By Sandeep P. Kishore, Kavitha Kolappa, Jordan D. Jarvis, Paul H. Park, Rachel Belt, Thirukumaran Balasubramaniam, and Rachel Kiddell-Monroe

DOI: 10.1377/hlthaff.2015.0375
HEALTH AFFAIRS 34,
NO. 9 (2015): 1569–1577

Overcoming Obstacles To Enable Access To Medicines For Noncommunicable Diseases In Poor Countries

ABSTRACT The modern access-to-medicines movement grew largely out of the civil-society reaction to the HIV/AIDS pandemic three decades ago. While the movement was successful with regard to HIV/AIDS medications, the increasingly urgent challenge to address access to medicines for noncommunicable diseases has lagged behind—and, in some cases, has been forgotten. In this article we first ask what causes the access gap with respect to lifesaving essential noncommunicable disease medicines and then what can be done to close the gap. Using the example of the push for access to antiretrovirals for HIV/AIDS patients for comparison, we highlight the problems of inadequate global financing and procurement for noncommunicable disease medications, intellectual property barriers and concerns raised by the pharmaceutical industry, and challenges to building stronger civil-society organizations and a patient and humanitarian response from the bottom up to demand treatment. We provide targeted policy recommendations, specific to the public sector, the private sector, and civil society, with the goal of improving access to noncommunicable disease medications globally.

Sandeep P. Kishore (sunny.kishore@gmail.com) is a fellow at Yale University, in New Haven, Connecticut, and president of the Young Professionals Chronic Disease Network, in Boston, Massachusetts.

Kavitha Kolappa is a resident in psychiatry at Massachusetts General Hospital, in Boston, a and board member for the Young Professionals Chronic Disease Network.

Jordan D. Jarvis is executive director of the Young Professionals Chronic Disease Network and a former postgraduate research fellow at the Harvard Global Equity Initiative, in Boston.

Paul H. Park is director of noncommunicable diseases for Partners in Health—Rwanda and a member of Universities Allied for Essential Medicines, in Washington, D.C.

Rachel Belt is a member of Universities Allied for Essential Medicines.

Thirukumaran Balasubramaniam is a Geneva representative at Knowledge Ecology International, in Switzerland.

Rachel Kiddell-Monroe is a special adviser for the Universities Allied for Essential Medicines, a board member for the Young Professionals Chronic Disease Network, and a member of the International Board for Médecins sans Frontières, in Geneva.

The modern access-to-medicines movement, which petitions for low-cost medicines to be made available to the global poor, grew largely out of the reaction of civil-society organizations, such as the AIDS Coalition to Unleash Power (ACT UP), the Student Global AIDS Campaign, and Treatment Action Campaign, to the rise of the HIV/AIDS pandemic three decades ago.[1] Thus far, access-to-medicines advocacy has been driven primarily by the urgent need to address communicable diseases such as HIV/AIDS, TB, and malaria. In contrast, access to medicines for noncommunicable diseases has lagged behind or, in some cases, has been forgotten by policy makers.

In this article we examine what causes the access gap with respect to lifesaving, essential medicines for noncommunicable diseases and what can be done to close the gap. We focus specifically on the gap of available noncommunicable disease treatments between high-income and low- and middle-income countries. However, even in high-income countries, treatment disparities (such as reduced availability for selected cancer medications) are secondary to inadequate health insurance (as is the case in the United States) or the absence of coverage of national formularies (as is the case in the United Kingdom).

Echoing Nobel Prize–winning political scientist Elinor Ostrom, we call for a new approach that integrates initiatives from civil-society organizations, the private sector, and the public sector to drive availability and affordability.[1] Until now, much of the literature on this topic has been prescriptive. In this article we highlight emerging trends related to increasing access to medicines for noncommunicable diseases, with

an emphasis on potential solutions. Given that noncommunicable diseases are a political priority and that the treatment of current and future noncommunicable diseases is a basic human right that must be financed,[2] we sought to conduct an extensive analysis of key solutions to improve the availability and affordability of medicines for noncommunicable diseases.

The most recent World Health Organization (WHO) study finds that in the public sector, medicines for noncommunicable diseases are even less available than those for communicable diseases: 36 percent availability for noncommunicable disease medications versus 53 percent for communicable disease medications.[3] Availability is measured by systematic surveys of shelf availability of selected medicines. There is evidence that the medications for noncommunicable diseases are also less affordable than medications for communicable diseases as well. One study from India showed that "an estimated 600,000 to 800,000 people were impoverished by the costs of caring for cardiovascular disease and cancer."[4] Here we adopt the WHO/Health Action International definition of *affordability*, which is based on the number of days' wages needed for the lowest-paid unskilled government worker to purchase a course of treatment (usually thirty days' worth of medication).[5]

The contribution to poverty of high out-of-pocket expenditures for health care and noncommunicable disease medications cannot be ignored. When medicines are available, affordability may remain untenable, particularly in low-income countries. After all, availability is moot if patients cannot afford the treatments in the first place.

