



Association for Accessible Medicines
2017 Annual Report

Table of Contents

AAM Mission	4
Letters	
From the Chairman	6
From the President and CEO	8
Executive Summary	
2017 at a Glance	10
Brand Advancement	
Reimagining the Brand	12
Driving the Conversation	14
Building a Welcoming Space for You	16
AAM Action	
Improving the FDA's Approval Process	18
Advancing Biosimilars	20
Market Imbalance	
Offering Solutions to High Drug Costs	22
Demystifying the Drug Supply Chain	23
Celebrating Access & Savings	24
Anti-Competitive Behaviors	
Shining a Light on Abuse	26
Championing the CREATES Act	27
Opposing "Shenanigans"	28
Policy Miscues	
Confronting Medicaid Generics Penalty	30
Countering State "Transparency" Legislation	31
Challenging the State of Maryland	32
Launching Opioid Abuse Education Program	34
Events & Conferences	
Access! 2017	36
Fall Tech	38
CMC	39
Leading on Biosimilars	39
GRx+Biosims	40
Become a Member	
Join Today	42
2017 Members	46
Contact Us	48

AAM Works to Ensure More Generic and Biosimilar Medicines Are More Accessible to More People Who Need Them

The Association for Accessible Medicines (AAM) works to improve access to FDA-approved safe, effective and high-quality generic and biosimilar medicines. Better access to medicine is relevant to everyone because we're all patients.

Generics and biosimilars help people live healthier and longer by:

- Driving down the costs of existing drugs so people can afford the medicines they need.
- Increasing competition so patients and payers have a choice in the marketplace.
- Enhancing access to safe, effective drugs so more consumers take their prescriptions.

As manufacturers of 9 out of every 10 prescriptions dispensed in the U.S., members of AAM form an integral and powerful part of the health care system.





From the Chairman

Dear Members:

Consider the events of last year: a new president and vice president of the United States were sworn into office, new cabinet heads were appointed for the 15 executive branch agencies, more than 50 new representatives and several new senators were seated in the U.S. Congress and eight new governors and nearly 1,400 new state representatives began their terms in office. A new commissioner took the helm at the FDA with a hard-hitting agenda of bold policy priorities. Whether you welcome these changes or not, there's no denying that the landscape around us looks much different today than it did just one year ago.

Here's what has not changed: health care continues to dominate the discussion in Washington and across the country, and the cost of prescription drugs remains of paramount concern. Now more than ever it is imperative that we tell our story across a broad base of stakeholders. As our industry changes within the evolving pharmaceutical ecosystem, we must speak with one voice to drive home the message that a robust generic drug and biosimilars marketplace is necessary to sustain affordable health care.

We are all pleased to present this report detailing the progress of our association in 2017. All of us have a rich heritage of public service to uphold. We all are beneficiaries of the vision and leadership of the generic industry pioneers who preceded us — men and women like Mike Puskar, Agnes Varis, Eli Hurvitz and Barry Sherman. With your continued engagement in our association, I am confident we will succeed in carrying on our proud tradition.

Thank you for being a valued partner in the quest to achieve our mission of supplying safe, effective and affordable medicines to consumers and patients around the world. I thank the AAM Board of Directors for lending its time and energy to our mission. And I thank Chip Davis and his AAM team for their diligent efforts on our behalf. It has been an honor to serve as your chairman and I look forward to many future successes as we continue working together.

Warm regards,

**Jeff Watson, Chairman of the Board, AAM
President, Global Generics, Apotex Inc.**





Letter from the President and CEO

To my colleagues:

Whether advocating for sensible health care policies, educating decision-makers about the value proposition of generics and biosimilars or working to support a competitive and sustainable market that provides growth opportunities for our members, our goal is always to expand patient access to safe, effective and affordable medicine.

Accomplishing this mission requires strategy, engagement and collaboration. Today our industry faces very real challenges: continuing consolidation in the buyer market, public policies that increasingly threaten the sustainability of a vibrant generic industry and unprecedented levels of anticompetitive actions by some drug manufacturers designed to prevent or delay generic or biosimilar competitors from entering the market. You can see it in the daily news headlines: diminishing margins, falling share prices, layoffs, plant closings and increasing concerns about the rise of drug shortages.

So the real question we need to ask ourselves is: how do we respond to these challenges? Do we hunker down in a defensive mode hoping “not to lose?” Or do we act aggressively and confidently with a “strive to win” mindset? Do we settle into a comfort zone, or do we advance toward the end zone?

I am proud that we have chosen to advance. In 2017, we took the bold step of rebranding our organization as the Association for Accessible Medicines.

We bolstered our association team by adding new talent and took a more assertive and muscular approach to our federal and state advocacy. And we increased our budget and sharply focused our resources. Together, these substantive actions have amplified our voice, enhanced our influence and enabled us to begin reclaiming the narrative that generic drugs drive savings. We are working proactively toward smart policy solutions that facilitate robust growth in the generic and biosimilars sectors.

As you read this report and recall the progress we made in 2017, I believe you will share my confidence that we are on the right course for our industry, for our association and for the many companies that provide quality, affordable, safe and effective medicine to patients around the world.

I am immensely grateful to the AAM Board of Directors and our member company representatives for their commitment to our shared cause. Your expertise, guidance and continued engagement will empower us to achieve our vital mission.

Best,

**Chip Davis, President and Chief Executive Officer
Association for Accessible Medicines**



2017 at a Glance

The theme of 2017's annual meeting, **Epic Challenges, Epic Opportunities**, was particularly prescient. The year began with President-elect Donald Trump declaring the drug industry was "getting away with murder." High prescription drug prices and the opioid epidemic fueled his remarks and inflamed public opinion. States around the country entered a gap they felt was created by federal inaction and began considering onerous laws to regulate the industry.

Against this challenging backdrop, the generic and biosimilars industry forged ahead to support the reauthorization of the fundamental laws governing our work, crystalize our value proposition in the minds of policymakers and advocate for sustainable competition.

Increased awareness and understanding are the key to realizing greater patient access to generics and biosimilars. The industry, through the association, took control of its narrative and told the story of generics and biosimilars to critical stakeholder groups – from lawmakers in Washington to state legislators, from the media to patient and consumer organizations.



JEFF WATSON (APOTEX),
REP. LISA BLUNT ROCHESTER (D-DE),
CHIP DAVIS (AAM)



DR. SCOTT GOTTLIEB (FDA)



CHRISTINE SIMMON (AAM)



JANET WOODCOCK (FDA)



BRUCE LEICHER
(MOMENTA PHARMACEUTICALS)



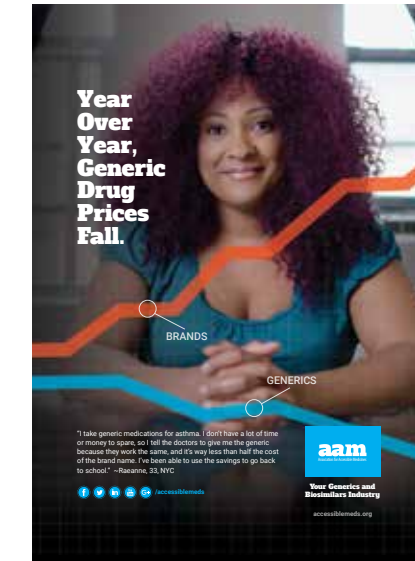
SEN. BILL CASSIDY (R-LA),
JOIE CHEN (THE ATLANTIC)

