Stephen J. Ubl – President and CEO, PhRMA, USA

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25.08.2017

Tags: USA, PhRMA, Association, Pharma, Innovation, Internationalization, Pricing, Regulatory Reform

In an exclusive interview, Stephen Ubl, President and CEO of the Pharmaceutical Researchers and Manufacturers of America (PhRMA), the association representing the leading innovative biopharmaceutical companies in the USA, discusses the onset of a new "golden era" in medicine. He goes on to discuss pricing issues, engaging in a constructive dialogue with the current administration, and building a stronger brand image for the pharmaceutical industry at large.

You have come to the association at a time of immense scientific transformation, but also at a moment of vigorous debate about what constitutes fair pricing. Are we entering a critical juncture for the future of the pharmaceuticals industry?

You are absolutely right: this is a really exciting time on the science side. In my first year, I undertook more than 60 trips to visit companies, tour the research labs and sit down with researchers and was really blown away by the scientific developments that are occurring both in this country and across the world. Treatment pathways are undergoing profound change. We're talking about real breakthroughs such as harnessing the body's own immune system to fight cancer or about taking cells out of the body, re-engineering them and then sending them back into the body. Just a few years ago, many of these techniques sounded like science fiction. But now we are really starting to witness the advent of personalized therapies and smart missions in which there is a real convergence underway between diagnostic technologies and drug device

combinations. We can genuinely talk about the onset of a new “golden era” of medicine.

The industry is really transforming the trajectory of disease through bioscience. In the last century, life expectancy almost doubled and mortality rates have come down across an entire range of conditions from HIV-AIDS to various forms of cancer. Furthermore, I am confident that we will continue to make a significant progress, as we learn more about human biology, the gene sequencing and biomarkers.

During this time, the trajectory of healthcare costs has also undergone considerable change. In many developed economies, and most certainly in the US, an overwhelming share of healthcare costs are today driven by a relatively small portion of the population afflicted with one or more chronic diseases. The brute reality is that some 90 percent of healthcare costs are, nowadays, generated by patients with chronic diseases. Meanwhile most of the cost associated with chronic disease occurs in the institutional setting: hospital care, visiting the physician and so on and so forth. From the macro perspective, better treatment for chronic disease is the key to ultimately reducing both the individual burden and societal burden. This is, without doubt, the correct way to bend the cost curve.

When you consider Alzheimer’s disease, for example, we are confronted with a ticking time bomb. In the United States, our national demography alone has trillion-dollar implications for the healthcare system if we cannot come up with some sort of solution. I think it is therefore really important to frame cost in the broader perspective. Otherwise you are at risk of formulating procedures that don’t speak to the broader trend of patient and societal need.

How do you evaluate the current cost climate then?

There are some signs that certain costs are moderating over time. In the United States, for example, three pharmaceutical benefit managers control 70 percent of the prescription market and have been leveraging that market dominance to drive a hard bargain with our members, which, in turn, clearly plays a role in constraining overall cost growth. Unfortunately, what shows little sign of moderating is what patients pay out of pocket. Recent data tells us that more than half of what patients pay out-of-pocket for brand medicines is based on the full list price.

It is frequently the case that patients enlisted in badly thought out healthcare plans end up paying full list price for the medicine. If you go to a hospital or physician, you are typically paying a negotiated rate. It is when you go to the pharmacy, that you are paying the full listed price for the

medicine. For our part, we are keen to encourage PBN's and health plans to pass on the fruits of negotiations to the patient at the point of sale.

When you think about it, the whole purpose of insurance is for heathy individuals to join the pool and offset the pool of individuals with chronic diseases. Unfortunately, we have the situation today that is almost the reverse whereby we are actually charging the sickest the most.

What measures does PhRMA advocate towards a resolution of this matter?

We engage directly with policy makers, but also try to hold discussions with all the other relevant stakeholders of the system as well: patient organizations, health providers, insurers, the medical community and so forth. We are seeking to evolve how we pay for medicines away from the prevailing discount model towards more innovative payment mechanisms such as outcome-based or performance-related contracts.

