Dan Leonard & Erik C. Komendant – Association for Accessible Medicines



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Dan Leonard, President and CEO of the Association for Accessible Medicines (AAM) and Erik C. Komendant, the organisation's Senior Vice President of Government Affairs, spoke to us about drug pricing issues in the United States and where the AAM stands with respect to the Biden administration's initiatives to make medicines more affordable for American patients.

AAM recently held its annual Access! meeting. Was it the first time you had been able to see most of your members in person?

Dan Leonard (DL): Yes, it was my first ever and the first in two years since the pandemic. It was a good experience to meet the leaders in our industry. We had a great agenda, participation from patients and terrific industry engagement. It was fantastic to be able to talk with so many stakeholders about ensuring that American patients have access to the medicines they need.

How aligned is your organisation with the Biden administration on pricing and the access to medicine issues in the US?

DL: 92 percent of the prescriptions written in this country are for generic medicines, but this 92 percent only accounts for 16 percent of overall drug spending. This is still a relatively young industry with only 35 years since the Hatch-Waxman Amendments [The Drug Price Competition and Patent Term Restoration Act], the founding legislation that established our industry. Since then, there's been a steady trajectory in the growth of generics use and a steady decrease in generic drugs' share of spending, making it a success story.

There are several areas where we are aligned with the administration and with Congress, while there are others where we are not. Typically, there is good policy, occasionally there is bad policy, but more often than not, these "bad policies" are well-intentioned policies with unintended consequences.

Regardless, if high drug prices are the problem – and this administration says that a lot – then generics and biosimilars are the solution. I think we are in alignment around the general idea that more affordable medicines for patients is the goal.

What are your thoughts on the exclusivity period for branded drugs and how it affects competition in the generics market?

DL: The way the model in this country is built, branded companies sometimes have a certain period whereby they do not have to worry about competition from generics and biosimilars. However, once competition opens up, prices decrease dramatically. The first generic to market can reduce the price of a drug by 40 percent and then more over time. With greater generic competition, you can even see a price drop by 90 percent.

The AAM has always talked about access and affordability but now your colleagues in PhRMA have also started highlighting these issues. What do access and affordability mean for AAM's members?

DL: What we mean by access is that patients can get the medicines they need at a price they can afford. Usually, they are mutually interchangeable terms. But access can be a little different in a market like the United States, where a product is placed on a formulary by a middleman. In 2021, in the Medicare drug program, only 21 percent of first generics that were launched in 2020 were covered by plan formularies. Data show that is normally takes 3 years for first generics to be covered on more than half of Medicare Part D formularies. That lag impedes patient access to

affordable medicines.

Erik C. Komendant (ECK): On access and affordability, everyone can share that goal, but what matters is how you get there and what you prioritize. There is often a trade-off between different goals. For example, in the insurance benefit design space, there is a trade-off between premiums, out-of-pocket costs and access. When you are looking at either a business decision or a policy decision, you must realize that you cannot have it all.

This is the second consecutive US administration that wants to lower drug prices. However, there are always disagreements on how to achieve this. What is Congress proposing and what does (or does not) AAM agree with?

DL: We support a number of bipartisan proposals that we believe would improve patient access to affordable drugs. These include reforming Medicare Part D to increase incentives for generic and biosimilar medicines, ensuring that Medicare drug formularies cover new generics, and creating reimbursement incentives for biosimilar adoption. However, some in Congress have proposed a drug pricing plan where Medicare sets the price of the brand drug. We believe this is short-sighted and would harm the availability of greater savings through generic and biosimilar medicines.

We are totally aligned on the fact that patients need more access and more affordability in their medicines. But we have significant problems with the way that prescription drug legislation constructed and hope to work with Congress to remedy it. If high prices are the problem, then generics are the solution. But we would go at it in a different way; we encourage a model with more competition. Again, getting to some of these intellectual property issues would also be a way to bring competition to the market sooner so patients could get more affordable medicines sooner.

You mentioned the government negotiating prices. In Europe this is common practise, but in the US would this mean that the Centers for Medicare & Medicaid Services (CMS) would negotiate, or would some other body be created for this purpose?

