



## **New Market Incentive to Encourage Innovation for Global Health**

### ***FDA Bill Creates Priority Review Voucher for Neglected Tropical Diseases***

#### **Summary**

Congress has created a new incentive for companies to invest in new treatments for neglected tropical diseases. A provision of the Food and Drug Administration Amendments Act (HR 3580) **awards a transferable “priority review voucher” to any company that obtains approval for a treatment for a neglected tropical disease.** Sponsored by Senators Sam Brownback (R-Kansas) and Sherrod Brown (D-Ohio), this provision adds to the market-based incentives available for the development of new treatments for developing world diseases such as malaria, tuberculosis and African sleeping sickness. The bill was signed into law on September 27<sup>th</sup>, 2008.

#### **How It Works**

The statute authorizes the FDA to award a priority review voucher to the sponsor (manufacturer) of a newly-approved drug or biologic that targets a neglected tropical disease<sup>1,2</sup>. The voucher, which is transferable and can be sold, entitles the bearer to a priority review for another product.

Under current Prescription Drug User Fee Act targets, FDA aims to complete and act upon reviews of priority drugs within 6 months instead of the standard 10 month review period. Actual FDA review timelines, however, can be longer than the target PDUFA review periods, particularly for new products that haven't previously been approved.

Companies that use the voucher will be required to pay a supplemental priority review user fee to ensure that the FDA can recoup the costs incurred by the agency for the faster review. The additional user fee also aims to ensure that the new program will not slow the progress of other products awaiting FDA review.

#### **BVGH Assessment**

The developing world needs new medical products to prevent, treat and diagnose infectious diseases afflicting millions of impoverished patients. However, perceptions of insufficient markets, and inadequate funding for R&D, have deterred companies from investing in global

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<sup>1</sup> Neglected tropical diseases include tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue, guinea-worm disease, fascioliasis, Human African trypanosomiasis (African Sleeping Sickness), leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis, yaws and any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, as designated by the Secretary.

<sup>2</sup> The provision applies to New Drug Applications (NDAs) and Biological License Applications (BLAs).

health solutions, believing that such investments will not earn a positive return for their shareholders. New market-based solutions are needed to leverage industry expertise and encourage greater investment in innovation for these neglected diseases.

In our consultations with industry over the last several years, executives and investors have expressed interest in this type of incentive. The new provision improves the economic value of neglected disease R&D and may make it more likely that industry will invest.

How the market ultimately values this voucher will be based on the perceived approval time saved and the anticipated sales of a new “blockbuster” product. Economists at Duke University, who published on this concept in 2006, estimated that priority review can cut the FDA review process from an average of 18 months down to six months, shortening by as much as a full year the time it takes for the company’s drug to reach the market<sup>3</sup>. For a company with a top selling drug with a net present value close to \$3 billion, the Duke researchers calculated the accelerated approval could be worth over \$300 million. At this level, the voucher would be expected to offset the substantial investment and risk required for discovery and development of a new treatment for a neglected disease.

If the time saved from gaining a priority review is much shorter, however, the value of the voucher will be significantly less. In fact, in 2006, median standard review times were 12 months, suggesting that a voucher could cut six months from the standard review period. An intangible benefit of the voucher is the value created for a company if the faster review provides them “first mover advantage,” allowing the voucher-holder’s product to be introduced ahead of a similar, competing product.

By taking advantage of existing market forces, patients in the developing world can have faster access to life-saving products that may not otherwise be developed. And sponsors of neglected disease drugs can be rewarded for their innovations.

This new financial incentive complements other market-based incentives to stimulate investment in global health R&D. Donor countries have recently committed to other new initiatives. Earlier this year, for example, five leading industrialized countries along with the Bill & Melinda Gates Foundation committed \$1.5 billion to a pilot Advance Market Commitment that guarantees a developing world market for pneumococcal vaccines.

To create the next generation of medicines for the developing world, we need to continue to develop and support these types of market incentives. And we need to ensure that we have appropriate tools in place to measure and improve their impact.

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<sup>3</sup> Health Affairs, 25, no. 2 (2006): 313-324.