

To further develop the promise of CHWs, policymakers and health system leaders could take five initial steps. First, the evidence base for CHW programs should be shored up, through both additional, pragmatic clinical studies and consensus assessment of completed research. The Community Preventive Services Task Force could perform the evidence assessment, building on the 2007 Community Health Worker National Workforce Study. Additional studies should move beyond examining disease-specific, single-site pilots to larger-scale analyses of CHW integration into primary care, drawing from global research paradigms.⁴

Second, policymakers could address continued stagnation in job growth by promoting CHWs as a linchpin for health system restructuring. Indeed, Section 5313 of the ACA was dedicated to grants for underserved communities to employ CHWs — but was left unfunded. Revisiting this possibility could be productive, since the federal government is investing \$67 million in the hiring and training of ACA “navigators” to help consumers with the new health insurance exchanges. Existing CHWs might be a natural fit for this role — and newly trained ACA navigators might consider becoming CHWs.

Third, the Department of Labor could support a harmonized

approach to CHW certification across states. Certification helps to professionalize the community health workforce, driving quality standards for training and performance. The experience that Massachusetts had with policy development toward its 2010 CHW-certification law may hold lessons for a national effort.⁵

Fourth, the \$1 billion second round of Health Care Innovation Awards from the Innovation Center of the Centers for Medicare and Medicaid Services (CMS) could include a focus on CHW-based interventions. If such innovations had beneficial effects on population health and cost, CMS could consider payment schemes to more broadly support CHW programs — for example, as part of Medicaid case management.

Fifth, dedicated community health workforce organizations could collaborate with insurance companies and hospitals to measure return on investment and to refine clinical protocols that support CHWs, as well as information technology linking patients, CHWs, and providers.

The most crucial lesson from global CHW programs is that the community rootedness of CHWs should be retained through careful, representative selection and by ensuring that CHWs spend most of their time in the community. In the United States, certain structural advantages, such

as the strong network of community health centers, could facilitate CHW integration into the health system. The timing for investment in CHWs is also propitious, given the post-ACA landscape and the potential for meaningful job creation. Although the operational challenges of CHW integration are manifold, the global experience offers hope for U.S. communities.

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1. Singh P, Sachs JD. 1 Million community health workers in sub-Saharan Africa by 2015. *Lancet* 2013;382:363-5.
2. Bhutta Z, Lassi Z, Pariyo G, Huicho L. Global experience of community health workers for delivery of health related Millennium Development Goals: a systematic review, country case studies, and recommendations for integration into national health systems. Geneva: World Health Organization, 2010.
3. Kangovi S, Long JA, Emanuel E. Community health workers combat readmission. *Arch Intern Med* 2012;172:1756-7.
4. Victora CG, Black RE, Boerma JT, Bryce J. Measuring impact in the Millennium Development Goal era and beyond: a new approach to large-scale effectiveness evaluations. *Lancet* 2011;377:85-95.
5. Mason T, Wilkinson GW, Nannini A, Martin CM, Fox DJ, Hirsch G. Winning policy change to promote community health workers: lessons from Massachusetts in the health reform era. *Am J Public Health* 2011; 101:2211-6.