One example of innovative contracting model would be indication-based reimbursement so if you have a product that work really well for lung cancer but the data is less mature for stomach cancer, the outcome based model will enable you to pay differentially for the product. It doesn't necessarily always make sense to have a single price for a specific drug.

Unfortunately, there are set of public policy barriers that are standing in the way of moving in that direction. The office of inspector general has written guidance that is two decades out of date and focused on serving a world that no longer exists as we increasingly move towards more capitated insurance models.

Speaking of getting all stakeholders together to achieve common objectives, how have your discussions with President Trump been progressing?

We had a very productive discussion with President Trump. My impression is that he understands that America's current prowess in the advancement of medical science is of great benefit to the nation's economic health and that the pharma industry is indeed one of the crown jewels of the United States economy. He wants us to continue to lead the world in terms of drug development. After all, this industry spends more than any other industry on research and development and accounts for 4.5 million high wage jobs that are often more than twice the national average in terms of manufacturing jobs.

Secondly, he is intent on fostering greater domestic investment. We therefore had a rich dialogue and discussed some of the incentive structures that could conceivably be put in place to stimulate greater domestic investment like a more competitive tax code. President Trump is especially concerned about trade and the reality that many of our retraining partners have not lived up to their commitments in terms of protecting intellectual property which, of course, has a negative impact on American jobs. There is a lot of common ground with the administration and I think that the President understands and appreciates the role we have in the economy and in the area of improving patients' lives. We have had, and will continue to have, a very constructive dialogue and continued engagement.

To what extent could the debate around pricing impact the ability or will to innovate?

I believe the pipeline is robust in the industry and we have conducted research that shows that there are over 7000 drugs in development, many of which will represent first class treatments. There is great excitement around the unraveling of human genome and the advent of targeted therapies. The real question is can we afford it? I believe the answer is we can, because the market place remains highly competitive and steps can be taken to render health spending radically more efficient and cost-effective. Such savings could free up funds to properly reward innovation

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We have talked about performance-related contracts. Then there is the role that generics and biosimilars can play in taking costs out of the system. Biosimilars represent a huge opportunity to restrain the cost curve. We calculate that there are some 60 billion dollars' worth of revenue at risk due to biosimilars entering the market in upcoming years.

Where do generics fit into the mix?

When you reflect upon much of the negative press attention in the past couple years, it has been focused on cases where old medicines are off patent and where there is lack of effective competition. Right now, it takes about two years to get a competitive product onto the market. We do have a system, and 90% of prescriptions are generics, but more has to be done to ease this

process.

I came from the device industry, which is not wholly unlike the generic industry. Small and mid-size players dominate both sectors. The FDA has to take this into account and work with generic manufacturers to ensure that they can manufacture the products and bring them to market in a swift and efficient manner. Let's remember that generics are not inventing anything. The recipe is provided. The question is whether they can manufacture the product effectively. More has to be done to encourage and accelerate market entry. It is time to start applying incentives such is already the case with pediatric or orphan drugs.

While many of the top 50 largest, most capitalized pharma are American, down the list many of the smaller, "mid-cap" players tend to derive from Europe or Japan. How do you account for this situation?

Pharma is a truly global industry, but the United States does account for a big chunk of that. What you have noticed about the origins of the mid-cap players relates very closely to our discussions with the Trump administration and how American pharma actors could be better supported. It could be argued that current tax policy disadvantages some types of US pharma entities and therefore we need to rethink how, first and foremost, American jobs in the pharma sector can be better protected and how greater levels of domestic investment can be incentivized and sustained.

You, nowadays, maintain offices in Japan and have established a prestigious reputation globally. Just how important is internationalization to you as an association?

It is crucial for us to be traveling around the world and engaging with policy makers on issues of best practice. Many economies around the world are grappling with exactly the same issues surrounding the evolution of public healthcare and how you go about paying for it. As national populations age, the need to create incentives for innovation and manage cost becomes more pressing and a lot can be learned from how other markets have gone about confronting these realities. For example, both Japan and China are, right now, looking into pretty comprehensive reforms of their respective healthcare systems, so we are absolutely have to be engaged in, and contributing to, those discussions. We are very eager to be proactively involved in this cross-pollination of policy ideas.