Reimagining the Brand

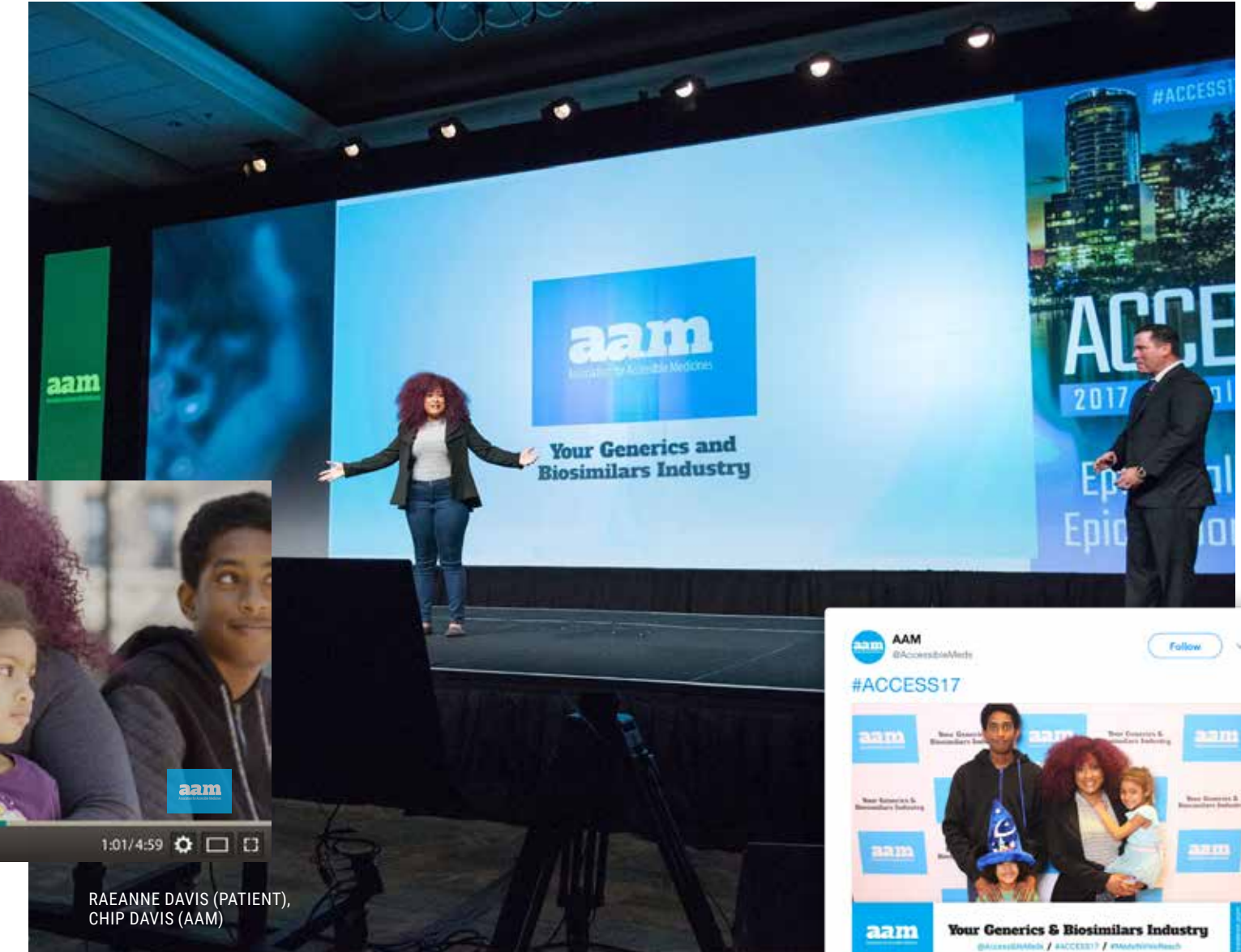
In February, the association shed the name Generic Pharmaceutical Association and unveiled a new transformational one: the Association for Accessible Medicines. The board and members welcomed the renewed focus on patients, noting that it fully embraced the biosimilars industry.

"All that we do each day, from ensuring competition to enhancing FDA's approval processes, ultimately delivers on the promise of putting treatments within reach for patients. When patients can afford safe, quality medicines, not only do their health outcomes improve, but they also have the resources to enrich other parts of their lives."
Chip Davis, President and CEO – Access! 2017

Attendees at the annual meeting met Raeanne Davis, a single mother from New York who communicated her personal yet common struggle to provide for her family while taking care of its profound health needs. This was the first time that a group of patients became the face of our association and Ms. Davis went on to be featured in a campaign with other patients that included video, print and online advertising.



RAEANNE DAVIS (PATIENT),
CHIP DAVIS (AAM)



Driving the Conversation

Digital engagement with a widening circle of stakeholders amplified our messaging efforts in 2017. CEO and President Chip Davis embraced social media for the association and himself, and a patient-centered multimedia advocacy campaign provided compelling, shareable content for patients, news media, lawmakers and industry professionals.

AAM @AccessibleMeds · 6/28/17
 cnb.cx/2toxK1l @SGottliebFDA @US_FDA need to fix abuses by pharma cos. that keep patients from accessing safe generics #drugprices

AAM @AccessibleMeds · 6/12/17
 [Just Released] 2017 Generic Drug Access and Savings in the U.S. Report: goo.gl/YjrKNm #generics #biosimilars @QuintilesIMS

Biosimilars Council @Biosim... · 6/14/17
 "We need to be focused on the #biosimilar competition to lower drug costs on specialty medications." - Christine Simmon #DistributionChain



Scott Gottlieb, M.D. and 5 others followed you

AAM @AccessibleMeds · 9/20/17
 Unfair CPI Penalty on generic drugs in Medicaid reduces competition and risks shortages: accessiblemeds.org/resources/pres...

AAM @AccessibleMeds · 9/28/17
 "For the sake of Iowa's patients @SenJoniErnst ought to co-sign this legislation." dmreg.co/2yw5QyQ @DMRegister Pass the #CREATESAct

Replying to @AccessibleMeds
 I'm a liver transplant survivor. My meds are expensive. It's drains our bank account. Thanks, Mary Kay Barbay.

CAPD @RxDrugCoalition
 .@AccessibleMeds' @chesterdavisjr: Generic drugs helped U.S. consumers save \$253 billion in 2016 #DrugCompetitionFTC

Sandy M. @Nesting4Awhile
 Replying to @AccessibleMeds
 I am a firm believer in generic drugs. Thankful they are available because they are very affordable. Thank you for your work. 👍

Scott Gottlieb, M.D. Retweeted
AAM @AccessibleMeds · 11/26/17
 We applaud @US_FDA 4 updating Orange Book to include date FDA receives the patent information from the brand co NDA holder. Knowing the brand co filed its patent submission in a timely way is critical for generic cos. to speed GRx 2 patients at earliest legally possible date.



Biosimilars Council @Biosims... · 7/6/17
 Recapping our event with @AtlanticLIVE on the future of #biosimilars on the blog: bit.ly/2ttO4ul

Anna Rose Welch @AnnaRoseWelch
 Great discussion here by @chesterdavisjr of the @AccessibleMeds about the unique supply-chain challenges facing #biosimilars and #generics.

Biosimilars Council @Biosim... · 7/25/17
 New on the blog: @AvalereHealth study finds that #biosimilars earn the trust of health insurers. bit.ly/2uUD2ID

AAM @AccessibleMeds · 3/21/17
 Remarks from FDA's Janet Woodcock at the user fee committee hearing last month. #generics #biosimilars #stopREMSabuse

Cornell Stamoran @stamoran · 3/2/17
 Replying to @AccessibleMeds
 thanks to David Gaugh for representing the #GDUFA Industry team as a witness at today's hearing - well done sir!

Chip Davis @chesterdavisjr · 5/30/17
 Commissioner @SGottliebFDA's Drug Competition Action Plan is an important effort that will enhance patient access while also reducing costs.

AAM @AccessibleMeds · 6/14/17
 Panel: Fostering Competition in the Generic Drug Distribution Chain @BrookingsEcon w/ Christine Simmon @BiosimsCouncil #DistributionChain

AAM @AccessibleMeds · 3/22/17
 .@DavidP4AD Members of the committee, that's the impact of REMS abuse, and it's part of the problem with drug prices in America...

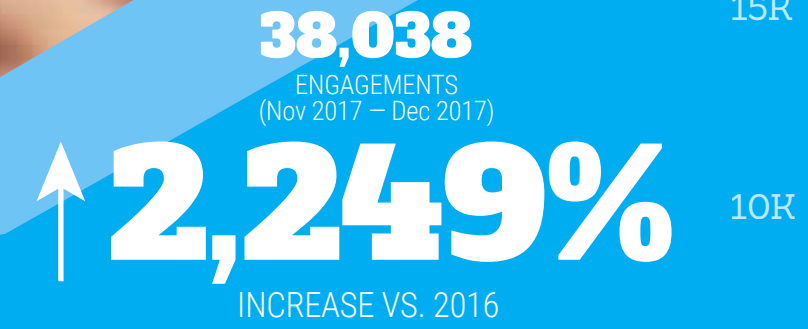
AAM @AccessibleMeds · 6/5/17
 #DrugPrices #StopREMSAbuse From the Maine State House: Vote yes to make prescription drugs cheaper in Maine centralmaine.com/?p=726997

AAM @AccessibleMeds · 6/23/17
 @AccessibleMeds applauds @amyklobuchar's leadership on CREATES Act and lowering drug costs for all Americans #drugprices

AAM @AccessibleMeds · 2/14/17
 Welcome to day 1, minute 1 of the Association for Accessible Medicines. - Chip Davis unveils the new brand. #access17

ENGAGEMENTS PER MONTH

ENGAGEMENTS PER MONTH



JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC



Building a Welcoming Space for You

With a growing team and a greater need for proximity to the corridors of power, AAM moved into new offices a few blocks from the U.S. Capitol. Around the corner from Washington's Union Station, the new office is easily accessible and offers guest offices and conference rooms for our board and member company staff to use when they are in Washington.

601 New Jersey Ave NW, Suite 850, Washington DC 20001



Improving the FDA's Approval Process

In August, the United States Senate passed the FDA Reauthorization Act of 2017 by a vote of 94-1.