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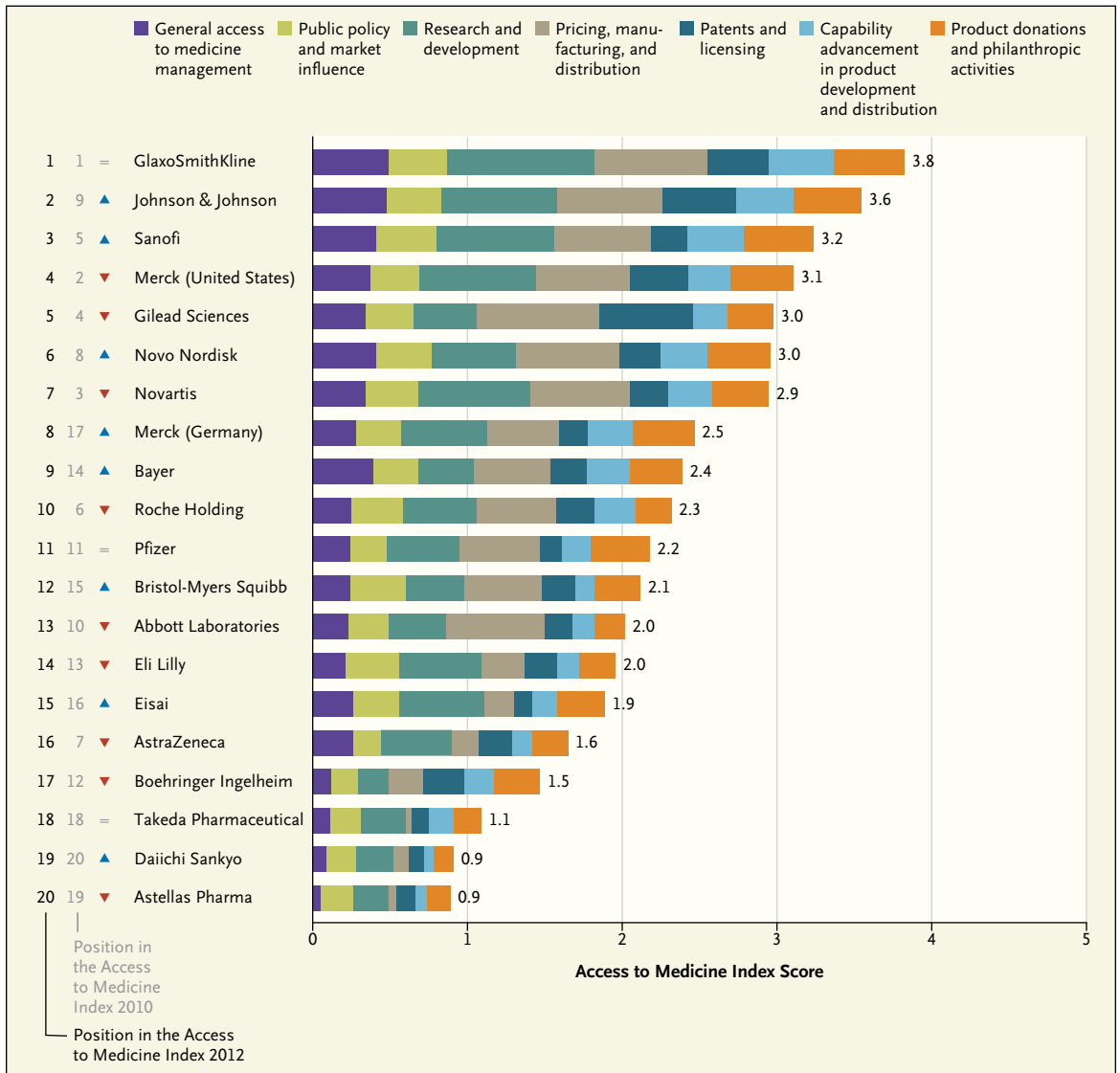
Big Pharma and Social Responsibility — The Access to Medicine Index

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Despite much progress in the past decade, about one third of the world's population still has no regular access to essential

medicines.¹ Many of the most neglected people live in sub-Saharan Africa, but another billion live in emerging economies that have

widening gaps between rapidly growing middle classes and poor people who live on less than a dollar a day.² Such people face



Access to Medicine Index 2012 Rankings of the World's 20 Largest Research-Based Pharmaceutical Companies According to Their Efforts to Make Their Products More Available, Affordable, and Accessible in Developing Countries.

Company scores range from 0 (lowest) to 5 (highest) and are based on a weighted average of scores on 101 indicators. The indicators are divided into seven technical areas (shown in different colors); within each technical area, four aspects of implementation are measured.

many barriers to obtaining necessary medications. Lack of research may mean that medications for their conditions simply do not exist — for instance, safe medicines for sleeping sickness or heat-stable insulin for treating diabetes in tropical climates. Medicines that do exist may be too expensive, may be unavailable in their country, or may not reach them in time. The products may

not be of assured quality, safety, and efficacy or may be formulated in unsuitable ways — for instance, there are hardly any fixed-dose combination syrups of anti-retroviral medicines for children with the acquired immunodeficiency syndrome. The responsibility for resolving these problems lies with many actors, one of which is the pharmaceutical industry.

Since 2008, an independent initiative called the Access to Medicine Index has been ranking the world's 20 largest research-based pharmaceutical companies according to their efforts to make their products more available, affordable, and accessible in developing countries. Its methods grew out of discussions among global health experts, investors, and Big Pharma itself. The index, which is

published every 2 years, aims to stimulate companies to do more by offering them insight into each other's policies and practices for improving access to medicines. And there seems to have been some movement in response: in 2012, for example, Johnson & Johnson rose from ninth to second position on the index. This rapid rise was due to progress on many different fronts, including the establishment of a global pharmaceutical access committee, board-level ownership, a robust performance-management system, a large portfolio of products for developing countries, tiered pricing for all relevant products, and excellent transparency.

The index focuses on what companies do to bring medicines, vaccines, diagnostic tests, and other health technologies to people in 93 low-income and lower-middle-income countries, plus 10 upper-middle-income countries with large within-country disparities in development, such as Algeria, China, Jordan, South Africa, and Thailand. Companies' rankings take into account drugs for a number of specific diseases, including the 10 communicable diseases and 10 noncommunicable diseases that account for the highest disease burden in developing countries, 14 neglected tropical diseases, and a range of maternal and neonatal conditions.