The financial burdens of medical treatment also frequently result in poor patient adherence. In Nigeria, for example, one study showed that 63 percent of patients did not adhere to chemotherapy largely because of high drug costs.[6]

The United Nations' (UN's) interest in noncommunicable diseases dates back to 2000, when the World Health Assembly adopted resolution WHA53/14, on the topic of a global strategy for the prevention of and control of noncommunicable diseases.[5] For only the second time in its history, the UN General Assembly convened on a global health issue (the first was on HIV/AIDS) and, on September 19, 2011, adopted the UN Political Declaration on Noncommunicable Diseases.[7] In November 2012 the WHO issued voluntary global targets on global mortality for preventable noncommunicable diseases (for people younger than age seventy) and health systems performance as well as a range of specific indicators aimed at reducing the incidence of noncommunicable diseases. These targets built on those laid out in the UN Political Declaration. Two of the WHO targets for access to noncommunicable disease medications were that 80 percent of essential medicines (defined as those on the WHO's essential medicines list) and technologies were made available to populations at low cost or free of charge and that coverage and a multidrug regimen for cardiovascular disease be extended to half of the world's population.[6]

To examine the factors that have hindered global access to medications for noncommunicable diseases, we use the example of access to antiretrovirals for HIV/AIDS patients as a point of comparison for our analysis. The HIV/AIDS movement has tackled and largely addressed the problems of inadequate global financing and procurement, intellectual property barriers, and affordability by building stronger civil-society organizations and encouraging a patient and humanitarian response to demand treatment. Below, using the experience of HIV/AIDS as a blueprint, we discuss a variety of barriers to obtaining noncommunicable disease medications, as well as policy recommendations to improve access and affordability.

Inadequate Global Financing And Procurement

OUT-OF-POCKET EXPENSES Up to 90 percent of the population of low- and middle-income countries purchase medicines out of pocket, making medicines the second-largest family expenditure after food.[2] Noncommunicable diseases are typically chronic illnesses, which drive a lifetime of health-related costs. Low- and middle-income countries have had difficulties in anticipating how much medicine is needed, determining high-priority medicines, and deciding how much the government should spend on medicines.[8]

The WHO has estimated a global cost of roughly US$1.60 per person per year to cover all individuals at risk for noncommunicable diseases. These "individual interventions" include drug therapy for cardiovascular disease and vaccinations for human papillomavirus and hepatitis B.[9]

Duties (customs) and sales taxes on imported medicines are another key barrier for both availability and affordability of noncommunicable disease medicines. For example, several countries currently apply tariff rates to cancer medicines such as methotrexate, tamoxifen, and paclitaxel, ranging from a 10 percent tariff in Russia and Trinidad and Tobago to 25 percent in Bangladesh and Iceland (Warren Kaplan, WHO Collaborating Center on Pharmaceutical Policy, personal communication, March 19, 2015).

In general, the hidden markups and middleman costs added to medicines are substantial.

We use the example of access to antiretrovirals for HIV/AIDS patients as a point of comparison for our analysis.

Alexandra Cameron and colleagues found that in both public and private sectors, low procurement prices were not strictly tied to patients' paying less for medications.[2] For instance, private-sector markups ranged from 2 percent to 380 percent across countries, and final retail markups ranged from 10 percent to 552 percent across countries.[2] It is worth noting that corruption at the local level and "informal markets," which are operations outside the scope of formal market transactions and oversight, can further weaken efforts to improve affordability in poor countries and drives a widening gap between procurement and end-user retail prices.

GLOBAL NONCOMMUNICABLE DISEASE DRUG PROCUREMENT Although an individual country can in theory negotiate lower prices for its citizens, the HIV/AIDS experience has shown that global, coordinated procurement of medicines in bulk by a central organization is an effective way to lower prices and improve availability for a large number of people. For example, the US President's Emergency Plan for AIDS Relief performs pooled procurement for HIV/AIDS medications,[10] and the Stop TB Partnership helps run pooled purchasing for key medications for tuberculosis.[11] The Asthma Drug Facility managed by the International Union against Tuberculosis and Lung Disease does the same for asthma inhalers.[12] The Pan American Health Organization, a regional arm of the WHO, has a fund that provides medicines in bulk to its constituent countries in the Pan American region.[13]

In light of this, a 2014 report by David Beran and colleagues calls for a noncommunicable disease drug information facility, housed within the WHO, to help augment and coordinate global procurement practices.[14] Under such a system, the WHO and affiliated global partners in the UN would govern the facility and help coordinate purchasing across various UN member states. At the second UN high-level meeting on noncommunicable diseases in July 2014, a delegate from Bangladesh argued for a global resource pool, which could be a major boon for reducing the incidence of noncommunicable diseases.[15]

