# Replenishing GAVI in 2014

Options for U.S. Engagement



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# Replenishing GAVI in 2014

### Options for U.S. Engagement

Katherine E. Bliss<sup>1</sup>

#### **Summary Introduction**

Toward the end of 2014, the Global Alliance for Vaccines and Immunisation (GAVI) will host a pledging conference to generate funds for activities to be carried out during 2016–2020.

The Alliance's ability to mobilize the funds it needs will be driven by the answers to three key questions:

- 1. How well is the current GAVI model of promoting vaccine uptake through advocacy, market-shaping activities (e.g., negotiating lower prices for vaccines), and health systems strengthening working, and what steps is GAVI taking to address problem areas?
- 2. Are GAVI-supported countries successfully moving toward greater cofinancing and sustainable "ownership" of domestic vaccine programs, and what are the Secretariat and partners doing to ensure smooth graduation transitions?
- 3. How robust is donor appetite for increasing contributions, and how realistic is it for GAVI to expand its resource base?

In many ways, the answers to the first two questions will determine the answer to the third.

This report reviews GAVI's progress and challenges during the current phase of operations and offers recommendations for U.S. policymakers to consider as they develop an approach to the upcoming GAVI replenishment.

#### **GAVI's Origins and Evolution**

The GAVI Alliance was launched at the 2000 World Economic Forum in Davos, Switzerland, to reverse the prior decade's decline in child immunization rates around the world.

<sup>&</sup>lt;sup>1</sup> Katherine E. Bliss is a senior associate with the CSIS Global Health Policy Center. She is grateful to CSIS colleagues, staff at the GAVI Secretariat, and Jon Andrus, Nicole Bates, Vinca LaFleur, Jennifer Kates, Victoria Fan, Heather Ignatius, and colleagues at PATH, and others for their help, comments, and suggestions in the preparation of this report.

For some observers, a deep ideological chasm between public-sector child health programs and private-sector vaccine research and development interests had exacerbated the challenges related to ensuring children were vaccinated. In 1990, the United Nations Children's Fund (UNICEF), World Health Organization (WHO), United Nations Development Programme (UNDP), World Bank, and Rockefeller Foundation launched the Children's Vaccine Initiative (CVI) "to help facilitate better and more extensive communication and cooperation between the public and private sectors." Yet despite its initial promise, the CVI's achievements were disappointing to some members, who believed the organization, which was housed at WHO, was hampered by the unease some in the United Nations system felt about working with profit-driven private-sector pharmaceutical firms.

In the late 1990s, a small group within the CVI began exploring a renewed approach to public-private cooperation on vaccines. These discussions inspired the creation of the Global Alliance for Vaccines and Immunisation (which later changed its name to the GAVI Alliance), with WHO, UNICEF, the World Bank, and the Bill and Melinda Gates Foundation as charter members.

Whereas other multilateral health organizations have relatively broad agendas, GAVI's mission focuses narrowly on the effort to "to save children's lives and protect people's health by increasing access to immunization in poor countries." Eighty percent of GAVI's program budget goes to purchasing and delivering vaccine commodities to public-sector programs. During its first decade, the Alliance relied on \$4 billion in partner-provided funds to carry out activities in 75 countries whose annual GNI per capita was less than \$1,000. By the end of 2010, achievements included preventing over 5 million future deaths, introducing a new meningococcal A vaccine in Africa, and rolling out a new pneumococcal vaccine in Nicaragua, among others. 5

But as GAVI officials calculated how much support they might need to fulfill the organization's goals over the next five years (2011–2015), it became clear that existing donor pledges of \$3.3 billion were not enough. Thus, in June 2011, GAVI organized its first replenishment, aiming to raise \$3.7 billion in additional operating funds.

The United Kingdom hosted a pledging conference, with Prime Minister David Cameron adding \$1.3 billion to his country's existing pledge, bringing the total UK commitment for 2011–2015 to \$2.45 billion. Joining the meeting in person, Bill Gates committed \$1 billion on top of his foundation's existing pledge, bringing its total to \$1.3 billion. Norway's final commitment was \$819 million. The United States, which historically had never made a multiyear pledge to GAVI, committed \$450 million over

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<sup>&</sup>lt;sup>2</sup> William Muraskin, "The Last Years of the CVI and the Birth of the GAVI," in *Public-Private Partnerships* for *Public Health*, ed. Michael R. Reich (Cambridge, MA: Harvard Center for Population and Development Studies, 2002), 115, http://www.hsph.harvard.edu/michael-reich/files/2012/09/Partnerships\_book.pdf. See also John Clemens et al., "Ten Years of the Global Alliance for Vaccines and Immunization: Challenges and Progress," *Nature Immunology* 11, no. 12 (December 2010).

<sup>&</sup>lt;sup>3</sup> Muraskin, "The Last Years of the CVI and the Birth of the GAVI," 116.

<sup>&</sup>lt;sup>4</sup> Global Alliance for Vaccines and Immunisation (GAVI), "The GAVI Alliance: Saving children's lives and protecting people's health by increasing access to immunisation in poor countries," fact sheet, January 2014.

<sup>&</sup>lt;sup>5</sup> GAVI Alliance, *Progress Report 2010* (Geneva: GAVI Alliance, 2010), 11, http://www.gavialliance.org/results/gavi-progress-reports/.

