

DRAFT

Making Markets for Vaccines

A practical plan to spark innovations for global health*

The importance of vaccines

Vaccines have saved millions of lives around the world in the last fifty years. They are one of the most cost-effective ways of enhancing human health because they are cheap to administer and prevent disease that is much more costly to treat. And improving health has wider benefits for reducing poverty, allowing families, workers and communities to be more productive throughout their lives.

Developing countries have made good use of vaccines that were originally created for rich countries. For example, three quarters of the world's children now get vaccinated for serious childhood diseases, such as polio, whooping cough and diphtheria — saving 3 million lives a year, and preventing long-term illness and disability in millions more.

This works for diseases from which both rich and poor countries suffer. But some of today's biggest killers — malaria, HIV, and tuberculosis — are not as widespread in the rich world. The 5 million people a year who die of these

diseases do not have money to buy medicines. The hard fact is that they do not constitute a profitable market. This means that companies have little economic motivation to invest in the creation of vaccines to meet their needs. As a result, less than 10 percent of total research and development is aimed at diseases that affect 90 percent of the world's population.

It is very expensive to develop and test a new vaccine — by some estimates, the cost is \$1 billion or more. Pharmaceutical companies cannot make this investment if they are not sure there will be a market for the vaccine. The market for vaccines for developing country diseases is small and uncertain, so there is very little privately-funded research into the diseases of the poor. Yet new vaccines are one of the best chances there is to transform health and living standards in poor countries.

Advancing the market

Diseases such as malaria, HIV and tuberculosis kill millions of people a year, and they reduce

This brief summarizes the conclusions of a Working Group convened by the Center for Global Development's Global Health Policy Research Network, with the support of the Bill & Melinda Gates Foundation, to examine a proposal to accelerate development of new vaccines for developing countries. The proposal is that donors would make a legally binding commitment, in advance, to contribute most of the cost of buying a vaccine, at a guaranteed price, if it were developed. This would create a market of sufficient size and certainty to create an incentive for firms to invest in the development of vaccines for neglected diseases. The Working Group was established to consider whether such a scheme would be legally feasible and whether it would work in practice. It consulted experts from industry, governments and international institutions, as well as experts in law and economics. It concluded that a contract could be designed based on generally accepted legal practice, which would meet the interests of all the stakeholders and create incentives to develop vaccines. The Working Group believes that this approach could make a significant contribution to harnessing the resources of the private sector to find new solutions to global health challenges. This briefing note summarizes why this is important; and how a scheme could be constructed. There is more detail in the Working Group report, available at www.cgdev.org/globalhealth

* A summary of the consultation draft of Making Markets for Vaccines by the Working Group on Pull Mechanisms.

the quality of life of millions more. If there were a vaccine available for these diseases, one of the most effective possible uses of donor funds would be to pay for them to be available to people who need them.

To accelerate the development of vaccines for neglected diseases in developing countries, sponsors could make a binding commitment that they would be willing to pay for a vaccine once it is developed. Firms would then be able to invest in finding a vaccine with confidence that there would be a market if they succeed.

As a result of such a commitment, the market for vaccines for neglected diseases would be comparable in size and certainty to the market for medicines for rich countries. This would enable biotech and pharmaceutical companies to invest in the development of new vaccines to tackle the world’s most pressing health problems, in the normal course of their business decisions.

AdvancedMarkets would be one way to accelerate the development of new vaccines. It would complement conventional approaches, including public and philanthropic funding of basic scientific research, and public-private partnerships to build up demand and to promote development of a vaccine.

AdvancedMarkets would be true payment by results: there would be no cost to sponsors unless the commitment succeeds and a new vaccine is developed. And for firms, the commitment would open up new markets in which they can invest and grow.

Which diseases would it cover?

For disease such as AIDS, TB and malaria there is no available vaccine, and none is on the horizon. For others, such as pneumococcus and rotavirus, which kill nearly 2 million people a year between them, vaccines are being developed. But on past experi-

ence, it will be many years before they are widely available in developing countries. Other diseases affecting the developing world for which no vaccine is available include shigella, schistosomiasis, leishmaniasis, chagas disease and dengue.

