Stephen J. Ubl â?? President & CEO, PhRMA

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Stephen J. Ubl, President & CEO of Pharmaceutical Research and Manufacturers of America (PhRMA) discusses the organisationâ??s initiatives to address health inequity in the US along with its opposition to the provisions in the Biden administrationâ??s Build Back Better Act to lower costs and improve access. He also comments on the US health insurance system.

Last time you spoke to PharmaBoardroom back in 2017, PhRMA was about to launch the GOBOLDLY campaign, and its messaging was very much focused on innovation. Since then, there has been a noticeable shift to speaking more about access and affordability; what has changed?

Our focus has always been on telling the innovation story and GOBOLDLY is an effort to do that; this campaign still lives on today online and in the events that we do. Through GOBOLDLY we developed a stronger relationship with patient organizations and there is now an army of individuals who have benefited directly from our industryâ??s innovations who are advocates for the industry. Our focus on access and affordability has multiple dimensions, but the biopharma industry has always worked to ensure that the medicines it makes are broadly accessible to patients.

Health equity is another hot topic the world over but means different things in different countries. How is PhRMA defining health equity and working to achieve it in the US?

The COVID experience laid bare many of the inequities plaguing our system; for example, the death rates associated with COVID were twice the rate in communities of color compared to for white Americans. The industry has long worked to address these inequities, but COVID catalyzed more focus and energy towards this push.

There are two main ways in which we are attempting to achieve greater health equity. This first is ensuring that our own organizations are diverse and inclusive. A strong body of evidence exists to suggest that diverse teams and leadership lead to better problem solving and, for our members, better development of medicines.

Secondly, we are looking to close gaps within the US healthcare system. Our studies have shown that only one in ten black Americans have been involved, or know someone that has been involved, in a clinical trial, which is unacceptable. An improvement in clinical trial diversity is crucial in rebuilding trust in communities of color that have historically been excluded from data collection efforts and mistreated in trials.

In 2021, as an industry we launched a three-pronged effort to address both of those dimensions. Internally, we are looking to develop talent from diverse communities, for example holding the first ever summit for graduate students in the STEM fields and exposing them to the opportunities in our industry. We had over 500 attendees from more than 200 universities. PhRMA has also forged partnerships with historically black universities and colleges, providing greater numbers of internships to students from these schools and exposing them to the opportunities that innovative biopharma companies have to offer. Within PhRMA itself, we are also taking steps to ensure that the organization is as diverse and inclusive as it can be.

On clinical trial diversity, our polling has shown that 84 percent of PhRMA members are committing energies towards partnerships with local communities to improve clinical trial diversity, although many of the issues around unequal access to healthcare in the US are systemic and complex.

As an industry, we have released a set of industry-wide principles and will shortly be rolling out a very significant initiative to help our companies put the principles into practice. It is important to note that we started this journey from a position of humility, holding a roundtable with over 500 participants from more than 150 organizations. There, our aim was to listen to those closest to the communities we are trying to better serve and learn from them how we can improve clinical trial diversity. PhRMAâ??s new initiative is focused on developing infrastructure in local communities to make it easier for both our companies to develop trial sites, as well as for patients to access those sites.

Most FDA approvals today come from smaller biotechs which perhaps have fewer resources to commit to issues such as clinical trial diversity; with that in mind, how much impact can PhRMAâ??s initiative really have?

This is a fair question, but it must be remembered that PhRMA represents 35 of the largest and most influential companies in the industry which continually partner with companies of all sizes. Additionally, PhRMA has long worked closely with the Biotechnology Innovation Organization (BIO) to create a more unified industry focus on these issues. These efforts are going to serve the entire industry, creating infrastructure in local communities that all companies can avail themselves of.

The problem today is the utilization of â??one and doneâ?? clinical trials with peripatetic participation. These trials tend to be for a single medicine and, once completed, there is no lasting infrastructure that other actors can use or which keeps talent close by. Proximity, as in many facets of life, is vitally important and we need infrastructure that is readily accessible both to the healthcare system as well as to underserved communities.

While some policymakers have proposed mandating clinical trial numbers as a solution, we feel that this is misguided. Without the right infrastructure that permits these trials to take place and encourages the right practitioners and patients to participate over time, we will not see significant change.