<sup>&</sup>lt;sup>6</sup> Ann Danaiya Usher, "GAVI funding meeting exceeds expectations," *The Lancet* 377, issue 9784 (June 25, 2011): 2165–66, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60945-8/fulltext.

the period between 2012 and 2014. By the end of the meeting donors had pledged \$4.3 billion, exceeding GAVI's original target.<sup>7</sup>

GAVI has proven to be an adaptive and flexible organization. Managed by a Genevabased Secretariat, supported by a network of public, industry, and civil society partners, and advised by a board willing to take chances and learn from experience, it has made important gains in improving the dissemination and use of life-saving vaccines in low-income settings. As CEO Seth Berkely reported at an October 2013, midterm review in Stockholm, Sweden, the Alliance is well on its way to meet its goal of preventing 4 million future deaths through routine immunization by the end of 2015. This is laudable and life-saving progress, to be sure.

Nevertheless, reaching some of the most vulnerable populations with vaccines; managing the relatively new country graduation process; and generating data to make the case that investing in GAVI is a public health "best buy" remain persistent challenges. And with the Alliance set to release its next five-year plan of action in June 2014, including plans to scale-up activities in many implementing countries, GAVI's projected budget needs for 2016–2020 will almost certainly grow.8 It logically follows, therefore, that GAVI will be asking its traditional donors, as well as newer partners, to increase their contributions as it launches its second replenishment process on May 20, 2014, at a meeting in Brussels to be hosted by the European Commission (EC).

Yet, GAVI's unconventional public-private status, and the fact that it is not directly engaged in immunization activities but rather channels products and funds to government health programs for their use, makes it difficult to explain its impact and thus its value—to policymakers. And while GAVI has bolstered its fundraising outreach in the United States and in Europe, it needs greater capacity for diplomatic engagement and resource mobilization from newly active and emerging global health partners.

#### The U.S. Role

The United States' future commitments to GAVI will help determine the organization's prospects over the next five years. A long-time champion, the United States was one of GAVI's first donors, committing \$48 million in 2001. To date, the United States has supplied or pledged more than \$1 billion to GAVI; devoted countless hours of staff service on the GAVI Board and its technical and policy subcommittees; and provided in-country technical and implementation support. 9 The United States currently sits on

<sup>&</sup>lt;sup>7</sup> In 2011, the CSIS Global Health Policy Center and Center for Global Development released an analysis of GAVI's prospects in the upcoming replenishment: Lisa Carty, Amanda Glassman, J. Stephen Morrison, and Margaret Reeves, "GAVI's Future: Steps to Build Strategic Leadership, Financial Sustainability, and Better Partnerships," June 2011, http://csis.org/files/publication/110609\_Carty\_GAVI\_0.pdf.

<sup>&</sup>lt;sup>8</sup> Debbie Adams, "Review of decisions: GAVI Alliance Board meetings, Phnom Penh, Cambodia, 21–22 November 2013."

<sup>&</sup>lt;sup>9</sup> Kaiser Family Foundation, "The U.S. & the GAVI Alliance," fact sheet," December 2011, http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8198-02.pdf. The United States, represented by the U.S. Agency for International Development (USAID), currently occupies one of five rotating donor government seats on the GAVI Board. There are 28 board seats, which are allocated to diverse constituencies: permanent members (UNICEF, WHO, World Bank, Bill and Melinda Gates Foundation); independent members; developing country governments; donor governments; research and technical

Evolution of the GAVI Alliance				
2000	The Global Alliance for Vaccines and Immunisation (GAVI) is launched at the World Economic Forum (WEF) in Davos, Switzerland.			
2001	The United States commits \$48 million as one of the first government donors to GAVI.			
2003	GAVI reports commitments of \$1 billion for immunization programs in 68 countries.			
2005	GAVI begins to offer health system strengthening (HSS) support.			
2006	The International Financial Facility for Immunisations (IFFIm) is launched.			
2007	IFFIm reports having generated nearly \$1 billion to support GAVI programs in 43 countries.			
	The Advance Market Commitment (AMC) program is launched to accelerate access to the pneumococcal disease vaccine.			
	GAVI introduces the country cofinancing policy.			
2008	Bolivia is the first country to introduce rotavirus vaccine with GAVI support.			
2010	Nicaragua is the first GAVI-supported country to introduce pneumococcal vaccine.			
2011	GAVI introduces country graduation policies.			
	The United Kingdom hosts GAVI's first pledging conference, at which GAVI raises \$4.3 billion, with the United States making an unprecedented three-year pledge of \$450 million.			
2013	The midterm review for the 2011–2015 period is held in Stockholm.			
2014	GAVI launches its second replenishment process.			

the GAVI Board, joining Australia in representing a "constitutent" bloc that includes Japan and South Korea.

There are several reasons for the United States to intensify its GAVI support. Most fundamentally, promoting child health and ending preventable child deaths through immunizations are U.S. health priorities both domestically and internationally, and U.S. investments in GAVI complement the vast range of bilateral U.S. child health programs in GAVI-eligible and non-GAVI countries. These include activities directed toward immunization systems strengthening; helping to improve national budget transparency and financial planning for vaccine programs; and the provision of

health institutes; and civil society organizations. A representative of the U.S. Centers for Disease Control and Prevention (CDC) currently occupies a seat on the board for research/health institutes.

technical assistance in writing GAVI grant applications and carrying out post-vaccine introduction follow-up assessments.10

The United States has strongly supported the Global Polio Eradication Initiative, and the GAVI Board's November 2013 decision to include the Inactivated Polio Vaccine (IPV) among the vaccines it offers to countries comes at a critical time in the global campaign to eradicate polio. 11 In addition, GAVI's policies of country cofinancing and graduation from GAVI support resonate with the emphasis on country ownership and sustainability that characterizes the Obama administration's 2009 Global Health Initiative (GHI).