The AdvancedMarkets commitment could be made for diseases where a vaccine has been developed, but is not yet available on the market (called “late-stage products”) as well as for diseases where no vaccine is yet in sight (“early-stage products”). For late-stage products, such as pneumococcus and rotavirus vaccines, sponsors could agree to long term contracts with the firms that will be in a position to supply the vaccine in a few years, to create an incentive to accelerate testing in developing countries, and to invest in sufficient production facilities for developing country markets. If these incentives are not put in place, we risk repeating the experience of other recently-developed vaccines, which have not been widely available in developing countries more than a decade after they became available in rich countries.

For early-stage products, such as vaccines for malaria, HIV and tuberculosis, it is not yet clear which companies will develop an effective vaccine first. In these cases, the contract would be an open offer to any company that was able to develop a vaccine that met the specification of what is required.

How much would it cost?

A commitment would aim to create an overall market size of about \$3 billion for a single disease such as malaria. This is a little above the average rich country market for which drugs are developed.

If four sponsors contributed to this evenly, each would be committed to spending about \$90m a year each, over about 6 years, if and when the vaccine was developed.

An outline of an AdvancedMarkets commitment in practice	
ADVANCEDMARKETS PRINCIPLE	ILLUSTRATIVE EXAMPLE FOR MALARIA VACCINE
Legally binding contracts,	Offer made by a group of sponsors enforceable by law
Sponsors guarantee a price that offers a reasonable return to the developer	\$15 per treatment at first
Price guarantee applies to a maximum number of treatments	First 200 million treatments bought at \$15
Guaranteed price is for treatments sold in eligible countries	Vaccine Fund recipients
In return, the developer guarantees to sell subsequent treatments at a low price	\$1.00 per treatment in the long run
Recipient country makes a co-payment for the vaccines they buy, or a donor makes the payment on its behalf	\$1.50 paid by recipient (or donor) \$13.50 paid by sponsors
First developer gets the guaranteed price, unless and until superior product invented	
Independent Adjudication Committee established to oversee the arrangement.	

Advantages and Risks of Advanced Markets

FOR SPONSORS	FOR FIRMS	FOR DEVELOPING COUNTRIES
<p>Advantages</p> <ul style="list-style-type: none"> ■ no cost unless & until vaccine is developed—can continue other programs in the meantime ■ vaccines are a very cost-effective form of aid – even if bought at higher prices ■ demonstrably good use of tax dollars—can show measurable benefits. Commitment increases productivity of aid spending ■ long term sustainability built in (contract includes drop in price) ■ firms have incentive to develop good products 	<ul style="list-style-type: none"> ■ big increase in potential market for vaccines ■ greater certainty about future procurement of vaccines enables investment ■ removes pressure to sell vaccines at loss, and reinforces confidence in intellectual property regime ■ quicker returns on vaccines produced for developing countries ■ good public relations to be involved in making vaccines for global health challenges 	<ul style="list-style-type: none"> ■ accelerated development of vaccines for most important health challenges ■ quicker affordable access to vaccines once they have been developed — no more long delays ■ long term sustainability because price drops once the initial doses are bought ■ small costs to administer additional vaccines once delivery system in place ■ co-payment mechanism ensures that developing countries have final say on what is bought
<p>Risks & points to watch</p> <ul style="list-style-type: none"> ■ sponsors will need to pay more for vaccines than current vaccine prices ■ contract design must avoid being required to pay out for an inappropriate vaccine 	<ul style="list-style-type: none"> ■ need a legally binding commitment and independent adjudication ■ contract must prevent “me too” products taking the guaranteed market ■ quantity is not guaranteed, so firms still depend on demand for their product 	<ul style="list-style-type: none"> ■ contract must allow take-up of superior products if they are developed ■ must provide co-payment for vaccines when developed from own resources or from donors

For example, sponsors could commit to underwriting a price of \$15 per treatment for a malaria vaccine for the first 200 million treatments. This would be to create a sufficient market size.

