

## **IMPACT & INNOVATION SERIES**

# Perspectives from Industry: Tiered Pricing and Vaccine Access

### An Interview with Mark Feinberg, Suresh Jadhav, and Jean Stéphenne

n June 2011, global leaders from science, industry, and policy gathered at the Pacific Health Summit on "Vaccines: Harnessing Opportunity in the 21st Century" for two days of discussion and debate focusing on increasing the accessibility and affordability of vaccines on a global scale. Last August, NBR spoke with Ambassador <u>Mark Dybul</u>, Co-Director and Distinguished Visiting Scholar of the Global Health Law Program at the O'Neill Institute of Georgetown University, about the need for a revised multi-tiered vaccine pricing framework to address the issue of access in low- and middle-in income countries.

As a follow-up to the 2011 Summit and the interview with Ambassador Dybul, NBR spoke with pharmaceutical industry leaders Mark Feinberg (Vice President & Chief Public Health and Science Officer, Merck Vaccines at Merck & Co.), Suresh Jadhav (Executive Director, Serum Institute of India Ltd.), and Jean Stéphenne (Chairman & President, GSK Biologicals) to gather industry perspectives on the key issues surrounding access to and affordability of vaccines worldwide. Together, they touch on the challenges and complexities of vaccine research and development and explain the need for collaboration between diverse stakeholders.



FEBRUARY 2012

Mark Feinberg, Vice President & Chief Public Health and Science Officer, Merck Vaccines, Merck & Co., Inc.

Mark Feinberg focuses on global efforts to implement vaccines and infectious disease therapies at Merck

Vaccines. In this role, he is also responsible for developing initiatives and partnerships that accelerate the global availability of Merck's drugs and vaccines, and that enable Merck's R&D expertise to help address health challenges impacting resourcepoor countries. Prior to joining Merck in 2004, Mr. Feinberg worked for over 20 years in both academia and government where he was actively engaged in basic and clinical research, patient care, and health care policy--with a primary focus on HIV/AIDS pathogenesis, treatment, and prevention research.



**Suresh Jadhav**, Executive Director, Serum Institute of India Ltd.

Suresh Jadhav has served since 1992 as Executive Director of Serum Institute of India Ltd., Pune, which he joined as a manager, quality control (QC) in 1979. He has been

instrumental in the development and adoption of the latest QC techniques and in elevating the Institute to standards on par with Western manufacturing facilities. Mr. Jadhav's 34 years of technical expertise covers areas including biologicals, quality control and assurance, and good manufacturing practice techniques, and regulatory affairs. He was the past President of Developing Countries Vaccine Manufacturers' Network (DCVMN) and also served as a Member on GAVI Board for two terms.



Jean Stéphenne, Chairman & President, GSK Biologicals

Jean Stéphenne has overseen GSK Biologicals since 1991, serving as Vice President and General Manager, then Senior Vice President and General Manager until his

appointment as President and General Manager in 1998. In March 2010, Mr. Stéphenne was appointed Chairman, Biologicals, in addition to his role as President and General Manager. This appointment signaled the beginning of a twoyear transition period prior to Mr. Stéphenne's retirement from operational responsibility for the business. At the end of this transition period, Mr. Stéphenne is expected to continue to fulfill the role of Chairman, GSK Biologicals on a part-time basis. **Q.** At the 2011 Pacific Health Summit on vaccines, there was a clear call from policy, civil society, and industry alike for a new framework for global vaccine pricing to improve global access to vaccines. From a manufacturer perspective, why isn't the existing tiered pricing structure for vaccines sufficient in the 21st century?

#### Suresh Jadhav

From my perspective, the very fact that there was demand from almost everybody during the 2011 Pacific Health Summit for establishing more tiers indicates that such a change is "justified". In fact, UNICEF already has two clear, separate mechanisms for purchasing vaccines for 1) GAVI<sup>1</sup> eligible countries and 2) middle-income countries. UNICEF issues the tenders separately, wherein the manufacturer can quote different prices for these two markets. In addition, if the manufacturer is supplying products to the developed world or is selling its vaccines in the country of manufacture, there are different pricing policies in place, depending upon varying government rules and regulations.