ECK: The CMS is part of the Department of Health and Human Services (HHS). HHS would be directed to negotiate, but in concert with the CMS because the CMS is administering the Medicare program. This would apply to both drugs in Medicare Part B, and Medicare Part D.

I would say that “negotiations” is a misnomer. The process is that there is a specific list of stipulated drugs, and a certain number of drugs are eligible from that list. Then there are specific limits based on the price of the drug that are imposed. There’s an ability for HHS to go lower than that price, but there is a ceiling.

But the problem is that the so-called negotiations begin after manufacturers have made decisions to invest in the development of a generic or biosimilar competitor – at a cost of up to $250 million for a biosimilar. Branded drugs are still provided with their protective periods, and generic and biosimilar manufacturers will not know if a drug is going to be “negotiated” until they’re preparing to launch their competitor. This uncertainty could harm the willingness of manufacturers to invest in generics and competitors, resulting in less competition and ultimately higher prices than if you simply prioritized generic and biosimilar adoption.

Our members are already experiencing several challenges in getting new generics and biosimilars to market. If we are not able to get there in a timely manner, and able to benefit from being on the market, and then reinvest in bringing new drugs to market, this creates significant concern about generic and biosimilar competition in the long run.

Is, however, negotiating with the government the lesser of two evils compared to negotiating with pharmacy benefit managers (PBMs). Can you share your thoughts on PBMs?

DL: No. As we mentioned, so-called government price negotiation fundamentally undermines generic and biosimilar competition that we believe will generate greater savings.

But we have to address the market abuse of the dominant PBMs. For instance, PBMs are moving low-cost generics to tiers with high co-pays. They should instead be on generic tiers that are the most affordable to the patient, but now patients are being forced to pay more even as the generic price goes down. And I mentioned the delay in coverage of new generics. This is a result of PBM preferences for high-priced and high-rebated brand drugs over generics and biosimilars with lower prices. The rebates that the PBMs have in the channel and that money that changes hands can have perverse impacts that disadvantage lower-priced medicine and leads to higher out-of-pocket costs for senior citizens.

As I explained, generics in the United States account for 92 percent of prescriptions filled last year. That is up from 90 percent the year prior. And they are responsible for 16 percent of drug

spending, down from 18 percent in 2020. What is truly astonishing is that despite the decline in generics' prices, patients are spending more for these medicines. The distortion of formulary design creates a dynamic where generics account for a disproportionate 65 percent of patient out of pocket costs. The system is broken but can be fixed through rather sensible and straightforward policies like requiring generic drugs be placed on generic tiers in Medicare Part D.

Last time we spoke, you touched on some of the perverse incentives inherent in the US system such as biosimilars being reimbursed at an average selling price (ASP) of plus 6 rather that plus eight percent—have you seen any developments on that front?

DL: The basic premise behind that is that providers need to have incentives to prescribe the lower cost medicine. Under the current system, Medicare pays the same add-on payment regardless of whether a provider uses the high-cost brand or lower cost biosimilar. We believe that it's simple – if you want providers to use the lower cost biosimilar, you have to create an incentive for them to do so. You can do this through a simple 2 percent increase – to ASP plus eight – in the add-on payment. You can also do this through a shared savings reimbursement approach, which the Biden Administration has expressed interest in. The result would be greater biosimilar adoption along with savings to patients and taxpayers.

ECK: Biosimilars hold enormous potential. We have seen their success in Europe and are trying to emulate that. In the U.S., we have seen biosimilars that successfully launch average 50 percent of the cost of brand biologics. With this kind of clear benefit, what approach can help drive biosimilar adoption and uptake? Part of what our research and other independent research in the US has shown is that with the launch of biosimilars, there is still a need for education and experience, both from the patient and physician perspectives. People need to get comfortable with using these new treatments.

We are getting better, but we need policy incentives to achieve the goal. For instance, the use of biosimilars saved more than $12 billion in 2020 and reduced the spending growth rate in oncology by half. And biosimilars are projected to save $130 billion by 2025. This will require robust adoption in other indications. Humira, for example, will have seven biosimilars next year. The successful launch, adoption, and use of those is going to be an important test, both for biosimilar developers and for the healthcare system in the United States. We still have a way to go, and we think that both Congress and the Biden administration should take some bold action here to spur biosimilar adoption, because, if we are serious about addressing the prescription drug cost challenges in the

US, biosimilars are going to offer that competition in a sustainable way that will really get at the root of the problem.

