THE ROLE OF PHARMACEUTICALS IN PUBLIC HEALTH

ACCESS TO ESSENTIAL MEDICINES AS A KEY DETERMINANT TO UNIVERSAL HEALTH COVERAGE

September 15, 2016

Boston University School of Public Health

SPH Symposium Papers – Number 3

BU School of Public Health

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Dean's Symposia

This is part of a series of reports issued by the Boston University School of Public Health (BUSPH), emerging from symposia and other convenings of experts exploring contemporary public health issues. The goal of these meetings is to engage difficult issues, to generate discussion among our school community and global thought leaders, and to generate collaborations across sectors that can lead to solutions that improve the health of populations. This series was launched on the occasion of the school 40th anniversary in 2016.

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Access to essential medicines as a key determinant to universal health coverage

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BUSPH DEAN'S SYMPOSIA 2016

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Introduction/Overview

The purpose of the third in the Dean's Symposia series, *The Role of Pharmaceuticals in Public Health*, was to open a dialogue among pharmaceutical industry executives, human rights advocates, and leaders in health care delivery from around the world, in order to explore how we can ensure pharmaceuticals are a core part of what makes populations healthy.

Dean Sandro Galea opened the day's conversation by noting that the field of public health has long struggled with how to deal with the topic of pharmaceuticals, as they are typically only considered in the realm of medicine. Professor of Global Health at BUSPH, Richard Laing, has spent much of his 30 years in the field studying how public health methods can be applied to the pharmaceutical industry to meet unmet health needs around the world. Because of the leadership of Dr. Laing and others at BUSPH, students, through a formal certificate program, are now also grappling with the question – what is the role of pharmaceuticals in public health?

The morning portion of the symposium focused on the pharmaceutical industry's role in public health, and featured an in-depth debate about drug pricing – including topics such as factors that determine manufacturers' selling prices, patents and intellectual property, mark ups, and confidential government pricing agreements. The afternoon discussion turned more toward exploring universal health coverage (UHC) – what it means to achieve UHC, and an in-depth assessment as to whether achieving UHC is enough.

What Role does the Pharmaceutical Industry Play in Public Health Issues Today?

Stefan Oschmann, President of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and CEO of Merck KGaA, Darmstadt, Germany, brings many years of experience in academia, international organizations, and in the public and private sector. Dr. Oschmann's answer to the question of the role of pharmaceuticals in public health can be boiled down to this: improving public health is everyone's business and everyone's responsibility, including the pharmaceutical industry. Surrounded by prejudices and criticisms that abound about the industry, and admitting to some, he said he reminds himself of the values Merck's founder instilled in his sons of transparency, honesty, and truthfulness when making decisions in business.

Dr. Oschmann detailed three of the biggest challenges global health faces today and shared what the pharmaceutical industry has done to address them. The industry has joined with many other public and private partners in working to achieve the London Declaration – a commitment to eliminate neglected

tropical diseases (NTDs), antimicrobial resistance (AMR), and non-communicable diseases (NCDs) by 2020. The first of these, NTDs (lymphatic filarisis, schistosomiasis, guinea worm disease, and visceral leishmaniosis), affect 1.7 billion people, killing 500,000 annually. The industry has increased its donation of tablets to combat NTDs, and there has been significant progress toward eliminating those diseases. The second challenge, AMR, is one that Dr. Oschmann views as the single largest threat facing health today, the one that has the potential to compromise the progress that has been made in health to date. In 2014, 700,000 deaths were attributed to AMR, and that number could reach 10 million by 2050 if left unchecked. A Joint Industry Declaration on Combatting AMR was announced in January 2016, from a convening of 85 companies from across the medical field to work on this issue. Because AMR affects everyone across the world, Dr. Oschmann stressed the importance of partnerships working together to set the right incentives to solve the issue of AMR. Lastly, Dr. Oschmann introduced the topic of the growing global burden of NCDs, but all of the speakers touched on this problem throughout the day. NCDs (cancer, obesity, diabetes, cardiovascular disease, chronic respiratory disease, etc.) are the main drivers of disability and mortality nationally. Sixty percent of disease worldwide is now attributed to NCDs, and 80% of the deaths that occur as a result of an NCD occur in low- and middle-income countries. Improving access to medicines to treat NCDs is now one of the main priorities of the 2025 goals of the World Health Organization (WHO). Dr. Oschmann is proud of the contributions the industry has made toward helping to reach the goals of the London Declaration, but admits there is still a lot of work to be done.