At this price, the contract would be highly cost-effective use of aid, costing less than \$500 for every life saved. Once a vaccine is developed, and a poor country decides to use it, the sponsors would cover the majority of the cost. The recipient country would make a small co-payment, or a donor would make the payment on its behalf. If no vaccine is ever developed, there is no cost to sponsors.

Once the full number of treatments had been bought at the guaranteed price, the supplier would, in return, be committed to selling further treatments at a very low price. This would ensure that developing countries could go on buying the vaccine once the supplier had recovered its investment.

Is it possible in practice?

Governments enter into long-term contracts every day, for everything from aircraft to catering. There is no reason in principle why they could not sign a long-term contract for vaccines. It is unusual to enter into a contract for a product that does not yet exist; but with the assistance of experienced corporate lawyers, the Working Group

established that there is no obstacle to writing the necessary contracts. The Working Group report includes sample contract term sheets as annexes. The Working Group also finds that there is no budgetary obstacle that prevents donors from making this form of commitment.

The main features of the proposed commitment are set out in the box, with an example for a malaria vaccine. This outline is designed to meet the needs of all the stakeholders, and ensure that the contract creates the right incentives for everyone.

What happens now?

The Working Group was satisfied that an Advanced Markets commitment would be likely to accelerate the development of vaccines for diseases which impose the highest burden in developing countries, and that it would be a cost-effective development intervention for donors to make. Alongside other measures to build access to essential medicines, including continued public funding of scientific research, it could make a significant contribution to global health and poverty reduction.

The Working Group is discussing its draft report further with the pharmaceutical industry and with sponsors, to build awareness of the proposal and to refine the proposal.

The **Center for Global Development** is an independent, non-partisan, non-profit think tank dedicated to reducing global poverty and inequality through policy oriented research and active engagement on development issues with the policy community and the public. A principal focus of the Center's work is the policies of the United States and other industrialized countries that affect development prospects in poor countries. The Center's **research** assesses the impact on poor people of globalization and of the policies of governments and multilateral institutions. In collaboration with civil society groups, the Center seeks to identify **policy alternatives** that will promote equitable growth and participatory development in low-income and transitional economies. The Center works with other institutions to improve **public understanding** in industrialized countries of the economic, political, and strategic benefits of promoting improved living standards and governance in developing countries.

The **Global Health Policy Research Network (PRN)** is a program of the Center for Global Development that brings together leading experts in public health, economics and other social science and technical fields to develop original, focused research on high-priority global health policy issues. The PRN, which is supported by the Bill & Melinda Gates Foundation, seeks to improve the outcomes of donor decision-making in global health by:

- **Providing a rich evidence-base** about policy opportunities and constraints to effective public and private aid in the health sector.
- **Bringing new people and perspectives** — both multidisciplinary and global — into health policy analysis to increase the robustness of the debate.
- **Supporting the development of innovative solutions** to global health financing and other policy problems.

In addition to AdvancedMarkets, other PRN Working Groups have contributed to *Millions Saved: Proven Successes in Global Health* and are exploring:

- **How to build a comprehensive, credible base of information** about financial flows to global health, which is responsive to advocacy, program and policy data needs.
- **How to stimulate development agencies** to conduct rigorous impact evaluations of major development projects, so that they contribute to global knowledge about what works.

For more information on CGD's Global Health Policy Research Network, please visit www.cgdev.org/globalhealth

How can I find out more?

A consultation draft of the Working Group report is available at <http://www.cgdev.org/globalhealth> or on request by email. This brief is also available there, with hyperlinks to the relevant sections of the report. The report sets out the analysis in full, and includes a more detailed explanation of how an AdvancedMarkets commitment could be designed. Also on the website is a spreadsheet tool to enable you to analyze the financial implications of the commitment, under a range of assumptions about eligibility and effectiveness.

If you would like a copy of the draft report, if you want to discuss the AdvancedMarkets proposal, or you would like further information, please contact Owen Barder at the Center for Global Development, at obarder@cgdev.org, or at 1776 Massachusetts Ave. NW, Suite 301, Washington DC 20036. Phone (202) 416-0700 .

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Working Group members serve in a personal capacity, and this report does not necessarily represent the view of the organization to which they are affiliated.