This means that there are already essentially four different tiered-price policies that currently exist among vaccine manufacturers. These are: 1) pricing in the country of manufacture, taking into account local regulations and discounting system, such as commission to the distributors or chemists; 2) differential pricing for export in the private market (again taking into account local commission structure); 3) pricing for GAVI eligible countries; 4) pricing for middle-income countries.

The main difference is that manufacturers from developed countries have access to markets where they can supply their products at very high prices, and this liberty does not exist today for developing country vaccine manufacturers. Vaccine pricing structures for middle-income countries – many of whom are not eligible for GAVI prices – depend upon who procures the product; i.e., whether a vaccine is purchased directly by a government, through agents from government "...Manufacturers from developed countries have access to markets where they can supply their products at very high prices, and this liberty does not exist today for developing country vaccine manufacturers."

Suresh Jadhav

organizations, or by the private market. Factors such as these need to be taken into account by the manufacturer when they quote the price for these markets, and therefore, there is no "one size fits all solution." The manufacturer has to consider the dynamics in each country and the rules and regulations that they have to follow as dictated by the procurement agencies.

#### Jean Stéphenne

Vaccines are essential to protection against disease wherever you live in the world – from those who live in the poorest of nations to those in the wealthiest countries. In order to protect human kind in the broadest sense, it is my belief that pricing structures should aim to provide access to vaccines across the wealth spectrum, which also reflects GSK Biologicals' mission. The term middle-income country refers to a heterogeneous group of countries in which economic status, demography, and healthcare infrastructure vary significantly. Therefore, a twotiered approach to pricing would be insufficient, and frankly, inequitable. Vaccine pricing structures should be flexible, with

> many different levels, to improve affordability and increase access for patients at lower income. At my own company, GSK, we have introduced a flexible pricing strategy to improve the affordability of our vaccines and increase access for patients with lower income levels, while remaining profitable.

<sup>1</sup> The GAVI Alliance is a public-private partnership that provides funding to improve low-income country's access to critical vaccines. GAVI eligible countries must have a gross national income per capita less than US\$1520.

#### Mark Feinberg

As the result of rapid economic growth over the past decade, a significant number of countries have transitioned from being categorized as low-income countries to middleincome status. However, due to within-country income inequalities and demographic trends, it is estimated that over 70 percent of the world's poor-or almost a billion people—now reside in middle-income countries that have graduated from a previous low-income status. As the level of country investment in health and the integrity of the healthcare infrastructures of these now middle-income countries have not yet increased sufficiently to ameliorate prevailing health inequities, the magnitude of the overall remaining disease burden for many important vaccinepreventable diseases is also now greater among people living in poverty in middle-income countries than in low-income countries. Because wealthier countries have the ability to pay higher prices for vaccines and low-income countries are usually eligible for heavily discounted prices offered by manufacturers and made available to countries with substantial procurement subsidies though the GAVI Alliance or other donor mechanisms, the wealthiest and the poorest countries tend to get the best access to vaccines, while the countries in the middle often are still working to find effective, predictable and sustainable solutions. This is particularly true in lower middle-income countries with poor access to resources and a high disease burden, and in countries that are economically better off overall, but that have significant disparities in income levels and access to health services. As many global health donors, such as the GAVI Alliance, set eligibility thresholds for funding based on overall national income levels, lower-middle-income countries are not eligible for support regardless of their prevailing disease burden. If a solution to this challenge does not emerge soon, it is anticipated that the trend for countries to "graduate" out of support by GAVI and other donors will continue in the coming years, even if the overall number of poor people in these same countries does not change substantially.

In the context of this evolving dynamic of country economic status, the integrity of their vaccine delivery infrastructures, country eligibility for donor support and the relative prices of different vaccines available in different countries, there is emerging evidence that vaccination rates for basic childhood vaccines are lower in many middleincome countries than they are in many low-income countries. Furthermore, a number of important newer vaccines—such as those targeting Hib, rotavirus, and pneumococcal disease—are being introduced sooner and more widely in low-income countries than they are in public sector programs in many middle-income countries. As such, much more needs to be done to ensure that all of the people in all of these countries can gain access to appropriate vaccines.

