March 23, 2016

UN High-Level Panel on Access to Medicines

Dear UN High Level Panel Members and Colleagues,

Thank you for the opportunity to contribute comments to the UN High Level Panel following meetings held in London and Johannesburg.

I valued the opportunity to testify to the Panel in London, and participate in the open dialogue session moderated by Andrew Jack. The comments and conversation presented important and different perspectives on the issue of access to medicines in low-and middle-income countries (LMICs) as well as in high income countries. Some comments were emotional and personal, including Jamie Love's reference to his wife's situation and the system. Yet, it is innovation within the current system that is responsible for Jamie's wife's dramatic improvement and so many others who are alive today because of new innovative medicines.

My earlier contribution to the High-Level Panel referenced several industry led programs enabling access to medicines in LMICs. Most programs were donation based and focused on neglected infectious diseases, while one was addressing access to fifteen drugs for non-communicable diseases at a cost of $1 per month. During the London discussion several people commented that donation was not the answer. I believe the companies managing these programs would agree. Yet, until there is a better option, companies are committing significant resources toward making these products available to patients who desperately need them. Millions of patients benefit through these donations every year.

Companies are not only providing access to their products in LMICs or just for infectious diseases. Pharmaceutical companies have compassionate use programs that enable access to products across therapeutic areas. A few participants were quite negative about compassionate use programs, yet for the millions of patients that gain access to needed treatments each year through compassionate use programs, these programs make all the difference. I do not consider compassionate use programs the solution or answer to access, but they are helping a lot of patients around the world. The panel should learn from these programs.

Novartis has been making Glivec available through their Glivec International Patient Assistance Program to more than 80 low-to middle-income countries for years. They also provide Tasigna and Exjade on a compassionate or cost sharing basis. More companies could create programs like the Novartis GIPAP and the panel could consider how to make this program larger and more sustainable for a company like Novartis.

I would encourage the High Level Panel to commission a report evaluating all drug access programs and look at what is working and what is not. Michel Sidibé encouraged more partnerships and more innovation within the current system. I had the pleasure to speak with him after his talk and I believe he would be a valuable advisor to the Panel. He is a strong supporter of multi-stakeholder partnerships involving local government and adapting to the needs of a country. If governments are at the table and committed to improving healthcare, companies will participate. That is the experience BVGH has had with our oncology hospital program and partnerships in Côte d'Ivoire. I am confident the Côte d'Ivoire program will become a model for other countries and other therapeutic areas.

I could reference many, many programs that companies have underway to enable access to their products across therapeutic areas. I do not suggest these programs are the answer, but I am certain they are benefiting many patients and provide a basis for us to learn as we move forward to implement programs that increase access to medicines for all patients that need them.

There were a few comments made during the dialogue session that I do not believe are accurate. I'm sure the panel is well aware of this information but I am referencing a few points that I heard during the day:

It was indicated that companies have too much independent control over the design and running of clinical trials.

Clinical trials are not designed independently or even close to independently by pharmaceutical companies. Companies do not have direct access to patients for clinical trials. They are required to work through primary investigators (PIs) at hospitals across the country. These PIs have considerable influence over the study design. The hospital ethics committee reviews every proposed clinical trial and also weighs in on the study design and impact and benefits the study is anticipated to have on their patients. In addition to the PIs and hospital ethics review committee, the FDA has a lot to say about the study design and what end points need to be achieved in order for the drug to be considered a significant and worthwhile benefit to the patient.

In my experience, companies do not invest in developing drugs that will not have an important and meaningful benefit to patients.

A question came up about the link between supportive IP policies and economic factors.

The gentleman from the US Chamber of Commerce referenced a couple of studies supporting the link between IP policy and positive economic indicators. The US Chamber of Commerce International IP Index Annex was updated in 2016 and studies the correlation between IP policy and several economic factors.

The study below shows that strong IP protection actually results in faster access to products in developing countries. I believe Corey Salsberg from Novartis commented that IP translates into faster introduction of medicines.

> Recent studies show that strong IP protection results in faster launch and faster access to new medicines in developing countries. (Cockburn, Iain M., Jean O. Lanjouw, & Mark Schankerman. "Patents and the Global Diffusion of New Drugs." 2016. American Economic Review. 106(1): 136-64; Margaret Kyle and Yi Qian. "Intellectual Property Rights and Access to Innovation: Evidence from TRIPS," National Bureau of Economic Research, Dec. 2014: Working Paper No. 20799. Web. 22 Feb. 2016. <http://www.nber.org/papers/w20799>.)

Andrew Jack encouraged us to look ahead to consider solutions and recommendations for the panel. I thought several ideas were proposed that will be helpful to the panel including:

Aiden Hollis suggested a tiered pricing system could be beneficial to both patients and patent holders as the innovator would capture a larger market for their drug. In fact, we have tiered pricing systems

already and this might be an area that the Panel could look at and consider implementing in partnership with LMIC governments.

The independent journalist from Uganda said, access is politically driven and most African politicians do not invest in health systems for the entire population. She suggested governments in these countries should be held accountable and invest in domestic health systems.

I believe the Panel has the ability through the UN agencies to influence governments to do more and to support them through UN agencies in doing more to improve health.

The panel could learn from governments committed to improving healthcare and access, such as Rwanda and now Côte d'Ivoire. These governments are establishing partnerships across countries and industries to improve the health of their citizens.

Andrew Jack asked why countries have not pursued health impact funds. I would advise the panel to consider recommending a pilot program to evaluate these funds. There are publications and individuals in health, finance and modeling that believe health impact funds would work in developing countries. I would be happy to connect the Panel with contacts at the Milken Institute and MIT who have expertise in this area.

There are a many, many initiatives underway that support and provide access to medicines in LMICs, across therapeutic areas. And there are a number of new programs being developed that will soon be implemented. We are seeing more collaboration and coordination across companies and sectors to implement access programs. A lot has changed in recent years. I urge the Panel to look ahead and consider some of the programs and initiatives around access to medicines and create pilots to scale and expand those programs. I have ideas of how this could be done and would be pleased to support the Panel on any programs or planning.

I strongly believe that, with the right programs and opportunities, companies will participate in more research and access initiatives focused on the needs of LMICs. I advise the Commission to complete a full analysis of access to medicines programs. A proactive approach to developing innovative, multi-sectorial initiatives to address the complex issues of access to medicines is needed. So much more can be done when we communicate and work collaboratively to develop solutions. LMIC governments must be at the table and committed to implementing access to medicines programs.

Sincerely,

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