



A New Global Framework to Bring Vaccine Pricing into the 21st Century: A Balancing Act

An Interview with Ambassador Mark Dybul

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In a world where middle-income countries are achieving wide-ranging rates of socio-economic growth and development, the established two-tiered model for vaccine pricing is no longer sufficient. This week, NBR spoke with Ambassador Mark Dybul about the need for a new vaccine pricing framework, one that would easily translate into use in other areas of healthcare. This interview was published on the NBR website: <http://www.nbr.org>.

Ambassador Mark Dybul is Co-Director and Distinguished Visiting Scholar of the Global Health Law Program at the O'Neill Institute of Georgetown University, and is also Inaugural Global Health Fellow at the George W. Bush Institute. Previously, Ambassador Dybul served as the United States Global AIDS Coordinator during the presidency of George W. Bush, in which he led the implementation of the President's Emergency Plan for AIDS Relief (PEPFAR), the largest international health initiative in history for a single disease.

At the 2011 Pacific Health Summit on vaccines, there was a clear call for a new “compact” or model for global vaccine pricing, which would establish multiple tiers for pricing. Why doesn't the existing two-tiered pricing structure for vaccines work in the 21st century?

The current structure no longer works simply because of economic growth. Countries are doing what development intended to do—they're growing themselves internally with governance and democratic structures, and therefore growing their own economies and social development. They are effectively growing themselves out of opportunities for external support.

However, while they're making progress, many of these countries still don't have the resources to do everything they need to do. And part of it is the financial crisis—it's becoming clear that there will be little to no financial support for middle-income countries and that we're going to have a problem. So we're ending up with a world of people in low-income countries who have access to significant resources for vaccines and other health commodities and programs through multilateral and bilateral organizations. But middle-income countries that are effectively growing themselves no longer have access to resources that they still need. So in the case of vaccines, children in middle-income countries are actually at risk of going without vaccines that will be available to low-income countries.

What are some present examples of a growing middle-income country?

Brazil, South Africa, India, Mexico, Indonesia, and China are all growing middle-income countries. Botswana and Namibia are middle-income countries. Nigeria should be and will probably be one in the next 5-10 years.

As you can see from that list, they're very different countries with different socio-economic strata at different stages in their economic development. That's why this is so complicated. We're also talking about billions of people when you put India and China together. So this range gives you a sense of the diversity among middle-income countries. Of course, there are different kinds of classifications of low- and middle-income countries, but that's not sufficient to start setting tiers.

How would a new multi-tiered vaccine pricing framework look? How close are we to establishing an agreed-upon framework, and what elements still need to be sorted out?

We don't have a new multi-tiered pricing structure yet; that's what we need to work on developing. It sounds easier than it is, but it's actually rather complicated. Some complications stem from the fact that not all middle-income countries are on the same playing field anymore, similar to how not all low-income countries or all high-income countries are the same. Some countries have emerging economies and rapid economic growth and many resources, but they also have a lot of people below the poverty line.

We also don't have a good understanding yet of how we would set price tiers. Do you do it by GDP, GNP, GNI, some other marker, or all of the above? Do you need four tiers, five tiers, six tiers? How would you enforce it? What do you do as countries move from tier to tier? How do you weigh middle-income countries with a significant number of people below the poverty line—by absolute number, percent, both? These are not easy questions to deal with, but they're manageable questions, and we can't deal with them if we don't start discussing them and move toward a framework.

But to date, we really haven't had that conversation. What we've had are pharmaceutical companies basically being attacked and defending themselves, and advocates, not inappropriately, fighting for access. But we don't always look forward to long-term solutions, in terms of the constant need for new commodities, new vaccines, and healthcare products, as resistance develops. As we need better and better commodities, we also need investment in those futures. But we also need widespread access for people in need today.

When this framework is established, will it be an easily transferable model to other areas of healthcare beyond vaccines?

Absolutely. Multi-tiered pricing isn't a solution just for vaccines; it's a solution for healthcare. We have the same problem with antiretroviral drugs for HIV. We have the same problem with antimalarial drugs. We have the same problem with pretty much every health commodity.

And if you look at it, the TRIPS agreement¹ already has a category of drugs and products that is in a different category because of the diseases they deal with in low- and middle-income countries.

In some respects, vaccines are the easiest entry point to establishing a multi-tiered pricing model. But this is not about just vaccines. It's setting tiers that allow for strata in healthcare overall.

Who are the critical stakeholders in creating a multi-tiered pricing framework for vaccines, and have they teamed up to begin designing the new model?

What I believe is necessary is a consensus that is developed across a range of health experts, both in-country and globally, as well as economists, ethicists, lawyers, and the corporate sector—both multinationals and in-country manufacturers, both innovators and producers of generics.² We still don't have a consensus on how we develop a tiered pricing structure that makes sense.

Unfortunately, the key stakeholders are at different tables. That's the problem. We need everyone to be at the same table. That's going to take a period of building trust. There's not a lot of trust right now. There's not a lot of understanding of where people are coming from. Negotiation is all about understanding where someone else is coming from, and building trust. You can't have a negotiation otherwise. And we don't have that yet.

We need the conversations to begin now because it's going to take a while, and the longer we wait, the longer it's going to take to reach an agreement, and the more people will suffer.