A Closer Look at Pricing Strategies

High Drug Prices

The most heated moments of the symposium centered on the topic of drug pricing strategies. Dr. Oschmann, as the pharmaceutical industry representative, was subject to many pointed remarks and questions from human rights and consumer advocates on the panel and in the audience. Peter Maybarduk, Director of Public Citizen in Washington, DC, blasted Dr. Oschmann on drug pricing strategies, specifically on the policy by manufacturers to set drug prices not based on research and development costs or value, but on the tipping point – how much they can charge before hitting pushback from the government and insurers. From his experience working in drug development, from early-stage discovery to commercialization, Vin Sharma responded to Mr. Maybarduk's concerns by highlighting the many factors that determine a manufacturer's selling price. He discussed the many rigorous and expensive steps that take place over a long period of time (sometimes up to 14 years) to bring a drug from a concept to a marketable product. He detailed the immense amount of research and development that go into the making and refining of a new drug, the effort and time needed for the many rounds of clinical trials, the lengthy process of securing regulatory approvals, and the raw materials costs to mass produce the drug. He maintains that all of those steps involve a huge up-front cost that manufacturers must be allowed to recoup when the drug is brought to market by setting a high price point. If legislation is introduced mandating drug prices be regulated by the government, as Mr. Maybarduk advocates, Mr. Sharma and Dr. Oschmann worry that there will be insufficient incentives for pharmaceutical companies to focus on innovation.

Margaret Ewen offered a different perspective on high drug prices. She believes the fault does not lie solely with the pharmaceutical industry. She highlighted that the mark ups and incentives that are

added on along the supply chain are a key problem in the availability and affordability of medicines. These mark ups include importers, wholesalers, exporters, pharmacies, taxes, and duties. This is especially significant in low-income countries where unregulated mark ups allow prices to skyrocket, in some cases doubling the original manufacturer's selling price. Dr. Oschmann agreed, saying the poorer the country, the higher the mark up. Ms. Ewen pointed to Yemen, where ten middle men stand between the manufacturer and the patient, all adding to the final cost. She advocates for governments to step in and actively reduce these mark ups in the supply chain.

Patents and Intellectual Property

The discussion of drug price setting also elicited the topic of patents and intellectual property. To clarify, patents refer to the exclusive rights granted to an inventor for the public disclosure of an invention for a set period of time. Intellectual property is similar, but also includes intangible assets like scientific discoveries. Again, Dr. Oschmann and Mr. Maybarduk had opposing views of the role of both in terms of medical innovation and access to medicines. Mr. Maybarduk maintains that prolonged high prices for patented innovative medicines constitutes a systemic problem on many levels. He argued that this monopolistic power to price set by the industry inevitably leads to treatment rationing. It also deters entry of cheaper generic alternatives, so only the relative few who can afford the high prices will get that medicine. He shared that it was this point in particular that led him to his career path of passionately advocating for those who cannot afford the drugs they need and are forced to wait until patents expire to receive treatment. "For someone with no access to a drug, there is no tomorrow." Even if a drug is available, if it is not affordable, then it is not accessible to large numbers of people. He strongly feels that if we were to start from scratch in our discussion of how to pay for medical innovation, it would be "a massive failure of imagination" to think there is not a better way than the current model of patents and intellectual property.

While Dr. Oschmann admitted that there is room for patent regime to evolve, he wholeheartedly rejects fundamental criticism of the patent system. He strongly feels that managed properly, intellectual property is good for patients. "How can we be so simplistic to think if we abolish patents that we solve problems?" He informs us that 95% of the drugs on essential medicines lists are off patent, and maintains that poor access to off patent drugs in many countries around the world is the problem. He urges partners to broaden the discussion and tackle larger issues like infrastructure, distribution networks, logistics, number of health centers, and availability of specialty physicians. Dr. Oschmann feels that only by addressing those challenges holistically can there be any real impact on the availability, affordability, and accessibility of medicines.

Brooke Baker, a policy analyst at Health Gap, speaking from the audience, attempted to unify the discussion by highlighting a shared commonality – the agreement among all parties of the need for continued medical innovation. The challenge then becomes how to fund research and development for that innovation. He called for panelists to work together to craft a new incentive model that keeps the end goal of accessibility and affordability at the forefront of the conversation. He advocated for a system that would allow pharmaceutical companies to be paid along the way for their work, thus eliminating the need to recoup large margins at the end of the process. Jonathan Quick, CEO of Management Sciences for Health, also speaking from the audience, warned panelists not to fall into an either/or situation – that a mixture of systems allowing for more options is needed in order to get medicines to people who need them. Mr. Sharma agreed that we need to continue the discussion and

find a balance between innovators recouping their investment and patent expiries to allow generics to come into the market.