Q. Would a global pricing structure with more tiers than the current system allow companies to increase access to and supply of vaccines broadly, and perhaps even lower overall prices for vaccines over the long-term? Are there other factors in addition to vaccine pricing that influence access?

#### Jean Stéphenne

I absolutely believe that a multi-tiered pricing strategy is one of the key pillars to improve access to vaccines on a global basis - although we must not forget the role of health systems for delivery and advocacy in ensuring vaccines get to those who need them. While vaccine companies can play a key role in ensuring that prices are affordable, valuing prevention and providing financing for vaccines at a country level is critical. Over two decades ago, GSK pioneered a tiered pricing model, which allows us to have a sustainable business model and provides for continued investment in R&D, while offering our lowest prices to the poorest countries. In addition to pricing our vaccines based on the countries' ability to pay (based on the Gross National Income as defined by the World Bank) we also factor in the order size and the length of contracts. UNICEF and GAVI have provided access to vaccines for countries with GDP below US\$1500. Additionally, sustainable purchase of vaccines based on predictable forecasts for high volumes through supranational organizations, such as UNICEF for GAVI countries, helps ensure demand predictability, which is an essential component for GSK to provide low prices in these settings. This model lets us deliver more than 70% of our total volume to developing countries.

Tiered pricing is not a new concept for us, but the strategy is being adopted more broadly as part of new vaccine

financing mechanisms to ensure faster access to innovative vaccines. In fact, the ability to tier prices underlies GSK's ability to be able to participate in innovative financing schemes such as Advance Market Commitment, which is bringing pneumococcal vaccines to children in GAVI eligible countries in record time and at a record discount to those seen as more economically developed countries. For the first time in history, this model has allowed for the introduction of new modern vaccines in parallel across Europe and GAVI countries.

# "...While price is one consideration, and it is an important one, it is by far not the only consideration."

Mark Feinberg

#### Mark Feinberg

When discussing the concept of "tiered pricing", it is important to understand how these activities are currently regulated and implemented, as well as some of the specific circumstances that also influence vaccine production, procurement and delivery in different countries. Within the existing tiered pricing frameworks, each manufacturer, acting on its own, makes decisions about how best to approach the pricing of each of its products in each market. In addition, the current process by which many countries procure vaccines is through tenders where they express interest in procuring vaccines and different companies competitively bid for those tenders. More often than not, vaccine tenders involve a winner-take-all system and the winning price bid is generally not publicly disclosed. If one is proposing alternative pricing frameworks, there may be some merits for that, but it would be fundamentally different from the practices, constraints, and legal frameworks underlying the current tendering system. One additional consideration that often doesn't come up in discussions of tiered pricing is that a number of countries that are important, with respect to providing vaccines to many economically disadvantaged

people, maintain requirements for market access that extend beyond price. For example, regardless of price, some countries, like Brazil and China and Russia, often require that the innovator and vaccine developer agree that some component of local vaccine production of the vaccine, or even technology transfer leading to complete local vaccine production, will take place in their country in order to gain access to their markets. In addition to these considerations, some wealthier countries still want the least expensive prices for vaccines—namely, those that are made available to the world's poorest countries—and that is difficult to achieve with a tiered pricing strategy that is both effective at enabling innovation and fair to poor countries.

When discussing the issues of vaccine price and access, there are several factors that must be considered: 1) a country's ability to pay for vaccines; 2) the price that the country is *willing* to pay; 3) the vaccine manufacturers' ability to sustainably provide a vaccine at the price that a country can afford and/or is willing to pay and 4) whether mechanisms are in place that enable resource-limited countries that cannot afford to pay full price for vaccines to be able to gain access to them, such as global funders.

While price is one consideration, and it is an important one, it is by far not the only consideration. Structural impediments also now limit the ability of many low-income individuals to gain access to needed vaccines, and these represent critically important issues for all stakeholders to help resolve. Increased awareness of the nature of these structural impediments, and the development and implementation of effective plans to overcome them, will be crucial to enable increased access to vaccines. For example, appreciation of the importance of preventing a vaccine-preventable disease is not uniformly manifest in different countries around the world, so to improve access to vaccines, there is a need to generate and communicate a compelling evidence base to support vaccine introduction and to establish a clearly defined process through which local policymakers can gain a better understanding of the disease burden in their country and to enable them to make appropriate decisions about which vaccines to prioritize.

