Ideas to Encourage Innovation for Diseases without a Market

Introduction

This paper is an overview of a variety of ways that have been suggested to encourage innovation/research and development (R&D) for diseases that are endemic to the developing world but not the developed world (neglected diseases).[1] Because the economic market for these diseases is very limited while the average cost for bringing a product to market exceeds $1 billion, additional incentives are needed to encourage R&D for these neglected diseases.[2,3] Without proper economic incentives companies in aggregate will not be able to engage in the optimal level of R&D to find products for these diseases.[4] Therefore, strategies and incentives to encourage innovation focused on developing products for neglected diseases are necessary.

While the economic conditions of the developed world can not in the short run be replicated in the areas where these neglected diseases are endemic, there are a variety of incentives that might be provided that would help encourage companies to engage in R&D into neglected diseases. Some of the ideas presented in this paper have been tried with varying degrees of success. Others have not been tried and remain only theoretical. Connected to each idea is a list of advantages and challenges/limitations. The list of advantages and challenges/limitations associated with the different ideas are not exhaustive, but rather, the list should serve to give the reader an idea of some of the benefits and some of the problems that might be encountered with the different strategies. One should not construe a problem as insurmountable. Rather, one should view the listing of a problem as raising awareness that the issue is potentially present. Finally, it should be noted that all of these incentives could be designed and implemented in a variety of ways, and the differences in the specifics of the design and implementation could profoundly affect the outcomes. Truly, the "devil is in the details" for these proposals. That being said, what follows can serve as a basis to begin understanding ways to encourage innovation for these diseases.

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[1] The biodefense market shares some similar characteristics to the neglected diseases market. Specific measures (e.g., Project BioShield and Barda) that apply to that area are covered in Appendix 2. Many of the incentives outlined here could with appropriate changes be used to stimulate R&D in the biodefense market.

[2] Products used in this context are used to denote pharmaceuticals, biologics or vaccines used to treat or cure diseases.

[3] DiMasi, Joseph and Grabowski, Henry. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics 2007 28(4-5):469-479.

[4] It must be noted that biopharmaceutical companies currently are undertaking and supporting research in the area of neglected diseases. Further, they also provide many treatments and supplies at low or no cost in the developing world. For a fuller description of these efforts, see for instance "Research and Development for Neglected Diseases: Lessons Learned and Remaining Challenges." International Federation of Pharmaceutical Manufacturers Associations. November 2004.

Overview of Incentives

Advanced Market Commitments[5]

Description: One or more sponsors would commit to a minimum price to be paid for each dose up to a certain number of doses.[6] For additional purchases, the price would eventually drop to close to marginal cost.

Advantages/Challenges:[7]

Advantages	Challenges / Limitations
• Creates a market for neglected diseases • Encourages wide utilization of the product • Promotes multiple entrants	• Large up front commitment • Guarantee needed • Specificity of criteria • Has the potential to lower other types of aid

Entities Involved

- Sponsor
- Underserved Market
- Industry

Role of Different Entities

Sponsor: commits (in advance of product development and licensure) to fully or partially finance purchases of products for poor countries at a pre-specified price. This can be accomplished by signing a contract underwriting a guaranteed price for the company that develops the product.

- Qualifications: Must be credible (i.e. financially solvent and thought to be unlikely to renege on a commitment)
- Examples: Government, bilateral/multilateral aid agencies

[5] For a fuller discuss of this concept, please see: Berndt, Ernst R. et al. "Advance Market Commitments for Vaccines Against Neglected Diseases: Estimating Costs and Effectiveness" Health Economics 2007 (16): 491 – 511.
[6] The term „dose" is used loosely here. The price could also be paid for individual pills or the full treatment regimen. With respect to vaccines, the price could be paid for each person vaccinated, so if vaccine required three doses, the manufacturer would be paid after the 3 doses had been administered. Alternatively, the price could be paid for each shot administered.
[7] For a fuller description of each advantage and each challenge/limitation in this incentive, please see Appendix 1.

