

# The Medical Innovation Prize Fund

## A New Paradigm for Supporting Sustainable Innovation and Access to New Drugs: De-Linking Markets for Products from Markets for Innovation

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### Table of Contents

|                                                                    |   |
|--------------------------------------------------------------------|---|
| Overview of the Medical Innovation Prize Fund.....                 | 1 |
| Introduction .....                                                 | 1 |
| The Medical Innovation Prize Fund.....                             | 2 |
| Board of Trustees.....                                             | 2 |
| End Product Prizes.....                                            | 3 |
| Allocation of Funds to Prior Research.....                         | 4 |
| Open Source Dividend.....                                          | 4 |
| Competitive Intermediaries.....                                    | 4 |
| Appendix 1: Economics.....                                         | 5 |
| Valuation Term.....                                                | 6 |
| Priority Research.....                                             | 7 |
| Follow-on Innovation.....                                          | 7 |
| Open Source Dividend.....                                          | 7 |
| Competitive Intermediates for Open Source and Interim Rewards..... | 7 |
| Appendix 2: International Legal Issues.....                        | 8 |
| Article 30.....                                                    | 8 |
| Article 31.....                                                    | 9 |
| Article 44.2.....                                                  | 9 |

## Overview of the Medical Innovation Prize Fund

### Introduction

The Medical Innovation Prize Fund (S. 1137, 112<sup>th</sup> Congress) is a proposal to change the system of rewards to induce R&D investments.

One fundamental element is to separate the markets for products from the markets for innovation. The proposed legislation would eliminate patent and other intellectual property barriers to the introduction of generic medicines. Replacing product monopolies would be a new Medical Innovation Prize Fund, that would provide more than \$80 billion in annual rewards for useful investments in R&D for new medicines and vaccines.

Patents would still be available for medicine related inventions, and valuable in making claims against the Prize Fund, but they would not be used to block generic competition. Research placed in the public domain would also be eligible to receive rewards from the Prize Fund.

By **de-linking** R&D incentives from product prices, it is possible to price drugs at marginal costs, eliminating price sensitive drug formularies and expanding access to new drugs. De-linkage also makes it possible to reward a wider range of activities. The Medical Innovation Prize Fund system includes an **open source dividend** and a system of **competitive intermediaries** to reward interim research and development activities.

The reforms in the Medical Innovation Prize Fund are designed to (1) lower the overall costs of outlays on medicines, (2) focus innovation investments on the most useful and important products, (3) stimulate greater openness and sharing of information and materials, (4) increase the rate of innovation, and (5) expand access to new products.

## **The Medical Innovation Prize Fund**

The bill creating the Medical Innovation Prize Fund seeks to reconcile the dual objectives of supporting innovation and access to new medicines. It does so by radically changing the mechanisms to reward investments in R&D.

The legislation eliminates all legal monopolies on the sale of qualifying products for FDA approved drugs and vaccines, making it possible to buy inexpensive generic versions from competitive suppliers. Competition is expected to lower the cost of drugs by more than \$250 billion per year for the U.S. domestic market, with the saving shared by health insurers, employers and patients.

The rewards for innovation would be provided by the new Medical Innovation Prize Fund that would be funded at 0.55 percent of the gross domestic product of the United States, an amount equal to more than \$80 billion per year at current levels of GDP.

All federal and non-federal health reimbursement and insurance programs would contribute to the Prize Fund. The \$250 billion or more savings on drugs would more than off-set the \$80 billion cost of the prize fund.

### **Board of Trustees**

The Medical Innovation Prize Fund would be managed by a 13 member Board of Trustees, including heads of four federal agencies and nine persons appointed by the President:

- Administrator of the Centers for Medicare & Medicaid Services
- Commissioner of Food and Drugs
- Director of the National Institutes of Health
- Director of the Centers for Disease Control and Prevention
- Two representatives of businesses that provide health insurance to employees
- Two representatives of entities that provide health insurance
- Two representatives of the medical research and development sector, including at least one representative of the nonprofit private medical research and development sector
- Three representatives of consumer and patient interests, including at least one representative of patients suffering from orphan diseases

There would also be six expert advisory boards, on the following topics:

- Economic evaluation of therapeutic benefits
- Business models and incentive structures for innovation
- Research and development priorities
- Orphan diseases
- Financial control and auditing
- Open source biomedical science

The \$80 billion per year in innovation prizes would be allocated through the following programs:

### **End Product Prizes**

Some of the prize money would be allocated to the first person registering a new drug or biologic product, or developing a new manufacturing process for such product.

