Senate Confirms Dr. Robert Califf for FDA Commissioner

On Feb. 15, the Senate confirmed Dr. Robert Califf as FDA Commissioner, a position he previously held under the Obama administration. Dr. Califf is a well-respected clinical trial researcher who served as founding director of the Duke Clinical Research Institute and as a member of the National Academy of Medicine. AMCP <u>congratulates</u> Dr. Califf on his confirmation and looks forward to continuing our work with him to improve patient access to innovative, high-value treatments. The day before his confirmation vote, AMCP joined a pharmacy stakeholder letter supporting Dr. Califf's nomination.

Read AMCP's press release.



Eye On Washington

AMCP Submits Comments on Aduhelm Coverage Decision

On Feb. 9, AMCP submitted comments to CMS on the agency's Proposed National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid of the Treatment of Alzheimer's Disease. AMCP supports CMS's proposal to cover the treatment class of anti-amyloid monoclonal antibodies (mABs), including Aduhelm, under its Coverage with Evidence Development (CED) pathway. AMCP echoed concerns from the Institute for Clinical and Economic Research that current clinical evidence does not support broad coverage of Aduhelm and requires more research into safety and efficacy. AMCP also noted that broad coverage could burden Medicare beneficiaries who would pay higher premiums and state Medicaid agencies that would shoulder the out-of-pocket costs for dual-eligible beneficiaries.

Read AMCP's comments.

ICYMI: AMCP 2022 Policy Outlook Webinar

Last month, AMCP staff and the policy and government relations experts at Tiber Creek discussed the key legislative and regulatory issues facing the Biden administration and Congress this year. They shared the latest insights on the political dynamics shaping the 2022 policy agenda, as well as key players in the administration and Congress that wield power over health care policy. A recording of the webinar is available for AMCP members.

View the webinar.

Advocacy Tip

Stay up-to-date: Read AMCP's Letters, Statements and Analysis on all legislation and regulation impacting managed care pharmacy. The Cures 2.0 Act (H.R. 6000) is an important follow-up to the 2016 21st Century Cures Act (P.L. 114-255). Cures 2.0 proposes many strong policy ideas that AMCP supports, including improving strategies to expand use of cell and gene therapies, strengthening the collection of confirmatory data for accelerated approval drugs, and expanding access to innovative medical technologies, including digital therapeutics. The bill would also create the Advanced Research Projects Agency for Health (ARPA-H) to focus on developing new treatments. We also support the inclusion of additional provisions to strengthen the bill's efforts. Please use our Action Center to encourage your Representatives to co-sponsor and vote for this important piece of legislation.

Read more about AMCP's suggestions in our **Cures 2.0** issue brief.

AMCP
675 North Washington Street, Suite 220, Alexandria, VA 22314
703.684.2600 | www.amcp.org

Manage My Emails