Underserved Market: Beneficiary government buys a given product at a low and affordable price (e.g. $1/dose), with the remainder of the cost subsidized by the sponsor. This allows attractive market returns for the developer that can compete with other average-revenue biopharmaceutical products (Although not part of the contract, there would be nothing to stop the original sponsors or other donors from covering the low price on behalf of the underserved market at the time of purchase)

Industry: Once the full number of treatments has been purchased at the guaranteed price, the supplier in return would commit to either selling further treatments at a price approaching marginal cost, or to licensing the technology to other manufacturers

Effect on IP: [8]

The effect on IP is unclear. For instance in one case the producer of the product could retain the intellectual property rights and also agree to the price for the specified number of doses. The producer also would agree that the price would come down to a certain level after the specified number of doses has been reached. This arrangement would allow the producer to produce or license the product as the produce desirers. Alternatively, the producer might retain the IP rights until a specified number of doses are sold and then the IP rights could be transferred to the organization that funded the AMC. The organization would then have the right to license the product to other producers to bring the price down.

Examples

Pilot Advanced Market Commitment for Pneumococcal Diseases:
A consortium of donors has contributed nearly $1.5 billion dollars into a pool towards the development of an effective vaccine for pneumococcal diseases. These funds are committed to the purchase of the most effective vaccine as specified by the group of donors. The committed funds will subsidize the purchase of this vaccine for a country that demands the product. Should a more effective vaccine be approved during the span of the advanced market commitment, the country maintains the ability to reallocate committed funds towards the newer product. [9]

[8] The effect on IP in this incentive and the incentives that follow is speaking in general terms. As was stated in the introduction there are a myriad of ways in which these incentives could be designed and implemented in a variety of ways.
[9] http://www.vaccineamc.org/index html

Tax Incentives for R&D

Description: Tax credits given for certain types of expenses associated with the research and development of products for neglected diseases.

Advantages/Challenges:[10]

Advantages	Challenges / Limitations
• Lowers R&D costs • Increased certainty • Promotes multiple entrants	• Must be accruable and transferable • Does not ensure wide distribution of the product

Entities Involved

- Government
- Industry

Role of Different Entities

Government: Commits to a tax break on the costs associated with research and development going towards a product serving an underserved market

Industry: Develops a product for an underserved market, and receives a tax break on the costs associated with the research and development of that product, increasing economic feasibility and profitability

Effect on IP:

This incentive as it is currently structured in the example below would not impact IP rights.

Examples

Orphan Drug Act:
The Orphan Drug Act, which was passed in 1982, is designed to encourage research and development of products for rare diseases. One of the incentives provided by the act is a tax credit for qualified clinical trials. The act has proven quite successful. In the decade prior to the passage of the act only 10 products were brought to market; however, in the 25 years since the act was passed, over 200 products have been brought to market. [11]

[10] For a fuller description of each advantage and each challenge/limitation in this incentive, please see Appendix 1.
[11] See URL: http://www.fda.gov/orphan/ - last accessed March 13, 2008.

Priority Review Vouchers[12]

Description: Developers of products for neglected diseases would receive a transferable voucher that would entitle the bearer of the voucher to priority FDA review for another drug. The voucher could also be sold to another company.

Advantages/Challenges:[13]

Advantages	Challenges / Limitations
• Certainty • Codified • Promotes multiple entrants	• Challenges in assessing the value of a voucher • Does not ensure wide distribution of the product

Entities Involved

- Government (FDA)
- Industry

Role of Different Entities

Government (FDA): issues a transferable voucher to the developer of a product created for an underserved market. This voucher guarantees an expedited FDA review process (estimated reduction of 18 months to 6 months) for a product of the manufacturer's choice.