THE ESSENTIAL MEDICINES LIST The WHO's essential medicines list could be an efficient tool for improving availability and affordability of medicines, but it has not always been used effectively. Launched in 1977, the essential medicines list is meant to be a model, a basic formulary of the most important medicines that should be available for free or for the cheapest price possible. It is important to note that the list itself does not place any requirements on governments to offer medicines to their populations; it is used as a technical guide. The list garnered international attention in 2002, when researchers and treatment advocates for HIV/AIDS argued for the inclusion of high-price antiretrovirals on the list. Countries, in turn, followed the WHO recommendations to amend their own national essential medicines lists and provide these medicines for free. More than 150 countries have national essential medicines lists and may be reluctant to add medicines to their lists if those medicines are not yet on the WHO's list. One of the authors of this article, Sandeep P. Kishore, helped add a statin (a cholesterol-lowering medication) to the WHO's essential medicines list[16] by presenting data on the epidemiology, effectiveness, and cost of the medication. In a first analysis of the inclusion of statins on the essential medicines list in 2007 (see the online Appendix),[17] we found that nearly 70 percent of national essential medicines lists published after 2007 now include a statin.

In the case of HIV/AIDS, the inclusion of antiretrovirals on the WHO's essential medicines list, among other steps, led to a series of activities and policies that reduced the costs of antiretrovirals by more than 90 percent.[18] For instance, antiretroviral inclusion was accompanied by WHO treatment guidelines. Inclusion on the essential medicines list appears to be an important requirement to provide rational guidelines for the use of essential medicines. Additionally, including drugs on the WHO's essential medicines list can help facilitate the "prequalification" process, which allows the WHO to certify select generic producers of medicines, thereby expediting and augmenting national and multilateral procurement agencies' access to these medications. This process is currently restricted to selected communicable diseases and reproductive health. In the case of generic antiretrovirals, prequalification would have been difficult, if not impossible, without their inclusion on the WHO's essential medicines list. The process has been essential for creating the market for generic medications for communicable diseases,

90%

Reduction

Including antiretrovirals on the WHO's essential medicines list, among other steps, led to activities and policies that reduced antiretrovirals' costs by more than 90 percent.

and similar benefits could be expected if the process was used for noncommunicable disease medications as well.

On May 8, 2015, the WHO formally revised the list of anticancer medicines on its essential medicines list (as discussed above), on the basis of the potential impact of certain medicines to treat various cancers. This revision follows a review conducted by the Union for International Cancer Control, following submissions by the civil-society organizations Young Professionals Chronic Disease Network, Knowledge Ecology International, and Universities Allied for Essential Medicines for selected cancer medications to be added to the WHO's essential medicines list. The WHO ultimately recommended that sixteen of the twenty-two cancer medicines be added to the list, to guide countries in their national formulary development and investments. We believe that this was a watershed moment, because many of these medicines were not considered cost-effective per the WHO's own definition (that is, cost per disability-adjusted life-year, or DALY, saved in country is less than three times the gross national income per capita). By way of example, of the twenty-two cancer medicines reviewed by the WHO as priority essential medicines, fifteen (68 percent) are currently patented in the United States, which raised concerns that they were not cost-effective.[19]

The addition of high-cost medicines for cancer to national essential medicines lists underscores the need to make available key treatments for noncommunicable diseases across the globe, especially in poor countries. Therefore, this move pressures international suppliers and governments alike to provide these medicines to their populations at the cheapest prices possible, if not for free.

POLICY RECOMMENDATIONS We endorse a number of specific policy changes that could address the barriers outlined above. For one, we suggest the creation of a global facility or a foundation that coordinates drug purchasing and procurement for noncommunicable disease medications on an international scale. Additionally, we suggest that treatment guidelines (such as those seen for hepatitis C and HIV/AIDS) be created and distributed to guide the use of essential medicines for high-priority conditions. We also urge expanding the WHO prequalification process for generic drugs to include noncommunicable disease medicines, beginning with insulin.

Additional policy steps include exempting imported medicines from duties (customs) and sales taxes. In the past, as part of its qualification process, the Global Fund required a recipient country to remove taxes, duties, and import tariffs on medicines.[20] Governments have also made exceptions for other health care goods, such as wheelchairs.[21] This is not currently done on a large scale for noncommunicable disease medicines. This results in the differential taxing of the sick and, because of the chronicity of most noncommunicable diseases, puts the lifetime burden of cost on patients, pushing some further into poverty.

We also recommend using and adapting existing European Union and US drug registration policies in low- and middle-income countries to expedite local drug registration in country.

Finally, we urge civil society to address the gap between procurement and retail prices for noncommunicable disease medications. Civil-society and watchdog groups should adopt, support, and expand accountability mechanisms to highlight local corruption, high end-user prices, and high import tariffs in selected settings. This could be hosted on an open-source platform available to the public (such as the Open Society Institute's Stop Stock-Outs Campaign).[22] Financial and legal sanctions by ministries of health and finance for retailers that exploit patients through high markups on medications should be instituted.

