AAM Position Paper on the HHS 180-Day Exclusivity Proposal

The HHS Proposal Will Jeopardize Affordable Generic Drug Alternatives for Patients By Reducing Generic Drug Competition and Increasing Drug Prices

The 180-day exclusivity provision is critical to promoting earlier entry of generic competition.

For its entire history, the Hatch-Waxman Act has granted a 180-day period of exclusivity to the first generic company that successfully challenged a patent protecting an expensive brand drug. This provides a strong incentive for generic companies to shoulder the financial and legal burden of contesting weak or questionable patents that block generic competition.

By promoting patent challenges, exclusivity encourages earlier entry of safe and effective generic alternatives that are less expensive than the brand. The 180-day exclusivity provision thus has been critical to the Hatch-Waxman Act's 30-year track record of success in promoting generic competition.

The HHS proposal could reduce generic drug competition by undermining the main incentive for generic drug companies to challenge weak or questionable patents.

Although more detail is necessary, the HHS proposal could significantly weaken the primary incentive for generic companies to challenge brand patents. In many cases, generic drug approval or tentative approval occurs before the completion of patent litigation. In such situations, FDA itself has agreed it is reasonable for generic companies to wait until they prevail in patent litigation before going to market to avoid potential treble damages.

If the 180-day exclusivity were triggered by the tentative approval of a subsequent applicant rather than commercial marketing by the first applicant, it would become virtually worthless. Without reasonable certainty that 180-day exclusivity could be retained until after a decision in patent litigation, generic drug manufacturers will be much less likely to take on the enormous expense of challenging brand name drug patents in the first place.

The HHS proposal may have the perverse effect of increasing drug prices.

With fewer patent challenges, more weak and questionable patents will stay in place, blocking the entry of generic drugs into the marketplace. And patents can last up to 20 years. Because the HHS proposal will weaken the incentives for generic companies to challenge blocking patents, it will reduce generic competition and thereby increase drug prices for patients, payors and the healthcare system as a whole.

The HHS proposal is unnecessary and does not address costly brand name drug prices.

The statute already contains provisions that prevent 180-day exclusivity from blocking approval of additional generic products for extended periods of time. In particular, 180-day exclusivity can be forfeited in several ways that prevent it from being "gamed" by brand or generic companies. These forfeiture provisions were added by Congress in 2003 and carefully balance the need for reasonable certainty of 180-day exclusivity with the need to prevent unduly delaying the approval of subsequent generic products. The HHS proposal could sabotage this carefully crafted Congressional solution. That is why the generic industry has strong concerns about this proposal: it is not necessary to remove blocks on generic access. Moreover, this proposal does nothing to address the costly brand name drug prices that comprise three-quarters of prescription drug spending.

The HHS proposal appears to be based upon the faulty assumption that subsequent generics will go to market when first applicants won't.

But that assumption could be wrong. Even if 180-day exclusivity were removed as a barrier, in many cases, subsequent applicants would be just as likely as first applicants to wait until patent litigation is resolved before going to market. In addition, the HHS proposal could weaken the main incentive for generics to challenge patents without stimulating additional generic competition. Perhaps this is why the proposal is expected to save only $1.8 billion over 10 years, when under the current Hatch-Waxman system generics already save the health-care system nearly $5 billion every week.

The HHS proposal is a blunt instrument that could unfairly penalize generic companies that are diligently working to address deficiencies.

The budget documents released thus far fail to describe the scope and nature of the problem at issue. The reality is that a generic applicant has significant incentives to move its application to final approval. There is no regulatory rationale for a generic applicant to fail to respond to deficiencies in its application as identified by the FDA. In fact, the proposal is likely to harm applicants that are in the process of correcting deficiencies, but a second applicant happens to be ready before the first applicant.

The following scenarios are illustrative of likely harms under the proposal:

- Often generic applicants purchase the active pharmaceutical ingredient (API) from different suppliers. FDA inspects these API suppliers to ensure the current Good Manufacturing Practices (cGMPs) which are critical to the safety and efficacy standard are met. If FDA inspected a particular API supplier and finds deficiencies, addressing such deficiencies may take some time (e.g., if the API is difficult to manufacture or there was an unforeseen event such as an explosion or other natural disaster at the API facility). Finding an alternative supplier can prove difficult despite the generic applicant's best efforts. In some situations, a subsequent applicant may have an exclusive arrangement with the only other available API supplier. Assuming the first applicant finds another API supplier, FDA must review the records from that supplier and an FDA inspection may be necessary to clear the manufacturing facility. If that facility is located abroad (e.g., China), then FDA's inspection schedule may be delayed because of difficulties associated with obtaining the necessary clearances to inspect the foreign manufacturing facility. Under the HHS proposal, through no fault of

the first applicant, the subsequent applicant that happens to be ready for tentative approval would trigger the 180 day exclusivity.

- A common practice in the generic industry is to employ a Contract Research Organization (CRO) to conduct bioequivalence (BE) testing necessary to obtain FDA approval. If a first applicant contracts with a CRO to conduct a BE study that FDA later determines is inadequate because of potential study conduct issues at the CRO, the first applicant must repeat the BE tests on its own or find a new CRO to conduct such tests. During that delay, a subsequent applicant that used a different CRO might be ready to obtain tentative approval. Under the HHS proposal, the first applicant in this case would lose its 180-day exclusivity through no fault of its own, and due to an issue over which the first applicant had no control.

- Brand companies routinely abuse FDA's Citizen Petitions (CP) pathway by filing CPs as a means of delaying approval of a generic competitor. These CPs often target a particular generic applicant (i.e., instead of targeting all generic applicants for a certain drug) and cite formulation-specific attributes or BE methodologies that may differ among generic applicants. If the brand company files a CP that urges FDA to refrain from approving the first generic application, the FDA may delay final approval until the first applicant resolves the issues identified in the petition. In the meantime, under the HHS proposal, subsequent applicants that are not affected by the CP could be tentatively approved and trigger the first applicant's 180-day exclusivity even if the first applicant is working diligently to address the CP issues.

This paper addresses the proposal discussed in the HHS FY 2019 Budget in Brief as of February 19, 2018.