Industry:

a) Small Developer: could either use the voucher toward its own product or sell the voucher to a larger manufacturer

b) Large Manufacturer: use the voucher toward the expedited review of a product. For a blockbuster drug it is estimated that this voucher would be worth $300 million in increased earnings to a manufacturer.

Effect on IP:

This incentive as it is currently structured in the example below does not impact IP rights.

[12] For a fuller discussion of this concept, please see: Ridley, David B. et al. "Developing Drugs for Developing Countries" Health Affairs 25(2): 313 – 324.
[13] For a fuller description of each advantage and each challenge/limitation in this incentive, please see Appendix 1.

Examples

Amendment to the FDA Revitalization Act, September 27th, 2007: *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-KS), and Sherrod Brown (D-OH), this provision adds to the market based incentives available for the development of new medicines for developing world diseases such as malaria, tuberculosis and African sleeping sickness*.[14]

[14] *BioWorld Today*, March 12, 2008

Transferable Exclusivity[15]

Description: A developer that licenses a product for a neglected disease would receive additional time on patent for a different product. The right could be sold to another company.

Advantages/Challenges:[16]

Advantages	Challenges / Limitations
• Certainty	• Cost to US patients • Does not ensure wide distribution of the product

Entities Involved

- Government
- Industry

Roles of Different Entities

Government: provides more time on a patent

Industry: A developer that licenses a product for a neglected disease would receive additional time on patent for a different product. This right could be sold to another company.

Effect on IP:

In order to benefit from this incentive the company would need to license the product to encourage its wide distribution. The company would effectively lose its ability to exclude others from producing the product.

[15] For a fuller discussion of this concept, please see: Ridley, David B. et al. "Developing Drugs for Developing Countries" Health Affairs 25(2): 313 – 324.

[16] For a fuller description of each advantage and each challenge/limitation in this incentive, please see Appendix 1.

Prizes[17]

Description: A fund that would create rewards for products which would be paid in a lump sum once such a product obtained regulatory approval

Advantages/Challenges:[18]

Advantages	Challenges / Limitations
• Creates an incentive for research into neglected diseases	• Large upfront commitment • Guarantee needed • Specificity of criteria • Only first product to market awarded a prize • Has the potential to lower other types of aid • Does not ensure wide distribution of the product

Entities Involved

- Sponsor
- Industry

Role of Different Entities

Sponsor: Establishes a goal without determining who is in the best position to reach the goal or what the most promising technical approach is. The sponsor may be able to leverage additional funding from foundations, philanthropists, and contestants who value the reputational benefits of winning the competition. The prize money is awarded only if someone is successful.

Industry: contestants compete to accomplish a particular goal, and then receive the monetary commitment of the sponsor if their invention satisfies contest specifications

Effect on IP:

The effect on intellectual property rights depends on the stipulations of the prize. For instance, the intellectual property right could reside with the winner of the prize but in return the winner would have to sell a specified number of doses at a specific price. Alternatively, the intellectual property could become the property of the organization that funded the prize in order for them to license the product as they wished.

[17] For a fuller discussion, see: Kalil, Thomas. "Prizes for Technological Innovation" The Hamilton Project. The Brookings Institution. Discussion Paper 2006-08. December 2006.

[18] For a fuller description of each advantage and each challenge/limitation in this incentive, please see Appendix 1.

Examples:

- Determining longitude at sea
  In 1714 the British government through an Act of Parliament offered a reward for a simple and practical method for determining a ship's longitude at sea. William Harrison came up with the solution to the problem with his invention of the chronometer. Although Harrison's invention met the criteria for the prize in 1764, the Longitude Board was unwilling to award him the prize. It took the intervention of the King and an Act of Parliament in 1773 to finally award him the prize.[19]

- Transatlantic flight
  The Orteig Prize was offered in 1919 by Raymond Orteig for the first person to fly non-stop flight from New York to Paris or Paris to New York. It was awarded to Charles Lindbergh in 1927.