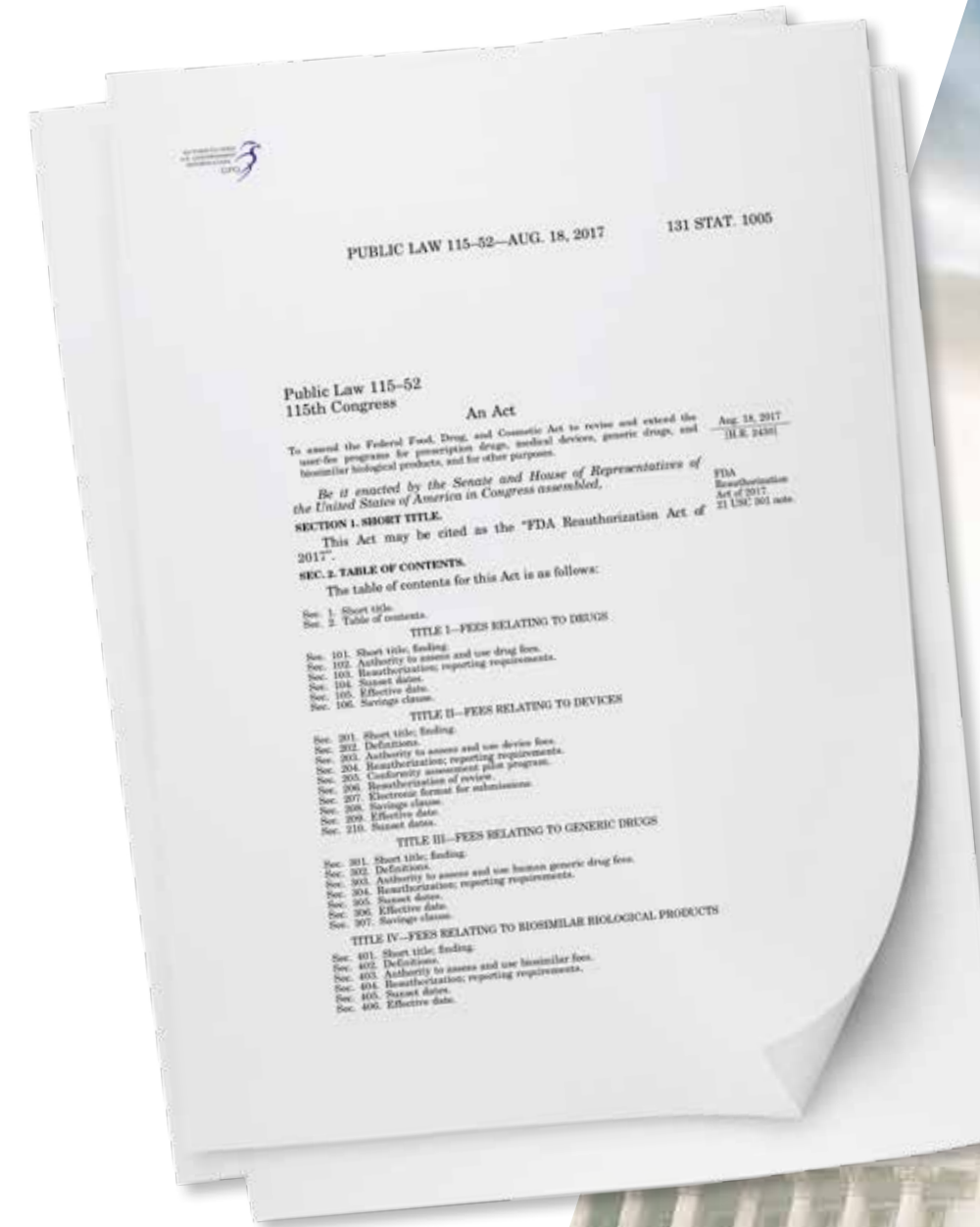
"As the country grapples with the high price of health care, the strong bipartisan vote in the Senate recognizes the most effective and efficient way to contain prescription drug costs is to enhance competition by increasing the number of generic and biosimilar medicines available to patients."

Chip Davis, President and CEO

The Generic Drug User Fee Act (GDUFA) promotes safety, access and transparency in the generic pharmaceutical industry. More specifically, the program holds all foreign and domestic companies to consistently high-quality standards; speeds the availability of affordable, safe, effective generic drugs through more predictable review processes for Abbreviated New Drug Applications (ANDA); and increases transparency between manufacturers and the FDA by requiring the identification and registration of all facilities involved in the manufacturing of generics and their active ingredients.

The GDUFA II and Biosimilar User Fee Act (BsUFA) II agreements put in place the framework for using the best processes and science available to approve new safe, effective and affordable generic and biosimilar medicines. AAM and its members share and fully support GDUFA and BsUFA objectives with 100 percent industry-generated funds.

AAM recommitted to working with the FDA to increase the number of applications reviewed and approved, and to ensuring a sustainable and competitive market for generics and biosimilars that will serve the best interests of patients.

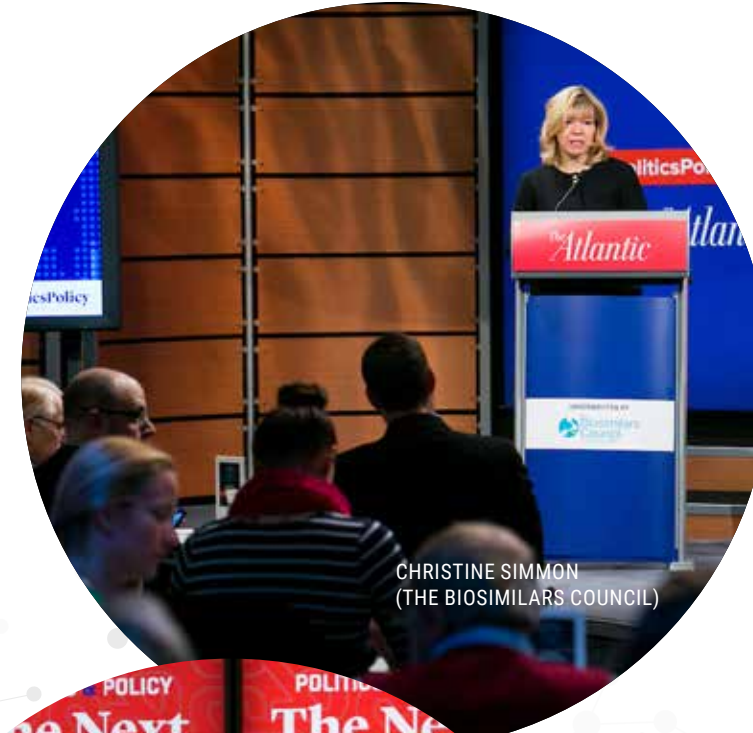


Advancing Biosimilars

In 2017, The Biosimilars Council commanded a higher profile than ever before. It educated a variety of stakeholders and advocated for policies that enhance the regulatory and business environment to provide greater patient access to biosimilar medicines.

The council collaborated with The Atlantic on events, including **The Next Drugs: The Future for Biosimilars – An Atlantic Policy Briefing** at the Newseum in Washington, D.C. The standing room-only event welcomed influential lawmakers and policy experts.

In the fall, AAM and The Biosimilars Council held a two-day conference, **Leading on Biosimilars**. It featured presentations from key industry leaders, U.S. government agency officials and academic experts exploring the burgeoning market for these medicines.



CHRISTINE SIMMON
(THE BIOSIMILARS COUNCIL)



KIMBERLY GRECO (AMGEN),
DAVID ROSEN (FOLEY LARDNER),
HILLEL COHEN (SANDOZ),
JOIE CHEN (THE ATLANTIC)

2017 Biosimilars Milestones

Approvals. The FDA approved five biosimilars in 2017, bringing to nine the total number of biosimilars licensed for marketing in the U.S. Together, these new products represent safe and affordable alternative treatments for brand-name reference biologics, which cost the U.S. health care system \$35.2 billion in 2016.

BsUFA II. In August, Congress passed the FDA Reauthorization Act of 2017, which included BsUFA II, the Biosimilar User Fee Act. The Biosimilars Council worked with the FDA to negotiate a “next-generation” approval process for these cutting-edge medicines.

Biosimilar Education. In October, the FDA released educational materials that includes online courses, webinars and video presentations designed to help doctors and other health care professionals better understand what biosimilars are, how they are licensed and why they are safe to use as alternatives to their counterpart brand biologic.

Biosimilar Substitution. In 2017, 10 additional states enacted biosimilar substitution laws to allow for the dispensing of interchangeable biosimilars. This brings to 37 the number of states that have biosimilar substitution laws on the books.

Biosimilars Reimbursement in Medicare Part B. The Centers for Medicare & Medicaid Services revised its biosimilars reimbursement policy in Medicare Part B to provide each non-interchangeable biosimilar with a unique billing code and payment rate, starting in January 2018.

Led by AAM’s Biosimilars Council, a variety of stakeholders urged the agency to make this change and an AAM-supported report by The Moran Company found this revision would save the federal government \$11.4 billion over the next 10 years.