In addition, a country needs to be willing to invest in the health of its own people, and to invest in healthcare delivery infrastructure and products needed to deliver the best possible health outcomes for them. If a country has the resources to pay a fair price for products that are cost effective and effective at preventing disease, they should be willing to prioritize making appropriate investments to protect the health of their citizens. For countries that cannot successfully accomplish vaccine introduction on their own, mobilization of appropriate and sustainable donor resources and programmatic support will be necessary. Price is one component of this dialogue, but any discussion that does not look at the continuum of access is not going to deliver the most effective solutions.

I do believe that there is significant room for improvement. What often happens is that the discussion ends up being focused on the actual price of vaccines and the comparison is made to traditional inexpensive vaccines rather than thinking about the current vaccines, which are inherently more complicated and carry more development risk. Such discussions are often disassociated from the cost effectiveness of the vaccine within the economic circumstances of a country and whether the vaccine is actually a good value at a given price. One has to think about the value of vaccine innovation and what an appropriate vaccine price is based on its value and a country's ability to pay. Important issues of "affordability" and "sustainability" are also often used in these discussions, but rarely are these terms clearly defined in a manner that allows all partners to gain a common understanding of the challenges and to be able to work together to achieve positive and effective solutions. Derivation of common, clear, and operationally useful definitions of these terms would be very helpful in advancing this important dialogue.

#### Suresh Jadhav

In principle, this is the most logical way forward for any manufacturer. However, with the increasing number of manufacturers that are getting World Health Organization (WHO) prequalification<sup>2</sup> to supply their products to United Nations Agencies, the competition also increases, which itself results in the lowering of prices. However, manufacturers must be careful to look pragmatically at the future market size for a given vaccine when determining the quantity they want to produce, based upon infrastructure working at full production capacity. This is very important as it is only when full capacity is utilized (when a manufacturer produces the maximum number of vaccines possible given their infrastructure) that the price of vaccines will decline.

**Q.** To incentivize innovation in the vaccine industry, what key factors and drivers—such as intellectual property and ROI—will need to be considered under a revised, global, multi-tiered vaccine pricing structure?

#### Suresh Jadhav

In the current scenario, international agencies, procurement agencies, and private foundations often place pressure on multi-national companies to reduce their prices. We have already seen several manufacturers substantially drop their prices for supplies to GAVI as a result, and this pressure will likely continue. If the products are made for use in developing countries only, however, then there will be very little revenue generated for investment in R&D because prices are already so low in those markets, which can negatively impact innovation. But, if a similar product can be sold at the market price in the developed world, then there could still be scope for generating revenue, which can then be invested in R&D. At present, this luxury is available to manufacturers in the developed world and not for manufacturers in the developing world.

#### Jean Stéphenne

The science of vaccines has advanced dramatically, and we are now developing vaccines that are much more complex than those of the past. Therefore, we must ensure that our production and pricing strategies keep pace with these advancements.

In the past, the pharmaceutical industry tended to focus on higher income sectors of society in developing countries that were able to afford healthcare provision. We have made

<sup>2</sup> WHO prequalification ensures that vaccines used in national immunization services in different countries are safe and effective for target populations at the recommended schedules, and that they meet particular operational specifications. Every year, billions of U.S. dollars-worth of medicines and vaccines are purchased by international procurement agencies for

distribution in resource-limited countries. Prequalification is intended to give these agencies the choice of a wide range of quality medicines for bulk purchase. For more information, see the WHO webpage, "A system for the prequalification of vaccines for UN supply," http://www.who.int/immunization\_ standards/vaccine\_quality/pq\_system/en/index.html.

it our business to take a different approach where we focus on getting our products to those who need them most – and indeed believe that business growth will only be sustainable if it delivers greater access to medicines for these lower income groups.