As U.S. policymakers head into the replenishment process, they will want to consider the efficacy of GAVI's model of program support and operations; the long-term sustainability of country-level programs initiated with GAVI support; and the prospect that GAVI will be able to expand its base of donors and supporters in this and future funding cycles.

#### Three Key Questions

1. How well is the current GAVI model of promoting vaccine uptake through advocacy, market-shaping activities (e.g., negotiating lower prices for vaccines), and health systems strengthening working, and what steps is GAVI taking to address problem areas?

GAVI's most important strategic goal is to accelerate uptake and use of underused vaccines in developing countries, and to decrease the time it takes to provide access to new vaccines. GAVI's earliest programs focused on promoting the adoption of the Hepatitis B vaccine in China and the Yellow Fever vaccine in West Africa. A more recent priority has been promoting access by developing countries to newer vaccines, such as those that protect children against infection with rotavirus, pneumococcal disease, and human papillomavirus (HPV). In 2001, GAVI introduced the pentavalent vaccine, which protects recipients against tetanus, diphtheria, pertussis, Hepatitis B, and Haemophilus Influenzae B (responsible for pneumonia and meningitis), and is more cost-effective and easier than individual vaccines for health workers to administer and track. The pentavalent vaccine is now routinely used in 72 of the 73 GAVI-eligible countries, with South Sudan expected to introduce it in 2014.

In 2008, Bolivia became the first GAVI country to introduce the relatively new rotavirus vaccine, which had subsequently been introduced in 19 countries by the end of March 2014. Drawing on resources made available through an Advance Market Commitment (AMC) pilot program, "to stimulate the manufacture of an adequate supply of affordable pneumococcal vaccines for developing countries," GAVI then

<sup>&</sup>lt;sup>10</sup> See USAID, "Global Flagship Immunization Support from USAID's Maternal and Child Health Division," fact sheet, March 2014.

<sup>&</sup>lt;sup>11</sup> GAVI Alliance, "GAVI Alliance to Support Introduction of Inactivated Polio Vaccine in World's Poorest 73 Countries," press release, November 22, 2013, http://www.gavialliance.org/library/news/pressreleases/2013/gavi-alliance-to-support-introduction-of-inactivated-polio-vaccine-in-worlds-73-poorestcountries/. See the recent notice, UNICEF, "Joint [Gobal Polio Eradication Initiative] GPEI-GAVI Statement on the Availability and Price of Inactivated Polio Vaccines," press release, February 28, 2014, http://www.unicef.org/media/media\_72738.html.

collaborated with Johns Hopkins University and other partners to accelerate the introduction and scale-up of a pneumococcal vaccine capable of protecting children in developing countries against the strains of the bacterium most common where they live. <sup>12</sup> The Alliance rolled out the pneumococcal vaccine in 2010, with plans to expand to more than 50 countries by the end of 2015. <sup>13</sup> In May 2013, GAVI launched the first demonstration projects focusing on the introduction of HPV vaccine in countries with a proven record of reaching adolescent girls through immunization programs.

As was announced at the midterm review in Stockholm, Sweden, in October 2013, the results for the current period are promising: 97 million children have been fully immunized through GAVI programs since 2011, with the Alliance on track to reach 243 million children fully immunized through GAVI-supported activities by the end of 2015.

That said, an estimated 22.6 million children around the world are still unvaccinated (of whom an estimated 19.6 million are within GAVI-supported countries), and coverage rates for some newly introduced vaccines have been slow to climb. Observing that "supply constraints for particular formulations and/or country-readiness issues have jeopardized the achievement of coverage goals in the short term," GAVI's 2012 Progress Report notes that by the end of that year coverage for pneumococcal vaccine across GAVI-supported countries was just 10 percent, and just 3 percent for the rotavirus vaccine.<sup>14</sup>

Additionally, GAVI partners lament the persistent problem of reaching the so-called "5th child"—that is, the most impoverished and vulnerable 20 percent of children around the world. Because these children often live in remote rural areas or, increasingly, in informal peri-urban settlements, they can be difficult—and more expensive—to reach through the predominantly state-run public programs GAVI supports.

GAVI officials and partners assert that child vaccinations are a public health "best buy," arguing that money spent on vaccines preempts greater expenditures that might be associated with disease treatment and lost productivity down the road. In order to make the case as persuasively as possible, however, the quality of GAVI's vaccine coverage data must continue to improve.

GAVI relies on implementing country governments and civil society organizations, as well as international organizations with field presence, including Alliance partners WHO and UNICEF, to help develop information about program reach. Staff within implementing country health offices track vaccine coverage data and provide it to WHO, which verifies the numbers. The data is then "triangulated" with other information, including census figures and vaccine delivery manifests, but coverage numbers remain imprecise. To remedy some of these deficiencies, GAVI has recently

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<sup>&</sup>lt;sup>12</sup> Nina Schwalbe and Ibrahim El-Ziq, letter to the editor, *The Lancet* 375, issue 9715 (February 20, 2010), http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673610602681.pdf.

<sup>&</sup>lt;sup>13</sup> GAVI Alliance, "Advance Market Commitment for Pneumococcal Vaccines: Annual Report," April 1, 2012–March 31, 2013.