- Soviet Union
  The Soviet Union used prizes as a standard method of motivating individuals in lieu of patents. The Soviet experience was characterized by low levels of monetary compensation and poor innovative performance.[20]

- X PRIZE
  "An X PRIZE is a multi-million dollar award given to the first team to achieve a specific goal, set by the X PRIZE Foundation, which has the potential to benefit humanity."[21] *The Ansari X Prize was awarded in 2004 for being the first to launch a reusable manned ship 100 km above the earth's surface twice within a two week period.*

[19] See for instance: Sobel, Dava. Longitude: The True Story of a Lone Genius Who Solved the Greatest Scientific Problem of his Time Walker Publishing Company, Inc. 1996.
[20] DiMasi, Joseph and Henry Grabowski. "Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D."
[21] See URL: http://www.xprize.org/x-prizes - last accessed March 13, 2008.

Track II Patents[22]

Description: A voluntary system under which a company could choose how a patent is applied – either through the traditional way of utilizing exclusionary rights over the manufacturing and sale of the product (Track I) or earn credit from Track II. Under Track II governments would make multiyear commitments to contribute to a large fund from which owners of a registered patent could opt to be paid periodically in proportion to the product"s contribution to reducing the global burden of disease.

Advantages/Challenges:[23]

Advantages	Challenges / Limitations
• Encourages wide utilization of the product • Promotes multiple entrants	• Large upfront commitment • Committee assigns values • Guarantee needed • Has the potential to lower other types of aid

Entities Involved

- Government
- Committee
- Industry

Role of Different Entities

Government: Under track II governments of developed and developing countries would make multiyear commitments to contribute to a large fund (eventually on the order of tens of billions per year, expressed in US dollars) from which owners of a registered patent could opt to be paid periodically in proportion to the product"s contribution to reducing the global burden of disease Assuming continued product use and benefit, payments could continue longer than the life of the patent

Committee: A group of people will allocate money from a fund to producers of products for neglected diseases. The allocation would be based on the impact of the different products impact on the global burden of disease.

Industry: Choosing track II would be voluntary, and a company would be able to switch a given product from track I to track II as it recalculates its prospects for profit.

[22] For a fuller discussion of this concept, please see: Nathan, Carl. "Aligning Pharmaceutical Innovation with Medical Need." Nature Medicine March 2007: 13(3).
[23] For a fuller description of each advantage and each challenge/limitation in this incentive, please see Appendix 1.

Effect on IP:

The producer of the product would have a choice to either retain its patent rights and receive no funding from the fund or to exchange its patent rights for future payments from the fund, the amount of which would be determined by a committee.[24]

Conclusion

The paper is by no means an exhaustive list of potential ideas nor is the treatment of an idea meant to be meticulous rendering of the intricacies associated with the idea. Rather, the list above provides a basis for thinking through ways to encourage companies to conduct R&D of products for diseases that are endemic to the developing world but not present in the developed world. As the list above demonstrates, there are an abundance of ideas of how incentives might be provided in order to spur research and development for treatments for neglected diseases. Associated with each idea is a variety of benefits and potential problems. Whether or not the benefits of a proposed solution would be realized depends on the implementation of the solution. Similarly, the way in which an idea is implemented could mitigate or exacerbate the identified problems.

[24] Please note: The amount that the company would receive would not be guaranteed at the time when the company chose to opt into the Track II option. Rather, the amount received would be determined in the future by a committee.

Appendix 1:

Explanation of Advantages and Challenges/Limitations:

Advance Market Commitments/Advance Purchase Commitments

Advantages:

- Creates a market for neglected diseases
  If the price per dose is large enough, this idea effectively creates a market. Thus, this idea gives companies an incentive to commit the resources to developing a product for a neglected disease.