Supreme Court Ruling in Amgen v. Sandoz. In accordance with an amicus brief submitted by The Biosimilars Council, the Supreme Court provided clear guidance that biosimilar applicants may provide 180-day notice of commercial marketing prior to the FDA’s licensing of their application, instead of waiting until after FDA had licensed their product. This means that an applicant that provides early notice of its intent to commercially market a biosimilar product may be able to launch that product immediately upon receiving FDA approval. This ruling will allow biosimilar products to go to market faster and increase patient access to these life-saving products.

Implementation of the WHO Decision to Put International Non-Proprietary Name (INN) Biologic Qualifier (BQ) on Hold. As proposed, use of the BQ naming convention would assign a random code to the INN for biological substances. In short, it would stifle uptake and be a barrier to competition to new biosimilar versions of expensive brand biologics. AAM and the council are pleased that the WHO has heard the voice of advocates for policies that support patient access to biosimilars and hope that they will not move forward with any proposal that adds identifiers to a biosimilars INN in the future.

Offering Solutions to High Drug Costs

Throughout the year, AAM leveraged congressional appearances, media interviews and other forums to communicate the need for sustainable competition for generics and biosimilars to ensure patient access and contain drug pricing. The generic and biosimilars industry has positioned itself as the solution to the challenge of skyrocketing health care costs.

In October, the Senate Health, Education, Labor and Pensions Committee, under the leadership of Senators Lamar Alexander (R-TN) and Patty Murray (D-WA), convened a hearing to explore why drug prices are so high.

AAM President and CEO Chip Davis provided the committee with an understanding of both the scope of generic drug and biosimilar savings for patients and how the respective generic drug and biosimilar business models are different from that of branded drugs. He explained to lawmakers that generics operate in a deflationary market, not an inflationary market. While brand-name drugs are able to keep increasing their prices because of their government-granted monopolies, generics are more like commodities. Hyper-competition in the generic drug market, combined with a limited number of buyers, drives down the cost of prescription drugs.

Demystifying the Drug Supply Chain

2017 was a year of congressional hearings exploring ways to address prescription drug costs. Generally, members of Congress expressed frustration with the entire ecosystem's finger-pointing and inability to present concrete recommendations to alleviate the burden on patients.

In December, AAM President and CEO Chip Davis testified before the U.S. House of Representatives Energy and Commerce Health Subcommittee and presented policy prescriptions that would increase generic and biosimilar competition – the one proven way to contain costs.

In our testimony, AAM stressed that competition can be enhanced by addressing the:

- Challenging market dynamics and reimbursement frameworks;
- Abuse of laws and regulations by bad actors; and,
- Failure of policy to account for the unique challenges facing generic and biosimilar medicines.



CHIP DAVIS (AAM)

Celebrating Access & Savings

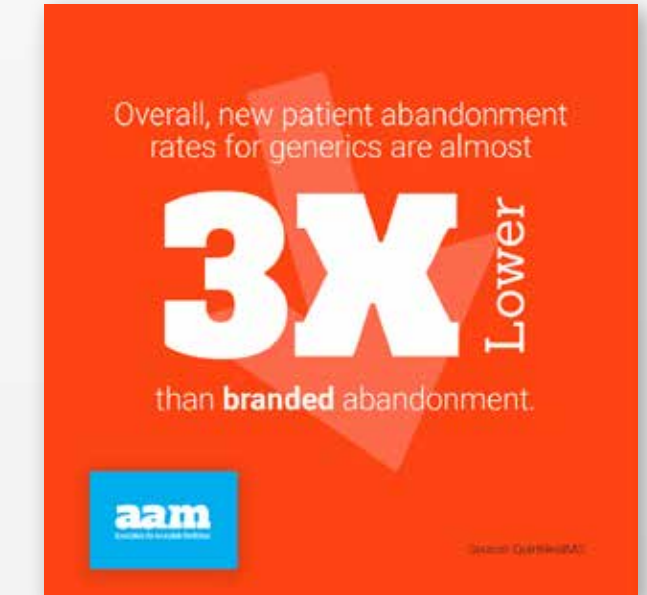
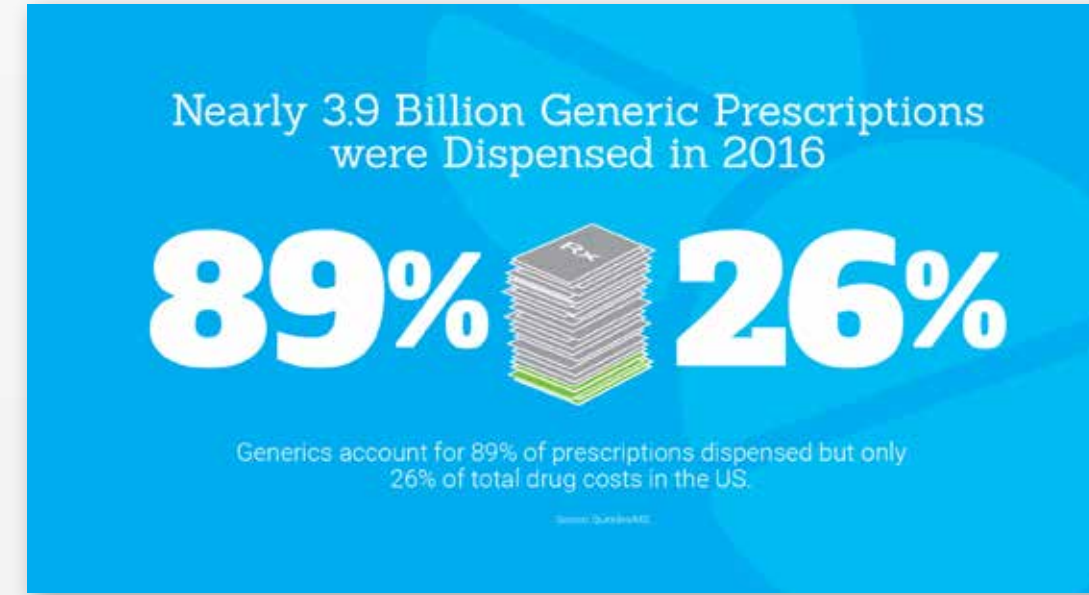
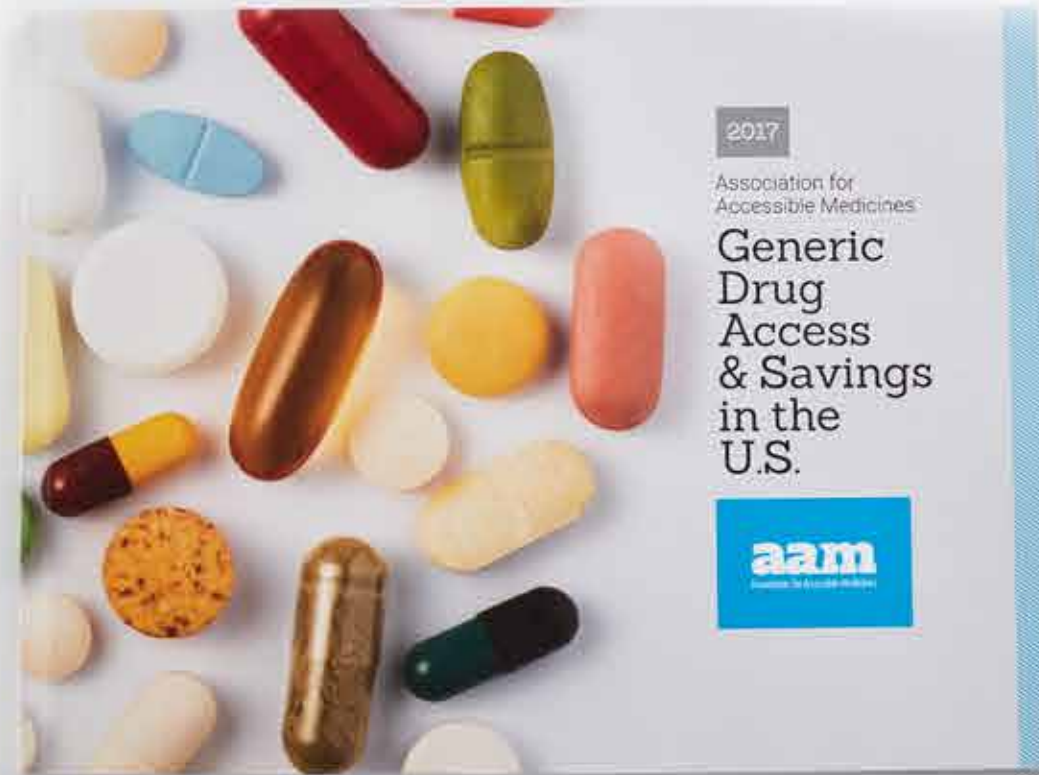
In the spring of 2017 AAM released a new version of our annual publication showcasing the vital role generics and biosimilars play in the nation's health care system. Rebranded *Generic Drug Access and Savings in the U.S.*, the report provided data quantifying both financial savings and patient access.

