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Focusing on the generic and biosimilar market could make us a more secure, healthier nation.

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John Murphy, President and CEO of the Association for Accessible Medicines (AAM), outlines a compelling vision for improving access to high-quality, affordable medicines in the US. He stresses that by directing greater focus to the generic and biosimilar market, tackling structural challenges, safeguarding supply chains, and enabling strategic domestic investment, the nation can not only reduce costs for patients but also bolster its long-term healthcare security.

What has been your career journey from working with branded pharmaceuticals to leading AAM?

I have never followed a formal career plan and have tended to embrace opportunities that appeared interesting and worthwhile. Since graduating from law school, my professional life has been rooted in the prescription medicines space. I began at a Washington D.C. law firm with a strong biopharma client base, working extensively on drug pricing compliance and reporting. This experience led to a position with the Biotechnology Innovation Organization (BIO), where I was tasked with building a state government affairs and policy team, offering me a broader perspective on the medicines supply chain.

After several years, I joined the general counsel's team at the Pharmaceutical Research and Manufacturers of America (PhRMA), a role that allowed me to return to legal practice while engaging closely with branded industry priorities. I later returned to BIO as chief healthcare lawyer, continuing to operate within the branded sector, where much of the focus in Washington centres on safeguarding innovation and resisting policies perceived as threats to it. While I was familiar with generics and biosimilars, my understanding was shaped largely from this branded perspective.

When the opportunity to lead AAM arose, it felt like a natural progression. This role, at the intersection of access and affordability, spoke directly to my long-standing work on patient access issues. In my first year, I have seen first-hand the lengths to which our members go to maintain an affordable market for patients in the United States, a commitment that is both deeply pragmatic and central to the health of the overall system.

How would you describe the current landscape for generics and biosimilars in the US, and what do you see as today's main challenges?

In the US, discussions on prescription medicines often focus on high prices, yet a less appreciated fact is that we pay, on average, only 60 percent of what European countries pay for generics. While this may appear advantageous from an affordability standpoint, it has contributed to significant market atrophy. Today, there are between 300 and 350 ongoing shortages of key generics, a situation not mirrored in Canada or Europe, both of which have comparable regulatory frameworks. This is caused by reimbursement levels being so low that manufacturers cannot justify investment in stockpiles, diversify their supply chains, or maintain backup production capacity.

The vulnerability of this model became evident last year when a hurricane in North Carolina disabled a facility responsible for producing the vast majority of sterile saline used in US surgeries. With a unit price of around 50 cents, there was no surplus capacity to absorb the disruption. Other producers existed but faced their own labour and operational constraints. By contrast, branded medicines, which represent USD 750 billion in annual spending, have the financial flexibility to maintain such reserves.

The imbalance is striking. Of six billion prescriptions written last year, 5.4 billion were for generics and 600 million for brands. Yet generics accounted for just USD 60 billion in spending, compared to USD 700 billion for brands. As former FDA commissioner Robert Califf has observed, the US faces a dual pricing problem of paying too much for branded medicines while paying too little for generics. This neglect risks eroding the stability of the generics market to the point where patients may be

unable to obtain essential medicines. As Richard Saynor of Sandoz aptly put it, manufacturers feel a moral obligation to ensure patient access, but there comes a point where the economics no longer work, and products inevitably disappear from the market.

With Medicare drug price negotiations and other pricing proposals under discussion, what implications do you see for the generics sector?

For the vast majority of generic medicines, there is no further margin to reduce prices. The greater concern now lies in the difficulty of securing formulary placement. Both the Inflation Reduction Act's (IRA) Medicare drug price negotiation provisions and the president's "most favoured nation" (MFN) pricing proposal begin from a sound premise of targeting high-priced branded medicines that have not faced generic competition. Yet the reality is that many brand products are avoiding such competition altogether by employing strategies around patents, rebates, and market access to extend their exclusivity.

