Dan Leonard – President & CEO, Association for Accessible Medicines (AAM)



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Dan Leonard, president and CEO of the Association for Accessible Medicines (AAM) since August 2020, outlines his key agenda priorities as head of the USA's largest generic industry body, how the COVID-19 pandemic has altered the discussion around generics and essential medicines, and his hopes for the Biden administration

Dan, last time we spoke you were at the National Pharmaceutical Council (NPC). Why the switch to the Association for Accessible Medicines (AAM) – an organisation with quite a different mandate – and what has struck you the most in your initial months on the job?

Six months into my time at the AAM, it has already been very gratifying. During my time at the NPC, I came to understand the importance of innovation, investment, new treatments, and new cures. However, I now have a more holistic view of the whole pharmaceutical arc, from drug development to access and affordability; both when drugs first become available to patients and then when they go generic. I am now leveraging these years of experience and enjoying working with a great group of people on the generics and biosimilars side. It has been a comfortable, seamless move and one that I feel very good about!

How have you gone about connecting with stakeholders in this new role and what are the key concerns that your members are bringing to you?

The pandemic has certainly made communication more challenging, with plenty of one-on-one calls with my board members, many of whom I still have not met in person. These conversations are important to get a sense of their priorities and what the burning issues are in our industry.

One key theme that has emerged is the sustainability of the industry in a market with incredibly fierce competition. Our business proposition is to maintain high quality but to compete on price – where we do a great job – but the environment is becoming more challenging for many of our member companies. Payers, whether the three large payers on the PBM side or the three large wholesalers, have significant market power and dominance. Generic companies are all competing to get contracts with those payers – a model which is proving incredibly challenging and which is not necessarily sustainable over the long term.

Generics represent 90 percent of drug volume in the US but only 20 percent of the total cost spent on drugs. The inverse of that is that 10 percent of drugs drive 80 percent of costs. This tells the story of the affordability of the medicines that our members produce – but the margins are so thin as to become a barrier to operation. It is a good consumer story but a very competitive business.

Are there risks that certain products will be discontinued and has COVID-19 reinforced the importance or shifted the definition of ‘essential medicines’ that must be present in the market?

I would separate those points. The role our companies played during the pandemic is a very good story.; the traditional generics business is a tough one, but all our members are very committed in that space. When the pandemic struck, nobody was quite sure what was going to happen and there was a lot of concern around drug shortages because of the global makeup of the industry and increased demand for certain drugs. However, this did not really happen: We saw the supply chain bend, but not break, it was stressed but still held up. Certainly, COVID-19 has been a wake-up call that we need to do more with our supply chain to ensure that America’s patients are served well by the security and proximity of production of critical medicines. AAM will be doing a lot of work around supply chain issues as we move forward.

Another important story that has not been told as much as it should have is the role that generics played during the pandemic. Thinking back a year, there was a lack of therapeutics on the market

and certainly no vaccine. Although amazing and fast work has been done to get vaccines out, to this day when patients get ill and go to the hospital they are mostly treated with generics. As the science and the treatment protocols for COVID have evolved, corticosteroids have proven to be quite effective in reducing lung inflammation. There is even new evidence suggesting SSRIs can be effective in the battle against COVID. Moreover, we have seen mortality rates drop for COVID patients with other generic medicines being used to treat those who need to go on ventilators.

The tools available to frontline healthcare workers have, for the most part, been generic treatments, which is something our members are very proud of. Generics are the bridge to vaccines and a return to normal.

Against this backdrop, what policy proposals will AAM be bringing to legislators in Washington in 2021 and 2022?

In the short term, COVID is still the priority, which is an agenda shared by the Biden administration. We want to play a significant role in COVID-19 relief. In the medium term, there will be a lot of attention around supply chain issues and making sure we have a supply chain that ensures medicines get to where they need to go. This could potentially involve more domestic production, for which there is certainly an appetite on Capitol Hill and within the new administration.

Looking further ahead, we will come back to issues around drug pricing. The generics industry is the answer to the drug pricing question. Generics and biosimilars are really the only proven solutions that bring down the costs of medicines over time. We have a legislative agenda dedicated to issues around drug pricing and essentially shoring up our market for generics, which will help bring down prices for patients.

The innovative side have a very different message, sounding the alarm that without these high prices in the US, developing new medicines and saving lives will be impossible. Is there a need for greater collaboration between these two sides?

Given my previous position, I have great empathy for their position and understand the importance of a robust innovation system where R&D investments can be made to help bring new treatments to market. The breakdown comes toward the end of the patent life of a brand medication. We need more certainty that when those patents run their course there can be a rapid generic entry into that space. That is what leads to dramatic drops in prices. Moreover, when multiple generics can

enter a marketplace, that is when we really shine. The model as designed in Hatch-Waxman still works, but a perversion of this model leads to trouble.

AAM is also extremely optimistic about biosimilars and the role that they can play. The most expensive drugs today are biologics that do not have competition. Therefore, when new biosimilars enter the market, we will see significant price reductions. Currently, there are some issues keeping biosimilars out of the US market and meaning that we lag behind Europe in terms of biosimilar adoption.

What do you see as the cause of this low biosimilar adoption rate in the US and what reforms are you proposing to remedy it?

We have some legislation on this issue that was introduced in the last Congress and we are optimistic that it will be introduced in the new Congress as well. One is payment reform, which would move biosimilars' average selling price (ASP) to plus eight percent. Today biosimilars are reimbursed at an ASP of plus six, but many physicians are still incentivised to write prescriptions for the higher-price biologic because the reimbursement rate does not cover that differential. This is especially relevant as biosimilars – which must be administered in the hospital or clinic setting by a doctor – primarily sit in Medicare Part B. An ASP of plus eight will be an important step to change that.