Intellectual Property And The Pharmaceutical Industry

INTELLECTUAL PROPERTY Some trade officials and representatives from the pharmaceutical industry routinely assert that intellectual property regulation and free-trade agreements do not affect access to medicines for noncommunicable diseases. They argue that many medicines for noncommunicable diseases are off patent and therefore low cost. Although medications are off patent and some are low cost (for example, aspirin), intellectual property still remains a proven barrier of access to current lifesaving medicines, as well as medicines that will be introduced in the future.[14,23] This obstacle is evidenced by the high prices of patented cancer drugs, such as dasatinib (Sprycel, marketed by Bristol-Myers Squibb) for leukemia and trastuzumab (Herceptin, marketed by Roche) for selected breast cancers. The price for Sprycel in India is US$108 per day at current exchange rates, or twenty-five times the average daily income in the country.[19]

Herceptin is one of the world's ten best-selling prescription drugs,[18] indicated for the treatment of breast cancers associated with the HER2 gene. Annual prices of the drug are approximately US $23,000 in India, US$45,710 in South Africa, and more than US$78,000 in Brazil.[21] These prices could be lowered significantly by the entry of

Intellectual property remains a proven barrier of access to current lifesaving medicines, as well as medicines introduced in the future.

generic versions of the drug. One supplier reportedly could provide a generic version of the medication at 1 percent of the annual price that Roche charges (US$242 per year in India).[24]

Although generic drugs typically cannot be produced until the patent expires on a brand-name medication, the case of the kidney and liver cancer drug sorafenib mesylate provides an example of how one country brought a generic version of a key medicine to market sooner. In March 2012, India's Controller General of Patents, Designs, and Trademarks issued a compulsory license on sorafenib, which was marketed by Bayer in India at the price of US$69,000 for a full course of treatment. This enabled a party other than the patent holder to produce the drug before the original patent had expired. Among the grounds cited by the Indian authorities in granting the compulsory license to Natco Pharma, an Indian generic manufacturer, was the fact that sorafenib was not "available to the public at a reasonably affordable price."

In response to India's compulsory license, Bayer's CEO, Marijn Dekkers, provided an insightful glimpse into the industry's view at a December 2013 *Financial Times* conference, stating: "Is this going to have a big effect on our business model? No, because we did not develop this product for the Indian market, let's be honest. ...We developed this product for western patients who can afford this product, quite honestly."[25]

RESEARCH AND DEVELOPMENT The main factor contributing to the high cost of medicines for certain noncommunicable diseases, particularly those that treat cancer, is the current research and development system, which has put many new essential medicines beyond the reach of the world's poor. Barriers under the current research and development system include the discontinuation of older, off-patent products by companies to promote newer, patent-restricted products that do not clearly provide additional medical value.[26] In addition, data exclusivity, which is the period of time after market approval during which no one else may use the innovator firm's data to obtain marketing approval, keeps key clinical data proprietary, further prohibiting generic production of key drugs and raising prices. The result is that companies must often repeat clinical trials on human subjects to release their products, which is a violation of Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, which prohibits identical trials on human subjects if beneficial results are already established.[27] In many cases, the term of data exclusivity extends longer than the patent protection itself. Some countries (for example, Greece and Spain) have limited data exclusivity to the lifetime of the patent.[28] Exceptions to data exclusivity, although often not invoked, can be made for the public interest. Such a public-interest clause has been included in Article 231 in a trade agreement between the European Union and Colombia and Peru.[29]

As WHO Director-General Margaret Chan noted in February 2015: "In 2012, the US Food and Drug Administration approved 12 drugs for various cancer indications. Of these 12, 11 were priced above US$100,000 per patient per year. How many countries can afford this cost?"[30]

Although it is well accepted that the development of new drugs is costly, there is a lack of transparency and comprehensive data from the pharmaceutical industry on the actual costs of pharmaceutical research and development. A recent study from the Tufts Center for the Study of Drug Development estimated that it costs $2.6 billion to bring a new drug to market.[31] However, this is more than $1 billion higher than the estimate of the costs of pharmaceutical research and development from a 2012 Astra Zeneca–funded study by the UK Office of Health Economics.[32] Estimates of research and development expenditures for products developed by nonprofit drug developers, such as the Drugs for Neglected Diseases Initiative, paint a much different picture. Although the analogy may not be perfect, given differences between the for-profit and nonprofit markets, the Drugs for Neglected Diseases Initiative estimates that research and development costs for the full development of a new chemical entity, including the costs of failed products that never reach the market, are $112–$169 million.[33]

Public funding is also important for the development of new medicines,[34] and it is unclear how these funds are factored into the estimates of research and development expenditures. Gov-

ernments and charities around the world fund cancer research. The annual budget for the National Institutes of Health's National Cancer Institute, for instance, is nearly $5 billion. The pharmaceutical industry benefits from these substantial public investments at the front end, yet in the Tufts study cited above, these investments are not factored into the estimates of the preclinical development costs of drugs.