As an example of perhaps such universality- PhRMA claims that the provisions in Section 340B of the Public Health Service Act are not effective, that benefits are not passed on to patients, and that some USD 38 billion is instead being diverted towards hospitals and pharmacists. Why has the association reacted so strongly to this program and what does it suggest as an alternative?

340B is a well-intentioned and industry supported program intended for patients in those healthcare facilities that treat a disproportionate share of uninsured or underinsured individuals. However, 340B has grown exponentially and is now on track to become even bigger than Medicaid; many for-profit entities are benefiting from the program at the expense of patients. These entities include large hospital systems, pharmacy benefit managers (PBMs), and contract pharmacies such as Walgreens and CVS. Today, it is unclear how much of the benefits of these discounts are making their way to patients and there is very little in the way of transparency or accountability requirements for the facilities that receive them.

Not long ago, these rebates and discounts were around USD seven billion, but they have grown to 38 billion in recent years and, again, there is very little evidence that these savings are being used to lower the drug costs of patients. We must get back to the original intent of the program: the facilities treating the patients most in need. Without this, the program will remain unsustainable.

From a European perspective, much of this inequity seems to be baked into the US healthcare system; how would you counter that?

I am a great believer in the US system and feel that there is a lot of misinformation about it. We have a universal system, much like Europe, for our 65+ population as well as our Medicaid population, and boast a robust employer-provided insurance market. However, insurance is not what it used to be and care for those that fall in the gaps between the 65+ and Medicaid populations, and even for those within them, could be improved. These are some of the core issues that weâ??re trying to address as an association.

The Biden administrationâ??s Build Back Better Act (BBB) contains several provisions to lower health costs and improve access to care via drug pricing reform, but PhRMA has strongly opposed it. Can you explain your opposition to this legislation?

The biggest concern that we have with BBB is that it gives the government sweeping new authority to set the prices of medicines. Currently, patients in the US have access to over 90 percent of new

treatments and cures approved by FDA, whereas those in Europe have access to only around 50 percent of this total, and in Asia only a third. We have seen how this movie ends and, however limited such reform might be to begin with, allowing government to set medicine prices is a bright red line for our companies. Even the Congressional Budget Office, our third-party arbiter in Congress which looks at legislation and renders an opinion for Congress, has said that similar legislation allowing the government to set the price of medicines would prevent up to 60 new treatments and cures from being developed by our companies.

Additionally, for companies that fail to comply with this â??negotiationâ?• and do not reach an agreement, the government can impose a 95 percent tax. Just like the famous line from the movie, *The Godfather*, this is â??an offer they canâ??t refuse;â?• if a 95 percent Sword of Damocles hangs over a negotiation, it cannot really be called a negotiation.

A recent Ipsos poll showed that Americans are overwhelmingly frustrated with their health insurance coverage and would support policies to lower out-of-pocket costs and bring greater transparency and accountability to the health insurance system. What would positive change in the US health insurance system look like to PhRMA?

Today, three PBMs cover upwards of 80 percent of the covered lives in the US. These organizations are now typically vertically integrated with health plans, which were formerly standalone, and have enormous marketplace leverage as a result.

Medicine net prices have reduced by three percent year on year according to IQVIA, due to almost USD 200 billion in rebates and discounts in 2021, which is being absorbed by PBMs and other actors in the supply chain such as insurers, and government mandated programs like 340B and Medicaid.

Because of this, our companies are now capturing less than 50 cents on the dollar of the list price of the medicine. This is a crazy situation for companies which, at the end of the day, are the inventors of these medicines. PBMsâ?? value proposition is far lower; they typically negotiate with our members and determine formulary placement on behalf of large purchasers, like employers. Despite this, PBMsâ?? profits have soared and there are more in the latest Fortune 500 top 20 than ever before.

The core issue we need to focus on is, if prices are falling and rebates and discounts are rapidly growing, out of pocket costs should be going down. However, these costs have actually risen by 50 percent since 2014 for patients with a deductible.

A third of US patients have described a financial hurdle in terms of accessing medicines. Therefore, PhRMAâ??s focus has been on pocketbook issues related to lowering what patients pay at the pharmacy counter. This includes initiatives such as requiring health plans and PBMs to share rebates and discounts at the pharmacy counter, such as for insulin, and smoothing those costs over the calendar year to allow for more predictability in drug costs month by month. Another proposal would be to set an out-of-pocket cap for Medicare Part D, which stands out among other programs for not having such a cap.

