LEUKEMIA & LYMPHOMA SOCIETY® is now

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June 4, 2026

The Honorable Darrell Issa
Chair
House Judiciary Subcommittee on
the Courts, IP, AI and the Internet

The Honorable Henry Johnson
Ranking Member
House Judiciary Subcommittee on
the Courts, IP, AI and the Internet

Statement for the record Re: House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence and the Internet "Medicines and IP: Balancing Innovation and Access"

Dear Chair Issa and Ranking Member Johnson –

On behalf of the more than 1.7 million Americans living with a blood cancer diagnosis, Blood Cancer United (previously The Leukemia & Lymphoma Society) appreciates the opportunity to provide this statement for the record which speaks to the nation's rising prescription drug costs and the impact these costs have on patients and their families.

As the largest nonprofit organization dedicated to blood cancer patients and their families, we advocate for policies that ensure access to affordable, comprehensive, and high-quality healthcare without compromising patient outcomes. Patients living with blood cancers face not only the physical burden of disease but also financial toxicity — the cumulative cost burden of treatment, care, and survivorship that can threaten patients' ability to continue therapy or maintain financial stability. Blood Cancer United launched our Cost of Cancer Care initiative in 2017 to address this growing issue, and we continue to advocate for aggressive but feasible cost-cutting policy solutions that would not sacrifice quality of care.[i]

Breakthroughs in prescription drug therapies for blood cancer have revolutionized the treatment of these cancers and saved untold thousands of lives over the last decade alone. Due in part to Blood Cancer United's investments in research, the current drug development pipeline includes promising new drug therapies that will continue this trend and produce new therapies and cures for additional patients. While drug innovation has had a significant positive impact for patients, innovative new therapies often come with an extremely high price tag. The combination of high prices at the point of market entry and routine price hikes throughout the patent life of many brand-name drugs has led to prices that—if extrapolated into the medium term—could easily become unsustainable. If the healthcare system is to be sustainable, drug manufacturers have an obligation both to continue to invest in innovative new products and to recognize that drug prices must reflect the value of the drug to the patient and the healthcare system, rather than simply reflecting what the market will bear.

We offer the following policy recommendations for the Committee to consider to help lower the cost of prescription drugs which are a significant contributor to the growing healthcare affordability crisis:

Reform biosimilar interchangeability rules
Under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), an "interchangeable" biosimilar is defined as a biosimilar that is expected to produce the same clinical result as the reference product in any given patient. It may be substituted for the reference product without prescriber

intervention, and the safety or efficacy risks of switching or alternating between biological products are no higher than those of using the reference product alone. Since the passage of the BPCIA, years of experience have shown that many of the extra steps required of biosimilar manufacturers to demonstrate interchangeability aren't needed. In fact, the FDA itself no longer recommends them. In 2024, the FDA released draft guidance recommending eliminating the need for switching studies as part of the biosimilar interchangeability approval process. Removing these costly requirements would speed up competition and help bring down drug prices for patients. Additionally, designating some biosimilars as "interchangeable" but not others based on outdated requirements not only adds unnecessary costs and delays to biosimilar market entry, but also creates confusion amongst providers, patients, and payers. Congress should consider legislation like the Biosimilar Red Tape Elimination Act (H.R.5526), which would automatically deem all biosimilars upon FDA approval as interchangeable.

Reform U.S. biosimilar naming rules to align with international standards

There continues to be confusion regarding the suffix that FDA has determined should be added to a biosimilar's International Non-Proprietary Name (INN). These suffixes do not align with World Health Organization (WHO) and European Union standards. Biosimilar acceptance might be slower in the U.S. than in the European Union in part because biosimilars in the U.S. must bear suffixes while those in the EU do not. Yet it does not appear that the absence of suffixes on European biosimilars has, in any way, compromised patient safety. It may be that adding the suffix burdens U.S. biosimilars without any commensurate benefit for patients. An added concern has been reports that reference drug sponsors have implied that the reference listed product, without a suffix, is superior to the biosimilar with a suffix.

Accordingly, Blood Cancer United urges Congress to require FDA to align federal biosimilar naming rules with international standards where possible, with particular focus on removing the current suffix requirement, given that it appears it may impose a burden upon U.S. biosimilars without advancing patient safety.

Prevent 'pay-for-delay' agreements

Generic and biosimilar products have the potential to drastically reduce costs for patients and the healthcare system. However, recent pricing examples prove that biosimilar and generic markets with limited competitors do not produce the level of savings expected by payers and patients. Further, some companies have engaged in tactics to delay the entry of generics and biosimilars to the marketplace. To address these issues, Congress should provide additional authority to the Federal Trade Commission (FTC) to prevent 'pay-for-delay' settlements that can be used by a brand drug manufacturer to inappropriately delay the entrance of one or more generic or biosimilar drug manufacturers in order to maintain monopoly pricing power. Blood Cancer United recognizes, though, that some patent settlements between such manufacturers are not always inappropriate. As a result, Congress should provide FTC with the authority to judge such settlements on a case-by-case basis in order to prevent agreements that harm consumers by increasing prices. Congress should consider legislation, such as the Preserve Access to Affordable Generics and Biosimilars Act (S.1096), which does not currently have a House companion but would strengthen the hand of the FTC in preventing brand pharmaceutical companies from compensating generic and biosimilar manufacturers to delay the market entry of generics and biosimilars competition.

