DEAR SUPPORTERS:

With your continued support, the Alliance for Patient Access and Institute for Patient Access have experienced unprecedented growth in 2015. Now in its ninth year, AfPA enjoys the support of over 700 physicians and health care providers. IfPA has expanded its capacity to inform the public about pivotal health policy access issues. And as AfPA and IfPA continue to communicate how the physician-patient relationship drives quality health care, they target an increasing range of issues areas with innovative educational resources.

New Issue Areas & Working Groups

This year, AfPA stepped up to meet the growing need for advocacy in the areas of patient access to hepatitis and respiratory therapies by creating two new working groups. The Hepatitis Therapy Access Physicians Working Group convened its first two meetings, identified group leadership, and issued its first white paper and policy video. The Respiratory Therapy Access Physicians Working Group held its inaugural meeting in November to identify key challenges for its health care providers and their patients. Both groups look forward to continued growth in 2016.

The Global Alliance for Patient Access extended its scope to encompass advocacy efforts in Latin America, Europe, Australia, and Asia. While continuing to address patient access challenges related to biological therapies, GAfPA also initiated advocacy efforts for oncology and pain management therapies.

AfPA assumed leadership of the National Coalition for Infant Health, formerly the National Premature Infant Health Coalition. Under AfPA, the coalition has benefitted from the leadership of a new medical director, initiated a series of educational policy briefs, and held an incredibly successful national policy summit.

New Online Resources

AfPA introduced two new online resources to support patient access education and advocacy. Prescription Process is a comprehensive online center for education, legislative tracking, and advocacy related to the challenges patients face in accessing their prescription medications. SurveyHub provides a repository of attitudinal research on patient, physician, and public opinions regarding health care access. Both websites supplement and support AfPA’s broad base of advocacy efforts.

New Advocacy & Education Offerings

Finally, AfPA and IfPA continue to explore innovative ways to educate and advocate. This year AfPA expanded its video education offerings to include white board, or “quick draw”, videos. These complement AfPA’s traditional videos by taking a brief, straightforward look at specific policy challenges such as step therapy, biosimilar substitution, medication labeling, and clinical pathways.

IfPA took a bold step in co-sponsoring the 2015 Preemie Matters National Policy Summit. The event brought together members of Congress, advocates, parents, health care providers, and industry representatives to explore the health care needs of preterm infants and their families. The event’s success opened a new and valuable avenue for advocacy.

With this annual report, we mark the achievements of 2015 and express our sincere appreciation for stakeholders, health care providers, and advocacy partners who helped make 2015 a year of progress toward our continued goal: patient access to approved medical therapies and appropriate clinical care.

Sincerely,

Brian Kennedy
Executive Director

David Charles, MD
National Chairman
2015 BY THE NUMBERS

700+ AfPA members

9 policy briefs

42,825 2015 YouTube video views

603 Facebook friends

632 Twitter followers

44 states represented by AfPA members

37 competencies represented by AfPA members

1,401 e-newsletter recipients

18 events and meetings sponsored

41 physician legislators in AfPA’s Health Policy Council

47 congressional champion awards presented

5 working groups

3 continents on which AfPA/GAfPA produced programming

105 blog postings
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DISTINCT MEDICINES NEED DISTINCT NAMES
INFORMED PRESCRIBING REQUIRES TRANSPARENT LABELING
COMMUNICATION PROTECTS PATIENTS—AND THE PHYSICIAN-PATIENT RELATIONSHIP
MESSAGE: DISTINCT MEDICINES NEED DISTINCT NAMES

“Distinct names help physicians and regulators track adverse responses. Physicians and patients must know with certainty which medication was taken—the original biologic or the biosimilar.”
“Congress’ vision—patient access to biosimilars—will come to fruition only if physicians have confidence in prescribing these medications. To instill that confidence, regulators must put into place standards that prioritize transparency and safety.”

MESSAGE: INFORMED PRESCRIBING REQUIRES TRANSPARENT LABELING

UNRESOLVED POLICY ISSUES IMPACT PATIENT ACCESS TO BIOSIMILARS

BIOLOGICS

TRANSPARENT BIOSIMILAR LABELING

BASIC IDENTIFICATION
Prescribing information should indicate if the medication is a biosimilar.

STUDY SOURCE
Prescribing information should indicate whether each study was conducted with the biosimilar or original biologic.

TESTING DATA
Prescribing information should include data from studies with the biosimilar.

TESTING GROUPS & DISEASE STATES
Prescribing information should specify the patient groups and disease states in which the biosimilar was tested.
Using the original biologic’s prescribing information for a biosimilar is an approach that lacks transparency. It fails to provide physicians with full information about the biosimilar, even though physicians are responsible for prescribing the medication and treating adverse side effects that may result.

The approval of biosimilars is an important step toward improving patient access to medical therapies. With complete and transparent data about these medications, physicians can have the information they need to give patients the best care possible.