<sup>&</sup>lt;sup>14</sup> GAVI Alliance, *Progress Report 2012* (Geneva: GAVI Alliance, 2012), 15, http://gaviprogressreport.org/2012/. According to WHO, in 2012 global coverage for rotavirus vaccine was 11 percent, with coverage for pneumococcal vaccine 19 percent. See WHO, "Immunization Coverage," fact sheet, February 2014, http://www.who.int/mediacentre/factsheets/fs378/en/.

released new guidelines that require countries applying for new support to have a plan for third-party analysis of data quality. 15

GAVI's official midterm report offered some promising results about vaccine impacts, but more information is needed about the broad economic and social effects of GAVIsupported vaccines. In Kenya, for example, the annual number of hospital admissions of children suffering from pneumococcal disease fell dramatically in one district within three years of the vaccine's introduction. In Uganda, the number of Hib meningitis cases plummeted 85 percent in the four years following the introduction of the pentavalent vaccine. 16 Since 2013, the Secretariat's Monitoring and Evaluation Section has been working with a variety of Alliance partners to develop models to estimate vaccine-associated benefits beyond deaths or hospitalizations averted, such as productivity gains and impact of GAVI-supported vaccine programs on reducing catastrophic expenditures for health. 17 Academic research about the health and economic impacts of specific vaccines within the GAVI arsenal has begun to appear, as well.18

GAVI's success in expanding vaccine coverage and communicating the impact of its programs during its next phase of operations will depend, to some extent, on the partnership's progress toward a second strategic goal, which is to strengthen the capacity of integrated health systems to deliver immunization programs. With roughly 80 percent of GAVI's program funds used to pay for vaccine commodities, the remainder is channeled to countries in the form of cash grants, which are intended to help improve the overall functioning of implementing country immunization and broader health systems.

GAVI's health systems strengthening (HSS) program began in 2006, following a 2004 study by the Norwegian Agency for Development Cooperation (Norad) on "Alleviating System Wide Barriers to Immunization" and a subsequent board recommendation urging "enhanced effort" for countries missing their coverage targets by 10 percent or more. 19 The HSS program had an initial five-year plan and was supported by \$500 million from GAVI and the International Finance Facility for Immunisation program (IFFIm), an investment fund initiated in 2005 by France, Italy, Spain, Sweden, and the United Kingdom and to which multiple donors can contribute for rapid disbursement of support for immunization programs.

<sup>&</sup>lt;sup>15</sup> See the discussion in Victoria Fan, "GAVI Moves on Better Data Verification," Center for Global Development, March 11, 2014, http://www.cgdev.org/blog/gavi-moves-better-data-verification. <sup>16</sup> GAVI Alliance, "Delivering Together on the 2011–2015 Strategy: Mid-Term Review Report," October 2013, 8, http://midtermreview.gavialliance.org/deliveringbeyond/.

<sup>&</sup>lt;sup>17</sup> Interview with Peter Hansen, GAVI Secretariat, December 2013.

<sup>&</sup>lt;sup>18</sup> Miloud Kadar, Patrick Lydon, and Ruth Levine, "Financial challenges of immunization: a look at GAVI," Bulletin of the World Health Organization 82, no. 9 (September 2004): 697-702; Chunling Lu et al., "Effect of the Global Alliance for Vaccines and Immunisation on diphtheria, tetanus, and pertussis vaccine coverage: an independent assessment," The Lancet 368, issue 9541 (September 23, 2006): 1088-95, http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673606693379.pdf?id=baaK2zO8Yvx8qxpeqrvu; Sun-Young Kim et al., "Health and economic impact of rotavirus vaccination in GAVI-eligible countries," BMC Public Health 10, no. 253 (May 2010), http://www.biomedcentral.com/content/pdf/1471-2458-10-253.pdf.

<sup>&</sup>lt;sup>19</sup> GAVI Alliance and Norwegian Agency for Development Cooperation (Norad), "Alleviating System Wide Barriers to Immunization: Issues and Conclusions from the Second GAVI Consultation with Country Representatives and Global Partners," Oslo, Norway, October 7-8, 2004.

HSS participants reported significant challenges in the effort's initial phase, including the Alliance Secretariat's lack of coherent vision for HSS, concerns that the work might ultimately detract from GAVI's mission, and unclear delineation of roles between the Secretariat and partners on the ground when it came to providing technical assistance. 20 Following a 2009 review, the Secretariat committed to undertake reforms in some key areas, including identifying ways to improve the provision of technical support to the countries receiving the grants and enhancing annual reporting and program monitoring processes.<sup>21</sup>

While some cash grants have supported the development and strengthening of civil society and advocacy groups, GAVI reported in 2012 that "countries are applying most GAVI HSS support to strengthening peripheral health service delivery," with activities including training health workers, creating performance-based allowances for community health workers, and establishing outreach health services in remote areas.<sup>22</sup> GAVI has committed some funds to "support CSO engagement in national health policy dialogue," and in some cases, governments have involved civil society groups in their HSS grant application processes.<sup>23</sup> To supplement the cash grants, GAVI works with WHO and UNICEF, as well as bilateral partners, to provide technical assistance to help countries strengthen their health systems for improved immunization outcomes. Considering that the Global Fund and the World Bank are also funding health systems strengthening programs, it may be helpful for the three organizations to consult and better coordinate on their HSS work at the country level.24

A third strategic goal is to "shape vaccine markets to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries." Introduced in 2011, this is one of GAVI's newest goals and one where the partnership's engagement with the private sector is essential. Broadly speaking, GAVI's marketshaping work is focused both on creating a predictable demand for underutilized vaccines and on creating a stable supply of vaccine products, all of which must be WHO prequalified.

