



Powerful Ideas for Global Access to Medicines

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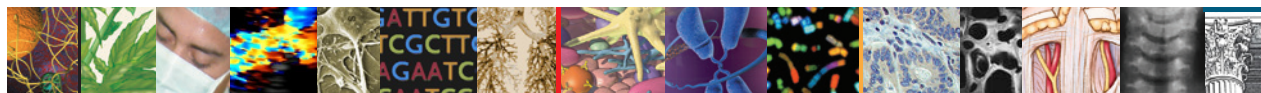
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Perspective

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Powerful Ideas for Global Access to Medicines

Suerie Moon, M.P.A., Ph.D.

One of the few issues uniting U.S. voters in the 2016 election was outrage over the high prices of medicines. From the quadrupling of EpiPen prices to \$1,000-per-pill hepatitis C treatments,

from six-digit pricing of cancer drugs to the 55-fold price increase on a 62-year-old toxoplasmosis drug, the scandals keep coming. In Europe, where government involvement in price negotiations means that new drugs, diagnostics, and vaccines (“medicines”) can cost less than half their U.S. prices, there is nevertheless serious concern that yearly price increases will break health system budgets. Worldwide drug spending grew by about 9% in 2014 and 2015, outpacing both overall health expenditures and economic growth.¹

But what has recently been headline news in high-income countries has long been a concern everywhere else. Whether low- and middle-income countries (LMICs) are struggling to treat millions of

people living with HIV or to immunize refugee children against pneumonia, unaffordable prices mean that many people simply go without. Meanwhile, despite billions of public and private dollars invested in pharmaceutical research and development, urgent needs for new antibiotics and tools for other public health priorities go unmet. Unaffordable medicines and inadequate innovation have become global issues. Like climate change, they require new public policies and international cooperation.

Responding to concerns raised by patients and health advocates worldwide, in 2015 United Nations (UN) Secretary General Ban Ki-Moon convened a High-Level Panel on Access to Medicines led by two former heads of state, Ruth

Dreifuss of Switzerland and Festus Mogae of Botswana, together with 13 international experts with wide-ranging perspectives. Even before the report was published in September 2016 (www.unsgaccessmeds.org/final-report), it had attracted an unusual degree of attention — both positive and negative — from governments, the pharmaceutical industry, and civil society. Some of the reaction, epitomized by the U.S. Chamber of Commerce statement “condemn[ing the] U.N. report attacking patents,”² reflected a decades-old debate over the appropriate relationship between intellectual property monopolies and medicine prices. Yet the report does not generally go beyond pre-existing international agreements on patents. Rather, the true source of consternation may be that it reframes the access-to-medicines challenge not only as involving prices in LMICs, but also as requiring systemic changes to the prevailing research-and-development business model for the sake

of all countries. The panel then advances some powerful ideas regarding such changes.

One of those ideas is transparency. Reliable, thorough public information is not generally available on the safety, efficacy, prices, patent status, sources of investment, and costs of developing life-saving medicines. Given its profound implications for the public interest, the drug-development system is shrouded in a disproportionate degree of secrecy. The panel recommended that governments mandate disclosure of information on various aspects of pharmaceutical development, including research-and-development costs. Depending on the information source and the methods used, estimates of the cost of developing a new drug vary by a factor of 40 or more — ranging from \$92 million to \$4.2 billion.³ Transparency could introduce some measure of reason and evidence into heated pricing debates, which too often deteriorate into hyperbolic claims that any interference with free-market pricing would destroy innovation. A more granular understanding of research and development could also shed light on the efficiency of the processes involved and spark debate about how society ought to appropriately compensate investment, outcomes, and risk and calibrate financial rewards to the degree of therapeutic advance offered.

Transparency is also key to another powerful idea endorsed by the panel: ensuring public return on public investment in medicine development. Drug development is a public-private enterprise, with the public investing in basic research and early-stage discovery through taxpayer funding of academic and public laboratories and

then purchasing the medicines that private firms develop through insurance policies or out-of-pocket expenditures. In areas in which the market fails to offer adequate incentives for innovation — such as neglected diseases, emerging infectious diseases, or antimicrobial resistance — public funding and priority setting play an even greater role, subsidizing all stages of product development. For example, the U.S. government's Biomedical Advanced Research and Development Authority has funded private firms to develop medicines for use in potential outbreaks and has obtained approval from the Food and Drug Administration for 24 products since its founding in 2006. Transparency regarding public contributions to the research underlying a medicine could provide a foundation for tempering excessive pricing, either in advance through conditions imposed on public financing or after development through government regulation.

