Alliance FOR AGING RESEARCH

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June 3, 2026

The Honorable Darrell Issa
Chairman
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary
U.S. House of Representatives

The Honorable Hank Johnson
Ranking Member
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary
U.S. House of Representatives

Dear Chairman Issa, Ranking Member Johnson, and Members of the Subcommittee:

My name is Sue Peschin, and I serve as President and CEO of the Alliance for Aging Research (AAR). I write on behalf of our nation's older adults and their family caregivers ahead of the Subcommittee's June 4, 2026, hearing, "Medicines and IP: Balancing Innovation and Access," regarding proposals related to pharmaceutical patents, including the Eliminating Thickets to Increase Competition (ETHIC) Act and the Skinny Labels, Big Savings Act.

The Alliance for Aging Research is the nation's leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equal access to care. We oppose these proposals because they misinterpret how the patent system functions and, if enacted, would weaken the innovation ecosystem that supports the development of future treatments older Americans urgently need.

For millions of older Americans living with cancer, Alzheimer's disease, cardiovascular disease, autoimmune disorders, and other chronic illnesses, medical innovation has made the difference between decline and stability, between dependence and independence, and in many cases between life and death. The patients affected by these policies are not only those receiving treatment today, but also those still waiting for the next breakthrough.

The Alliance strongly supports the Subcommittee's efforts to improve affordability and access to FDA-approved medications. Nearly 70% of older adults take at least one prescription drug, and more than 20% take five or more. Policymakers are right to examine policies affecting drug spending and competition. At the same time, those discussions must be grounded in evidence.

Consider the ETHIC Act's approach to so-called "patent thickets" and terminal disclaimers.

Critics of the pharmaceutical patent system often refer to "patent thickets"—a derogatory term used to describe multiple patents protecting different aspects of a single product. The implication is that these patents exist primarily to block competition rather than protect genuine innovation.

Medicines frequently incorporate multiple innovations that may independently qualify for patent protection, including the medication's active ingredient, variations on method of use for different diseases, updated formulations, unique manufacturing processes, and new delivery mechanisms. Each innovation is often the result of years of continuing research and development and clinical trials, aimed at improving treatment outcomes and patient experience, while reducing side effects. Those inventions each deserve separate patent protection. Importantly, each application must independently satisfy the same statutory standards for patentability, including novelty, non-obviousness, and usefulness. These are not easy legal hurdles.

On the other hand, related patents are often connected through terminal disclaimers—meaning that the related patents expire at the same time and remain under common ownership.

For instance, a company may initially patent a new therapeutic compound and later seek additional patent protection covering related aspects of the same therapy. An example of this is when a patented medication for one FDA-approved indication later receives FDA approval for a second indication covered by a second, related patent. A terminal disclaimer ensures that both patents expire at the same time (i.e., 20 years), rather than extending the overall patent exclusivity period.

In other words, terminal disclaimers protect *against* improper patent extension.

Unfortunately, the ETHIC Act *wrongly assumes* that terminal disclaimers extend patent life. This bill proposes to prohibit patent owners from enforcing more than one patent from any such group. This would allow generic manufacturers to infringe on what the brand manufacturers spent additional time and money researching—and it would do so under the false pretense of preventing an imagined patent extension. Such legislation is counter to the idea of American ingenuity as a foundational cultural and economic value in the United States.

We think it is important to state this again: *terminal disclaimers limit all patents for a given medication to the original 20 years of the first patent obtained*. The ETHIC Act would wrongly limit innovators' ability to enforce patents connected by terminal disclaimers—even when multiple valid patents are infringed.

There is no evidence that drugmakers systematically abuse terminal disclaimers to extend pharmaceutical monopolies or block competition. We ask you to press generic manufacturers for cases of this, and you will find that they do not exist.

You will not be the only ones to discover this. In a 2024 report requested by Congress, the U.S. Patent and Trademark Office found no correlation between the number of patents associated with a medicine and the timing of generic entry. Another USPTO analysis also concluded that large patent families are "not commonly found" in the pharmaceutical sector and are significantly more common in the electrical and high-technology industries.

At the same time, generic competition in the United States remains robust. More than 90% of prescriptions dispensed in the United States today are generic medicines, and most branded medicines face generic or biosimilar competition after approximately 13 years—even though a basic drug patent term is 20 years.

The Alliance strongly supports generic and biosimilar competition, which plays an essential role in reducing costs and expanding patient access. But policymakers should resist conflating biopharma IP and patent protections with patient affordability and access issues. Weakening IP and patent protections is going to disincentivize research and development a lot more than it will ever lower drug prices. The Congressional Budget Office analyses of the proposed bills prove this—CBO estimates these proposals would reduce average drug prices by less than 1% on average.

For older patients waiting for the next generation of cancer treatments or Alzheimer's therapies, the long-term consequences of weakening innovation would far outweigh any modest short-term savings or political points these proposals may promise. Biomedical research requires long development timelines, billions of

dollars in investment, and enforceable intellectual property protections. When those expectations become less certain, investment in high-risk therapeutic research *will* decline. We hope you will choose differently.

We have similar concerns with the Skinny Labels, Big Savings Act. The Alliance for Aging Research worries that the legislation could weaken incentives for follow-on innovation by narrowing longstanding patent protections for newly discovered therapeutic uses.

Under existing law, generic manufacturers may introduce knockoff versions of brand-name medicines to treat conditions that are no longer protected by "method of use" patents, even if those brand-name drugs are also used to treat *other* conditions that are still protected by method-of-use patents. In these cases, generic manufacturers must use "skinny labels"—and essentially avoid marketing their knockoff product as a treatment for the still patent-protected use cases.

For example, imagine a branded medicine was initially approved to treat high blood pressure, and then later discovered to also be effective at preventing heart failure. Once the method-of-use patent as a high blood pressure treatment expires, a generic manufacturer could introduce a knockoff version, so long as it omits the still-patented heart failure use from its label.

However, some generic companies elide this distinction, and deliberately market their products for both non-patent-protected as well as patent-protected conditions. The recently introduced "Skinny Labels, Big Savings Act" would make it difficult to bring patent infringement claims against generic manufacturers that engage in these marketing practices.

We are also concerned that the legislation would assign legal authority to the FDA that currently, and appropriately, belongs to the courts.

The FDA's role is to evaluate the safety and efficacy of our nation's medicines—*not* to adjudicate patent disputes or redefine the scope of patent liability. Courts are equipped to determine whether conduct qualifies as infringement under existing law. We urge Congress to proceed cautiously before creating this new authority at the FDA.

Thankfully, the FDA has always served as a beacon of support for American innovations that improve public health. Tasking the Agency with enforcement of new, overly broad statutory safe harbors runs counter to innovation, and will position the FDA as a barrier to it.

Weakening IP protections could create significant, generational consequences for continued biomedical research and investment. Families facing Alzheimer's disease, cancer, cardiovascular disease, and other serious illnesses are counting on continued progress toward new and improved treatments. As Americans live longer with more complex health needs, we urge you to reject policies that threaten the investment incentives required to translate scientific discoveries into lifesaving treatments.

Thank you for your public service and for considering our comments.

Sincerely,

Sue Peschin

Sue Peschin, MHS
President & CEO
Alliance for Aging Research