By expanding the number of suppliers of prequalified vaccine, GAVI has been able to bolster supplies of older, underutilized vaccines, as well as negotiate lower prices for some of the more recently introduced and costlier vaccines, such as the rotavirus, HPV, and pneumococcal vaccines. <sup>25</sup> It also helps maintain healthy competition

<sup>&</sup>lt;sup>20</sup> Joseph F. Naimoli, "Global health partnerships in practice: taking stock of the GAVI Alliance's new investment in health systems strengthening," International Journal of Health Planning and Management 24, no. 1 (January-March 2009): 3-25.

<sup>&</sup>lt;sup>21</sup> GAVI Alliance and HLSP, "GAVI Health Systems Strengthening Support Evaluation 2009 RFP-0006-8: Volume I: Key Findings and Recommendations," October 8, 2009; see also GAVI Alliance, "GAVI Secretariat management response to the GAVI Health Systems Strengthening Support (HSS) Evaluation 2009," November 10, 2009.

<sup>&</sup>lt;sup>22</sup> GAVI Alliance, "Investing in Immunisation through the GAVI Alliance: The evidence base," November 2012, http://www.gavialliance.org/library/publications/the-evidence-base/.

<sup>&</sup>lt;sup>23</sup> See GAVI Alliance, *Progress Report 2012*, 31. Also, communication from GAVI Secretariat, March 2014. <sup>24</sup> See The Global Fund, "Health Systems Strengthening," http://www.theglobalfund.org/en/about/diseases/ hss/; World Bank, "Health Projects and Programs," http://www.worldbank.org/en/topic/health/projects. <sup>25</sup> In its first years of operation, for example, GAVI relied on 5 suppliers in 5 countries, but by 2012 it had expanded that number to 10 in 8 countries. According to The Lancet, GAVI anticipated that the addition of Serum Institute and Panacea Institute of India to the list of producers of vaccines for GAVI would have the effect of lowering the cost for pneumococcal vaccine to \$2 a dose. See Usher, "GAVI funding meeting

between suppliers, and reduces risks that come from having too few manufacturers. By purchasing vaccine commodities through UNICEF, GAVI is also able to remove some risk for manufacturers and secure lower prices associated with bulk orders, although some observers have expressed concern that UNICEF's role is not subjected to independent scrutiny and that its position as both permanent GAVI board member and major beneficiary presents a conflict of interest.

As a result of working with suppliers to reduce costs for vaccine products, GAVI reports that from 2010 to 2012, the total cost to GAVI-supported programs of vaccinating a child with pentavalent, pneumococcal, and rotavirus vaccines has dropped from \$35 to \$23.<sup>26</sup>

2. Are GAVI-supported countries moving toward greater cofinancing and sustainable "ownership" of domestic vaccine programs, and what are GAVI and partners doing to ensure smooth graduation transitions?

In 2006, the GAVI Board adopted a resolution calling for country cofinancing for vaccine programs, a departure from the previous policy of providing vaccines to GAVI-eligible countries free of charge. The cofinancing policy was launched in 2007 and revised in 2010 "to put countries on a trajectory towards financial sustainability in order to prepare them for phasing out of GAVI support for new vaccines altogether."

In the current GAVI cofinancing policy, countries are divided into three groups: countries classified as "low income" according to World Bank annual gross national income (GNI) per capita estimates pay 20 cents a dose; an "intermediate" group pays an additional 15 percent per year for vaccines; and a "graduating group," which includes countries with GNI per capita of \$1,570 or more, can no longer apply for further vaccine support.<sup>28</sup>

Getting the cofinancing program right is critical. Between January 2011 and August 2013, country cofinancing commitments totaled \$125 million—which represents just 8 percent of GAVI's total bill for vaccines. Assuming that countries will continue to grow economically and progress from lower income to intermediate to graduating country status—and that, over time, more countries will introduce the newer, costlier vaccines—GAVI anticipates the cofinancing figure will rise to a total of \$1.8 billion by 2020.

GAVI reports that nearly all of the 67 cofinancing countries have met their target of 100 percent timely copayments, a prerequisite for any new application for support to be approved by the GAVI Board. At the Stockholm midterm review, however, Awa Marie Coll-Seck, minister of health of Senegal, described her country's challenges in increasing the annual domestic budget for vaccines from \$730,000 in 2002 to \$2,036,000 in 2013; several other ministers joined her in acknowledging the difficulties

<sup>28</sup> Ibid.

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exceeds expectations," 2166. In 2012, suppliers of vaccine to GAVI were located in the United States, Brazil, the Russian Federation, Belgium, France, India, Indonesia, and the Republic of Korea. Interview with Melissa Malhame, GAVI Secretariat, December 2013.

<sup>&</sup>lt;sup>26</sup> Interview with Melissa Malhame, GAVI Secretariat, December 2013.

<sup>&</sup>lt;sup>27</sup> GAVI Alliance, "GAVI Alliance Revised Co-financing Policy," December 1, 2010.

they face in securing adequate budget support for vaccines from their own finance ministries.