The report also calls for testing and implementing new business models of research and development that would build affordability into the product-development process by delinking research financing from end-product prices. Some such models have already been proven to work in not-for-profit drug-development efforts. For example, with \$290 million from public funds and philanthropic contributions, the Drugs for Neglected Diseases Initiative (DNDi) put 26 candidate products into the development pipeline and brought 6 to market in 10 years; because the research costs have already been covered, DNDi's products can be sold for approximately the cost of production.⁴ Though there are important

differences between drug development for neglected diseases and other therapeutic areas, this example offers proof of principle regarding better ways to manage public and private investments to channel research and development in the public interest.

Finally, the panel called for governments and companies to adhere to established agreements to protect access to medicines under international trade rules. For example, governments have the authority to decide when a private patent right can be set aside in the interest of public health — a right that has been reaffirmed in every relevant UN political declaration since 2001. Though the pharmaceutical industry has criticized the report as an attack on patents, the panel in fact recommended only that preexisting agreements be enforced; it did not recommend additional patent flexibilities beyond what has been agreed on for 15 years. Indeed, some panel members and civil-society organizations expressed disappointment that it did not call for a more dramatic overhaul of intellectual-property treaties.

Among the report's authors is the chief executive officer of GlaxoSmithKline (GSK), Andrew Witty, who has occasionally become a thorn in his industry's side by taking positions ahead of the curve. For example, he has called the \$1 billion research-and-development price tag a myth reflecting inefficiencies rather than required costs; he expanded GSK's policy of licensing generic versions of patented medicines in some LMICs beyond HIV to include cancer; and he has endorsed new research-and-development models to combat antimicrobial resistance and pathogens of pandemic po-

tential. His peers may wish to reexamine some of the business models advanced in the report, which could continue rewarding innovation while satisfying growing public demands for affordability and needs-driven innovation.

Given the charged politics of debates over access to medicines, I believe Secretary General Ban was courageous to convene this panel — though the report's fate in the UN system is uncertain, given that there is a new secretary



An audio interview with Dr. Moon is available at [NEJM.org](http://nejm.org)

general, a new U.S. president, and a new director general of the World

Health Organization in 2017. Nevertheless, the panel's greatest impact may be realized not through intergovernmental talks, but by stimulating public debate over ways of reforming the research-and-development system to better

serve the global public interest. The Netherlands' trade and health ministers recently echoed three panel recommendations, calling for transparency of pharmaceutical research-and-development costs, adequate public return on public investment, and testing of new business models.⁵

This report comes at a time when the public appetite for change is growing, the pharmaceutical industry's reputation is in the doldrums, and demand for a more equitable global trade system is building. It puts forth ideas that deserve a fair hearing in countries struggling to provide access to medicines for their people and in the boardrooms of companies with the vision to try new ways of delivering innovation. Business as usual is no longer an option.

Disclosure forms provided by the author are available at [NEJM.org](http://nejm.org).

From the Global Health Centre, Graduate Institute of International and Development Studies, Geneva; and the Department of Global Health and Population, Harvard T.H. Chan School of Public Health, Boston.

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Social Risk Factors and Equity in Medicare Payment

Melinda B. Buntin, Ph.D., and John Z. Ayanian, M.D., M.P.P.

Medicare is steadily shifting from volume-based fee-for-service payments to value-based payment models, including accountable care organizations, episode-based bundled payments, and penalties for hospitals with relatively high Medicare readmission rates.¹ These models typically provide financial bonuses or penalties related to the efficiency and quality of care, thereby shifting more financial risk to hospitals, medical groups, and other providers. Through a star rating system, bonuses are also provided to high-

quality health plans in the Medicare Advantage program.

A growing body of research indicates that social risk factors, including low socioeconomic position (as indicated, for example, by income or educational level), minority race or ethnic background, lower degree of acculturation, minority sexual orientation or gender identity, limited social relationships, and living alone or in a deprived neighborhood influence health outcomes.² These findings are a concern for health care providers and policymakers because

Medicare beneficiaries with such social risk factors are often concentrated among a subset of providers, particularly in inner-city or rural communities, and in some Medicare Advantage plans.

Without accounting for such risk factors, Medicare quality reporting and payment programs that financially reward or penalize health care providers according to the health outcomes of their patients will understate the quality of care provided by clinicians and organizations that disproportionately serve these populations and give