Where I differ from these approaches is in the reliance on artificial price controls. Experience shows that these measures risk signalling to both innovators and generic manufacturers that the government will eventually step in to dictate prices, which can weaken the incentive to invest. A more sustainable path lies in ensuring earlier, more competitive entry for generics and biosimilars. Under fair regulatory conditions, this would allow the market to do the work of lowering prices. This was the vision behind the Hatch-Waxman Act of 1984, which established the modern US generic drug approval process, and the Biologics Price Competition and Innovation Act (BPCIA) of 2010, which created a pathway for biosimilars. Yet we now see some branded products remain on the US market for over two decades without biosimilar competition, despite years of competition in Europe.

The way the IRA has been implemented adds to these challenges. The Centers for Medicare & Medicaid Services (CMS) chose to assess "meaningful competition" in the market rather than consider whether a biosimilar or generic was already in development. This creates a dynamic in which by the time a product reaches market it may already be subject to a negotiated price, undermining the commercial viability of the launch. This comes after five or six years of development and, in the case of biosimilars, around USD 300 million in investment to develop the generic product.

Addressing these issues requires structural reform through initiatives like ending patent games, advancing pharmacy benefit manager (PBM) reform, and ensuring that formularies actually cover

generics. Our study of Medicare Part D found that, on average, a newly launched generic takes more than three years after FDA approval to achieve even 50 percent formulary coverage. During this time, patients continue paying higher co-pays for branded products, and employers face premiums based on brand prices, meaning the intended savings from competition never materialise. Over the next few years, we have a genuine opportunity to work with policymakers to remove these barriers, restore a truly competitive market, and ensure that patients benefit from timely access to affordable medicines.

Why does biosimilar adoption in the US continue to lag behind Europe, and what can be done to accelerate uptake?

When the Affordable Care Act created a regulatory pathway for biosimilars, there was a strong sense of optimism across the industry. At the time, I was working in the sector and saw this as a long-anticipated opportunity to bring competition to markets dominated by biologics that had revolutionised treatment for conditions like cancer and rheumatoid arthritis. More than a decade on, that promise has only been partially fulfilled. While the FDA has approved more than 40 biosimilars, market penetration remains limited. In the case of adalimumab, for example, ten biosimilars now compete, yet together account for only about 20 percent of the market, with Abbvie’s branded product still holding over 80 percent.

The consequences are substantial. *The Biosimilars Void*, a study we conducted with IQVIA, examined biologics expected to lose exclusivity over the next decade. We found that fewer than 10 percent have a biosimilar in development for the US market, representing over USD 250 billion in annual spending with no competitive alternative on the horizon.

Several structural and policy-related factors are driving this shortfall. Under the Hatch-Waxman Act, once a generic entered the market, brand-name drugs typically ceded share relatively quickly. Today, originator companies deploy increasingly sophisticated strategies to protect market dominance, often maintaining exclusivity for two or three decades through extensive “patent thickets.” It is not uncommon to see portfolios containing more than 100 patents, around half of which would not be granted in other jurisdictions like Canada or Europe, yet still block US competition. Bipartisan proposals such as the Eliminating Thickets to Increase Competition (ETHIC) Act aim to tackle this issue.

A further uniquely American challenge lies in the “interchangeability” designation. In the US, a biosimilar can be approved but still requires additional switching studies to secure

interchangeability status which allows automatic substitution at the pharmacy level. This process is costly and time-consuming, with no scientific equivalent in Europe, where biosimilars that meet safety and efficacy standards can be prescribed and reimbursed in place of the originator. Even the FDA has now signalled support for removing this requirement, acknowledging that it adds unnecessary complexity without delivering additional clinical benefit.

Biosimilar development in the US also carries a significantly higher price tag, averaging around USD 300 million due to extra regulatory steps and protracted litigation. Compounding this, recent court decisions have undermined the practice of “skinny labelling,” which previously allowed biosimilars to launch for non-patented indications while brands retained exclusivity over protected uses.

