ACHP
ALLIANCE
OF COMMUNITY HEALTH PLANS

ACHP Recommendations: FDA Prescription Drug User Fees Reauthorization
May 2017

The Alliance of Community Health Plans (ACHP) is a national organization bringing together innovative health plans and provider groups to lead the nation towards a value-based health care financing and delivery system. Members are non-profit, provider-aligned organizations or subsidiaries of non-profit health systems. They provide coverage and care for more than 18 million Americans across 27 states and the District of Columbia in the commercial market and Marketplaces and for Medicare, Medicaid, and federal, state, and local public employees.

ACHP supports reauthorization of the Food and Drug Administration (FDA) prescription drug user fee agreements and encourages Congress to include additional provisions to improve transparency around prescription drug pricing to foster a more competitive and effective pharmaceutical marketplace.

Support for reauthorization of the FDA user fee programs

As primary purchasers of prescription drugs and medical devices for the 19 million Americans they serve, our member organizations understand the great value that these medical products provide. Innovative therapies have helped millions of people conquer illnesses and live healthier, longer lives. Generic drugs and biosimilars are equally as important and help ensure competition and improve affordability in the marketplace.

ACHP believes it is important that the FDA has the resources it needs to adequately review the safety of these products in a timely manner and enthusiastically supports efforts to reauthorize the FDA user fee programs.

ACHP is particularly supportive of the enhancements proposed by the FDA and industry for the reauthorization of the Generic Drug User Fee Act and the Biosimilar User Fee Act. Specifically, ACHP recommends:

- Providing resources to the FDA so it can continue clearing the generic drug application backlog;
- Establishing an 8-month review time for priority generic drug applications, that will help foster competition in the marketplace or help alleviate drug shortages;
- Enhancing program design and engagement between the FDA and generic drug applicants to ensure a review process that results in timely access to safe and affordable generic drugs and biosimilars;

- Establishing firm timelines throughout the process in which FDA will provide industry with guidance on the biosimilar pathway, especially how to demonstrate interchangeability with a reference product.

Improve transparency and competition in the pharmaceutical marketplace

ACHP and its member organizations remain concerned about the high-cost of some pharmaceutical products and the burden it places on patients. Our organization believes that increased transparency and competition are critical steps toward addressing the rising price of pharmaceuticals. Specifically, ACHP recommends:

- **Efforts to reduce anti-competitive behavior in the pharmaceutical marketplace.** ACHP offers its support for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017. This bipartisan legislation would help prevent tactics used to delay generic competition, such as preventing access to samples necessary to demonstrate that a generic product is equivalent to a branded drug. **ACHP recommends Congress include this commonsense, bipartisan legislation in the FDA user fee reauthorization currently under consideration.**

- **Efforts to restore the Orphan Drug Act to its original Congressional intent.** Additional, well-established anti-competitive activities are employed by biopharmaceutical companies to prevent or delay the market entry of generic products. These tactics include the liberal application of the Orphan Drug Act by companies as a pathway to extend exclusivity for their branded, more expensive, pharmaceutical products. **ACHP recommends Congress include narrow and clarifying language in the FDA user fee reauthorization this year in order to restore the intended purpose of the Orphan Drug Act so that it is not used as a vehicle to artificially extend patent monopoly of expensive branded pharmaceutical products.**

- **Efforts to improve communications between pharmaceutical manufacturers and health plans.** ACHP believes that enhanced dialogue between pharmaceutical companies and health plans, particularly about health care economic information (HECI), would provide greater stability to the marketplace, and will help plans make decisions about managing their formularies. **As part of the FDA user fee reauthorization, ACHP recommends Congress direct the FDA to finalize its guidance outlining how prescription drug manufacturers can communicate with health plan stakeholders regarding economic information such as pricing**

information for specific pharmaceutical products. Communication with certain pharmaceutical companies earlier in the review and approval process will help improve the quality of abbreviated new drug application (ANDA) submissions.

- **Efforts to improve transparency on prescription drug pricing.** In December 2015, the Department of Health and Human Services released a Medicare Drug Spending Dashboard providing information on prescription drug spending in both Medicare Part B and Part D drugs. Specifically, the dashboard included information on drugs with high spending on a per user basis, high spending for the program overall, and those with high unit cost increases in recent years. ACHP believes this is a useful tool that provides greater transparency on how public dollars are being spent on pharmaceuticals. **As part of the FDA user fee reauthorization, ACHP recommends Congress amend the Public Health Service Act to direct the Secretary of Health and Human Services to continue publishing this dashboard in its current form.**

<u>Encourage entry of biosimilar products in the pharmaceutical marketplace</u>

In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to encourage competition in biologic markets and reduce prices. The BPCIA established parallel pathways to approve biologic drugs and bring them to market by directing the FDA to establish guidelines for companies to meet the standards of *biosimilarity* and *interchangeability*. The *biosimilar* designation establishes that there isn't any clinically meaningful difference between the biological product and the original FDA-licensed reference product. The *interchangeable* designation allows for automatic substitution by pharmacists without the consent of a physician, which is the point at which the health care system is projected to achieve significant savings. However only two biosimilar products are currently offered for sale in the U.S., and additionally the FDA has not finalized its rulemaking to provide pharmaceutical companies with achievable evidence guidelines to demonstrate interchangeability.

ACHP recommends Congress remove barriers to biosimilar market entry by requiring the timely review of large molecule and specialty products by FDA, as well as the timely release of final rulemaking containing realistic clinical targets for companies to achieve interchangeability.