A related topic of discussion in Stockholm was whether increasing domestic financing for GAVI-provided vaccines takes money from other immunization programs or diverts funds from other health priorities. A 2011 study notes that not all countries within the same income group are able to manage the cofinancing requirements equally, and that "countries with low levels of government spending on health relative to their income are likely to find co-financing payments harder to assume."<sup>29</sup>

A second critical issue is ensuring that "graduating" countries are able to sustain their financing of domestic vaccine programs once weaned from GAVI support.

Building on its cofinancing policy, in 2011 GAVI instituted a "graduation policy" under which countries that achieve a GNI of \$1,570 per capita lose their eligibility for new GAVI support. Once they pass the threshold, they enter a five-year graduation process, during which they pay incrementally higher prices for vaccines. At the end of the five years, according to the policy, the graduating countries are expected to be able to pay the total (GAVI) price for vaccine products.

GAVI currently lists 20 countries in the graduation "pipeline": Angola, Armenia, Azerbaijan, Bhutan, Bolivia, Republic of Congo, Cuba, Georgia, Guyana, Honduras, Indonesia, Kiribati, Moldova, Mongolia, Nicaragua, Papua New Guinea, Sri Lanka, Timor Leste, Ukraine, and Uzbekistan (although Cuba and Ukraine are reported not to have any current or pending GAVI-supported projects).<sup>30</sup> According to estimates for the group of 14 countries that entered the pipeline in 2012, "graduation" means that between 2012 and 2018, the financial burden for the vaccines that GAVI currently provides for these countries will jump from \$8 million to \$90 million, with an assumption that the countries will continue to benefit from access to GAVI-negotiated low prices for vaccines rather than pay the full market price charged in the United States or Europe.31

At the midterm review in Stockholm, Moldova's minister of health, Andrei Usatîi, expressed concerns that his country might reach the end of the graduation period unable to sustain financing for existing vaccines at the total price, much less introduce new vaccines.<sup>32</sup> A 2012 pilot study in Bhutan, Republic of Congo, Georgia, Moldova, and Mongolia showed countries as "highly heterogeneous in their capacity to assume responsibility for the immunization programs" and underscored that transition planning is essential.<sup>33</sup>

In addition, GAVI acknowledges that some graduating countries still have levels of vaccine coverage below 70 percent. At its November 2013 meeting in Phnom Penh, the

<sup>&</sup>lt;sup>29</sup> Helen Saxenian et al., "An Analysis of How the GAVI Alliance and Low- and Middle-Income Countries Can Share Costs of New Vaccines," Health Affairs 30, no. 6 (June 2011): 1129.

<sup>&</sup>lt;sup>30</sup> Helen Saxenian et al., "Overcoming challenges to sustainable immunization financing: early experiences from GAVI graduating countries," *Health Policy and Planning* (February 2014): 1–9, http://heapol.oxfordjournals.org/content/early/2014/02/08/heapol.czu003.full.pdf+html. Cuba and Ukraine are also scheduled to graduate, but neither has current vaccine support from GAVI.

<sup>&</sup>lt;sup>32</sup> Breakout session, GAVI Alliance Mid-Term Review, Stockholm, Sweden, October 30, 2013.

<sup>33</sup> Ibid.

board directed the Secretariat to allocate an additional \$2 million to the 2014 business plan to "scale up engagement with graduating countries," including through supplementary HHS support.<sup>34</sup> The Secretariat is overseeing assessments to anticipate challenges and make additional funds available to graduating countries in need. 35

While the Secretariat and partners determine how best to ensure countries can successfully manage the graduation requirements, the challenges point to a larger question about middle-income countries and vaccine access. 36 With evidence that the global poor are increasingly concentrated in populous middle-income countries, GAVI's eligibility criteria are being carefully scrutinized. Some analysts suggest that even if middle-income countries themselves are not eligible for GAVI support, enabling eligibility for impoverished states or districts within middle-income countries may be appropriate.

Ongoing discussions between GAVI and the Pan American Health Organization (PAHO) over vaccine pricing highlight also some of the challenges with different pricing approaches, Since 1979, PAHO's Revolving Fund for Vaccine Procurement has provided countries in the Americas with access to low-cost vaccines for use in public programs. Two aspects of the Revolving Fund policy are relevant for GAVI's work: First, the Revolving Fund seeks to provide participating countries with the lowest price (globally) of specified vaccines; second, all countries in the region, most of which are classified as middle income and are not GAVI-eligible, enjoy the same low price, regardless of GNI.37

When GAVI introduced the pneumococcal and rotavirus vaccines, the GAVI Secretariat had asked PAHO to make an "exception" to the Revolving Fund's "lowest price" policy to allow GAVI to seek lower prices for the two vaccines for GAVI-eligible countries than the prices available to PAHO member countries. The director of PAHO at the time granted the exception, but in October 2013, the PAHO Directing Council decided to revisit the issue. <sup>38</sup> A change in PAHO pricing policies could affect GAVI's future ability to secure the lowest prices for new vaccines for the GAVI-eligible countries. GAVI and PAHO report that they are working to find a sustainable solution.

Anxious to address the larger question of middle-income country eligibility, members at the November 2013 GAVI Board meeting requested the "Secretariat to conduct analyses and consultations to develop and propose instruments to support access to affordable prices for all Lower Middle Income Countries (LMICs), including graduated

<sup>&</sup>lt;sup>34</sup> Adams, "Review of decisions," 38.

<sup>&</sup>lt;sup>35</sup> Communication from GAVI Secretariat, March 2014.