In any case, companies that enjoy temporary monopolies on new drugs because of patent exclusivity set prices that markets can bear, even in cases where public monies have helped subsidize research and development. This is a broken system that leads to rationing—a system antithetical to the basic right to health, which is a universal minimum standard to which all humans are entitled.

POLICY RECOMMENDATIONS We propose a number of steps to address the barriers outlined above. We recommend that UN member states make use of flexibilities enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and affirmed by the Doha Declaration on the TRIPS Agreement and public health, which would allow governments and generic drug firms to produce noncommunicable disease medicines at low costs. The flexibilities allow governments to issue compulsory licenses in poor countries to increase the availability of essential medicines for noncommunicable diseases, including the sixteen newly added medicines for cancer to the WHO's essential medicines list. Suppliers themselves can negotiate voluntary licenses, which are licenses that are voluntarily undertaken by one firm to another, to increase production of generic medications. Both compulsory and voluntary licensing will have the additional benefit of empowering local innovation centers in poorer countries.

With respect to data exclusivity, cost sharing, which occurs when companies use clinical trials data provided they pay a set amount to the originator company for the use of the data, should be promoted by governments—particularly if such trials violate the Helsinki Declaration. In fact, such a proposal was made by the US Senate in 2009 (Amendment 2858).[27]

Another step that could improve the affordability of treatment for noncommunicable diseases is greater use of fixed-dose combinations of drugs, known as polypills, which, in the case of cardiovascular disease, use medicines already on the WHO's essential medicines list and are therefore inexpensive. There is evidence that polypills for cardiovascular disease will help improve patient adherence (by an estimated 33–44 percent) and may improve health outcomes (such as through modest decreases in cholesterol and blood cholesterol).[35,36] The pill Polycap, developed by Cadila Pharmaceuticals in India for the treatment of cardiovascular disease, could be offered at US$0.13 per day (less than US$4.00 per month).[36]

UN member states also should explore the range of research and development incentive schemes promoted by the WHO's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property,[37] such as support for open-source methods, access to compound libraries by voluntary means, and the sharing of new knowledge and technologies to facilitate the development of new health products.

We also recommend delinking the cost of medicines and health-related technologies from the cost of research and development by eliminating monopolies on final products, as proposed in a study commissioned by the World Intellectual Property Organization,[38] and by facilitating a crowd-funded system of production and marketing, which involves raising financial contributions from the public. This could include the funding of clinical trials for new therapies such as the two million British pounds raised by the group iCancer to fund a clinical trial for neuroendocrine cancer.[39]

Financial incentives, such as prizes, might also attract more innovators to the noncommunicable disease drug space. This model has been used in the spacecraft innovation and TB diagnostics industries, as well as the recently launched Longitude Prize for antibiotics.[40] Under such a scheme, rewards could be paid to the creators of newly developed noncommunicable disease treatments that have the greatest impact on health outcomes.

Lastly, governments should reward developers and organizations for intermediate and final solutions toward the development of low-cost tools to facilitate diagnosis of noncommunicable diseases for the poor. This could, for example, include a low-cost diagnostic test for HER2-positive breast cancers proposed to the WHO by the government of Colombia and the group Knowledge Ecology International.[41]

The Role Of Civil-Society Organizations And A Humanitarian Response

ACCESS TO MEDICINES AS A BASIC HUMAN RIGHT A human rights–based framework has guided efforts to address HIV/AIDS, leading to a dramatic reduction in the cost of first-line HIV/AIDS treatments.[42] Over the past three decades, activist groups such as the Treatment Action Campaign in South Africa and ACT UP in the United States have demanded access to lifesaving anti-

Laws such as those pertaining to intellectual property are meant to protect companies, not people.

retrovirals for people living with HIV/AIDS.[8] There is no such strong and robust treatment activist organization in the noncommunicable disease policy arena. The dearth of activism around access to noncommunicable disease medications may stem from the branding of these diseases as afflictions of the rich and the elderly or as issues of personal responsibility.[43] Another issue is that civil-society organizations have not found a clear way to showcase patients with noncommunicable diseases.

There are some examples of grassroots organizations aimed at increasing access to noncommunicable disease medications. For instance, the Campaign for Affordable Trastuzumab, a civil-society organization based in Delhi, India, that includes people living with breast cancer, treatment activists, and public interest lawyers, is aiming to make this drug affordable in India by urging local development of biologically similar versions of the drug (biosimilars) in order to lower the drug's price in competitive markets. The campaign has strongly opposed the issuing of secondary patents (which can extend the life of a patent of a drug) on trastuzumab in India, addressed technological issues involved in the production of biosimilars, advocated that the government make trastuzumab available at no cost to patients in public hospitals, and supported the bid to add trastuzumab to the WHO's essential medicines list.