Who would be in charge of a new tiered pricing model? Will it be upheld by an existing institution, a new institution, or some other new mechanism entirely?

Creating an institution for this isn't going to work. One already exists—WTO (World Trade Organization). Other various organizations have also tried to negotiate some of the key issues. The problem is that everyone's going in different directions. We need a global framework, and I don't think it requires anything as elaborate as a new institution.

It requires a group of people with gravitas and technical skill to come up with a framework that can then be embedded through existing organizations. If you develop a framework and you have enough buy-in from a couple of middle-income countries and pharmaceutical companies—both innovator and generic—then you can start actually using it and see how it works. As you move toward a global agreement, it would be institutionalized in an international body like the WTO.

¹ TRIPS (trade-related aspects of intellectual property rights) is a comprehensive multilateral agreement on intellectual property rights (IPR) and is applicable to member countries of the WTO. The main areas that TRIPS address are: standards of protection for IPR, domestic enforcement of IPR, and IPR dispute settlements between WTO member countries. For more information, please visit http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

² The term "innovator" refers to those pharmaceutical companies that engage in research and development (R&D) for new vaccines. These companies are generally large, multinational pharmaceutical companies. The term "generic" refers to those pharmaceutical companies who manufacture generic versions of vaccines for which they do not hold the original vaccine patent. Many vaccine manufacturers, particularly those in the emerging economies, both manufacture generic vaccines *and* are beginning to engage much more in vaccine R&D.

How would a more comprehensive tiered pricing model affect innovation for the development of new vaccines and improvements of existing ones? What key factors in innovation, such as intellectual property, will need to be considered under a revised multi-level pricing structure?

What we're trying to do, both in innovation and overall, is to find balance. Right now, we have no balance. How do we have a world in which there is access to vaccines now, as well as the protection of intellectual property for the future so that we have those newer and newer commodities? How do you put all that together? We haven't had those conversations. People either want to protect or eliminate all intellectual property.

So we're not balanced there. We're not balanced between the need for ongoing innovation, the need to develop newer and better products, the need to protect intellectual property to provide the incentives for that to occur, and the need, which is just as strong, for immediate access to therapies and vaccines.

How you balance all of those needs and do so in a framework that is acceptable and beneficial for everyone? Again, we have the problem, which is a good problem in some respects, of countries growing out of low-income status to higher-income status. Repeatedly you'll hear a lot of people say, "Well, this isn't relevant," because, in Africa for example, only a few countries actually have patents, so why do you have to protect intellectual property when there aren't any patents?

Well, the goal is economic growth, which means these countries are all ideally going to be growing—and they have been growing at high rates. So eventually, they're all going to come out of low-income status, sooner rather than later, we hope. They're all going to want to enter most-favored-nation (MFN) trade status, or enter into trade agreements with high-income countries that are important for their further growth but also lead to intellectual property issues.

So this issue is actually going to become more, not less, complicated. And it seems to me that the people who are saying, "This isn't an issue," are sticking their heads in the sand just because few countries have patents or patent laws yet. Thinking that this matter isn't an issue is really just short-sighted.

There's this necessity to balance the need for intellectual property protection to incentivize innovation and the need for immediate access. And I think one of the most substantial ways to address that balance is with a multi-tiered system, because two tiers isn't going to work—in effect, the two-tier structure penalizes countries for economic growth by affecting their healthcare and their ability to provide healthcare to their citizens.

We're not yet in the mindset to set a balance between those two important and, in some ways, opposite, demands. But they don't need to be in opposition. There's a solution here. We just need to sit down and create it.

How might a new framework enable middle-income countries to better support their own national vaccination programs beyond commodity procurement?

The new framework is very much related to countries better supporting their national vaccination programs. For example, look at commodity delivery. There's no reason or incentive to start setting or working on your supply chains if you don't have the commodities to run through the system. These elements need to go hand in hand. There's a lot of inefficiency in supply chain systems. For example, we currently have wastage of childhood vaccines as high as 20% because the supply systems aren't functioning well. That means if we had good supply systems, we could actually be vaccinating 20% more children with the resources we have today in low-income countries.

And remember that a successful vaccination program is not just about supply chains. It's education. It's having the healthcare workers, it's developing the campaigns. There's a lot that goes into vaccination programs. There's a lot that goes into healthcare beyond procurement and the supply chain. But without procurement and supply chains, you can't provide healthcare.

Looking ahead five to ten years, what are the consequences of not creating a revised global framework that accommodates countries' diverse rates of growth? What is at stake?

First, we're going to have fewer and fewer people with access to healthcare, which is exactly what we don't want to have happen. Second, we'll have countries being penalized in their ability to provide healthcare because they're growing economically, which is the end goal of development.

As poorer countries grow over time, they'll gain resources, but there's a period in which they're coming out of low-income status. During this time, they don't have the resources to provide healthcare to all of their people. They *could* provide it if there was a tier that allowed them to move along different stages of pricing as they move along different stages of economic growth.

If we don't address this dilemma, countries are going to grow out of the ability to provide healthcare as they're developing economic growth. And that is a terrible outcome.

Finally, there are going to be battles over intellectual property. At the same time that countries are moving toward most-favored-nation (MFN) status and entering trade agreements, they therefore have to have some intellectual protection regime and won't have the resources yet to provide for their people. And that's a disaster waiting to happen.