Transparency in Drug Prices

A United Nations high-level panel issued a landmark report earlier this year on access to medicines (www.unsgaccessmeds.org/final-report). Among other recommendations, the report urged greater transparency in drug pricing, including delinking patient prices from research and development costs. Both Mr. Maybarduk and Ms. Ewen also advocated for governments and the pharmaceutical industry to be more open and forthcoming with drug prices, including mark-ups, incentives, rebates, and special deals. As Ms. Ewen pointed out, governments use public money to buy medicines, so the public should have a right to know what the government paid for them. Often, drug companies will offer discounts to governments if they keep the selling price a secret, or they offer a lower price but add on conditions, like market exclusivity for a period of time, that hinder competition. Ms. Ewen asserted that disclosing these confidential negotiations would be favorable in reducing drug prices. Richard Laing offered the example of South Africa, which after banning rebates and discounts, saw dramatic reductions in medicine prices. Mr. Sharma contended, however, that these confidential pricing arrangements give companies an edge on their competitors. He worries that making prices public is a slippery slope and could change the dynamic of pharmaceutical incentives. Dr. Oschmann warned of the dangers of getting caught up in conspiracy theories, and maintained that confidentiality in pricing is good for the consumer and for the industry and must be allowed to continue.

Universal Health Care

The afternoon segment of the symposium shifted focus to a critical look at universal health care (UHC) around the world. Many governments worldwide either have committed to, are working toward, or have achieved UHC. While reaching UHC is unquestionably an important step forward, unfortunately, it is almost always viewed as an end goal, even in high-income countries. As BUSPH Associate Professor on Global Health, Veronica Wirtz advocated, we should be viewing UHC as the start, not the end, of the process. Olusoji Adeyi, a Director at the World Bank in Washington DC, described the challenge of UHC as finding a balance between scale (population covered), scope (content of services), and protection from financial ruin (high out of pocket costs). Simply watching insurance affiliation rates (scale) and believing the work is done when rates reach optimal levels leaves many gaps in the system. In order to fully reach UHC, governments must delve deeper and look at what services are included (scope) and ensure appropriate financing of essential medicines that is sustainable. For people covered by insurance, their consultations might be free, but their medications might not be – resulting in large out-of-pocket costs. Dr. Adeyi spoke about the importance of moving away from point of service costs. Every year, 11 million people in Africa fall into poverty because of catastrophic health expenditures. Margaret Ewen highlighted those specifically unable to sustain a lifelong need for medicines to treat NCDs because of high medicine costs. Dr. Wirtz provided an example from the US that 1 in 10 people on Medicaid and 1 in 7 uninsured people do not take their prescribed medicines to save on costs. It is imperative that governments find affordable, equitable, and sustainable financing of medicines to combat these staggering and unsustainable out of pocket costs.

Dr. Adeyi asserted that equitable access to medicines is a central piece of UHC and, further, that access to medicines is a human right guaranteed under the right to health. When informing policy and practice, keeping in mind the right to medicine is imperative. He warned that "ideological absolutism

and romantic attachments to perfection are not virtues in public policy practice." Dean Galea agreed, saying that if our goal truly is to improve population health, we are not well served by absolutism or perfection.

Counterfeit Medicines

Affordable medicines are a key piece of UHC, but equally important is ensuring that those medicines are of consistently high quality. As Dr. Laing pointed out, we in the US are confident in the quality of the medicines we receive. However, across much of the world, the distribution of counterfeit medicines is a huge problem. Pius Tih, who works with a Faith Based Organization (FBO) in Cameroon, detailed a heart-wrenching account of a man who brought his sick child to the hospital. The child was prescribed a medicine to combat his malaria; the father administered the medicine according to directions, only to have his child die because, after testing the medicine, it was found to be without the active ingredient. Several FBOs, including the one Professor Tih works for, routinely conduct random sampling of drugs using the Global Pharma Health Fund Minilab. Between 2011 and 2016, one in twenty (5%) of the drugs tested were determined to be without an active ingredient, or not have enough of the active ingredient to be effective. In the case of drugs found to be of substandard quality, the WHO will issue an alert and the company that manufactured the drug will be warned, but there is little incentive not to reoffend. Professor Tih suggests stronger sanctions for companies that promote the production and distribution of counterfeit drugs, likening it to attempted murder. Until meaningful steps to combat the counterfeit medicine problem have been achieved, and until FBOs are viewed as full health care provider partners with governmental funding, efforts to reach UHC in countries like Cameroon appear to be futile.