CMS’ recently proposed rule approaches biosimilar coding as it would with conventional medications and their generic counterparts. The strategy ignores subtle differences between biologics and biosimilars, as well as the challenges of potential immune responses from patients taking biological medications.
“…As more biosimilar medicines become available, most patients will want their doctor—not their pharmacist—deciding which medication is right for them. At the very least, they’ll want their doctor to know which medication they’re taking.”

“Ultimately, this legislation is about protecting the physician-patient relationship, because physicians need accurate information to monitor patients’ progress with disease progression and medication side effects to direct treatment.”

“With communication provisions in place, physicians can have confidence they know which biologic medicine their patient is taking.”
2 PAIN

MULTI-FACETED PAIN REQUIRES MULTI-PRONG TREATMENT

PROTECTING ACCESS WHILE CURBING ABUSE
MESSAGE: MULTI-FACETED PAIN REQUIRES MULTI-PRONG TREATMENT

Integrated Care Addresses the Multiple Features of Chronic Pain

Pain is multifaceted. So is its treatment.

TREATMENT
- Occupational therapy
- Anti-depressant medications

SYMPTOMS
- Physical therapy
- Psychological therapies
- Exercise
- Medications

CHRONIC PAIN
- Occupational challenges
- Physical pain
- Sleep disturbances
- Psychological challenges
- Anxiety
- Depression

“The effectiveness of integrated care, combined with the complex and multifaceted nature of chronic pain, challenges the medical community to implement a more comprehensive and balanced approach to chronic pain management.”

ACCESS TO INTEGRATED CARE FOR CHRONIC PAIN

Institute for Patient Access

Alliance For Patient Access: Annual Report 2015
MESSAGE: PROTECTING ACCESS WHILE CURBING ABUSE

“For this new technology to help reduce prescription opioid abuse, it must be available to the patients who need it.”

“A PRESCRIPTION FOR REDUCING OPIOID ABUSE

“Several states have passed or are considering legislation to encourage the use of abuse-deterrent medications.”

E-BRIEF

THE PAIN DEBATE

Health Policy Council
Without access abuse-deterrent pain medications can’t help the patients who need them.

"Crackdowns on so-called pill mills—pain management centers where financially motivated physicians over prescribe opioid pain medications—are designed to reduce abuse and overdoses. But in several states, these efforts are impeding access for patients with a legitimate medical need for pain management."
ONCOLOGY

BURDENSOME COST-SHARING UNDERCUTS CANCER CARE
BREAKTHROUGH THERAPIES PRESENT ACCESS CHALLENGES
COST-FOCUSED PATHWAYS HINDER INDIVIDUALIZED CARE
DO VALUE MODELS REFLECT PATIENTS’ VALUES?
MESSAGE: BURDENSOME COST-SHARING UNDERCUTS CANCER CARE

“Specialty tier medications may include treatments for cancer, multiple sclerosis, psoriasis, kidney disease and other life-threatening or debilitating diseases. These medications, like oral medicines for cancer, may cost a patient between 25 to 50 percent of the total cost of the drug...patients could...pay thousands of dollars each year for their medication.”
**MESSAGE: BREAKTHROUGH THERAPIES PRESENT ACCESS CHALLENGES**

“Clinical studies showing that immuno-oncology can help some patients with advanced cancer who don’t respond to other treatments have excited researchers, patients, and healthcare providers alike.”

Alan Marks, MD

**MESSAGE: COST-FOCUSED PATHWAYS HINDER INDIVIDUALIZED CARE**

“When clinical pathways prioritize cost-savings instead of individual patients, they can have an unpleasant result: a one-size-fits-all approach to patient care.”
MESSAGE: DO VALUE MODELS REFLECT PATIENTS’ VALUES?

INFOGRAPHIC

The Centers for Medicare & Medicaid Services’ ONCOLOGY CARE MODEL

CAUTION

This model could Create Access Challenges
The required savings margins may compel physicians to cherry pick patients, avoiding the costliest and most severe cases.

This model could Pose Barriers to Breakthrough Medicines
Pressured to reduce expenses, physicians may stick with lower-cost drugs, even if a patient might benefit from a newer, more expensive option.

This model could Reduce Transparency
Rewarding physicians for keeping patient care costs low may introduce distrust into the physician-patient relationship.

This model could Overlook Patient Values
CMS’ definition of value may not reflect that of patients, who often prioritize quality of life and choice in care.

LEARN MORE
“ASCO’s value framework... acknowledges the importance of the physician-patient relationship, though some stakeholders question whether it adequately reflects patients’ experiences and needs.”

“The [National Comprehensive Cancer Network] blocks score blood cancer therapies on a scale of one to five... But the approach overlooks a key factor—whether out-of-pocket costs allows for patients to access these medications in the first place.”