<sup>&</sup>lt;sup>36</sup> See Amanda Glassman, Denizhan Duran, and Andy Sumner, "Global Health and the New Bottom Billion: What Do Shifts in Global Poverty and the Global Disease Burden Mean for GAVI and the Global Fund?" Center for Global Development, October 2011, http://www.cgdev.org/sites/default/files/1425581\_ file Glassman Duran Sumner MIC global health FINAL.pdf.

<sup>&</sup>lt;sup>37</sup> Pan American Health Organization, "Principles of the Pan American Health Organization Revolving Fund for Vaccine Procurement," 52nd Directing Council, 65th Session of the Regional Committee, September 30, 2013.

<sup>&</sup>lt;sup>38</sup> Interview with PAHO Deputy Director Jon Andrus, January 2014. Pan American Health Organization, "Principles of the Pan American Health Organization Revolving Fund for Vaccine Procurement."

countries and non-GAVI LMICs," with the options to be presented to the board this year.<sup>39</sup>

## 3. How robust is donor appetite for increasing contributions, and how realistic is it for GAVI to expand its resource base?

The biggest unknowns surrounding the upcoming replenishment are whether GAVI's traditional donors will boost their contributions and whether the Alliance can mobilize new government and private-sector support.

Donors have four ways to contribute to GAVI: directly; via a matching fund supported by the United Kingdom and the Bill & Melinda Gates Foundation; through the Advanced Market Commitment (AMC) process; or by making a long-term commitment to IFFIm. <sup>40</sup> Most contributions take the form of direct funding or long-term pledges to IFFIm. GAVI uses the direct contributions to support operations and program activities, and the IFFIm "uses long-term pledges from donor governments to sell 'vaccine bonds' in the capital markets, making large volumes of funds immediately available for GAVI programs." <sup>41</sup> IFFIm reports that between 2006 and 2013 it provided 39 percent of the funding for GAVI's vaccine purchase and delivery programs. <sup>42</sup>

If GAVI aims to secure increased direct contributions, the December 2013 replenishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria may have previewed what to expect. The Global Fund secured \$12 billion in donor pledges—a big number, yet \$3 billion short of the Fund's \$15 billion goal. Evidently, donors are still willing to fund public-private partnerships, but not as robustly as in the past.

In addition, the Global Fund's traditional donors are challenging new partners to boost their contributions. Mindful that statutory language limits the U.S. contribution to the Global Fund to no more than one-third of the total, President Obama exhorted donors not to "leave our money on the table," as he announced the U.S. pledge of up to \$5 billion. Similarly, the United Kingdom's commitment (of up to \$1.6 billion in this round) can be no more than 10 percent of the total amount raised by the Fund. Some of GAVI's donors could take a cue from the Global Fund experience and offer conditional funding to inspire greater commitments from others. Multiple matching requirements present opportunities and challenges for GAVI; while they could help promote support from others, they could also create negative incentives, causing reverberating reductions that spiral downward.

President Obama's FY2015 request for \$200 million for GAVI is the largest since the first U.S. contribution in 2001, suggesting the administration is open to a modest yearly increase, if not a major one. Historically the United States has only made direct

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<sup>&</sup>lt;sup>39</sup> WHO, "Summary of the November 2013 GAVI Alliance Board Meeting," http://www.who.int/immunization/sage/meetings/2014/april/1\_Executive\_summary\_GAVI\_Alliance\_Board\_Nov13.pdf.

<sup>40</sup> GAVI Alliance, "Key Figures: Donor Contributions and Pledges," http://www.gavialliance.org/funding/donor-contributions-pledges/.

<sup>&</sup>lt;sup>41</sup> IFFIm, "Overview," http://www.iffim.org/about/overview.

<sup>&</sup>lt;sup>42</sup> IFFIm, "Disbursements," http://www.iffim.org/funding-gavi/disbursements/.

<sup>&</sup>lt;sup>43</sup> The Global Fund, "Global Fund Launches Replenishment with Support from President Obama," http://www.theglobalfund.org/en/mediacenter/newsreleases/2013-12-02\_Global\_Fund\_Launches\_ Replenishment\_with\_Support\_from\_President\_Obama/.

contributions to GAVI, since the multiyear, longer-term commitments typical of IFFIm support are anathema to the yearly budget request and appropriations process.

Some GAVI observers believe that the United States should invest more in the Alliance, especially given U.S. leadership and support of other global health partnerships; the resonance between GAVI's cofinancing and graduation programs and the GHI's emphasis on sustainability and country ownership; and the priority attached to ending preventable child death within U.S. domestic policies, as well as U.S. foreign assistance initiatives. These observers note that while the United States has been a long-term GAVI supporter, its total contribution to GAVI since 2000 is around \$1.2 billion, or less than an average of \$100 million per year—in contrast to the more than \$13.5 billion the United States has pledged and contributed to the Global Fund to Fight AIDS, Tuberculosis and Malaria since 2002.

GAVI observers seem to agree that securing greater contributions from other global health donors will also be essential. There may be some room for increases among Germany, Japan, and the European Union, but getting more in this round from longtime supporters France and Italy may be tricky, given both countries' fiscal challenges. Other long-term supporters, including the Netherlands, Denmark, and Australia, have also tightened their aid budgets.

It is not clear how much effort GAVI should expend on cultivating contributions from the newest partners and emerging economies—at least for this replenishment. For example, South Korea, which became a first-time GAVI donor in 2010 with an initial contribution of \$3.6 million, could be encouraged to increase its pledge in 2014, but a modest increase from South Korea or other new partners is not likely to add the \$500 million-\$1 billion necessary to significantly enhance the replenishment total. India, which is still eligible for GAVI support, recently announced a direct contribution of \$4 million over four years. 44 Over time, perhaps India, too, could be encouraged to increase its yearly contributions, but its potential to dramatically affect the upcoming replenishment seems low.