The persons entitled to these prizes would be, for a drug or biological product, the first person to receive FDA marketing approval, and for a manufacturing process, the holder of the patent with respect to such process. Suppliers of innovations would compete against each other for shares of the prize fund money. In considering the claims, the administrators of the Prize Fund would consider<sup>1</sup>:

- (1) The number of patients who would benefit from the drug, biological product, or manufacturing process involved.
- (2) For antibiotics and other products for which drug resistance is a significant public health problem, the expected life cycle benefits of the products, taking into consideration appropriate adjustments in the valuation methodology to reward measures conserving resources from resistance.
- (3) For products used in stockpiles for potential threats to public health, the risk adjusted benefits of the stockpiled products.
- (4) 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. For cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, the comparison is to products that were not recently developed.
- (5) 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); and

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<sup>1</sup> Other factors may also be considered by the Board.

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

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

(7) The extent to which knowledge, data, materials and technology that are openly shared have contributed to the successful development of new products or improved processes for manufacturing products.

### **Allocation of Funds to Prior Research**

The Prize Fund Board is tasked with establishing minimum budget categories for priority research. Initially, these will be:

- (1) 4 percent for global neglected diseases;
- (2) 10 percent for orphan drugs; and
- (3) 4 percent for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.

### **Open Source Dividend**

In order to induce greater access and the open sharing of knowledge, data, materials and technology, at least five percent of the prize payments will be dedicated to Open Source Dividend Prizes. At current levels of GDP, this would be at least \$4 billion per year.

The open source dividend prizes would reward the open, non-discriminatory and royalty free sharing of knowledge, data, materials and technology that has contributed to the development of the new medicines or improved manufacturing efficiencies that qualified for the end product prizes. In this part of the competition, the Prize Fund would consider:

“the extent to which knowledge, data, materials and technology that are openly shared have contributed to the successful development of new products or improved processes for manufacturing products.”

### **Competitive Intermediaries**

The Medical Innovation Prize Fund Director would have the authority to authorize multiple non-profit intermediaries to manage prize fund payments that reward projects for **interim** research and development of new medicines, or for **open source** dividend prizes. Such intermediaries would compete for funding from non-federal entities that co-fund the Medical Innovation Prize Fund.

These competitive entities would provide prizes to persons or communities that achieved useful R&D outcomes of an interim nature, falling short of a final product, but which are considered valuable in the development of products. Examples of interim research and development projects would be the identification of biological markers, successful completion of early clinical trials, the creation of databases or libraries or other research

tools.

Because it is more controversial to value such achievements, the strategy in the bill is to create a competitive process that legitimatizes the choices of the entities making the decisions about the prizes.

The interim prizes require open, non-discriminatory and royalty free licenses to relevant intellectual property rights.

## **Appendix 1: Economics**

The incentives from the existing systems are based upon a complex system of exclusive rights, including those associated with patented inventions, exclusive rights to rely on regulatory test data, and marketing exclusivity relating to pediatric testing or the approval of products, and new indications involving less than 200,000 patients. Collectively, all of these government granted privileges are designed to create profitable monopolies on final products. There are several practical problems with this approach, including:

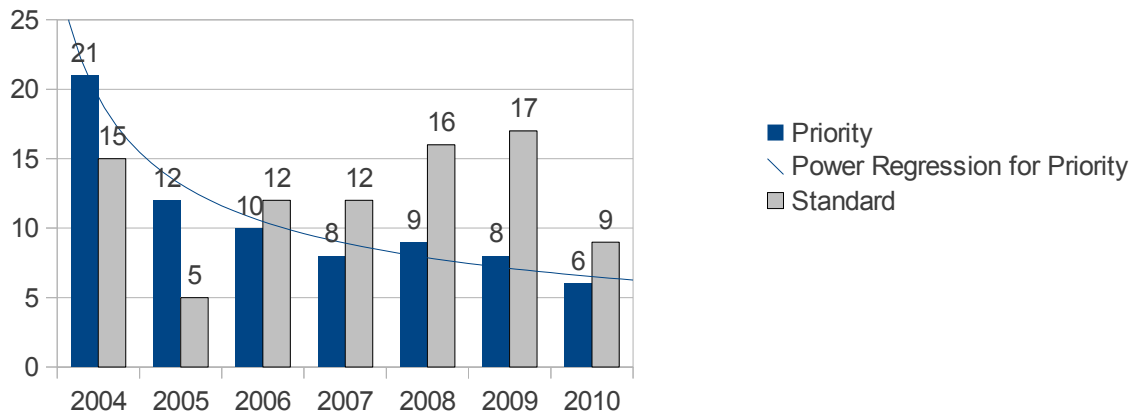
1. Monopolies lead to high prices.
2. When the reward is a marketing monopoly and high prices, firms make inappropriate and wasteful investments in marketing.
3. Time limited marketing monopolies provide incentives to overuse new antibiotics, leading to unwanted drug resistance.
4. When patents protection is narrow, firms often develop very similar products, leading to socially wasteful investments in medically unimportant products, and potentially diminishing returns for the medically important breakthroughs they imitate.
5. Monopolies on commercially successful products do not induce openness or sharing of knowledge, data, materials and technologies, or important and useful interim research and development projects, such as the identification of biological markers, or the completion on early clinical trials that establish the feasibility of other better products.

The current system is expensive and wasteful. Intellectual property legal monopolies on new medicines increase prices by more than \$.5 trillion per year globally, while less than 9 percent of global sales are reported by the industry as invested in R&D.

Despite large increases in the granting of patents, new intellectual property trade agreements and treaties, and rapidly growing global revenues from the sale of patented medicines, the rate of productivity for new drugs has fallen, as illustrated by the declining number of new molecular entities approved by the FDA that are considered priority products.

## NME: Priority and Standard Approvals

2004 - 2010



*Illustration 1: FDA approvals of New Molecular Entities, 2004 to 2010*

The Medical Innovation Prize Fund addresses these and other problems by eliminating final product monopolies, and introducing a more flexible, targeted, inclusive and efficient set of incentives that reward the types of activity that society values the most.

By setting the overall size of the prize fund as a percentage of U.S. GDP, the overall cost of rewarding innovation is fixed, so that on the margin, innovation is priced at zero, leading to much more efficient and more equitable use of products.

The new incentive scheme focuses rewards on new products that improve health outcomes when benchmarked against existing treatments, reducing economic incentives and rewards on medically unimportant products or inappropriate or wasteful marketing.

While the Board has to “consider” the number of patients benefiting from a treatment, it may consider other factors also.

For products used in stockpiles for potential threats to public health, the Board will consider the risk adjusted benefits of the stockpiled products.

For antibiotics, appropriate adjustments will be made in the valuation methodology to reward conservation when drug resistance presents risks to public health.

Other factors and modifications may also be considered by the Board.

### **Valuation Term**

Products and processes are eligible to participate in the reward system for ten years. Rewards in any given year are based upon the evidence available at that time.

For antibiotics or other products for which drug resistance is a significant public health problem, the Board considers the expected life cycle benefits of the products, taking into consideration appropriate adjustments in the valuation methodology to reward measures to conserve resources from resistance.

### **Priority Research**

Society has demonstrated a willingness to pay higher prices for treatments that concern small client populations (orphan drugs), and to make investments in certain types of priority research. The Board will manage a system of set asides for such research priorities.

### **Follow-on Innovation**

Products that are developed at roughly the same time are not benchmarked against each other, but rather, against “products that were not recently developed.”

If a new product “offers an improvement” or “competes with or replaces” an existing product, the older product will continue to receive reward payments, to the degree that it can demonstrate the new product “was based on or benefitted from the development” of the existing product. This also applies to manufacturing processes.

### **Open Source Dividend**

Under the current system, the open sharing of knowledge, data, materials and technology is not rewarded, even though such sharing is highly valued by society. Many pre-competitive research and development activities are also not rewarded by a system that requires commercial success, even though the economic value of such research spillovers is high.

The Medical Innovation Prize Fund has the flexibility to allocate resources to reward such activities, and thus to enhance openness, collaboration, and the investments in a wider range of useful research projects.

The Medical Innovation Prize Fund sets aside “at least” 5 percent of the total rewards for an “open source dividend” program. The Board will adopt rules to administer these rewards. One approach is to appoint juries to evaluate “nominations for persons or communities whose contributions were considered useful” to the development of a new product.