#### Mark Feinberg

The development of a new vaccine is a scientifically risky process. Many of the vaccines for diseases that were relatively easy to develop a vaccine for have already been created. As a result, as we work to develop vaccines targeting diseases for which vaccines do not already exist, it is a fundamentally more difficult challenge. The scientific obstacles to vaccine development are greater, and the product development risks are higher. Many recently developed vaccines, as well as the majority of vaccines currently in development, necessarily involve the use of more sophisticated and expensive technologies for their production. Further, to address contemporary regulatory standards, vaccine developers must now conduct significantly larger and longer clinical trials to assess vaccine tolerability and safety, and extensive requirements must be met to assure vaccine quality. Overall, the use of new technologies, along with the high and increasing expectations and regulations for vaccine safety and quality have all resulted in substantial increases in the total cost of new vaccine development over time. At present, all of the work to develop a new vaccine requires the investment of hundreds of millions of dollars or more, and it is all invested at risk without knowing whether a development program will ultimately yield a licensed vaccine. The costs of constructing and maintaining vaccine manufacturing facilities typically run into additional hundreds of millions of dollars. Thus, for companies to be able to prioritize investment in the development of new vaccines, they need to feel that there is an appropriate opportunity to get a return on that investment to enable continued innovation.

Also, when we are thinking about an ideal global market in which everyone has access to vaccines—regardless of their personal income or the income level of the country they live in—the scale, presentation and acceptable cost of goods of the product can change in fundamental ways. When developing a new vaccine, it is essential to know the prevailing economic, social, and medical circumstances of the countries that will want to introduce the vaccine once it is available. In "...[Manufacturers] must be able to balance what they individually view as getting a suitable return on their investment in innovation with the very important goal of accomplishing access regardless of one's ability to pay."

Mark Feinberg

the past, profiles of vaccines that were developed were often well matched for circumstances of wealthier countries, but not necessarily those of low-income countries. With greatly increased attention to global health, and the advent of new partnerships, such as the GAVI Alliance, and new funding vehicles, such as the Advanced Market Commitment (AMC)<sup>3</sup> and the International Financing Facility for Immunization (IFFIm)<sup>4</sup>, vaccine developers can now begin to view all of the world's population as their target audience. Looking to the future, new vaccine development programs should include attention to key design elements including whether the product appropriate for use in every country or if the product must be tailored by region to address different relevant strains; which delivery systems and devices would be optimal in different setting; and how issues of thermostability and cold-chain "footprint" can best be addressed. In addition to these factors, decisions

<sup>3</sup> AMCs are legally binding agreements that provide private companies with incentives to invest in manufacturing and supplying new vaccines, through subsidies provided by international organizations and/or foundations.

<sup>4</sup> IFFIm is an aid-financing entity that uses an innovative approach to raising funds for GAVI, in which long-term pledges from donor countries are used to sell "vaccine bonds" on the market to raise immediate funds. For more information, see the IFFIm webpage: http://www.iffim.org/.

that vaccine developers must make during the very early phases of product development can also impact the cost of goods for vaccine production and thus impact future vaccine affordability. As manufacturers approach these choices, they must be able to balance what they individually view as getting a suitable return on their investment in innovation with the very important goal of accomplishing access regardless of one's ability to pay. In an ideal world, this could be accomplished through a system that allows companies to get a return on their investment while enabling countries to get access to vaccines that are optimally suited to meet their needs at affordable prices based on their economic circumstances, disease burden, and willingness to pay.

As the high cost of constructing and maintaining state-of-the-art vaccine manufacturing facilities represents a major component of the overall costs of vaccine production, the extent to which these facilities are used as productively and efficiently as possible is a very important consideration. In this regard, when there is a high level of vaccine production that is well-matched by high demand and effective utilization of a vaccine, there may be meaningful opportunities to achieve lower overall production costs by virtue of economies of scale. To achieve the most favorable economies of scale and vaccine affordability, the clarity and accuracy of projections for the magnitude and timing of market demand, as well as whether and when impediments to vaccine access will be reduced, are all very important variables. This, in turn, demands a productive alignment between governments, policy makers, donors, and manufacturers. Right now, the predictability of demand and the support for procurement in many regions and countries in the world have major question marks associated with them.

"It is critical to not just set a 'high' price and a 'low' price, but also identify new approaches to pricing."