In short: savings generated from generic drugs continue to soar. Generic drugs have saved the U.S. health care system \$1.67 trillion in the last decade, generating \$253 billion in savings in 2016 alone.

Medicare savings amounted to \$77 billion (\$1,883 per enrollee) and Medicaid savings of \$37.9 billion (\$512 per enrollee). Generics account for 89 percent of prescriptions dispensed but only 26 percent of total drug costs in the U.S.

The report also highlighted state-by-state savings and generic savings by therapy area. Notably, the most savings from generic drugs were found in mental health (\$44 billion), hypertension (\$29 billion) and cholesterol (\$28 billion) treatments.

In addition to publishing online and sharing with the media, federal agencies and Capitol Hill offices, AAM mailed a bound version to state lawmakers across the country – providing many with their first understanding of the difference between brand and generic business models and supply chain dynamics.



Shining a Light on Abuse

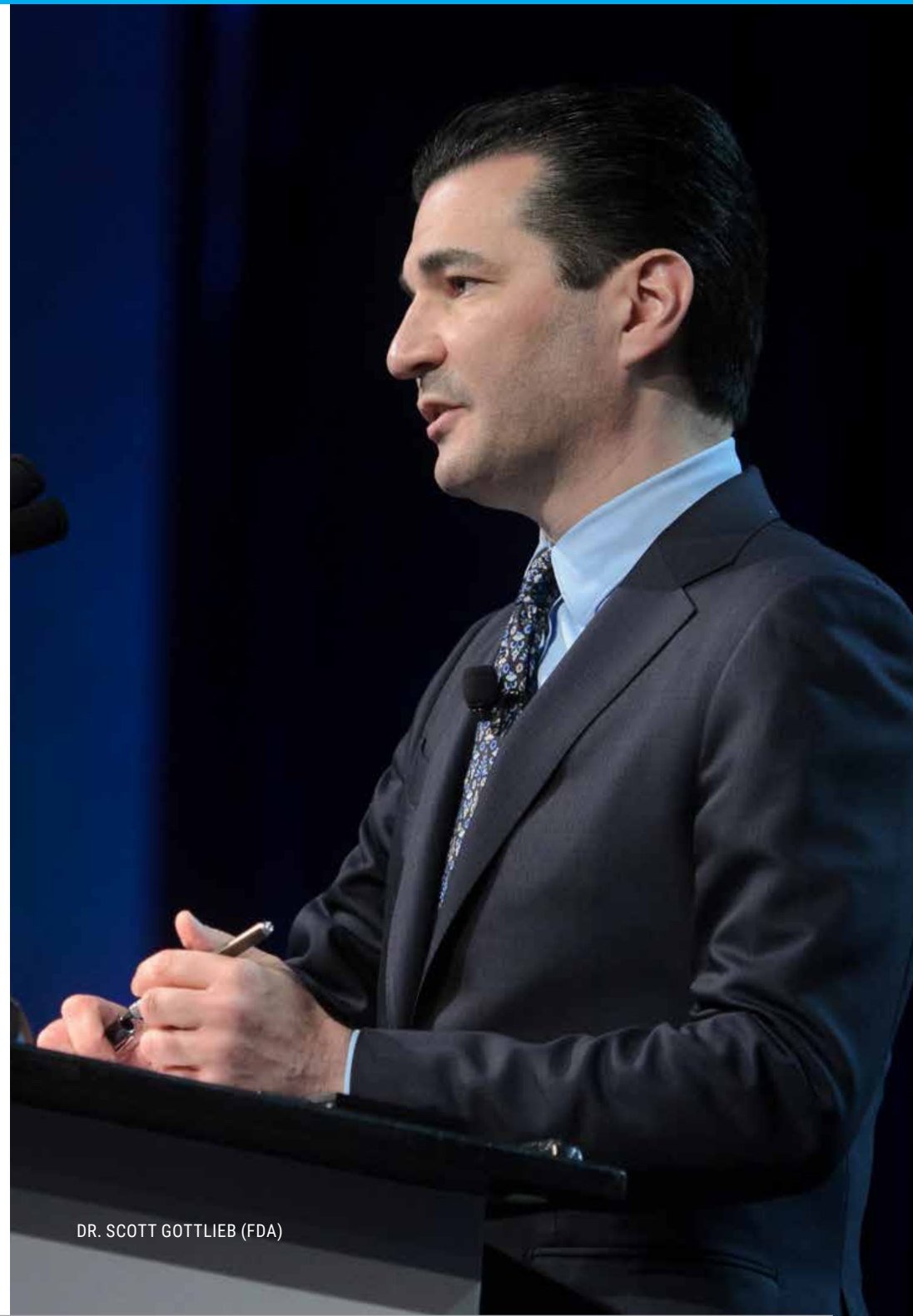
AAM promotes sustainable competition, which entails a balance between innovation and access. In 2017, we called attention to instances when brand-name manufacturers went too far to shield their monopoly position, undermining access and patient health. These machinations are systemic and intensifying. Exposing these practices and advocating for remedies is a priority for the association.

With amplified public concern over high drug prices, it is critical that policymakers understand the role anti-competitive tactics play in delaying patient access and artificially inflating costs.

One such abuse that AAM has elevated and inserted into the discourse from federal officials is the misuse of FDA's safety protections (so-called "REMS and restricted access" abuse). Certain brand companies are preventing generic and biosimilar manufacturers from purchasing the samples necessary to perform the testing and obtain FDA approval.

"My message is this: end the shenanigans. REMS abuse needs to stop. Drug makers' use of restrictive agreements with the pharmaceutical supply chain intermediaries, like specialty pharmacies, to frustrate or block the sale of branded drugs to a generic firm needs to stop. These tactics are unfair and exploitive practices, and they are in direct conflict to our broader public health goals. They frustrate the generic drug regulatory system that Congress created and that Americans depend on for FDA to execute."

FDA Commissioner Scott Gottlieb, M.D.



DR. SCOTT GOTTLIEB (FDA)



Championing the CREATES Act

Some brand drug manufacturers are taking advantage of loopholes in FDA safety programs to artificially extend their monopolies and keep generic or biosimilar versions of their products from coming to market.

In football terms, the referees would penalize a team for a "delay of game"; unfortunately, in this game, no penalty is ever called and patients continue to pay the high price of these branded drugs. In response to manufacturers' blocking access, AAM worked tirelessly to build support in Congress, with patient groups and the media and among employers for the Creating and Restoring Equal Access to Equivalent Samples

(CREATES) Act. This bill allows a generic drug or biosimilar manufacturer to obtain access to samples by closing regulatory loopholes and including penalties should brand companies fail to comply.

The broad base of support from across the political spectrum reflects the unimpeachable merits of the bill's approach to remedying this anti-competitive abuse that hampers generic and biosimilar drug makers and hurts patients. AAM will continue to advocate for the bill's passage while fighting off attempts by branded pharma to derail the legislation.

Opposing “Shenanigans”

In September, Allergan, the maker of Restasis, adopted an unprecedented strategy: it paid the St. Regis Mohawk Tribe millions of dollars to rent its tribal sovereign immunity in a blatant effort to shield the patents on Restasis from review. The maneuver deservedly attracted attention in the media and a broad group of members of Congress on a bipartisan basis.

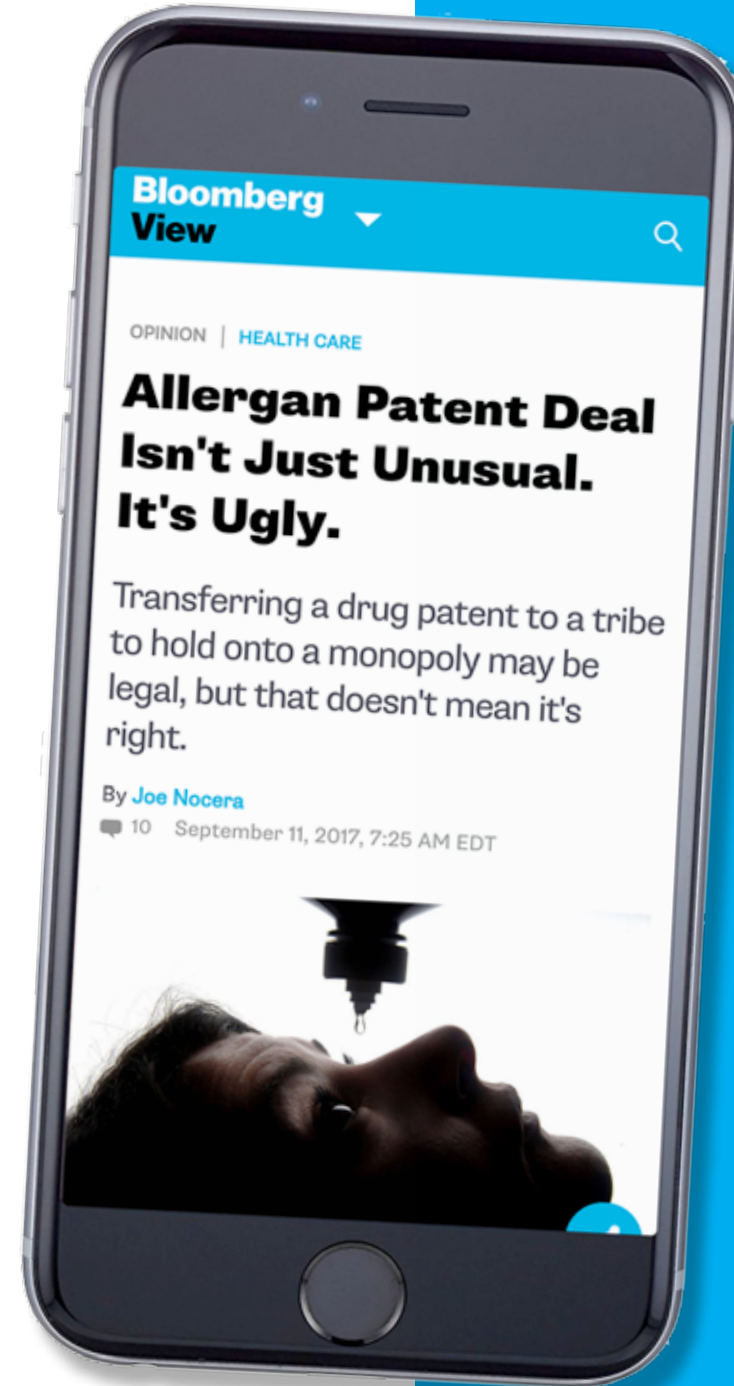
Allergan tried to escape review of its patents under the America Invents Act’s inter partes review (IPR) procedures, which apply equally to all patent holders. The goal of the IPR process is simple: to make sure that patents were properly granted in the first place.