### **Competitive Intermediates for Open Source and Interim Rewards**

The Board can also authorize certain non-profit intermediaries to manage open source dividend rewards, or rewards for interim research and development projects. These entities would compete against each other for resources that would be provided by the private sector entities that provide health care reimbursement insurance and co-fund the Prize Fund.

In essence, the system for competitive intermediaries would mandate private funding for something similar to venture capital funds, which would only be allowed to reward research projects that provide open, nondiscriminatory and royalty-free licenses to relevant intellectual property rights. The competing intermediaries would experiment with different methodologies and approaches to rewarding innovation, and justify their actions to the groups that choose the intermediaries that will manage their open source investments.

## Appendix 2: International Legal Issues

The Medical Innovation Prize Fund effectively eliminates the exclusive rights to make, use and sell covered products protected by patents. The legislation was drafted to be compliant with international legal norms, including the World Trade Organization agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS agreement).

Article 28 of the TRIPS agreement sets out the rights that normally are associated with a patent. However, these rights are subject to several areas of flexibility in the agreement.

In 2001, the WTO effectively expanded the flexibilities available for health care inventions, when it adopted the Doha Declaration on TRIPS and Public Health. Paragraph 4 of that declaration reads as follows:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The most important flexibilities in the TRIPS Agreement as regards the Medical Innovation Prize Fund are Articles 30, 31 and 44.

### Article 30

Article 30 of the TRIPS Agreement provides for a “three step test” for exceptions to patent rights.

#### Article 30 -Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.



The United States would argue that in light of the Doha Declaration on TRIPS and Public Health, it was appropriate to create a “limited” exception for patents on medicines and vaccines, that are reasonable as regards the “legitimate interests of the patent owner.” In arguing its case the United States would emphasize that the patent owners would participate in an \$80 billion per year reward system for medical innovation, and that the prize fund rewards were considerably larger than the rewards currently made to patent owners, in the U.S. Market.<sup>2</sup> The United States could also argue that the legislation was necessary “to promote access to medicines for all,” which is an obligation found in Paragraph 4 of the Doha Declaration on TRIPS and Public Health.

### **Article 31**

A second area of flexibility is Article 31 of the TRIPS Agreement, which provides for a set of rules under which non-voluntary use of patents can be authorized by a government or a court, in cases where “adequate remuneration” is available. The adequate remuneration standard is not difficult. More problematic are the following requirements:

#### **Article 31 Other Use Without Authorization of the Right Holder**

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

The TRIPS Agreement provides that the requirement for prior negotiation on reasonable commercial terms and conditions” in Article 31(b) “may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” The United States could argue that it was acquiring the patents for “public non-commercial use,” and that this use was to authorize the competitive supply of medicines to the public.

### **Article 44.2**

A third and more straightforward and legally compelling approach is to rely upon Article 44.2 of the TRIPS Agreement, which allows WTO members to **eliminate injunctions for patent infringement**, in two cases:

- Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members

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<sup>2</sup> New drug development involves the use of patented inventions, but also investments that are often not protected by patents. The revenue from sales rewards not only the inventions in the patented inventions, but also investments in non-patented activity, such as much of the clinical trial outlays, and the costs of manufacturing and marketing the products. Most of the employees of large pharmaceutical companies are engaged in marketing of products.

may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31.

- In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Article 44.2 of the TRIPS Agreement was provided in part to accommodate the practices in the United States to elimination of injunctions in cases of infringement of patents for civil nuclear power, and for cases where copyrights, patents, plant breeder rights, Semiconductor designs, boat hulls, and other useful original designs, are used "by or for" the U.S. Government, under 28 USC 1498. At the request of the United States, the following provision was included in the text of the Anti-Counterfeiting Trade Agreement (ACTA) on injunctions:

Notwithstanding the other provisions of this Section, a Party may limit the remedies available against use by government, or by third parties authorized by a government, without the authorization of the right holders to the payment of remuneration provided that the Party complies with the provisions of Part II of the TRIPS Agreement specifically addressing such use. In other cases, the remedies under this Section shall apply or, where these remedies are inconsistent with a Party's law, declaratory judgments and adequate compensation shall be available.

In the Article 44.2 approach, it is not necessary to eliminate the exclusive rights of patent. Instead, the government limits the remedies for the infringement of that patent. The WTO permits its members to eliminate injunctions for infringement, when "adequate" remuneration or compensation are available. By allowing patent holders to participate in an \$80 billion per year prize fund, the United States would clearly meet this test.