OVERCOMING INDUSTRY INFLUENCE The interests and motivations of multinational pharmaceutical industries that develop medicines for noncommunicable diseases are at times at odds with the interests and health needs of the public. Recent events in South Africa highlight this disconnect. In 2014 a leaked memo from a United States–based lobbying firm called Public Affairs Engagement revealed a proposed campaign by pharmaceutical firms to undermine South Africa's draft intellectual property legislation, which included progressive reforms to ensure access to medicines.[44] A second leaked e-mail from a pharmaceutical executive implicated two dozen prominent pharmaceutical firms in the proposed campaign against the legislation. Once this plan, now known as Pharmagate, surfaced, civil-society organizations in South Africa and elsewhere mobilized to stand up for the health care rights of South Africans.[20] The Pharmagate scandal revealed the tensions inherent in the struggle for access to noncommunicable disease medicines in the modern era—where the business interests of the pharmaceutical industry clash with the human rights movements of civil-society organizations.

Because several noncommunicable disease civil-society organizations and patient advocacy groups are heavily or completely funded by pharmaceutical and medical diagnostic companies, these conflicts of interest further hamstring the ability of civil-society organizations to mobilize support for increased access to noncommunicable disease medications.[42] In other words, it is often difficult to bite the hand that feeds you.

Additionally, as Pharmagate demonstrated, such conflicts can block legislative and regulatory progress toward equitable access. As civil-society organization participants in UN and WHO forums that set noncommunicable disease policy, we have observed that the priorities and demands of poor countries are repeatedly diluted or, in some cases, omitted from the final language of political declarations. For instance, references to the Doha Declaration, which reaffirms the rights of UN member states and World Trade Organization members to determine the grounds for compulsory licenses (for noncommunicable diseases or communicable diseases and beyond) and produce medications on a generic basis, were removed from the UN political declaration on noncommunicable diseases under pressure from developed countries, including the United States and members of the European Union. Leaked e-mail substantiates the involvement of trade representatives, particularly from the European Union, in slowing the support for access to medicines.[45]

This and similar developments led Deborah Cohen of the *British Medical Journal* to write, "Will industry influence derail UN summit?" on the heels of the first global meeting on noncommunicable diseases in the UN's history.[45] The article voiced concerns that the pharmaceutical industry, via trade representatives from high-income nations, led the effort to weaken regulations on intellectual property.

POLICY RECOMMENDATIONS In an attempt to address these issues, governments, philanthropic bodies, and development aid agencies should provide additional resources to strengthen civil-

society organizations' support for access to noncommunicable disease medicines advocacy and the response to noncommunicable diseases. A civil-society budget, potentially housed by leading civil-society organizations and funded by taxes on tobacco or airlines, instead of by the pharmaceutical industry, would also be an important step. As one example, the Civil Society Fund in Denmark grants up to ten million euros a year to Danish civil-society organizations that partner with local civil-society organizations in poor countries.[46] Lastly, the WHO and UN member states should safeguard low- and middle-income countries from multinational influence regarding access to newer medicines for the prevention and treatment of noncommunicable diseases.

Conclusion

The financial and regulatory barriers that threaten access to generic, reduced-cost medications for noncommunicable diseases are substantial, as we have outlined in this article. Laws such as those pertaining to intellectual property are meant to protect companies, not people, and advocates and lawmakers must continue to support patients' basic health rights. Existing and novel treatments for noncommunicable diseases must be incentivized and made available in the developing world. The advocacy, scientific, policy, and humanitarian sectors must apply today the lessons learned from access to medicines for communicable diseases to noncommunicable disease treatment to make a difference now. The price of inaction is too great. ■

This work was partially supported by the Open Society Institute. The views of author Rachel Kiddell-Monroe do not represent those of Médecins sans Frontières.

NOTES

1 Quick JD, Hogerzeil HV, Velasquez G, Rago L. Twenty-five years of essential medicines. Bull World Health Organ. 2002;80(11):913–4.

2 Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. Lancet. 2009;373(9659):240–9.

3 Hanna TP, Kangolle AC. Cancer control in developing countries: using health data and health services research to measure and improve access, quality, and efficiency. BMC Int Health Hum Rights. 2010;10:24.

4 Thakur J, Prinja S, Garg CC, Mendis S, Menabde N. Social and economic implications of noncommunicable diseases in India. Indian J Community Med. 2011;36(Suppl 1):S13–22.