“We might consider not just what such a model will save—but what it might cost in the form of a redefined approach to cancer care.”
4 HEPATITIS

CARE RATIONING BLOCKS PATIENT ACCESS
LENGTHY PRIOR AUTHORIZATIONS DELAY VITAL TREATMENT
MESSAGE: CARE RATIONING BLOCKS PATIENT ACCESS

1 IN 4 PATIENTS INITIALLY DENIED TREATMENT

INFOGRAPHIC

WHICH PATIENTS ARE SICK ENOUGH FOR A HEPATITIS C CURE?

3.2 MILLION
Americans have Hepatitis C.

Stage 1  Stage 2  Stage 3  Stage 4

Under many health plans, only the sickest can receive the cure they need.

KEY FINDINGS

Of patients prescribed sofosbuvir/ledipasvir to cure them of hepatitis C:

• 77% received initial approval; About 23% received initial rejection
• Nearly 14% of those initially rejected did receive treatment through the appeals process
• Patients had to wait an average of 26 days for a final approval or rejection decision on coverage

Yale University School of Medicine, August 2015
“...As state and federal governments struggle to balance the limits of their budget with the needs of their patient population, hepatitis patients are fighting for access—with varied success.”

“Curing hepatitis C before senior citizens age into Medicare could save tens of thousands of lives. And as a new study from Milliman reports, it could also save the Medicare system $3.9 billion over 10 years.”

MESSAGE: LENGTHY PRIOR AUTHORIZATIONS DELAY VITAL TREATMENT
“The Centers for Medicare and Medicaid Services has a message for state Medicaid programs: coverage policies cannot block hepatitis C patients’ access to ‘effective, clinically appropriate and medically necessary treatments.’”

“My patients don’t want to wait until they have advanced liver disease to be cured of hepatitis C, and many have not responded or failed treatment due to side effects of the older treatments.”

“Some patients will need to qualify through an extensive prior authorization process to get their medication. Such processes can include over a dozen individual requirements.”
ADVOCACY INITIATIVES OF AfPA & IFPA

5 CLINICAL TRIALS AWARENESS
INFANT HEALTH
RESPIRATORY ACCESS
BARRIERS TO PATIENT ACCESS
“Breakthrough medicines have the potential to treat cancer, Alzheimer’s, heart disease and many other conditions. But without participants joining clinical trials, these treatments never become available to patients.”
“Given the similarities between organ donation and clinical trials, a campaign similar to the organ donation initiative would likely be effective in promoting clinical trials awareness and participation.”
The Preemie Matters summit provided a solid foundation for a national strategy to guide the coalition in educating policymakers, the public, and media on issues regarding access and appropriate clinical standards. It was a success thanks to our expert panelists, informed speakers and engaged attendees.”

Mitchell Goldstein, M.D., Medical Director, National Coalition for Infant Health
“For many Americans with respiratory conditions, the struggle to breathe is now exacerbated by the struggle to pay out-of-pocket expenses for the medications that alleviate their symptoms.”

“...The recommendation would virtually eliminate the short, self-administered questionnaires now used in clinical settings throughout the country. Such questionnaires currently aid physicians in identifying patients who need follow-up and further testing, which can help especially with patients unfamiliar with COPD symptoms.”

KEY FINDINGS

• 32% patients reported that their severe asthma negatively affected their social life
• 23% patients reported it affected their work life
• 18% patients reported it affected their family life
“Non-medical switching does not just ignore the process physicians and patients underwent to find a successful medical therapy. It also disregards the impact of switching medications arbitrarily.”
Lacking cost-sharing details can be worse than inconvenient. For patients who depend upon medication to sustain quality of life—or life itself—surprise out-of-pocket costs could put vital medications out of reach.

50% $$$$$$$
50% Medicare beneficiaries with cancer spend more than 10% of their income on out-of-pocket health care costs.

2.65x
Cancer patients were 2.65 times more likely to go bankrupt than people without cancer.

28% $$$$$$$
28% patients spend more than 20%.

70%
Patients with higher co-payments ($53 or more) were 70% more likely to discontinue therapy in the first six months of treatment.

$4,800
The average amount that an insured cancer patient pays out of pocket per year is $4,800.

1999 196% 2013
Between 1999 and 2013, patients’ share of premiums has increased by 196%. Deductibles have almost doubled.

When cost-sharing turns toxic, patients may fall into nonadherence—spacing out chemotherapy appointments, delaying care, declining diagnostic procedures, and replacing prescription therapies with over-the-counter medications.

“Lacking cost-sharing details can be worse than inconvenient. For patients who depend upon medication to sustain quality of life—or life itself—surprise out-of-pocket costs could put vital medications out of reach.”
“Despite their years of medical training, doctors’ judgment—and the doctor-patient relationship—are being undermined by step therapy.”

“Sometimes the patients who need the drugs the most can’t access them because of cost.”