, blind trials, inappropriate. It also blurs the distincti

As Huber and others have noted, we need to do a better job of aligning the institutions that surround biomedical take going forward, as we seek diagnostic tools and treatments based on genetic information and biochemistry. W prize, which could be awarded to either for-profit or nonprofit entities.

The prize-grant would be a contract between a research organization and a funding institution, which typically w also could use this approach. The research organization would propose a study to test for a particular result. This a demonstration that a new diagnostic tool is more accurate than existing methods, or a population-specific treatm

The contract would specify the amount that the research organization will receive if the study produces a positive research organization receives nothing. Either way, the results of the study are placed in the public domain.

The contract would also specify a method for third-party verification of the result. The cost of verification would the research team, although the third party would be chosen by the funding institution.

A research organization would have to decide whether to proceed with a project, based on its view of the likeliho

funding institution is willing to assign to a successful result. The researchers and their backers, whether a drug co
make the decision whether to accept the contract and undertake the costs of the research.

The prize-grant contract would differ from a plain research grant in the following ways:

—Profit-seeking companies would be just as eligible as nonprofit research institutes to receive prize-grants. The

—The burden of assessing the probability of success would fall on the research organization, not on the funding
betting on its success.

—Those doing the research would have the incentive to use funds wisely and for their intended purpose. The cos
organization, not by the funding institution.

—The funding institution would have to screen applications to ensure that the research will be conducted safely
the researchers based on their scientific credentials and beliefs nor assess the probability of success. A team head
could obtain a contract, risking the team's resources that the oddball's idea will pan out.

—The funding institution would have to assign a value to a successful result before the research is undertaken, s
be the most administratively difficult part of the process, and each research organization would have to submit a

The prize-grant would differ from an ordinary prize in the following ways:

—The criteria for winning the prize would typically be first suggested by the researchers, with funding institutio

—Prizes often would be for incremental achievements, not just for spectacular accomplishments.

—Large pharmaceutical companies and other private firms would be just as eligible as nonprofit researchers to r

We can think of the current intellectual-property regime in medical research as a grant-prize approach in which t
patents in the following ways:

—The prize for a successful result is specified by the funding institution. With a patent, the value of the prize is
purchasing rules of insurance companies and governments, by legal jousting, and by gaming of the system.

—Useful research that does not result in a patentable product gets rewarded under prize-grants, whereas under th

—Regardless of the outcome of the research undertaken in pursuit of a prize-grant, findings would be immediate
term of monopoly on the use of information, during which the prices of patented products can be set far above pr

Governments, foundations, and individuals ought to experiment with prize-grants as a tool to promote medical re

One way to understand the prize-grant approach is to recognize that pharmaceutical research conducted by priva
stock of knowledge. If there were no public-goods aspect to pharmaceutical research, then we would not need pa
raises the prices of many pharmaceuticals, often by large amounts. If there were no patents, then the prices of dru
much lower than the prices charged for patented drugs. On the other hand, without patents, private firms would n

Patents have always been a problematic way to promote innovation. They raise prices of products far above marg
attacking, and defending patents. They provide an artificially high incentive to develop substitute products that d
disincentive to develop complementary products, because the high price of the patented product limits its market
complements.

The value of a patent need not correspond to its social value. Some patented products may have been preceded b
by the patent-granted firm on painstaking trial-and-error research. Other patented products might be based on ne

In pharmaceuticals, the challenges with using the patent system are increasing. As Huber has pointed out, the nat
rigid, blind clinical trials needs to be replaced by a regime of focused trials in which researchers learn and adapt
producing a brand new molecule that cures a disease and thereby justifies a patent. It may instead focus on deter
class of patients. A prize-grant would reward this sort of targeted research in a way that a patent cannot.

This modern approach to drug development combines biochemisty and genetics. It tends to blur the distinction b
that basic research looked at the biochemical mechanism of disease and applied research then tested cures (or so
basic research then tried to understand the mechanism of the cure). With personalized medicine, the process of te
biochemical mechanism of disease. The human trials that used to be considered applied research are now vital in

In conclusion, the genetics revolution poses challenges to the way that the FDA and the patent system influence
providing incentives for the sort of research that is now becoming valuable.

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