- Encourages wide utilization of the product
  By paying for doses distributed/utilized, there is an incentive for the company to create a product that meets consumers' needs and for the company to widely distribute the product. The distribution could be undertaken in a variety of ways (e.g., by the company itself, licensing to other companies)

- Promotes multiple entrants
  When payment is based on the doses administered, it is not a winner takes all incentive. Thus, there is a higher likelihood of multiple independent researchers working on the problem. The presence of multiple independent researchers working on a problem increases the likelihood of and shortens the time to develop needed, effective products. This leads to the potential for multiple entrants to the same therapeutic class. Having more than one product in a therapeutic class is important to patients and healthcare providers. Where one person may have a side effect to one medication, the same person may not have a side effect to another medication in the same class. Further, if resistance is developed to one medication, having another medication gives providers another option for treatment.[25]

Challenges/Limitations:

- Large upfront commitment
  This mechanism requires governments or others to commit in advance to pay for products. The sum of money needed for a prize is not insignificant. It may be difficult to encourage governments or others to fund a prize which is large enough to induce R&D.

- Guarantee needed
  Given that there is the potential of a substantial payout, there must be some sort of guarantee that the commitment will be kept. Doubt that the guarantee will be kept will cause uncertainty. Holding all else constant, an increase in uncertainty will lower the amount of resources devoted to an endeavor. If researchers are unsure that they will receive the prize once the stipulated requirements have been met, fewer researchers will engage in the risky and costly R&D endeavor than if there is certainty about a prize being awarded.

[25] The potential for multiple entrants could lower the expected payout to any one company. Thus, the potential for multiple entrants may require a larger total payout than if there were only going to be a payout to only one company.

- Specificity of criteria
  Given long lead time of development, the criteria need to be specific in order to increase the certainty that a given product will meet the requirements for the prize. The terms for awarding the prize must be detailed including:

  - *administration of treatment*
  - *dosage requirements*
  - *efficacy*
  - *side effects*

  Defining the necessary criteria can be difficult.

- Has the potential to lower other types of aid
  If donors set aside a certain amount of aid for developing countries each year, the allocation of money for this purpose could decrease other types of aid to these countries. Thought must be given to the relative benefit of the different aids in order for there to be an efficient allocation of resources.

  Tax Incentives for R&D

  Advantages:

- Lowers R&D costs
  The large R&D costs associated with the development of biopharmaceuticals coupled with low rewards associated with a neglected disease once a product has been brought to market results in less than optimal R&D being conducted. The size of the tax credit would determine the effect of this incentive on encouraging R&D. Most likely, this incentive would need to be coupled with one or more other incentives.

- Increased certainty
  Unlike many of the other proposals, there is more certainty that companies will be able to take advantage of this proposed incentive because there may be less time lag between when the R&D costs are incurred and when the R&D tax credit will be given.

- Promotes multiple entrants
  When payment is based on the doses administered, it is not a winner takes all incentive. Thus, there is a higher likelihood of multiple independent researchers working on the problem. The presence of multiple independent researchers working on a problem increases the likelihood of and shortens the time to develop needed, effective products. This leads to the potential for multiple entrants to the same therapeutic class. Having more than one product in a therapeutic class is important to patients and healthcare providers. Where one person may have a side effect to one medication, the same person may not have a side effect to another medication in the same

class. Further, if resistance is developed to one medication, having another medication gives providers another option for treatment.[26]

Challenges/Limitations

- Must be accruable and transferable
  Unless the credit is accruable and transferable, companies that are not profitable do not benefit because they have no tax liability.
- Does not ensure wide distribution of the product
  One of the issues associated with health care in the developing world is the logistical difficulty of supplying products to those in need. Once a suitable product for a neglected disease is developed, the problem of how to distribute the product still remains. Given the situations of extreme poverty, the distribution of the medicines may still require financing from outside sources.

Priority Review Vouchers

Advantages:

- Certainty
  There is greater certainty over what one is receiving for developing a product than there is with some of the other incentives. No government or donor group must come up with a large amount of funds.

