The Medical Innovation Prize Fund

S.2210, 110th U.S. Congress

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UNU-MERIT and KEI Workshop on Medical innovation prizes as a mechanism to promote innovation and access

Maastricht, the Netherlands
January 28, 2008

Motivation for the Prize Fund Approach

- The United States is the largest market for pharmaceuticals
- The current system of incentives to stimulate research and development for new medicines involves the granting of marketing monopolies.
- Monopolies lead to high prescription drug prices.
- High prices in turn create hardships on patients, employers, and taxpayers who pay for medicines, and lead to increasing restrictions on access to medicines, through the limited availability of high-priced medicines by health insurance plans.

Marketing monopolies create inefficiencies

- Companies have incentives to invest enormous sums in the marketing of products, and in the development of medicines that do not offer significant incremental medicinal benefits over existing products.
- According to the U.S. Food and Drug Administration, of the 1,284 new drug approvals from 1990 to 2004, only 289, or 22.5 percent, were for `priority' reviews (defined as a product that has `significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease'). Of these, only 183 (14.3 percent of the total) were new molecular entities classified as priority products.

Incentives based upon marketing monopolies don't address many public health priorities

- There are important gaps in treatments for many severe illnesses.
- There is too little R&D into diseases that primarily concern poor people living in poor countries. This results in immense suffering and death, undermines development, shrinks potential markets, and has long-term negative effects for United States security.
- Emerging diseases, viral mutations, and food-borne disease transmitted through international trade have negative effects on Americans and must be combated before they arrive on the Nation's shores.

In theory, prizes offer many advantages over monopolies

- By using prizes, it is possible to de-couple rewards for successful R&D from the price of the product.
- Incentives can be targeted at products that improve health care outcomes, and can stimulate research and development in the areas of greatest need.
- By eliminating legal monopolies on medicines, entry by generic manufacturers will lower prices for prescription drugs, eliminating the need for price-sensitive formularies, and reduce other barriers to access to new medicines.

S.2210: the Medical Innovation Prize Fund

- How it works
- The political strategy

S.2210 would create a fund for mega-prizes, to reward new drug development

- The current draft of the bill sets the annual level of funding at .7 percent of US GDP, which in 2008 is about USD $80 billion.
- The $80 billion per year in prizes is given to developers of new drugs that receive FDA approval.
- In a given year, the size of the prize fund is fixed, and the total amount of prizes awarded does not depend upon variables such as drug uses, new drug approvals, or other factors.
- The fixed size of the fund has two big advantages:
  - The budget for funding is known in advance
  - The party paying for innovation has no economic incentive to discourage access to new medicines, as increased utilization does not increase the (fixed) prize fund obligations

There is a zero sum competition for shares of the Prize Fund (which is fixed in size)

- Every drug developer wins something
  - But some win more than others.
- Prizes are based upon a variety of factors
  - The most important of which is the impact of the invention on health care outcomes
  - Impacts are measured against existing therapeutic alternatives

(c) Criteria- The Board shall, by regulation, establish criteria for the selection of recipients, and for determining the amount, of prize payments under this section. Such criteria shall include consideration of the following:

(1) The number of patients who would benefit from the drug, biological product, or manufacturing process involved, including (in cases of global neglected diseases, global infectious diseases, and other global public health priorities) the number of non-United States patients.

(2) The **incremental therapeutic benefit** of the drug, biological product, or manufacturing process involved **as compared to existing** drugs, biological products, and manufacturing processes available to treat the same disease or condition, except that the Board shall provide for cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, so that the comparison is to products that were not recently developed.

(3) The degree to which the drug, biological product, or manufacturing process involved addresses **priority health care needs**, including--

(A) current and emerging global infectious diseases;

(B) severe illnesses with small client populations (such as indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)); and

(C) neglected diseases that primarily afflict the poor in developing countries.

(4) Improved efficiency of manufacturing processes for drugs or biological processes.

A 10-year period is used to evaluate benefits from a drug

- Once a year, every year, prizes are awarded.
- Every new product (or process) is evaluated 10 times.
- In any given year, all products developed over past 10 years compete against each other for payments from fund.

Caps

- No more than 5 percent of the fund can be paid to any one product in a given year
  - About $4 billion for one year, or *more than* $40 billion over 10 years *(plus the growth in GDP).*

Three initial Set-Asides

(1) 4 percent ($3.2 billion) of such amount for global neglected diseases;

(2) 10 percent ($8 billion) of such amount for orphan indications; and

(3) 4 percent ($3.2 billion) of such amount for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.

Follow-on Innovation

Section 9, (d) (1)

In cases where a new drug, biological product, or manufacturing process offers an improvement over an existing drug, biological product, or manufacturing process and the new drug, biological product, or manufacturing process competes with or replaces the existing drug, biological product, or manufacturing process, the Board shall continue to make prize payments for the existing drug, biological product, or manufacturing process to the degree that the new drug, biological product, or manufacturing process was based on or benefited from the development of the existing drug, biological product, or manufacturing process.

Benefits of the Prize Fund

- In the US, **Prices** for medicine would fall dramatically.
  - Today manufacturers prices for generics are only 15 percent of prices for brand name products.
  - Over time, savings would be greater as trademark effects disappear, and medicines become true commodities.
- Price sensitive formularies would disappear
- R&D would be focused on products that improve health care outcomes.
- Set-asides would enhance R&D in areas of healthcare priorities.
- U.S. trade policy would no longer promote high drug prices.
  - *Focusing instead on medical R&D treaties*

Strategy

- Education
  - Present the Prize Fund approach to groups that would benefit from the paradigm change
    - For people who pay for drugs, discuss cost savings
      - Consumers
      - Labor Unions
      - Governors
      - Employers
    - For Patients,
      - Discuss the advantages of the Prize Mechanism in more effectively targeting R&D investments

Strategy

- Seek hearing in Senate HELP committee
- Gain endorsements of key constituencies
- Create social movement to end monopolies for new medicines