Pharmaceutical Health Disparities Among Low-, Middle-, and High-Income Countries

We have discussed a few examples of disparities in pharmaceutical health across low-, middle-, and high-income countries. These include a strong confidence in the quality of medicines in high-income countries versus the prolific counterfeit medicine situation in many low-income countries like Cameroon; and the unregulated mark-ups on medicines in low-income countries resulting in prices that are often double the manufacturer's selling price. The findings of a study Dr. Wirtz illustrated another disparity. Her study revealed that the survival rate for a breast cancer prognosis in high-income countries like the US was 80%, while the same prognosis in low- to middle-income countries yields a 57% survival rate. The discrepancy comes from a combination of late diagnosis, due to the absence of strong screening programs, and inadequate access to treatment. One last discrepancy that was highlighted over the course of the day's conversation was the dramatic difference in maternal mortality rates between high-income countries and low-income countries. As Professor Ye Lu was detailing some of China's recent improvements in health care, she noted that China's maternal mortality rate dropped from 34.2 to 21.7 per 100,000. Professor Tih was immediately struck by that figure, noting that in his country the maternal mortality rate was 700 per 100,000. Addressing and resolving these disparities are critical challenges necessary for achieving UHC in low-income countries.

Some Progress

Inevitably, any time a difficult conversation around a complex topic unfolds, many challenges and negatives rise to the surface. However, it is important also to remember the positives. As Dr. Adeyi

and Dr. Quick reminded us, 100 years ago there were virtually no medicines or childhood vaccinations against disease. The period following World War II saw a revolution in medicine development and production. An explosion of drugs for tuberculosis, mental health, antibiotics, vaccines, and oral contraception came onto the market that addressed most major diseases in the US. Dr. Oschmann conceded that the pharmaceutical industry had to learn its lesson first, but assured us that today the industry is increasingly working to meet health priorities and needs of people across the world. Evidence of improvements in health outcomes on all levels abounds. Since 2008, Professor Ye Lu reported that China has seen life expectancy rise from 73.1 to 76.3, infant and maternal mortality rates fall, increased insurance coverage for its citizens (97%), and a decrease in out-of-pocket costs. In Cameroon, FBOs are working to complement government programs in getting and distributing essential medicines to people who need them. There are UHC plans in some countries across the world, including Thailand, that have developed essential medicines lists and instituted reasonable co-pays. Keeping these advances and positive trends in mind when navigating the road ahead is essential to making further progress.

Dr. Laing highlighted two other important points to consider when discussing the road ahead. First, he noted the recent trend in schools of pharmacy toward reducing social pharmacy content in their programs. Second, BUSPH is currently the only school of public health that offers a substantial program in pharmaceuticals in public health. He firmly believes that the most promising answers to the challenges surrounding innovation, drug quality/safety, and access to essential medicines will be found at the intersection of public health and pharmaceutical science. BUSPH Pharmaceuticals Certificate Program Director Erin Hasselberg stated that graduate students in the program gain important insight through both classroom coursework and a skills-based practicum. In addition, they participate in a robust seminar series, coordinate an annual symposium, and attend networking and social events. One of the primary goals of these activities is to allow students to engage with the local community about the important role of pharmaceuticals in advancing public health. With 150 graduates to date, the growing Pharmaceutical Certificate Program at BUSPH is shaping the future role of pharmaceuticals in public health.

The Road Ahead

Progress often comes from intersection between disciplines – when the constraints of either one discipline or the other are loosened in an attempt to explore what can be found at their junction. What we find at the intersection of pharmaceuticals and public health is not one single simple issue or problem. Dr. Adeyi described it as, on one hand, a complex intersection of challenges and, at the same time, a compelling opportunity. Over the course of the day-long symposium, many of the challenges were discussed – those of balancing the cost of drug innovation with an affordable price to consumers, equitable access to essential medicines, ensuring high quality medicines and eliminating counterfeit drugs, and addressing disparities across low-, middle-, and high-income countries. Yet, the road ahead definitely presents a compelling opportunity – a renewed call for us to partner and work together, as Dr. Wirtz encouraged. All of the speakers seemed in strong agreement that partnership is the best way to find solutions to those challenges, and offers the best hope in achieving balance in matters of health. Both Dr. Oschmann and Mr. Sharma advised that a critical first step is for partners to establish common ground and align around common beliefs. Continuing an open debate on issues for which

partners hold differing beliefs is also essential. As we move forward on this topic, Dr. Wirtz urged us to look closely at the successes and failures from the last decade, and learn from them. As Dean Galea reminded us, these issues rest on deeply embedded social and political structures that are not going to change overnight. However, as Dr. Wirtz stated, "progress is not only possible but imperative and all of our responsibility." Dr. Oschmann assured us that the pharmaceutical industry is very willing and eager to do its share. The industry has committed to building sustainable partnerships in order to improve health in developing countries. Dean Galea views the role of a university in making progress on complex topics like this as three-fold: first, to gain knowledge by asking questions and finding answers; second, to transmit that knowledge to the next generation and entrust to them the difficult task of debating multiple positions around complex issues; and last, but most importantly, to be involved in the 'doing' – to engage in the construction of social narratives – "to be in the arena and bloodied."