While PBMs undoubtedly influence uptake and their practices warrant close scrutiny, a substantial share of the responsibility lies with originator manufacturers. We need to restore the principle that after a reasonable period of exclusivity, the market should be open to competition which allows generics and biosimilars to deliver the savings they were intended to provide. Without these changes, the US will continue to underperform in harnessing the full potential of biosimilars to the detriment of patients and the broader healthcare system.

With many large generic manufacturers coming from internationally, like in India, is there any concern from AAM members given the current US trade environment, particularly the ongoing discussions around tariffs?

While India is indeed a significant source of generics, as many assume, the reality is more nuanced. A large share of generic medicines are finished and filled in the US, but the industry still relies heavily on supply from Europe, India, and Canada, with China now playing a far smaller role than in the past. Over recent years, India and Europe have emerged as the dominant contributors to the global generics value chain.

In a market where margins are already extremely thin, the introduction of a 25 percent import duty on these products would pose serious challenges. Because most generics in the US are reimbursed through Medicare, Medicaid, or other government programmes, manufacturers are unable to raise prices and are subject to inflation penalties. This means that any additional cost from tariffs would have to be absorbed by manufacturers, potentially rendering certain products unprofitable to supply to the US market. Such a scenario risks not only further product shortages but also potential harm to patients.

Many AAM manufacturer members would like to expand their production footprint in the country, which could strengthen supply chain resilience. However, without addressing the underlying market dynamics, it is difficult for them to commit to the significant investments required. For this reason, the tariff environment presents a genuine risk to healthcare security.

I remain optimistic that the administration's ultimate focus will be on protecting patient access and ensuring supply chain stability, but tariffs are a powerful instrument, and their potential to disrupt healthcare should not be underestimated.

What do you consider the most pressing priorities to ensure the long-term sustainability and growth of the generics and biosimilars sector?

Several areas rise to the top. As I noted earlier, tackling patent thickets, eliminating the interchangeability distinction, restoring the pathway for "skinny labelling" so that generics can enter the market with a narrow label, and reforming how generics are reimbursed and tiered in both Medicare and Medicaid are all critical. These are pragmatic, bipartisan measures, and once Congress is back in session, there should be real opportunities to make progress.

Reforms should also go beyond market access and encourage greater domestic manufacturing of medicines to ensure the resilience of the supply chain. If we want manufacturers to invest in new API production facilities in the US, they must have confidence that those investments will be viable. With today's reimbursement rates set so low, it is far from certain that such projects would even recoup their costs. Without change, the economic incentive is simply lacking.

In Washington, the AAM positions itself as an educational and solutions-driven voice. We are not here to be histrionic or overly political. Instead, we present the facts and put forward practical, constructive proposals aimed at getting the market back on track. This is essential if we are to avoid being overly dependent on vulnerable supply chains that could be disrupted by the next natural disaster or a pandemic that halts global trade routes. Much of this infrastructure could be developed in the US or in trusted partner countries such as Canada or those in Europe, collectively creating a far stronger and more secure system.

We must also work with CMS to ensure that generics are consistently placed on the appropriate tiers in formularies so that patients see a tangible cost difference. At the moment, if a brand and a generic both cost a patient approximately the same, there is no reason for them to request the generic. This is especially true if it's their employer who is paying significantly more for the

branded medicine. Therefore, we need to make the value chain more visible to the public by showing that more favourable generic costs now will ultimately lead to lower overall healthcare system costs later and encourage the patient community to advocate for restoring that balance.

If you could leave readers with one key takeaway about the future of affordable medicines in the US, what would it be?

There is tremendous potential for patients in the US to benefit from far more affordable medicines, but achieving this will require confronting a few difficult, yet necessary, conversations. One of the most important steps is recognising that we have two distinct markets: the brand market and the generic/biosimilar market. It deserves far greater attention that the latter makes up 90 percent of all prescriptions filled in the US. By directing focus and resources towards strengthening this segment, we can move towards a more secure, sustainable, and healthier nation.

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