The ranking is made on the basis of information reported by the companies, cross-checked with other sources, and peer reviewed by experts. The index uses a framework that evaluates company commitments and activities on 101 indicators, divided into seven technical areas: overall organization and management of access programs (10% of the score); conduct of relationships

with policymakers, competitors, customers, and the public (10%); research and development aimed at relevant products (20%); pricing policies and distribution (25%); patent and licensing policies (15%); capability advancement in developing countries (10%); and product donation and philanthropic activities (10%).³

Within each of these technical areas, four important aspects of action are measured: level of commitment by the company (25%); transparency about its policies and activities (25%); actual activities and performance (40%); and the innovative nature of the activities (10%). The index focuses on commitments and activities in the relevant countries during the previous 2 years (which explains why, for example, the marketing activities of GlaxoSmithKline a decade ago in the United States were not included in the 2012 assessment).

The 2012 rankings are shown in the graph. GlaxoSmithKline remains at the top of the league, with the highest scores in most technical areas.³ However, it achieved that ranking by a narrower margin than it did in 2010, and two newcomers (Johnson & Johnson and Sanofi) moved into the top three. Sanofi advanced because of improvements in access-to-medicine strategies, leadership in anticorruption and ethical marketing policies, sustained investment in research and development relevant to developing countries, and robust pricing systems. There is now a distinct top group of seven companies, which also includes Merck (United States), Gilead Sciences, Novo Nordisk, and Novartis.

The industry as a whole is also making gradual progress in addressing global access, with 17

of the 20 companies having improved their absolute scores since 2010, despite the application of tougher standards. But as some companies move up, standing still in absolute terms means falling behind in ranking, as demonstrated by Novartis (which dropped from 3rd in 2010 to 7th in 2012), AstraZeneca (from 7th to 16th), and Boehringer Ingelheim (from 12th to 17th). At the bottom of the league are three Japanese companies.

The 2012 report also shows that companies are becoming more organized in their approaches to global access. At the highest-ranked companies, active leadership on improving access is coming from the top, and more companies are setting meaningful targets. Many companies have increased their investment in relevant research, and some now devote as much as 20% of their research resources to addressing the needs of the poor, for which the direct economic return is, at best, doubtful. For instance, Sanofi is adapting its leishmaniasis drug, which currently requires health workers to administer repeated injections, to develop a product that patients can apply to their skin at home. Johnson & Johnson is working on a simple, portable, rapid screening test for tuberculosis that is meant to yield results within minutes. More companies are using tiered pricing schemes and applying them to a broader range of products and in more countries, although the overall effect on affordability is still unclear.

Yet several areas remain in need of substantial improvement: transparency about lobbying practices and clinical trial conduct, expansion of tiered pricing schemes to encompass larger price differentials for more products

in more countries, adaptation of packaging to local needs, participation in patent pools, making drug donations more needs-based, and allowing regulators in developing countries to use clinical trial data for the accelerated approval of generic medicines.

In my opinion, this “wish list” for company behavior reflects the real potential of the Access to Medicine Index. In recent decades, pharmaceutical companies have seen their public images dramatically eroded. This process started in 1990s, when the South African Pharmaceutical Manufacturers Association and 39 mostly international pharmaceutical companies took President Nelson Mandela’s government to court, claiming that its attempts to increase the availability of affordable medicines violated the constitution and the international Agreement on Trade-Related Aspects of Intellectual Property. Big Pharma’s public image was further damaged by aggressive patent poli-

cies that seriously hamper access to generic medicines for developing countries and by highly visible court convictions for aggressive marketing — for example, in the United States and China.

In the past few years, several of the more enlightened companies have actively sought guidance from global health experts on improving both their performance and their public image. The indicators used by the Access to Medicine Index are a clear reflection of what the international public health community expects from a responsible pharmaceutical industry; the biennial Access to Medicine Index offers a mechanism for companies to report and be independently assessed on their policies and achievements in this regard.

The competitive nature of the index not only speaks to the companies but also to shareholders and institutional investors. A possible long-term outcome is that some companies may develop a

new business model whereby improving access to essential medicines for the poor in developing and emerging countries is no longer seen as ad hoc company philanthropy but rather as another sustainable way to do profitable business — by serving the long-term needs of 2 billion new customers. The best practices of the leading companies are the living proof of what can be achieved.

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1. The world medicines situation report. Geneva: World Health Organization, 2011 (http://www.who.int/medicines/areas/policy/world_medicines_situation/en).
2. Berger M, Murugi J, Buch E, et al. Strengthening pharmaceutical innovation in Africa. Geneva: Council on Health Research for Development (COHRED) New Partnership for Africa’s Development (NEPAD), 2010.
3. The Access to Medicines index 2012. Haarlem, the Netherlands: Access to Medicines Foundation, 2012 (<http://www.accessmedicinindex.org>).

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