Through legal briefs and on Capitol Hill, AAM stressed that the ramifications of Allergan’s novel use of sovereign immunity go beyond the pharmaceutical industry, potentially sabotaging IPR in every field of innovation.

Our industry believes true innovation deserves patent protection. The IPR system shields patients from attempts by some brand-name companies to maintain monopoly drug prices for years longer than Congress intended by patenting non-innovative features of their drugs.

We have made it clear that Allergan’s ploy jeopardizes the patent system overall and cannot be tolerated.

See more on this issue at www.stoprxpatentabuse.com.



Allergan's Mohawk Patent Defense Strategy Is Eyewash, Court Rules ~Fortune

Patents for Restasis Are Invalidated, Opening Door to Generics ~The New York Times

Senators question Allergan CEO on tribe patent deal ~ CNBC

Drug maker gives Mohawk Tribe patent in new strategy to protect profits ~ Burlington Free Press

Allergan deal with Mohawk tribe casts patent shadow ~Financial Times

Confronting Medicaid Generics Penalty

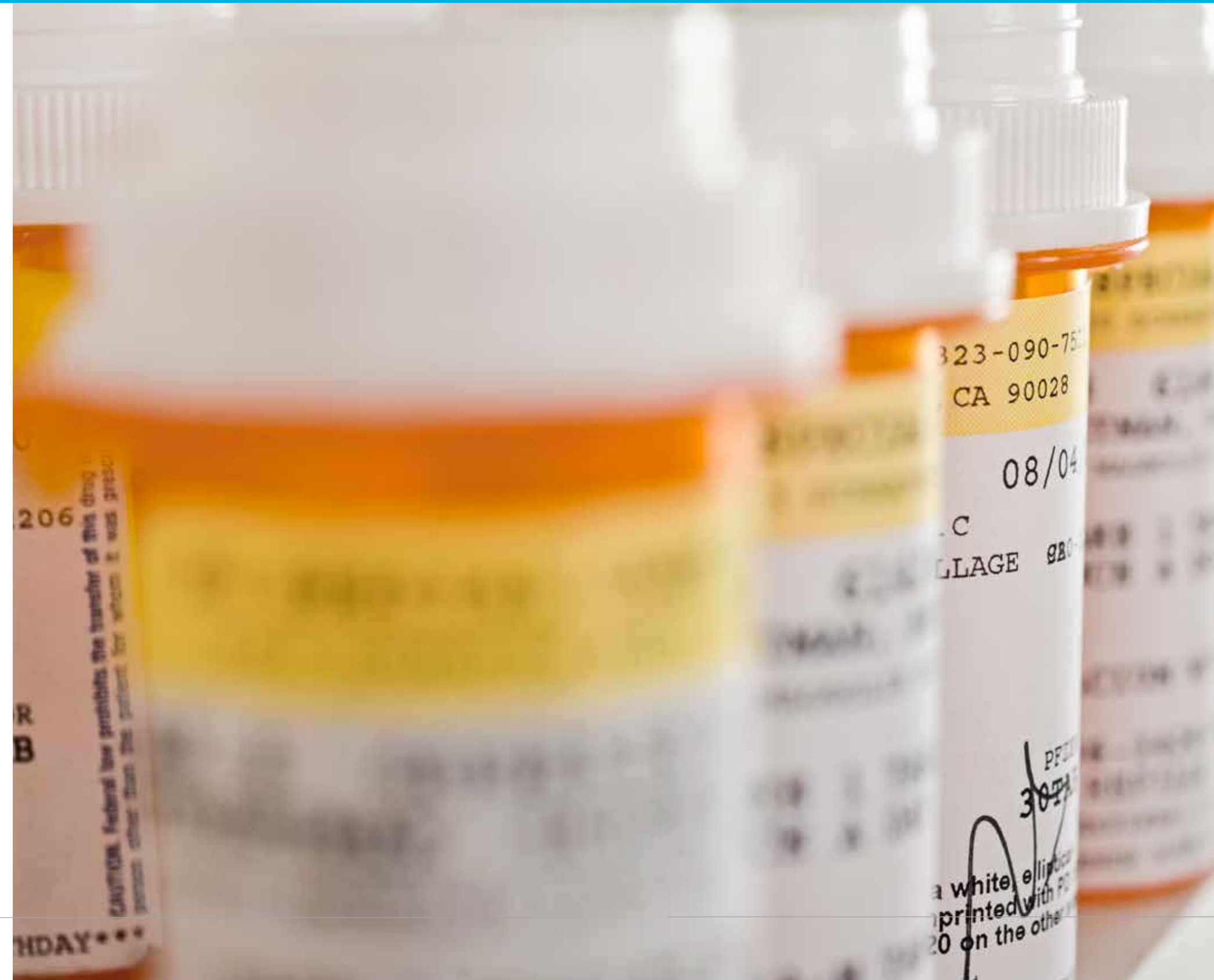
The Medicaid Generics Penalty is paid by generic drug manufacturers when the Average Manufacturer Price (AMP) of a generic drug sold to Medicaid rises faster than the Consumer Price Index over a three-month period. It is a policy that was designed for the brand industry but misapplied to generics.

Through direct advocacy with federal agencies and on Capitol Hill and through broader channels including social and traditional media, AAM worked throughout the year to try to roll back this little-understood provision that hurts Medicaid participants — the most vulnerable among us — and impedes access to affordable medicines for all patients.

The association commissioned the respected consulting firm Bates-White to prepare a white paper that quantified the economic impact of the Medicaid Generics Penalty, which AAM shared widely with all stakeholder groups as part of its ongoing effort to reverse this ill-conceived policy.

“The imposition of [consumer price index] penalties is likely to reduce competition in generic drug markets, lead to fewer companies competing in the market and increase the likelihood of shortages.”

Bates-White Economic Consulting



Countering State “Transparency” Legislation

In 2017, states across the country sought to fill what they felt was a void left by the federal government with regard to drug pricing oversight.

By August, 30 states had drafted or introduced drug price transparency legislation attempting to identify the costs contributing to manufacturer expenses and list prices. Needing to address the spate of bills and recognizing this activity would only intensify, AAM expanded our state advocacy efforts.

To educate lawmakers and key thought leaders around the country about what makes the generic industry unique and invaluable to patients in their states, the association added a number of experienced lobbyists to our state team and launched aggressive media outreach and a sophisticated marketing effort.

While the majority of bills were neutralized, California enacted a transparency law requiring a 60-day notification of price increases over a specified pricing threshold and mandating that health plans report the percentage of premiums spent on prescription drugs. A bellwether state, California has emboldened other states to introduce similar bills.



Challenging the State of Maryland

2017 saw the introduction of “price gouging” legislation around the country. The most notable of these efforts was in Maryland where the legislature passed a bill purportedly designed to protect its citizens from egregious drug price increases. The bill’s flaws are manifest:

- While branded drugs are responsible for three-quarters of patient costs, the bill applies only to generics and off-patent medicines;
- Vague language, including “not justified” and “excessive,” make it impossible for companies to know if they are breaking the law.
- In violation of the Commerce Clause of the Constitution, the bill regulates transactions occurring outside the state of Maryland.

AAM explained to Maryland Governor Larry Hogan that generic companies would risk prosecution for taking actions that normally occur during the course of business in the competitive free market. Although Governor Hogan refused to sign it, the law took effect in fall 2017 regardless.

