Protect and Defend Patient Access: The Advocacy Plan to Safeguard Affordable Generic and Biosimilar Medicines

America's patients are facing an urgent challenge that could jeopardize their access to life-saving, affordable medicines. Generics and biosimilars—cornerstones of the U.S. healthcare system—have provided a reliable safety net for millions of Americans, ensuring access to vital therapies at the lowest possible cost. Yet, a perfect storm of regulatory hurdles, patent abuses, and flawed policies now threatens the very foundation of this system, putting patients' health and financial stability at risk.

Generics and biosimilars are essential to our healthcare infrastructure. These medicines account for 90% of prescriptions dispensed in the U.S. but only 13% of total drug spending. Over the past decade, their widespread adoption has saved the healthcare system an astounding $3.1 trillion. This success is not just an economic achievement; it is a lifeline for patients who depend on affordable medicines to manage chronic conditions, treat serious illnesses, and maintain their quality of life.

But this success story is now in jeopardy. The overall value of generic sales in the U.S. has declined by $6.4 billion since 2019, despite increased utilization and new product launches. This decline isn't due to a lack of need—patients continue to rely on these medicines in greater numbers—but rather to systemic barriers that threaten the long-term sustainability of affordable access.

At the root of this crisis are a series of obstacles:

- **Regulatory Barriers:** Outdated and unnecessary FDA requirements delay the development and approval of lower-cost generics and biosimilars. For example, current biosimilar application requirements, including redundant clinical efficacy studies, impose excessive burdens that discourage competition and innovation.
- **Patent Abuse:** Brand-name drug manufacturers exploit the patent system to extend monopolies well beyond the original patent term, creating "patent thickets" that block generic and biosimilar competition. These anticompetitive tactics keep drug prices high and delay patient access to affordable alternatives.
- **Flawed Policies:**
  - Medicare policies and practices by pharmacy benefit managers (PBMs) often reward the use of higher-priced brand-name drugs over lower-cost generics and biosimilars.
  - Medicaid policies penalize generic products with unpredictable rebates even when there are no price increases.
  - IRA price controls remove predictability needed to support investment in developing new generic and biosimilar products.
  - These and other policies distort the market and directly harm patients, forcing them to pay more for the medicines they need.
- **Overall sustainability:** Due to a lack of adequate reimbursement, generic medicines are increasingly at risk of shortages. Without systemic reforms to stabilize and incentivize the generic drug supply chain, patients could face dangerous interruptions in their treatment.

If these challenges are not addressed, the consequences will be devastating. America's patients will lose access to reliable, low-cost therapies. Taxpayers will bear a greater burden as healthcare costs soar. The very principles of competition and innovation that have driven the success of generics and biosimilars will be eroded.

Protecting Access: A Call to Action

If policymakers are serious about protecting patients and ensuring sustainable access to affordable medicines, they must act decisively to address these systemic threats. This requires a comprehensive plan, including:

- **Streamline FDA Processes:** Ensuring quicker approvals, while maintaining FDA's high standard of safety, efficacy, and quality, will increase competition and lower prices. Policymakers should eliminate unnecessary FDA regulatory barriers that delay the approval of generic and biosimilar medicines, including through:
  - Streamlining FDA's approval process including the ability to utilize a global comparator and removing redundant clinical studies,
  - Passing legislation directing disclosure of the qualitative and quantitative differences (Q1/Q2) between generics and brands,
  - Updating the BPCIA to deem all biosimilars interchangeable; and
  - Restoring the Hatch-Waxman safe harbor for "skinny labeling."
- **Curb Patent Abuse:** Congress must stop the misuse of the patent system by limiting the number of patents brand-name manufacturers can assert, safeguarding the ability to enter into procompetitive patent settlements, and preventing anticompetitive practices that delay access to generics and biosimilars.
- **Stop PBMs and Medicare Policies from denying patients access to new generics and biosimilars:** Medicare and PBMs must stop prioritizing higher-priced brand-name drugs over generics and biosimilars. Congress and the Administration should ensure patient access to new generic and biosimilar medicines and reform PBM practices by encouraging PBM transparency and eliminating PBM profits from linking their fees to the drug list price (i.e., delinking).
- **Rollback Harmful Federal Policies:** Too many federal policies actively harm generic and biosimilar competition.
  - Congress should remove the Medicaid Generics Penalty and update Medicaid inflation penalties on generics to align with those included in the IRA.
  - Because generics and biosimilars save far more than arbitrary price controls, policymakers should ensure that the IRA price controls do not harm generic and biosimilar competition by refining and extending the biosimilar delay request, ending the unfounded and unclear "bona fide marketing" standard, and addressing the IRA biosimilar and generic "valley of death."

The stakes are clear: failing to act will mean higher costs, less access, and fewer options for patients. Generic and biosimilar medicines are more than a healthcare innovation; they are a means of survival for millions of Americans. Policymakers must move swiftly to protect this system and ensure patients are not forced to choose between their health and financial security.

This is not just about dollars and cents—it is about lives. Let's ensure that the promise of affordable, life-saving medicines remains a reality for all Americans.

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