We have also proposed a shared savings demonstration project to the Center for Medicare & Medicaid Innovation (CMMI) under the Centers for Medicare and Medicaid Services (CMS) and Department of Health and Human Services (HHS), which we think would go a long way to solving the issue of biosimilars.

Would it not be in the interest of the administrators of Medicaid and Medicare to promote biosimilars and get the lowest possible prices for patients?

This is another of the unique components of the American payment system that needs to be reformed. The way that biosimilars are reimbursed right now is disadvantageous to the field. There is work to be done, but 2019 and 2020 have been good years with a number of new market entries for biosimilars and it is only going to get better. Biosimilars are an important growth area for our industry.

What are some of the key findings from AAM's 2020 Access & Savings Report that you would like to highlight?

We are very proud of the savings we share in our annual Access & Savings Report. In the US alone, the overall savings for patients when generic medicines came onto the market was USD 313 billion in 2019! This is alongside the fact that generics make up 90 percent of prescriptions and only 20 percent of cost. I often mention these figures when talking to policymakers as it really opens their eyes to the huge savings we generate and the fact that, on volume, we are far and away the most important players in the prescriptions space.

Of that overall USD 313 billion in savings, roughly USD 100 billion was in Medicare and USD 50 billion was in Medicaid. We are saving taxpayers and patients money. However, it also points out the challenges of running businesses on very thin margins.

The value proposition of generics has always been based around savings; is it perhaps time – especially post-COVID – to shift the narrative to other topics?

Price, affordability, and access will always be the heart of the industry and the North Star of what our companies do. However, as medicine evolves, you are going to see the natural evolution of our industry too. Biosimilars, for example, are a natural evolution as more affordable versions of very complex biologic medicines for which a lot more development is needed.

The other evolution, which you will hear more and more of in the coming years, is complex generics. Of that 90 percent of all prescriptions generics comprise, the vast majority are pill-form solid oral treatments. Over time though, our companies will get further into complex generics, which include both more difficult to develop, complex products but also products with different mechanisms of action like inhalers, patches, and creams. Regulatory reviews for these more complex products will take longer so we are working with the FDA to help them understand our processes and make sure that the products receive reviews in a timely fashion.

With doctors perhaps tending to prescribe the most obvious courses of treatment, how important is getting these differentiated or more complex products listed on the different healthcare insurance formularies to ensuring they actually get used?

It is very important, which comes back to one of our legislative priorities around pricing and tiering. Last year in Medicare, over 50 percent of generic drugs were – somewhat counter-intuitively – placed on higher tiers than the generic tier. This speaks to some of the perverse impacts of rebates, where payers are being rebated at a higher level to give preferential formulary placement to the more expensive drug. A new piece of legislation on tiering would hopefully help to right that wrong in Medicare, specifically Medicare Part D. This goes on in the commercial markets as well, but it is harder to change.

These rebates are part of a uniquely American system. I do not say that fondly, but it is the system that we are working within.

The Trump administration was quite vocal about drug pricing; what are your hopes and expectations for the incoming Biden administration?

President Biden has been very clear about how he wants to move forward. Following the timeline that I laid out earlier, the administration is focused almost entirely on COVID-19 and making sure that we get our nation and our world through this pandemic. Work around the vaccine and treatments for COVID will be the new administration's priority number one in the short- and medium-term, and we will be right there with them.

Then, the Biden administration and the Democrats – now with more narrow margins in the House and Senate – will come back to these drug pricing issues. That is where we think we can play an important role in making sure that drug pricing is taken care of and that patients have access to affordable medicines. We look forward to working with the Biden administration on those issues.

Our legislative priorities also cover some of the issues previously touched on in Medicare and eliminating the Medicaid generics penalty, which was a piece of legislation passed three or four years ago. This penalty had good intent behind it – capping price increases on very expensive branded medicines – but has had unintended consequences that have harmed the generics industry. When the same percentage is applied to a one-dollar drug as a USD 50,000 drug, it creates unsustainability for those operating at the lower price point.

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The Democrats brought in the Affordable Care Act (ACA) in 2010, what are your hopes about how a new Democrat administration will approach this topic?

Quite frankly, the ACA was under fire from the last administration so there will be a commitment to solidifying the Act and making sure it lives up to its promise. The HHS Secretary designate, for example, was very involved in pushing through the legislation back in 2010.

What kind of work do you have to undertake at the state level where, for example, Medicare budget levels tend to vary?

We have been able to save USD 23.8 billion in California alone, showing that our savings message also resonates on the state level. However, we have lots to do there. The intricate web of regulations that come from the 50 states were a real eye-opener for me, coming into this new position. There is wildly different legislation between states in terms of price reporting and individual taxes that can be levied against manufacturers, meaning that staying on top of it all is several full-time jobs. All our companies work in all the individual states, so our excellent state team has to be very active in managing all that and testifying before individual state legislatures.

What message would you like to send to PharmaBoardroom's international readership?

I look forward to working with all our partner organisations around the world. I recently had a very good meeting with the Indian Pharmaceutical Association (IPA), with whom we have a number of initiatives. Similarly, we have a good relationship with the International Generics and Biosimilars Association (IGBA) and Medicines for Europe (MFE). While I have not been able to travel to any of these places, and they have not been able to travel to see us in Washington DC, things will open up and we will hopefully be back to business as usual relatively soon, reconnecting and building on those already excellent relationships. We are part of a global industry and look forward to telling our story in every market where we do business around the world.

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