5 World Health Organization. Global strategy for the prevention and control of noncommunicable diseases [Internet]. Geneva: WHO; 2000 Mar 22 [cited 2015 Aug 5]. Available from: http://apps.who.int/gb/archive/pdf_files/WHA53/ea14.pdf

6 World Health Organization. Global action plan for the prevention and control of noncommunicable diseases 2013–2020 [Internet]. Geneva: WHO; 2013 [cited 2015 Aug 5]. Available from: http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf?ua=1

7 United Nations General Assembly. Political declaration of the high-level meeting of the General Assembly on the prevention and control of noncommunicable diseases [Internet]. New York (NY): UN; 2011 Sep 19 [cited 2015 Aug 5]. Available from: http://www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf

8 Kishore SP, Vedanthan R, Fuster V. Promoting global cardiovascular health ensuring access to essential cardiovascular medicines in low- and middle-income countries. J Am Coll Cardiol. 2011;57(20):1980–7.

9 Abegunde D. Essential medicines for non-communicable diseases (NCDs) [Internet]. Geneva: World Health Organization; 2011 [cited 2015 Aug 5]. Available from: http://www.who.int/medicines/areas/policy/access_noncommunicable/EssentialMedicinesforNCDs.pdf

10 USA.gov. The United States President's Emergency Plan for AIDS Relief [home page on the Internet]. Washington (DC): PEPFAR; [cited 2015 Aug 5]. Available from: http://www.pepfar.gov

11 Stop TB Partnership [home page on the Internet]. Geneva: Stop TB Partnership; [cited 2015 Aug 5]. Available from: http://www.stoptb.org

12 Billo NE. Asthma Drug Facility, GARD meeting [Internet]. Paris (France): International Union against Tuberculosis and Lung Disease; 2007 Jun [cited 2015 Aug 5]. Available from: http://www.who.int/gard/news_events/5-6___Asthma%20Drug%20Facility-Dr%20N.billo.pdf

13 Pan American Health Organization. Strategic fund [Internet]. Washington (DC): PAHO; [cited 2015 Aug 5]. Available from: http://www.paho.org/hq/index.php?option=com_content&view=category&layout=blog&id=1159&Itemid=452

14 Beran D, Perrin C, Billo N, Yudkin JS. Improving global access to medicines for non-communicable diseases. Lancet Glob Health. 2014;2(10):e561–2.

15 United Nations. "Can we and should we not do better", panellist asks General Assembly as it concludes high-level meeting on non-communicable diseases [Internet]. New York (NY): UN; 2014 Jul 11 [cited 2015 Aug 5]. Available from: http://www.un.org/press/en/2014/ga11532.doc.htm

16 Kishore SP, Herbstman BJ. Adding a medicine to the WHO model list of essential medicines. Clin Pharmacol Ther. 2009;85(3):237–9.

17 To access the Appendix, click on the Appendix link in the box to the right of the article online.

18 Hoen E, Berger J, Calmy A, Moon S. Driving a decade of change: HIV/AIDS, patents, and access to medicines for all. J Int AIDS Soc. 2011;14:15.

19 Medindia. Drug information on Sprycelfi [tab] (dasatinib) from Bristol [Internet]. Chennai: Medindia; [cited 2015 Aug 5]. Available from: http://www.medindia.net/drug-price/dasatinib/sprycel-tab.htm

20 Kishore SP, Kolappa K. Unlikely allies. Huffington Post [blog on the Internet]. 2014 Feb 14 [cited 2015 Aug 5]. Available from: http://www.huffingtonpost.com/sandeep-