Some elements of the BBBA, including a USD 2,000 out-of-pocket cap spread out across the calendar year, are a clear step in the right direction and a significant improvement in terms of facilitating access to medicine. However, there is still work to be done to address abusive insurance practices.

Is the concept of value-based healthcare an area in which PBMs and PhRMAâ??s members can come to some agreement?

Value-based healthcare is an area of common ground between almost all actors; health plans get more information about our products in real world settings, companies learn more about their medicines, patients benefit because plans that include such additional information are typically able to lower out-of-pocket expenses.

The volume-based system we have today has created several distortions and has caused health plans and PBMs to arguably prefer higher-cost medicines that come with higher rebates. Therefore, engaging in value-based discussion with health plans is a much better approach.

In the context of the BBBA, I have been disappointed in health plansâ?? silence on the governmentâ??s sweeping new authority to set the price of medicines. If you take that to its logical extreme, why do we need health plans at all if the government is going to set the price?

A pluralistic market-based system allows people to vote with their feet and, if their health plan is not meeting their needs and providing a medicine or any other service they need, they can go to a different one.

Health Technology Assessment (HTA) is being adopted across the world as a way to assess the value and impact of innovation. While HTA is generally conducted by government entities in Europe, the US â?? although home to the independent body ICER â?? has pursued a different path and does not have government stewardship. What is your take on the importance of HTA?

We have concerns about the government conducting HTA for similar reasons to those we have about the government setting medicine prices. They are very closely related and having one entity arbitrating for the entire market raises the stakes in a way we believe is not conducive to patient access. In fact, we believe that HTA is used inappropriately in many markets, for budgetary reasons rather than improving patient access.

The US has a fragmented HTA system with ICER and other HTA organizations that provide information which gets picked up indirectly and used by private payers. HTA data is also available to government payers, although they have a more limited ability to use it, we think appropriately so.

We feel that comparative clinical effectiveness and providing better information to physicians and patients is the more appropriate use of HTA, because we now have several modalities that can be used in the treatment of the disease.

Patients want to know the best therapy for them, period. They do not want budget focused HTAs that argue that one set of therapies is marginally less effective than another from a fiscal perspective. Currently, we still lack sufficient information for many conditions, meaning that comparative clinical effectiveness will remain important. Additional academic work in this area is fleshing out HTAâ??s methodological limitations and how it can better take into consideration what most patients are focused on.

PhRMA is not opposed to HTA but remain concerned about governments having the unilateral authority to conduct it. We are focused on improving methodology and understand that HTA is here

to stay, but if the methodology is not improved, HTA should not be used unilaterally.

A lot of the value associated with our medicines would not be considered within a classic HTA exercise. For example, in Duchenne muscular dystrophy (DMD), HTA entities looking solely at longevity would argue that a new medicine that does not extend life lacks value. However, the parents of children who are impacted are not focused on longevity but on keeping their kids out of the hospital and improving their day-to-day lives. Therefore, having a more patient centered, holistic view of value is our focus.

Given the huge success of COVID-19 vaccines, where products were developed and brought to market in record time, what lessons has the industry learned from this process and what expectations do you have in terms of greater stakeholder understanding of the issues you are advocating for?

COVID really was our industryâ??s finest hour. It is incredibly difficult to create a new class of medicines, but to do it inside a calendar year is a modern medical miracle. In two years, our industry has managed to create 11 approved/authorized vaccines and therapeutics from a standing start, which really crystalized our value proposition and our status as a national security asset in the eyes of policymakers.

Since the outbreak of the pandemic, we have worked hand in glove with both administrations and have seen incredible levels of communication and collaboration with regulators and other officials. Early on, the focus was on streamlining clinical trials so that all companies involved had a clear understanding of endpoints, which was a huge success. Collaboration, both with government, but also within the industry, as companies put aside their competition to manufacture a competitorâ??s product, has also been a great story.

Other learnings include decentralized clinical trials, which play into the equity equation and can be applied in other disease areas. Moreover, real world evidence was used very effectively, and COVID trials also had a high level of participation from communities of color.

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