The sort of comprehensive reforms you mention that are being enacted across the world often tend towards fostering universal healthcare. In Europe, people are often therefore surprised by the policy debates going on in the United States surrounding health insurance. Where do you see the current debates in Congress ending up?

People in other countries often misunderstand the US health system. We have the Medicare and Medicaid programs so there is less of a focus on formulating new policies to improve access. In terms of healthcare reform in the United States, Congress has now reached an impasse about what to do with Obamacare and the likelihood now is that they are going to park the issue entirely and move on to areas like tax reform where a greater level of consensus is possible. At the end of the day, however, we are likely to see that the United States will have more autonomy in terms of shaping the insurance market, and health plans will be empowered to shape their insurance designs. My prediction is that we are soon going to start seeing some of these discussions at the federal level about innovation and cost being debated and replicated also at lower levels of administration because state policy makers are increasingly finding themselves wrestling with exactly the same needs and constraints.

What can be done to improve the brand image of the pharma industry?

I came away from my recent travels to labs and extensive discussions with the research and scientific communities with two overriding thoughts. One being that the industry is making great strides in the advancement of medical science and that this story deserves to be told and brought to the attention of the public. These are immensely exciting times because we are really entering a new era where science is flourishing again. I wanted to have a campaign that really got people excited about the science again, so we are featuring real researchers, scientists and patients who benefited from the product, communicating the new advances.

What other industry researchers and scientist wake up every single day with one goal in mind to improve the human condition? The role of the pharma industry under appreciated by people at large. We are realistic that it is going to take some time and effort to improve and turn around the industry’s brand image, but we are already confident that our communications campaigns are making a difference in educating both policy makers and all the different consumers of the work that our industry performs.

My second thought is that we have to acknowledge that the current public perception of our industry is very negative. Right now, people are feeling as if some guy in a hoodie has mugged

them. One particular guy in a hoodie raised the prices of an essential drug by some 5000% and has just been sent to jail for fraud. We need to counter this, in most cases erroneous, but nevertheless highly resonant negative image by replacing it with the people in lab coats who are actually doing the hard graft of research and development and are making real breakthroughs.

We have been actively attempting to differentiate our members from some of the less respectable pharma players and to that end have actually established minimum thresholds surrounding investment. That resulted in 22 companies, leaving the association. We feel that it is important to send out the signal that all of our members are making sustained long-term investments on research and development and taking substantial risks to the benefit of patients' health. Just the other day I was speaking with a company that spent 7 billion dollars in R&D last year and launched one drug. That is not uncommon in this industry and so we resolved to refocus our membership criteria to ensure we are representing those types of companies at the vanguard of advancing medical science.

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At the same time, we are holding a series of roadshows and events to raise awareness of precisely the sort of discussions that we have been having today about pricing and the adoption of creative alternative models that can deliver much greater value to all parties in the debate. It's vital that we get people collaborating together to put in place negotiated value-based arrangements. There is a great need to replace the prevailing discount model that we are operating today, where the patient really is not benefiting from the fruits of the negotiations and the definition of a new contract mechanism carries with it an opportunity to really align all the stakeholders.

To conclude our discussion, what do you see as your immediate priorities and tasks looking forwards?

We are trying to come to the table with solutions to the overall affordability challenges that customer face. I think we have to acknowledge patients are paying more for their healthcare, for their medicines, and there are a lot of complex reasons why patients' out of pocket exposure has increased over time. We believe there are extortions in the market place that expose patients and are committed to working alongside the policymaking community to resolve this state of affairs

surrounding the issue of risk shedding. Already we have put together a 10-page document that identifies pragmatic policies that could address some of these challenges and which encompasses not only the FDA level, but also issues of consumer transparency and the sharing of cost savings at the patient point of sales.

Looking forwards, we have an exciting agenda that reflects the recent membership changes and proactively sets about trying to improve the overall reputation of the industry and to contribute towards solving the pressing issues of our time about how best to fund innovation and better support the industry so that it can focus upon what it does best: advancing science and improving lives.

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