Jean Stéphenne

Q. In his August 31, 2011 interview with NBR, Ambassador Mark Dybul called for a range of stakeholders to come together at the same table to begin a meaningful dialogue about what shape a new global vaccine pricing structure might take. In particular, he noted that in some cases companies have found themselves forced to take a defensive stance on pricing issues. What kinds of concerns do vaccine companies face from policymakers, civil society, and other stakeholders around these issues? What role is there for industry in building trust among stakeholders from other sectors, and how can these stakeholders engage with industry more collaboratively?

#### Jean Stéphenne

The tiered pricing model holds great promise, and we need to continue adapting it to new situations. It is critical to not just set a 'high' price and a 'low' price, but also identify new approaches to pricing.

We see great value in our partners in the vaccines community validating the tiered pricing approach. In June, members of the vaccines community came together to strike a major blow against rotavirus, another major killer of children in developing countries. In the lead-up to GAVI's replenishment meeting, GSK worked with a broad group of partners to strike a deal to provide our Rotarix vaccine to GAVI at a price of US\$2.50 a dose, a 95% price reduction compared to industrialized markets. With the remarkable success of GAVI's fundraising efforts and the support of global donors, this lifesaving vaccine is now reaching those in need faster than ever.<sup>5</sup>

However, we also need to keep our minds open, and our approach flexible, to ensure that we continue to drive access through appropriate pricing structures and mechanisms. We need to constantly innovate and see more examples of how to drive access and help middle-income countries develop

<sup>5</sup> Since 2003, GSK and Merck have worked with the Rotavirus Vaccine Program, a collaboration between PATH, the WHO, and the U.S. Center for Disease Control, to conduct clinical trials of the rotavirus vaccine in developing countries. Leading up to the GAVI pledging conference on June 13, 2011, GSK, Merck, and Bharat Biotech each agreed to supply GAVI with rotavirus vaccines at a significantly reduce price.

their goals of increasing local capacity, partnerships, and joint ventures.

For example, GSK has a long-standing technology transfer partnership with Brazil's state-owned vaccine manufacturer, Fiocruz. Since 1985 we have worked together to transfer the scientific "know-how" behind many of GSK's vaccines, including MMR, rotavirus, and now pneumococcal disease. Fiocruz is now producing Expanded Program on Immunizations (EPI)<sup>6</sup> vaccines, which keeps costs down while advancing access in Brazil. The partnership has now come full circle, from access back to innovation; in 2009, GSK and Fiocruz launched an R&D initiative to develop new vaccines against dengue, a major health threat in Brazil.

"Although it seems like an excellent suggestion to bring all the stakeholders to the same table, my fear is that for products with insufficient profit margins, manufacturers will simply stop manufacturing [them]."

Suresh Jadhav

#### Suresh Jadhav

Are we really talking about a "New GLOBAL Vaccine Pricing Structure," or only one for GAVI-eligible countries and low- and middle-income countries? Although it seems like an excellent suggestion to bring all the stakeholders to the same table, my fear is that for products with insufficient profit margins, manufacturers will simply stop manufacturing the products. This has happened in the past for most of the basic EPI vaccines, which were originally produced and supplied by big pharmaceutical companies to UN Agencies. Once the manufacturers from developing countries stepped in, big pharma simply moved out of that market. This is a very sensitive issue and should be kept in mind during any discussions so that such action, which could result in the non-availability of a vaccine, can be avoided.

#### Mark Feinberg

From my perspective and Merck's, we would love to see our vaccines widely available in all locations of need, and we are working hard to be in a position where we can accomplish this goal. In order to do so, we recognize that the issue of affordability of vaccines is very important and we are working to be in a place where we can have our vaccines be available broadly, regardless of income level. We also recognize that achieving this goal is not something we can do on our own. Rather, we know that it will require proactive, positive and effective collaboration with both public sector partners as well as private sector ones. Examples of our efforts to forge new partnerships to improve global access to new vaccines include our partnership with the Wellcome Trust to establish the MSD-Wellcome Trust Hilleman Laboratories that is specifically dedicated to develop new and optimized vaccines designed to meet the needs of people living in poverty, and our recently established partnership with Serum Institute of India that is focused on advancing the global availability of pneumococcal conjugate vaccines. For all partners committed to the broader vaccine enterprise, success in achieving our shared goals of global access to important vaccines will depend upon the extent to which open communication, proactive collaboration and appropriate sharing of risks become the norm.