Price gouging – the target of the Maryland law and others being considered across the nation – is unacceptable, but we must employ sound public policy to both weed out bad apples and enhance a market where they cannot take seed.

AAM is challenging Maryland’s new law in court. With other states considering similar poorly conceived price gouging legislation aimed at generic drug makers, the association will continue to pursue all legal and advocacy options to prevail on behalf of patients and the industry.

The U.S. Congress last year provided the FDA authority to incentivize generic companies to bring competitors to market, including in instances when there is an older, off-patent brand-name drug, like Daraprim, exploiting its “sole source” status with predatory pricing. This is an approach with promise, because it recognizes that generic drug competition is the most effective method of bringing down prescription drug prices.



CHRISTINE SIMMON (AAM)



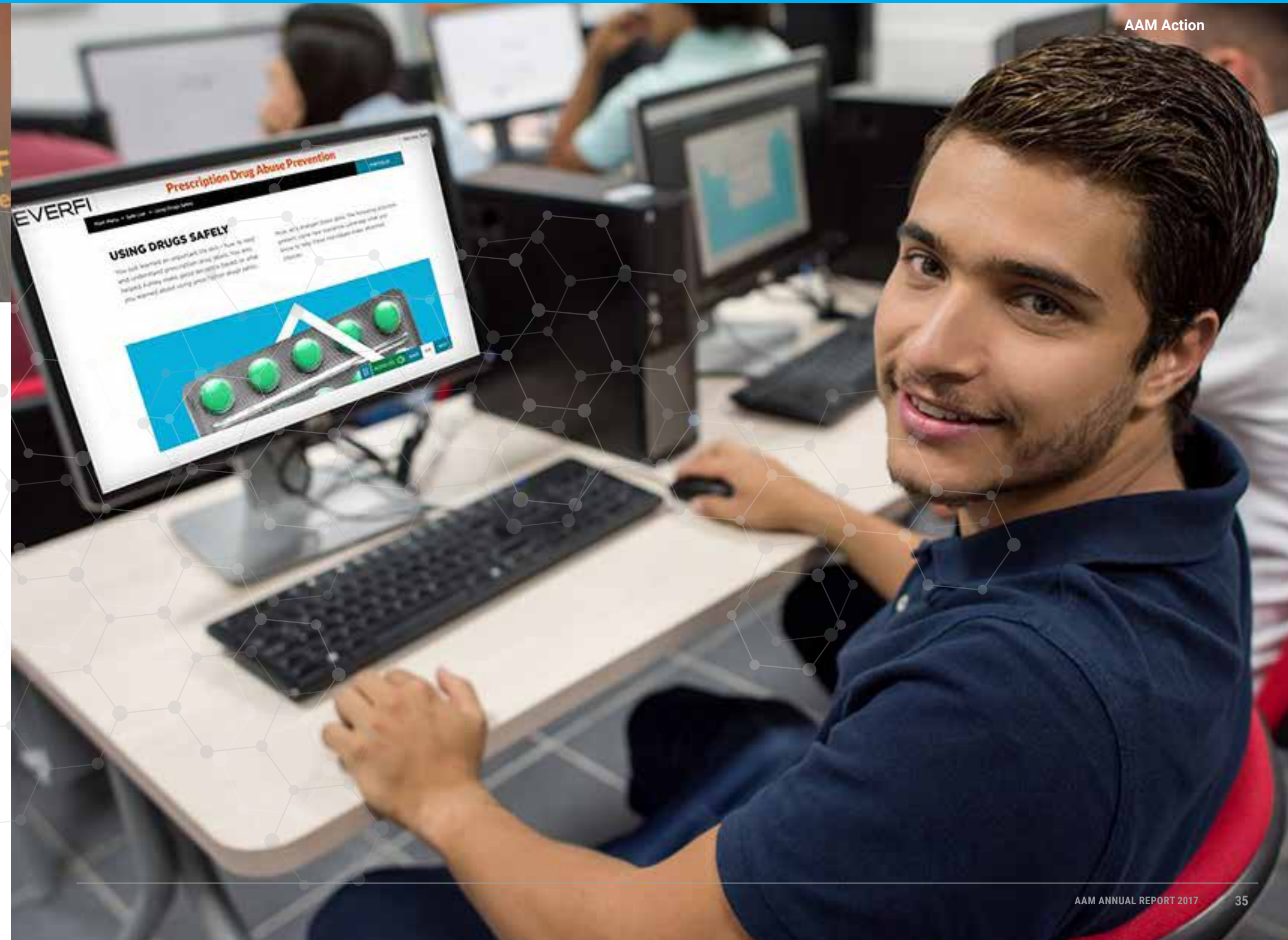
Launching an Education Program on Opioid Abuse

In 2017, AAM asked the education-technology company EVERFI to develop a program to help students understand the safe use, storage and disposal of prescription drugs.

With AAM's financial support, EVERFI, the leading provider of alcohol abuse and sexual assault prevention training for U.S. higher education, is making this prescription drug abuse prevention curriculum available for free to any college or university in the country. The evidence-based prevention approach of EVERFI's program was adopted in the final report of the President's Commission on Combating Drug Addiction and the Opioid Crisis.

More than 35,000 students have already taken the course and we are working with EVERFI to increase utilization nationally among college students.

AAM is also working with EVERFI, Walmart, the U.S. Chamber of Commerce Foundation and other partners to make a prescription drug abuse prevention program geared to younger students available to K-12 schools in the hardest-hit communities in our country.



Access! 2017

In February, more than 700 generic and biosimilar executives, industry professionals and, for the first time, representatives of patient advocacy groups, gathered in Orlando for Access! 2017.

AAM gave attendees the first look at the patient-centered **Medicines Within Reach** campaign telling the story of the millions of patients whose health and lives have been improved and saved through access to generic medicines. Captain “Sully” Sullenberger inspired attendees to aspire to new levels of excellence in life and business with his keynote remarks, **208 Seconds: A Lifetime of Lessons**.

Meanwhile, AAM celebrated notable individuals who have expanded access to medicines, bestowing a Champions of Access Award on National Consumers League (NCL) Executive Director Sally Greenberg in recognition of NCL’s unwavering commitment to ensuring that patients and consumers get the lifesaving and life-sustaining medicines they need. And the award was posthumously bestowed on Richard Egosi, executive vice president, chief legal officer and company secretary for Teva Pharmaceuticals.



Fall Tech

In November, AAM's Fall Tech Conference focused on ANDA review, GDUFA II enhancements, drug pricing, bioequivalence and data integrity.

The conference brought together industry leaders and decision-makers, including FDA Commissioner Scott Gottlieb, M.D., who outlined the Drug Competition Action Plan and declared, "I think this is a win-win. What's good for the generic drug industry and policies we are trying to craft is especially good for consumers."

AAM President and CEO Chip Davis delivered a State of the Industry Address, highlighting the progress being made toward prescription drug accessibility while recognizing threats from well-intentioned but misguided legislation and anti-competitive practices from some brand-name drug companies.

tech ence 2017



FALL TECH 2017

Leading on Biosimilars

In September, AAM and its Biosimilars Council held a conference featuring presentations from key industry leaders, U.S. government agency officials and academic experts regarding the dynamic landscape of the biosimilars industry.

Medicines for Europe Director General Adrian van den Hoven provided insight into the European experience with biosimilars and lessons U.S. biosimilars market stakeholders can use to maximize access for patients. A panel on **Market Access, Market Promise** focused on barriers biosimilars manufacturers face when trying to enter the U.S. market, including anti-competitive tactics used by brand manufacturers and reaction of the federal government and biosimilars industry.

Patient advocates from the Crohn's & Colitis Foundation, CancerCare, the Black Women's Health Imperative and the Cancer Support Community shared lessons learned from outreach efforts and gave their perspective on how to best inform patients and families about the promise of biosimilars.



DAVID GAUGH (AAM)

CMC

In May, AAM held a Chemistry, Manufacturing & Controls workshop to help participants stay on top of the latest developments in this field. FDA Office of Product Quality (OPQ) Director Michael Kopcha, Ph.D., R.Ph., delivered the keynote address.

Sessions focused on OPQ's life cycle approaches, first cycle approvals and quality metrics, along with an "Industry Corner," which presented case studies on topics including drug-device combination products and active pharmaceutical ingredient starting material.



MARIA-TERESA GUTIERREZ-LUGO (FDA)

GRx+Biosims

AAM listened to our members and conference attendees and has created the ultimate event for the industry. We combined all our conferences — with the exception of the annual meeting — into the single best opportunity to hear directly from government officials, learn best practices and connect with peers in the generic and biosimilars industry.

GRx+Biosims is the name of the combined event. The program will be comprehensive and the speakers are the top in their field. Whatever your interests, you will find what you need at GRx+Biosims.

With science, policy and the market in constant flux, it is critical to come together as an industry to “engineer the future of generic and biosimilar medicines.” AAM and The Biosimilars Council look forward to your joining us.