- Codified
  A version was codified in September 2007 with the passage of the FDA Revitalization Act. The appeal of this incentive is evident in that it was first proposed purposed in 2006 and codified less than 2 years later.

Challenges/Limitations:

- Uncertainty
  There is uncertainty over how much the voucher would be worth since the market size of a drug before market approval can not always be accurately measured.

- Does not ensure wide distribution of the product
  One of the issues associated with health care in the developing world is the logistical difficulty of supplying products to those in need. Once a suitable product for a neglected disease is developed, the problem of how to distribute the product still remains. Given the situations of extreme poverty, the distribution of the medicines may still require financing from outside sources.

[26] The potential for multiple entrants could lower the expected payout to any one company. Thus, the potential for multiple entrants may require a larger total payout than if there were only going to be a payout to only one company.

Transferable Exclusivity

Advantage:

- Certainty
  There is greater certainty over what one is receiving as for developing a product than there is with some of the other incentives. No government or donor group must come up with a large amount of funds.

Challenges/Limitations:

- Cost to U.S. patients
  This mechanism delays generic entry, and thus, there is a cost to consumers which rises as the length of time of exclusivity rises. Given the current climate surrounding prices of pharmaceutical drugs it is unlikely that an incentive of this type would prove to be very palatable to either consumers or politicians.

- Does not ensure wide distribution of the product
  One of the issues associated with health care in the developing world is the logistical difficulty of supplying products to those in need. Once a suitable product for a neglected disease is developed, the problem of how to distribute the product still remains. Given the situations of extreme poverty, the distribution of the medicines may still require financing from outside sources.

Prizes

Advantage:

- Creates an incentive for research into neglected diseases
  If the prize is large enough, a company that meets the stipulations for winning the prize would be able to recoup the R&D costs that were expended.

Challenges/Limitations:

- Large upfront commitment
  This mechanism requires governments or others to commit in advance to pay for products. The sum of money needed for a prize is not insignificant. It may be difficult to encourage governments or others to fund a prize which is large enough to induce R&D.

- Guarantee needed
  Given that there is the potential of a substantial payout, there must be some sort of guarantee that the commitment will be kept. Doubt that the guarantee will be kept will cause uncertainty. Holding all else constant, an increase in uncertainty will lower the amount of resources devoted to an endeavor. If researchers are unsure that they will receive the prize once the stipulated requirements have been met, fewer researchers will engage in the risky and costly R&D endeavor than if there is certainty about a prize being awarded.

- Specificity of criteria
  Given long lead time of development, the criteria need to be specific in order to increase the certainty that a given product will meet the requirements for the prize and be rewarded. The terms for awarding the prize must be detailed including:

  - *administration of product*
  - *dosage requirements*
  - *efficacy*
  - *side effects*

  Defining the necessary criteria can be difficult.

- Only first product to market awarded
  Because there are many false starts and dead ends when developing a biopharmaceutical product, a mechanism must be developed to reward more than just the first product to market in order to encourage competition and the pursuit of many avenues of research. The best way to ensure the successful development of a product is to have a number of independent researchers working on the problem. However, companies may be reticent to undertake research in an area if it is a winner takes all prize. In a winner takes all prize scenario, not only does a company have to meet the requirements of the prize, but it must be the first to meet the requirements. Further, a winner takes all approach means that there is no reward for a newer or improved therapies (e.g., easier dosing, fewer side effects, increased potency.)

- Has the potential to lower other types of aid
  If donors set aside a certain amount of aid for developing countries each year, the allocation of money for a prize could decrease other types of aid to these countries. Thought must be given to the relative benefit of the different aids in order for there to be an efficient allocation of resources.

- Does not ensure wide distribution of the product
  One of the issues associated with health care in the developing world is the logistical difficulty of supplying products to those in need. Once a suitable product for a neglected disease is developed, the problem of how to distribute the product still remains. Given the situations of extreme poverty, the distribution of the medicines may still require financing from outside sources.