<sup>6</sup> Initiated by the WHO in 1974, the EPI was developed with the objective to vaccinate children throughout the world against deadly and preventable diseases. EPI vaccines include: bacillus calmette-guérin, diphtheria-tetanus-pertussis, oral polio, and measles, hepatitis B, yellow fever in countries endemic for the disease, and haemophilus influenzae meningitis conjugate vaccine in countries with high burden of disease.

"...Middle-income countries...face significant challenges in delivering vaccines to their children without GAVI support. Some are even lagging behind GAVI countries in introducing new vaccines, even though they have nominally more financial resources."

Jean Stéphenne

**Q.** 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?

#### Suresh Jadhav

This is a very important issue. Many developing country manufacturers are concerned that not all countries will move at the same pace with respect to immunization. However, countries will still demand to procure vaccines for their population. Today they primarily depend on international agencies like GAVI for their supply of vaccines. This support from GAVI will eventually end. GAVI has a clear mandate to supply vaccines, initially free in some cases, to different countries, but GAVI still expects a co-payment, starting with a minimum of 15 to 25 cents per dose. Over a period of five years, recipient countries are expected to take full responsibility of procuring the product with their own internal finances. This has not happened at the pace that was expected, and in my opinion this is unlikely to happen with any GAVI-eligible countries, even over the next 15 to 20 years. This could result in immunization coverage dropping and many children remaining un-immunized in the future for those countries that do not take over procurement and funding responsibility after five years. For governments in many developing countries, increasing the health budget is not a high priority.

#### Mark Feinberg

If we don't move beyond where we are now, many individuals will not get full access to the vaccines that they need, and that would be very disappointing. Progress in realizing broad and equitable global access to vaccines will depend on effective cooperation between all parties, however. The discussions at the recent Pacific Health Summit served to clearly highlight the challenges before us, but also, even more importantly, to emphasize the promise that new and more effective partnerships between public and private sector organizations, which clearly share a common commitment to global access to vaccines, offer to overcome current access challenges.

For a vaccine developer, it is very encouraging to envision collaborative, forward-looking, and creative new ways to not only develop new vaccines to meet health needs in wealthier countries, but also to ensure that vaccines are developed that have global relevance with respect to their profile, level of affordability, and delivery characteristics so that they also achieve the greatest public heath impact in low- and middleincome countries as well. Not only are there now exciting opportunities for technological innovations to develop new, life-saving vaccines to protect against major global health threats, but innovations in novel partnership models, in vaccine financing solutions and in vaccine delivery strategies also provide promising avenues for future progress in enabling global vaccine access. If one could think of a world where access to vaccines were available to everyone, that would be a world where real innovation would flourish and be best situated to make a tremendous positive difference in the health of people all around the globe.

#### Jean Stéphenne

Over the past 10 years, we have made tremendous progress in both science and access to vaccines. The 21st century vaccine landscape will transform health in developing countries and will play a vital role in the development and progress in middle-income countries. However, we will all need to increase our commitments and do more if we are to truly make the next 10 years a 'Decade of Vaccines.'

In particular, middle-income countries – especially those in the lower range – face significant challenges in delivering vaccines to their children without GAVI support. Some are even lagging behind GAVI countries in introducing new vaccines, even though they have nominally more financial resources.

We must remain vigilant in ensuring new, innovative, flexible ways to bring vaccines to these markets. One way to do this is to develop a more flexible pricing strategy which takes into account multiple factors into account when setting price.

As I reflect on 2011 and look to the future, I find myself energized to know that as our world continues to grow, we have the ability to protect the health and wellbeing of our future's children better than ever before. I have great confidence that, together, we can rise to the occasion, and ensure every infant, child, adolescent and adult on this planet has an equal chance for a healthy life.  $\checkmark$ 

Published February 6, 2012 in the United States of America by The National Bureau of Asian Research (NBR) http://www.nbr.org

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