FDA Priority Review Vouchers for Biosecurity Threats

Proposal: Amend the existing FDA priority review voucher program for tropical diseases to include biosecurity threats. Expanding this program would reward the development of medicines and vaccines needed to protect Americans against bioterrorist attacks.

Background: Tradable FDA Priority Review Vouchers

Due to harsh economic realities, there is insufficient investment by biopharmaceutical companies in development of medicines and vaccines to counter infectious diseases that pose national security threats (e.g. anthrax, smallpox, Ebola). The Food and Drug Administration Amendments Act of 2007 (PL 110-85) created a priority review voucher program to reward developers of medicines and vaccines for tropical diseases. We propose expanding this program to include biothreat pathogens identified as material threats to the nation.

- Voucher: Biopharma companies would be rewarded for developing an FDA approved medicine or vaccine for a priority biosecurity threat by receiving an FDA Priority Review Voucher that can be applied to any other product in their development pipeline (would not need to be a biosecurity product), or that could be traded/sold to another firm.
- Value: A priority review voucher would significantly increase a firm's (net present) revenues, by reducing the product's time to market by 12 months – according to FDA's figures. This could be worth $300 million or more to the voucher user.
- Maximizing Value: The voucher would be applied to a product when the final application (NDA or BLA) is sent to FDA, and would expire upon product approval. To maximize the value of the voucher to industry by reducing risk, while adding no additional social cost, vouchers would be reusable if the product fails to attain FDA approval.
- Cost: Costs for priority review have been estimated to be $1 million in additional FDA labor, which will be billed to the voucher user.

Priority review vouchers are attractive from a policy perspective because they have almost no social costs. Unlike "wild card" patent extensions, the voucher would not delay the introduction of generics. In fact, the voucher would accelerate the introduction of both new drugs and generics.

References

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