Resulting from the pandemic, there is a lot of talk about supply chain issues and onshoring. What's on your agenda for these issues?

DL: Even before the pandemic, this was a big part of our agenda. Post-pandemic we published the *AAM Blueprint for Enhancing the Security of the US Pharmaceutical Supply Chain*, which talks about these issues. Onshoring, or nearshoring, getting the production closer to the end patient, is not going to be possible in every case. We should prioritize essential medicines, as defined by the FDA.

We think looking at the medicines that are critical in a pandemic or any other health emergency is a good place to start. But, the industry cannot do it alone. The U.S. government needs to be an active partner, working with the industry to incentivize the investment needed to make the U.S. pharmaceutical supply chain more resilient. This can be done, as we outline in our Blueprint, through tax incentives, grants, long-term contracts, and regulatory reforms. And, when looking at who can expand U.S. production, we strongly encourage the U.S. government to look at the companies that have already invested in this country, particularly those that may have excess manufacturing capacity available. That would be one of the quickest ways to increase U.S. manufacturing of needed essential medicines. Regardless, this is a big issue and it is important to have a redundancy in the system. Bringing everything to the United States is not feasible or advisable, but you should have manufacturing redundancy and resiliency around the world to meet demands. There are several pieces of legislation that have been introduced on this topic as well.

Would responsibility for this fall under the federal government, or under state governments which want to bring factories and jobs to their states?

ECK: We support both. There are several things that the pandemic exposed that are important to acknowledge and then address as we figure out how to prepare this country for future public health emergencies. Our members experienced significantly higher transportation costs and they had to re-route supply chains. Because of the resilience and redundancy of the current system, we were able to provide uninterrupted patient access to generics and biosimilars.

There were certainly demand spikes, but those were rectified by increasing manufacturing and by our members responding to that increased demand and meeting that challenge, but there is room

for improvement and needs to be serious commitment. Other countries around the world are doing it and we are seeing investment in their own domestic manufacturing capabilities and the US should do it too, because if our goal is to manufacture more essential medicines domestically then we have to put the investment in place.

What kind of investment exactly?

DL: Incentives, tax credits, grants through government agencies. In Medicare, there are a number of creative things that we've put in our blueprint that we have shared with policymakers.

Europe is building its own pharma plan relating to those topics and the possibility of prioritising European manufacturers: the European Commission's Pharmaceutical Strategy for Europe. Could such a plan work in the US?

ECK: One of the things we recommend is having that international alignment. If US allies are doing it in some way, that is the redundancy we need in the system. The US does not need to recreate the wheel. So, we have recommended the US entering an agreement with our allies to establish a plurilateral pharmaceutical supply chain agreement. When it comes to looking at the pharmaceutical supply chain, having the US get that agreement with our allies would be an important step to making sure that we have resiliency across the board. We do not want to be in a situation where, like in this pandemic, so much of the world shut down so quickly. Instead, we have to make sure that, even in moments of emergencies we are freely transporting essential goods.

What are your expectations for the next two or three years? You mentioned you wanted to collaborate with your colleagues in other geographies that are doing similar work to have a more cohesive agenda. Can you tell us about that?

DL: Everybody at AAM is very interested in strengthening collaborations around the world, especially as we were not able to meet during the pandemic. We are now coming together with organisations in other countries, including through conferences, and discussing some of these supply chain issues.

AAM has a number of good relationships with international associations like the International Generic and Biosimilar medicines Association (IGBA), Medicines for Europe, and the Indian

Pharmaceutical Alliance, but now we will be able to go and visit them again and go to their meetings. Additionally, we are very proud that one of our colleagues, Jonathan Kimball, is currently vice chair of IGBA and we anticipate doing more with them to make sure that there is global alignment within our industry. In addition, AAM's own Erica Klinger is the chairperson of this year's Global Biosimilars Week.

Do you have any other message to share with your global colleagues?

DL: It is a big planet, but a small world. We need to be working together. The US healthcare system is unique, but patient needs are the same everywhere. We need to make sure that patients are getting the safe, effective medications they need at an affordable price and that is what we try to do every day.

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