  <u>Track II Patents</u>
  Advantage:

- Encourages wide utilization of the product
  Paying for product's contribution to reducing the global burden of disease creates an incentive for a company to create a product that meets consumers' demand and that for a company to encourage the utilization of the product. Unlike the prize system and other incentives, this idea encourages the company to consider the needs of the patients and healthcare providers. Further, it creates an incentive for a company to distribute the product as widely as possible.

- Promotes multiple entrants
  By paying for product's contribution to reducing the global burden of disease, there is the potential for multiple entrants to the same therapeutic class. The presence of multiple independent researchers working on a problem increases the likelihood of and shortens the time to develop needed, effective products. This leads to the potential for multiple entrants to the same therapeutic class. Having more than one product in a therapeutic class is important to patients and healthcare providers. Where one person may have a side effect to one medication, the same person may not have a side effect to another medication in the same class. Further, if resistance is developed to one medication, having another medication gives providers another option for treatment.

Challenges/Limitations:

- Committee assigning value
  There is greater uncertainty surrounding the size of the revenue generated for developing a product than there is with the prize or an advance market commitment because impact on global burden of disease is not well defined. Further, it is a committee that decides after the product has been developed and utilized how much will be rewarded. This structure where a few people are making a decision on ill defined criteria in an unknown timeframe greatly increases the uncertainty faced by researchers. Finally, given that all products for neglected disease will be awarded money from the same pot, more products could result in potentially less money per product developed.

- Large upfront commitment
  This mechanism requires governments or others to commit in advance to pay for products. The sum of money needed for a prize is not insignificant. It may be difficult to encourage governments or others to fund a prize which is large enough to induce R&D.

- Guarantee needed
  Given that there is the potential of a substantial payout, there must be some sort of guarantee that the commitment will be kept. Doubt that the guarantee will be kept will cause uncertainty. Holding all else constant, an increase in uncertainty will lower the amount of resources devoted to an endeavor. If researchers are unsure that they will receive the prize once the stipulated requirements have been met, fewer researchers will engage in the risky and costly R&D endeavor than if there is certainty about a prize being awarded.

- Has the potential to lower other types of aid
  If donors set aside a certain amount of aid for developing countries each year, the allocation of money for a prize could decrease other types of aid to these countries. Thought must be given to the relative benefit of the different aids in order for there to be an efficient allocation of resources.

Appendix 2:

Procurement mechanisms: Project BioShield

Description: Establishes a funding source through which the federal government can procure medical countermeasures for which it is reasonable to expect licensure within 8 years. Current appropriations are for $5.6 billion over 10 years and through FY 2013.

Advantages	Challenges / Limitations
• Creates market for medical countermeasures that would otherwise not exist. • Multi-year funding appropriated.	• Does not address high costs and risks of advanced development. • Currently appropriated amount is insufficient to address all needs. • Coordination among various government entities has improved, but challenges still remain. • Purchase volumes and pricing can be unpredictable or unclear at time companies must engage in business decisions. • ROI must be competitive with other investment opportunities. • Contracting processes are perceived to be burdensome and costly by many.

Entities Involved

- Government
- Industry

Advanced Development Funding (BARDA)

Description: Authorization and funding for government to contract with industry for the advanced development of medical countermeasures. Intended to bridge the gap between early stage development and late stage development and increases probability of successful procurement and delivery of medical countermeasures.

Advantages	Challenges / Limitations
• Shared risk between industry and government for needed countermeasures that would otherwise not have a market. • Funding can apply to many aspects of advanced product development as well as research tools.	• Requires strong and predictable funding to provide incentives to industry to devote resources and programs in competition with other investment opportunities. • Funding is limited to date. • Absence of multi-year funding creates risks to industry that projects will not receive sufficiently sustainable funding. Raises opportunity costs. • Contracting processes are perceived

Entities Involved

- Government
- Industry