For emerging donors, long-term pledges to IFFIm may be more attractive than direct contributions. In 2007, South Africa became the first emerging economy to contribute to GAVI with a 20-year pledge of \$20 million in support of IFFIm. Similarly, Brazil has pledged \$1 million a year to IFFIm for the period 2014 to 2033. However, IFFIm contributions are less valuable to GAVI than direct contributions because of the costs of issuing and paying interest on the underlying bonds, and because donors see their long-term payments as contributions well after frontloaded bond proceeds to GAVI are exhausted.

This replenishment cycle is probably too soon to expect emerging economies and upper-middle-income countries to shoulder a significantly greater share of GAVI funding, but the Alliance will need a long-term diplomatic and resource mobilization strategy for increasing these countries' future engagement.

<sup>&</sup>lt;sup>44</sup> GAVI Alliance, "India commits US \$4 million to GAVI Alliance vaccine programs," http://www. gavialliance.org/library/news/statements/2014/india-commits-us\$-4-million-to-gavi-alliance-vaccineprogrammes/.

#### Options for U.S. Engagement

GAVI's continued success in 2016–2020 and beyond is integral to broader global efforts to protect child health, prevent suffering, and avert untimely death. While GAVI's model has faced challenges, the Alliance has proven itself resilient, innovative, and adaptive—achieving a great deal in nearly 15 years of partnership and collaboration. Through an expanded Secretariat and committed partners within the Alliance, GAVI is working to refine its approach and determine the best mix of market-shaping activities, cofinancing requirements, and donor contributions to ensure its operations from 2016 to 2020. Significantly enhancing the Secretariat's capacities to advance the Alliance's diplomatic and political agenda over the same period will put GAVI in an even stronger position as it looks ahead to the next phase.

GAVI's continued success is important to the United States as well. In considering its approach to the GAVI replenishment in 2014, the United States should:

- Increase its funding for GAVI, with a pledge for three years and a statement of intent to seek funding for an additional two—recognizing that U.S. commitments to GAVI and U.S. bilateral assistance programs focused on child health are mutually reinforcing and that increasing support for GAVI should not come at the expense of support for bilateral programs. However, U.S. policymakers may want to condition any future increases (beyond 2020) on GAVI's success in the 2016–2020 period in documenting and prioritizing activities that work best in improving vaccine coverage and equity; ensuring the sustainability of the current "graduation" schemes; and expanding the number of donor countries able to commit \$50 to \$75 million per year or more.
- Ensure that U.S. programs in the field strengthen and reinforce the existing investment in GAVI. For example:
  - USAID's Global Health Bureau should ensure that all health officers in GAVIsupported countries where USAID also has a mission are aware of GAVI's importance to U.S. interests and actively coordinate with GAVI-supported programs.
  - Where the U.S. Centers for Disease Control and Prevention (CDC) supports Field Epidemiology Training Programs in GAVI-supported countries, CDC trainers should ensure that program participants understand the importance of GAVI-supported programs to their work and identify opportunities to strengthen country immunization programs.
  - In regions where the U.S. Department of Defense Naval Medical Research Units (NAMRU) and the Armed Forces Research Institutes of Medical Science (AFRIMS) have a presence, lab personnel should also be made aware of GAVI's work at the country level and identify opportunities for relevant research coordination and support.
  - The United States should coordinate among the various agencies that support overseas immunization work to develop a government-wide

strategy on new vaccine introductions and immunization system strengthening.

- Work with the Secretariat and other GAVI partners to ensure the sustainability of graduation policies and consider options to assist middle-income countries where vaccination access remains a challenge.
  - To this end, the United States should share lessons learned from USAID's experience in developing graduation processes. For example, over the past five years USAID has "graduated" seven countries from its family-planning program portfolio: Dominican Republic (2009), El Salvador and Paraguay (2010), Nicaragua and South Africa (2011), Honduras and Peru (2012).
  - The Department of State's Office of Global Health Diplomacy should convene interagency partners to "deliver analyses, conduct systematic outreach, and develop policy options to raise the political will of GAVI countries to pay for vaccines," as a CSIS Global Health Policy Center report recommended in 2012.<sup>45</sup>
- Reach out, through Secretary of State John Kerry, to the members of the United States' GAVI "constituent" bloc, including Australia, Japan, and South Korea, to encourage their great contributions in the upcoming replenishment. U.S. ambassadors to middle-income countries that have begun to play a bigger role in global health could similarly encourage host governments to support, or to increase their support for, GAVI.
- Help strengthen GAVI's effort to address the challenge of noncommunicable diseases. GAVI is already purchasing and distributing key vaccines that prevent liver and cervical cancers, both leading killers of adults in the developing world. The United States has considerable experience addressing chronic diseases domestically and can share that experience with GAVI as global initiatives related to noncommunicable diseases move forward.

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<sup>&</sup>lt;sup>45</sup> See Amanda Glassman, "The GAVI Alliance," in *Global Health Policy in the Second Obama Term*, ed. J. Stephen Morrison (Washington, DC: CSIS, February 2013), 73, https://csis.org/files/publication/130214\_Morrison\_GHTransitionVolume\_Web\_FINAL.pdf.



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