p-kishore-phd/healthy-living-news_b_4781300.html
21 Creese A. WHO/HAI project on medicine prices and availability: review series on pharmaceutical pricing policies and interventions: sales taxes on medicines [Internet]. Geneva: World Health Organization; 2011 May [cited 2015 Aug 5]. (Working Paper No. 5). Available from: http://www.haiweb.org/medicineprices/05062011/Taxes final May2011.pdf
22 Open Society Foundations. Stop stock-outs campaign [Internet]. New York (NY): Open Society Foundations; [cited 2015 Aug 5]. Available from: http://stopstockouts.org/stop-stock-outs-campaign/
23 International Federation of Pharmaceutical Manufacturers and Associations. IFPMA framework for action on NCDs 2011–2012 progress report [Internet]. Geneva: IFPMA; 2011 Jun [cited 2015 Aug 5]. Available from: http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_Framework_for_action_on_NCDs_WEB.pdf
24 Knowledge Ecology International, University of California, San Francisco, Universities Allied for Essential Medicines. Proposal for the inclusion of trastuzumab in the WHO model list of essential medicines for the treatment of HER2-positive breast cancer [Internet]. Washington (DC): Knowledge Ecology International; 2012 Nov 30 [cited 2015 Aug 5]. Available from: http://www.who.int/selection_medicines/committees/expert/19/applications/Trastuzumab2_8_2_A_Ad.pdf
25 Gokhale K. Merck to Bristol-Myers face more threats on India patents. Bloomberg News [serial on the Internet]. 2014 Jan 28 [cited 2015 Aug 5]. Available from: http://www.bloomberg.com/news/articles/2014-01-21/merck-to-bristol-myers-face-more-threats-on-india-patents
26 Collier R. Drug patents: the evergreening problem. CMAJ. 2013; 185(9):E385–6.
27 Love J. Senator Sanders Amendment 2858 would replace data exclusivity with cost sharing, if new trials violate medical ethics. Knowledge Ecology International [blog post on the Internet]. 2009 Dec 4 [cited 2015 Aug 5]. Available from: http://keionline.org/node/707
28 United Nations Conference on Trade and Development. Using intellectual property rights to stimulate pharmaceutical production in developing countries: a reference guide [Internet]. New York (NY): UN; 2011 [cited 2015 Aug 5]. Available from: http://unctad.org/es/Docs/diaepcb2009d19_en.pdf
29 European Commission. Trade agreement between the European Union and its member states, of the one part, and Colombia and Peru, of the other part [Internet]. Brussels: European Union; 2011 [cited 2015 Aug 5]. Available from: http://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf
30 Chan M. WHO Director-General addresses ministerial meeting on universal health coverage [Internet]. Geneva: World Health Organization; 2015 Feb 10 [cited 2015 Aug 5]. Available from: http://www.who.int/dg/speeches/2015/singapore-uhc/en/
31 Tufts Center for the Study of Drug Development. Cost to develop and win marketing approval for a new drug is $2.6 billion [Internet]. Boston (MA): The Center; 2014 Nov 18 [cited 2015 Aug 5]. Available from: http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study
32 Mestre-Ferrandiz J, Sussex J, Towse A. The R&D cost of a new medicine [Internet]. London (UK): Office of Health Economics; 2012 Dec [cited 2015 Aug 5]. Available from: http://www.ohe.org/publications/rd-cost-new-medicine
33 Drugs for Neglected Diseases Initiative. An innovative approach to R&D for neglected patients. Ten years of experience and lessons learned by DNDi [Internet]. Geneva: DNDi; 2014 Jan [cited 2015 Aug 5]. Available from: http://www.dndi.org/images/stories/pdf_aboutDNDi/DNDiModel/DNDi_Modelpaper_2013.pdf
34 't Hoen E. Access to cancer treatment: a study of medicine pricing issues with recommendations for improving access to cancer medication [Internet]. Oxford: Oxfam; 2015 Feb [cited 2015 Aug 5]. Available from: http://apps.who.int/medicinedocs/documents/s21758en/s21758en.pdf
35 de Cates AN, Farr MR, Wright N, Jarvis MC, Rees K, Ebrahim S, et al. Fixed-dose combination therapy for the prevention of cardiovascular disease. Cochrane Database Syst Rev. 2014;4:CD009868.
36 Huffman MD, de Cates AN, Ebrahim S. Fixed-dose combination therapy (polypill) for the prevention of cardiovascular disease. JAMA. 2014; 312(19):2030–1.
37 World Health Organization. The global strategy and plan of action on public health, innovation, and intellectual property [Internet]. Geneva: WHO; [cited 2015 Aug 5]. Available from: http://www.who.int/phi/implementation/phi_globstat_action/en/
38 World Intellectual Property Organization. Committee on Development and Intellectual Property, fourteenth session [Internet]. Geneva: WIPO; 2014 Sep 19 [cited 2015 Aug 5]. Available from: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_14/cdip_14_inf_12.pdf
39 iCancer. People before profit. Let's crowdfund the anti-cancer virus that could save thousands [home page on the Internet]. [Location unknown]: iCancer; [cited 2015 Aug 5]. Available from: http://icancer.org.uk
40 Longitude Prize. Antibiotics [Internet]. London: Nesta; [cited 2015 Aug 5]. Available from: https://longitudeprize.org/challenge/antibiotics
41 Knowledge Ecology International. Standard template for a candidate demonstration project [Internet]. Washington (DC): KEI; [cited 2015 Aug 5]. Available from: http://keionline.org/sites/default/files/OpenSourceCancerDiagnosticsPAHO3Sep2013.pdf
42 Hogerzeil HV, Liberman J, Wirtz VJ, Kishore SP, Selvaraj S, Kiddell-Monroe R, et al. Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration. Lancet. 2013;381(9867):680–9.
43 Siegel KR, Feigl AB, Kishore SP, Stuckler D. Misalignment between perceptions and actual global burden of disease: evidence from the US population. Glob Health Action. 2011;4.
44 Motsoeneng T. South Africa slams big pharma in generic drug row. Reuters [serial on the Internet]. 2014 Jan 27 [cited 2015 Aug 5]. Available from: http://www.reuters.com/article/2014/01/17/us-safrica-pharma-idUSBREA0G0N720140117
45 Cohen D. Will industry influence derail UN summit? BMJ. 2011;343: d5328.
46 Civil Society in Development. The Civil Society Fund—funding for Danish CSOs [Internet]. Aarhus C (Denmark): CISU; [cited 2015 Aug 5]. Available from: http://www.cisu.dk/the-civil-society-fund/overview