Visit accessiblemeds.org/events for more information.

GRx+Biosims

Engineering the Future of Generic + Biosimilar Medicines

Join us on **September 17-19, 2018** in Baltimore, MD
accessiblemeds.org/events



Join Today

Powerful Together

Together, AAM's membership convenes for meetings, workshops, networking and education throughout the year. The association's daily newsletter, analysis and reporting keeps members current on issues, policies and market trends affecting our industry.

Together, we're more powerful. With a seat at the table alongside the nation's top decision-makers, we work to achieve a viable and sustainable marketplace.

Together, we assure access to safe, quality, effective medicines for patients. We hope you will join us.

AAM membership is company based; we do not offer individual memberships. **Contact us at info@accessiblemeds.org to learn more.**



"AAM is my go-to source for information about the policies affecting our business and our industry. I rely on AAM to help keep me on top of what's happening in the generic sector."

Steven Giuli, Vice President of Government Affairs & Trade Relations, Apotex Corporation

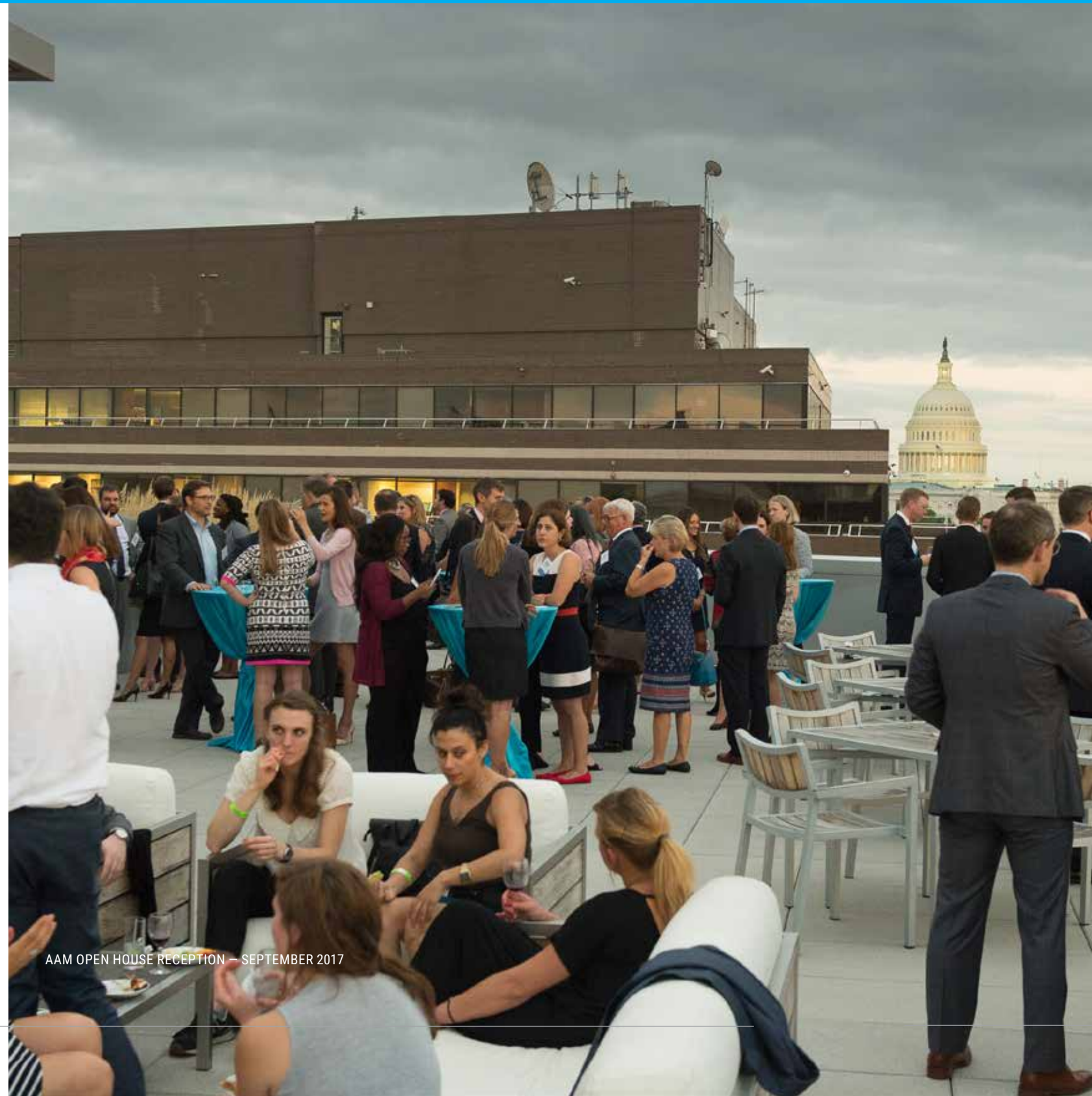


"As members of AAM, we are able to amplify our influence and increase our share of voice in shaping our industry's future."

Nimish Shah, Vice President, Federal Government Relations, Mylan, N.V.

2017 AAM Regular Members

3M HEALTH CARE BUSINESS
 ACCORD HEALTHCARE INC.
 ALVOGEN, INC.
 AMNEAL PHARMACEUTICALS LLC
 APOTEX CORPORATION
 ARGENTUM PHARMACEUTICALS, LLC
 AUROBINDO PHARMA USA, INC.
 BAXTER HEALTHCARE CORPORATION
 CIPLA USA INC.
 DR. REDDY'S LABORATORIES INC.
 FRESENIUS KABI USA, LLC
 GLENMARK PHARMACEUTICALS INC., USA
 LUITPOLD PHARMACEUTICALS, INC.
 LUPIN PHARMACEUTICALS, INC.
 MAYNE PHARMA GROUP LIMITED
 MOMENTA PHARMACEUTICALS, INC.
 MYLAN, N. V.
 SAGENT PHARMACEUTICALS, INC.
 SANDOZ INC., A NOVARTIS DIVISION
 SUN PHARMACEUTICAL INDUSTRIES, INC.
 TEVA PHARMACEUTICALS USA
 VIRTUS PHARMACEUTICAL, LLC
 WESTWARD PHARMACEUTICALS - A HIKMA COMPANY.
 ZYDUS PHARMACEUTICALS, INC.



AAM OPEN HOUSE RECEPTION — SEPTEMBER 2017

2017 AAM Associate Members

ACETO CORPORATION
 ACIC
 AMERISOURCEBERGEN
 BAKER DONELSON
 BEIJING SUNHO PHARMACEUTICAL CO., LTD.
 CAPSUGEL
 CARDINAL HEALTH
 CVS/CAREMARK
 CHEMWERTH, INC.
 COLORCON, INC.
 DIRECT RELIEF
 DISPENSARY OF HOPE
 DSQUARED PHARMACEUTICALS INC.
 ECONDISC CONTRACTING SOLUTIONS, LLC
 GEDEON RICHTER USA INC.
 GREENBLUM & BERNSTEIN, P.L.C.
 GYMA LABORATORIES OF AMERICA, INC.
 HAYNES AND BOONE, LLP

HUSCH BLACKWELL LLP
 INNOPHARMA LABS
 INTERCHEM CORPORATION USA
 IPG PHARMACEUTICALS INC.
 JOHNSON MATTHEY PHARMACEUTICAL MATERIALS
 KNOBBE MARTENS
 LACHMAN CONSULTANTS
 MIDAS PHARMACEUTICALS, INC.
 NEW CHEMIC (US) INC.
 NOVUM PHARMACEUTICAL RESEARCH SERVICES
 REN-PHARM INTERNATIONAL, LTD.
 RT SPECIALTY
 SOVEREIGN PHARMACEUTICALS, LLC
 SPEAR PHARMACEUTICALS
 SYMBIO LLC
 WALGREEN COMPANY
 WEST PHARMACEUTICAL SERVICES, INC.

Contact Us



General Information

Association for Accessible Medicines
601 New Jersey Avenue, NW
Washington, DC 20001
202-249-7100 Fax 202-249-7105
info@accessiblemeds.org



Biosimilars

Joseph Stewart
joseph.stewart@accessiblemeds.org
202-249-7136



Conferences & Event Registration/Sponsorship

Jennifer Soup
jennifer.soup@accessiblemeds.org
202-249-7127



Daily eDigest

Jewel Smith
jewel.smith@accessiblemeds.org
202-249-7108



Membership

Jewel Smith
jewel.smith@accessiblemeds.org
202-249-7108



Press Inquiries

Rachel Schwartz
rachel.schwartz@accessiblemeds.org
202-249-7147



Reports & Publications

Allen Goldberg
allen.goldberg@accessiblemeds.org
202-249-7110



Social Media

Erica Klinger
erica.klinger@accessiblemeds.org
202-249-7134

accessiblemeds.org



/accessiblemeds



TM



accessiblemeds.org

©2018 Association for Accessible Medicines.

AAMAF2017-012418