American Academy of Dermatology Association

Promoting Innovation, Improving Access to Treatments

Improve access to pharmaceutical treatments that produce better patient outcomes, meet personalized medical needs, and constrain costs for patients and the health care system.

ISSUE OVERVIEW

Dermatologists diagnose and treat more than 3,000 skin diseases, including psoriasis, eczema, skin cancer, infections, immunologic diseases, and many genetic disorders. Access to affordable medications and other treatments for these conditions is not only medically necessary, it is life-changing. This includes compounded medications, which play a key role in providing treatment for many dermatologic patients.

However, limitations in research funding threaten the development of new and more effective treatments while restrictions on prescribing compounded drugs reduce access to existing, effective treatments dermatologists rely on. Further, pharmaceutical costs continue to increase, due in part to reduced levels of competition for a variety of drugs, including generic, brand, and specialty medications.

AADA ADVOCACY POSITION

Promote innovation that brings new cures and treatments to market. The federal government has led the way and must continue to do so in promoting innovation, supporting basic research, and streamlining the drug approval process. New treatments have the potential to improve quality of life for patients, bring new efficiencies to the delivery of care, and reduce direct and indirect costs in the health care system.

In support of these goals the AADA advocates:

- Additional authority and resources the Food and Drug Administration (FDA) needs to expedite the drug review process and get additional drugs to market.
- Increasing support for biomedical research purchasing power at the National Institutes of Health (NIH).

LEGISLATIVE ASK

SUPPORT THE 21ST CENTURY CURES ACT (H.R. 6)

- H.R. 6 fosters the discovery, development, and delivery of cures and treatments while strengthening America's position as the world's biomedical innovator.
- Modernizes clinical trials, removes barriers to collaborative research, invests in the next generation of researchers, and provides incentives for the development of new drugs.
- Provides increased funding for the NIH and FDA.
- Last summer, the House of Representatives approved H.R. 6 with overwhelming support. The Senate Health, Education, Labor & Pensions (HELP) Committee has continued this effort in considering and approving measures as part of its companion effort known as Innovations for Healthier Americans.
- The AADA urges Congress to complete this important work, reach a bipartisan agreement, and pass final legislation that can be signed into law this year to make the goals of the Cures and Innovations efforts a reality.

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AADA ADVOCACY POSITION

Protect patients' access to compounded medications. Compounded medications are an integral part of dermatology practice and are vital in providing the best patient care. Dermatologists safely deliver compounded treatments to meet patients' needs, including those with orphan diseases that do not have an approved indication. Prescribing and administering compounded products in an office setting allows dermatologists to tailor treatments to each patient, resulting in better outcomes and lower health care costs.

Contrary to congressional intent, action taken by the FDA to implement the Drug Quality & Security Act (DQSA) has restricted access to these drugs. The FDA would require a traditional compounding pharmacist (503A) to obtain a patient-specific prescription prior to distributing the compounded drug to the administering health care practitioners, and suggests using outsourcing facilities (503B) to obtain compounded drugs for office-use. However, outsourcing facilities are not able to meet the needs of all patients and dermatologists for small volume and less frequently used compounded drugs.

LEGISLATIVE ASK

Urge the FDA to provide patients' access to compounded drugs in their physician's office.

CO-SIGN THE LETTER LED BY SEN. RAND PAUL (R-KY), which calls on the FDA to prioritize patients' needs and provide access to compounded and repackaged drugs in the physician office setting, preserve access to compounded drugs from 503A compounding pharmacies, and recognize emergent situations where physicians need a compounded drug to immediately treat a patient.

AADA ADVOCACY POSITION

Address rising costs and preserve access to generic medications. According to the Generic Pharmaceutical Association (GPhA), generic drugs represent approximately 88% of the drugs purchased in the U.S., and saved the health care system $1.68 trillion between 2005 and 2014. However, in recent years, a variety of factors have affected patients' access to generic treatments, including market forces that have led to manufacturer consolidation or elimination, slow approval processes for drugs, skyrocketing pricing due to lack of competition, shortage of raw materials, and manufacturers no longer producing drugs that have low profit margins in favor of newer, more expensive drugs. Dermatologists are committed to providing the most effective and cost-efficient care and therapies to their patients. **The AADA supports removing barriers to the development and entry of generic drugs in the marketplace, which will increase competition and lower prices of pharmaceuticals.**

LEGISLATIVE ASK

Promote measures that address market changes and ensure access to generic treatments.

CO-SPONSOR THE INCREASING COMPETITION IN PHARMACEUTICALS ACT (S. 2615), introduced by Sen. Susan Collins (R-ME) and Sen. Claire McCaskill (D-MO), and **THE LOWER DRUG COSTS THROUGH COMPETITION ACT (H.R. 4784)**, introduced by Rep. Kurt Schrader (D-OR) and Rep. Gus Bilirakis (R-FL). Together these bills would:

- Expedite FDA review of certain applications for generic drugs.
- Prioritize review of applications where there is a drug shortage or no comparable generic on the market.

For more information please contact AADA staff at 202-842-3555.