Explore patient-friendly remedies to combat 'product hopping' & 'patent thickets'

One common strategy utilized by some brand name manufacturers to extend their initial monopolistic market position is "product hopping" – a practice whereby customers are moved from one branded

drug to another very similar version of the drug that enjoys additional market exclusivity due to later patent expirations. This anti-competitive tactic raises complicated issues under patent law, antitrust law, the Hatch-Waxman Act, and state drug substitution laws.[ii] Another well-honed tactic by brand name manufacturers is the creation of 'patent thickets,' overlapping layers of dozens or even hundreds of patents on every element of a brand name product, presenting a deliberately daunting challenge to generic and biosimilar manufacturers that can prove difficult if not impossible to penetrate.[iii] Congress should consider policies that would prohibit product hopping and curb brand name manufacturers' ability to create patent thickets.

Protect generic drug use of 'skinny labels'

For decades, generic drug manufacturers have been able to take advantage of a pathway to limited market entry for their product even before full patent expiration of the brand name drug. Generics can be approved for a 'skinny label,' wherein approval is granted for only the uses of the brand name product where the patent on the specific use has expired. This is an important method for getting generic drugs to market sooner, but has come under threat from brand name manufacturers who have sued to prevent such generic approvals from moving forward. To protect and strengthen the option of skinny label approvals, Congress should consider the Skinny Labels, Big Savings Act (H.R. 6485).

Support inter-agency tracking of anti-competitive behavior

Blood Cancer United has strongly supported the efforts of the FDA to collaborate with the Federal Trade Commission (FTC) to deter anti-competitive behavior in the biosimilars space begun in 2020. We urge Congress to support continued cooperation between the FDA and FTC to track anti-competitive behavior by requiring and fully funding collaborative efforts between the agencies to collect evidence of anti-competitive behavior with respect to biosimilars.

Blood Cancer United also supports additional inter-agency collaboration to crack down on anti-competitive behavior related to small molecule and biologic patents. To this end, Congress should consider legislation like the Interagency Patent Coordination and Improvement Act (H.R. 4570), which would improve communication and coordination between the FDA and the United States Patent and Trademark Office (USPTO) regarding enforcement of each agency's purview relating to pharmaceutical patents.

Reform use of 'citizen petitions'

Citizen petitions are a tool by which a concerned individual or party can raise concerns with the FDA regarding potential safety or efficacy issues of a drug or biologic the agency is considering approving. Unfortunately, citizen petitions are all too often used by brand name manufacturers as part of their strategy to stall generic or biosimilar market entry. This can not only potentially harm patients by artificially delaying safe and effective medications from becoming available and driving down prices, but it also has put unnecessary strain on the FDA to respond to deluges of petitions filed by brand name manufacturers.[iv] To curb this abuse of the citizen petition, the Senate has introduced the Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act (Stop STALLING Act, S.1095). We urge the House to consider similar policies.

Prevent the patenting of REMS processes

Blood Cancer United continues to observe anticompetitive conduct by application holders that hinders the entry of generic competitors into the market, resulting in higher costs for patients, payers and the healthcare system. While the FDA can encourage and support positive behavior and shame companies that engage in blocking and delaying tactics, the agency's statutory

authority remains unchanged and limited. Blood Cancer United encourages Congress to pursue the following patent reforms that will reduce the risk of infringement that applicants confront from REMS-related patents:

1. Congress should require FDA to stop listing patents related to REMS methods or systems in the Agency's Orange Book and de-list such patents currently in the Orange Book. Though current FDA practice is to list REMS patents in the Orange Book, such listings may be invalid. This has significant consequences as such listings allow brands to obtain an automatic 30-month stay of generic approval.

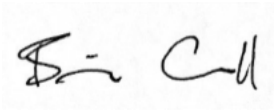
2. Congress should pass legislation deeming REMS methods or systems patents as within the "prior art," thereby limiting patent claims that branded companies have used to delay generic competition on REMS products. While the FDA mandates the use of REMS in certain situations, patents should not be permitted to bottleneck compliance with FDA requirements. This solution would limit patent claims that branded companies use to delay competition.

Conclusion

Blood Cancer United stands ready to work with you and your colleagues in Congress to advance the solutions we have outlined above and other proposals that would achieve savings without sacrificing patient access to appropriate cancer care. We share your belief that we are at a crucial juncture in our healthcare system, and we urge you and your colleagues to capitalize on this real opportunity to make the reforms necessary to promote patient access to appropriate care while eliminating incentives that drive unnecessary spending. We are grateful for your leadership.

If you have any questions or would like to discuss our comments further, please contact Jessica Burnell at jessica.burnell@bloodcancerunited.org.

Sincerely,



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