Statement for the Record by the Association for Accessible Medicines
Senate Committee on the Judiciary, Hearing on Drug Pricing
May 21, 2024

The Association for Accessible Medicines and its Biosimilars Council (collectively, "AAM") thank the Committee for holding a hearing on the important issue of combating higher drug prices. Forty years of experience show that protecting timely patient access to affordable generic medicines—and now, biosimilars as well—is the best way to use market competition to hold down drug prices. But generic and biosimilar access is threatened. AAM strongly supports the statutory safe harbor for carve-outs proposed by the Food and Drug Administration in its fiscal year (FY) 2024 budget and urges its adoption.

Since the enactment of the Hatch-Waxman Amendments in 1984, Congress has made sure that a narrow patent on one way of *using* a drug does not block access to generic substitutes entirely. When a drug's formulation and one or more ways of using it have moved into the public domain, patents should no longer prevent the marketing of a generic version. As the Supreme Court has rightly recognized, Congress provided for carve-outs so "that one patented use will not foreclose marketing a generic drug for other unpatented ones."

Hatch-Waxman accomplished that goal through the "skinny labeling" mechanism, which has allowed generic manufacturers to bring numerous generic drugs to the market. A skinny label allows the generic manufacturer to "carve-out" a brand drug sponsor's patented methods of use from the generic's FDA-approved labeling. For example, if a brand-name drug is approved for treating four different diseases, only one of which is covered by a patent, generic manufacturers can "carve-out" that patented method, gain FDA approval for the remaining three diseases, and bring to market a more affordable generic alternative.

The rationale for Hatch-Waxman's carve-out process is straightforward: it facilitates generic competition on unpatented uses of brand-name drugs and ensures patients have timely access to more affordable medicine. Indeed, Hatch-Waxman's carve-out process has served the public interest for over 40 years by increasing access to generic medicines, saving the healthcare system billions of dollars. In 2010, Congress added a pathway for biosimilars, which achieve similar savings through alternatives to some of the most expensive biologic medicines. Biosimilars, too, can sometimes avoid a patent block by omitting portions of the labeling of the brand-name reference product.

Despite this well-established practice, a recent decision from the U.S. Court of Appeals for the Federal Circuit threatens to undermine Hatch-Waxman's carve-out process. That decision, *GSK v. Teva*, holds that a generic can be liable for infringing the brand's patented method that the generic carved-out from its label, based on arguments that the carve-out was supposedly not broad enough, and that the generic publicly described its product as the equivalent of the brand product—something that is true of *every* generic. Although the federal government filed a brief to the Supreme Court explaining that the Federal Circuit's decision was wrong, the Supreme Court has declined to review the decision at this time.

As a result, the Federal Circuit's *GSK* decision threatens to nullify the longstanding carve-out mechanism that

allows generic manufacturers to quickly get affordable, FDA-approved medicines to patients. Many well-known generics currently on the market (including Crestor®, Abilify®, and Zytiga®) were able to launch years before expiration of the brand's method patents because of the carve-out mechanism. With the viability of carve-outs thrown into uncertainty, manufacturers will be discouraged from attempting early launch of generic drugs and biosimilars in the future, and patients will be forced to wait longer for lower-cost generics to be approved. And there is a risk that the uncertainty over carve-outs will become even worse, as the Federal Circuit is currently considering a case concerning a generic for an expensive triglyceride medicine (Vascepa®) that may lead the court to broaden the mistaken rule it announced in *GSK*. Absent a legislative change, brands will be able to grow larger and larger patent estates that delay access to more affordable medicines.

The FDA's FY2024 budget included a reasonable and targeted proposal to correct the mistaken *GSK* decision and provide a safe harbor so that generics can rely on carve-outs. It ensures that just submitting a generic application with a carve-out statement does not infringe the carved-out patent. It also ensures that if FDA approves the carved-out labeling—a decision that FDA will make based on the brand company's own descriptions of what parts of its labeling are protected by a method patent—marketing the generic product with that labeling does not infringe the method patent. The proposal also ensures that generics will not be accused of infringement simply for describing themselves as generics. In the *GSK* case and the new carve-out case before the Federal Circuit, the brand companies have argued that communications describing a generic with carved-out labeling as the "generic of" or "generic equivalent of" the brand product are in essence code words—that a jury could interpret them as urging the listener to prescribe the generic *for the carved-out use* without mentioning it. If such ordinary statements can carry nine-figure liability, generics and biosimilars cannot market their products and the carve-out system will not function.

We encourage the Committee to adopt the proposed statutory safe harbor. Enactment of this proposal will safeguard future generic competition through the carve-out mechanism as originally intended under Hatch-Waxman, thus ensuring that patients continue to have ready access to safe and lower-priced generic medicines and biosimilars.