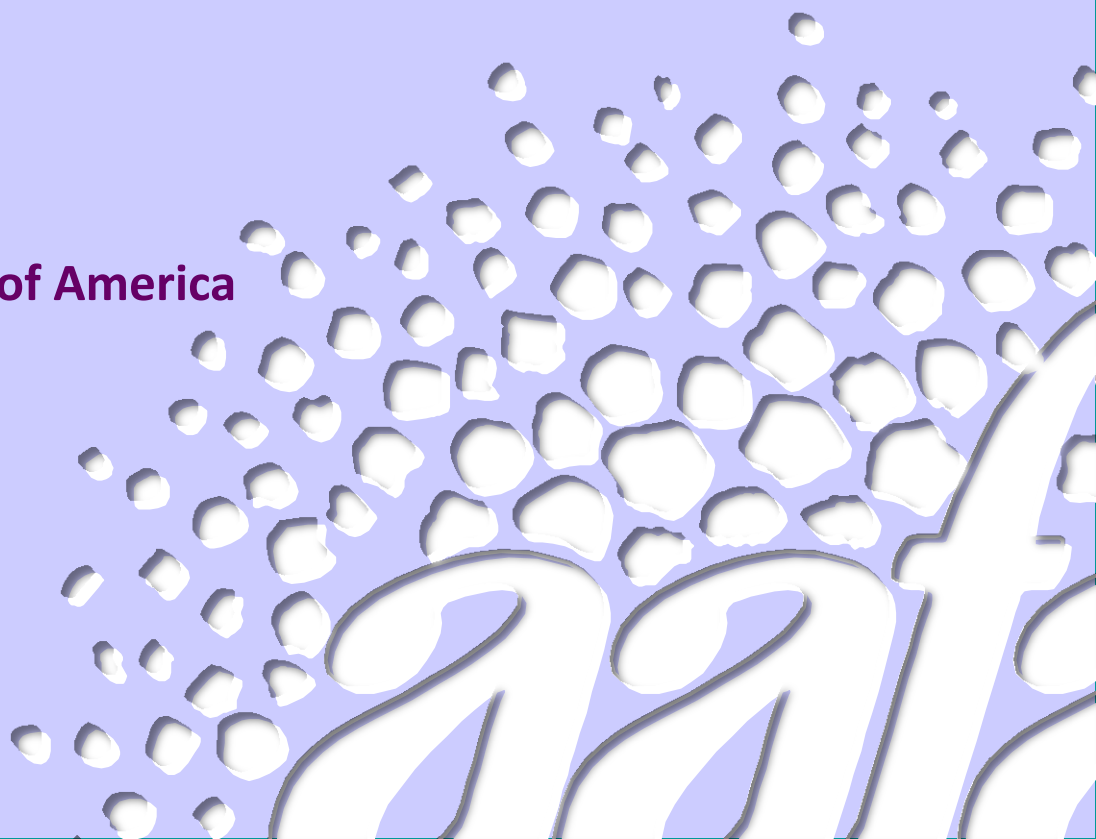




Asthma and Allergy
Foundation of America

The Impact of Specialty Treatments: Preparing for a Tsunami?

Cary Sennett, MD, PhD, FACP
President and CEO
Asthma and Allergy Foundation of America



ABOUT AAFA

- 501c3 dedicated to improving the lives of people with asthma and allergic disease
- Serves as the “voice of the patient” in national and state-level policy conversations (like today’s)
- Serves to educate and inform that voice through educational content and programs
- Increasingly involved in research—and the intersection of research, policy, and education

AAFA PUBLIC AWARENESS

- Awareness Campaigns – PSAs, rankings, seasonal
- Certification Program – healthy home
- Web Site – 3 million unique visit visitors per year
- Social Networks – Kids With Food Allergy (KFA), FB, Twitter, Inspire and Causes
- Publications – newsletters, product guides
- Information and Materials – flyers, brochures
- Toll-free Hotline: 1-800-7-ASTHMA
- National Asthma & Allergy Awareness Month



AAFA RESEARCH REPORTS

- **Asthma Capitals™** — An annual analysis of metro area asthma data that ranks the largest cities in the U.S. with respect to their success at achieving important outcomes for people with asthma.
- **State Honor Roll** — An annual report that identifies states with the most comprehensive and effective public policies supporting people with asthma, food allergies, anaphylaxis, and related allergic diseases in U.S. elementary, middle, and high schools.



AAFA PUBLIC POLICY

■ Improve Access to Care

- Health care that covers everyone, curbs costs responsibly, abolishes exclusions for pre-existing conditions, eliminates lifetime caps, and ensures long-term and end-of-life care
- Efforts to cover all uninsured children in the US to address health care disparities
- Access to safe, effective treatments for asthma and allergies that best meet the patients' interests

■ Increase Funding for Federal Research

- Support maximizing basic, clinical, preventive and health services research funding relevant to asthma and allergic diseases

■ Promote Prevention

- Support efforts to prevent asthma and allergies from developing and worsening the health of Americans, including strategies to reduce risks in the home, workplace, school and the environment

Source: www.aafa.org

ABOUT ASTHMA

- **Prevalent**
- **Morbid and mortal**
- **Care is costly—and inefficient**
- **Disproportionately affects vulnerable populations**
- **No cure**
- **Manageable—but challenging**
- **Access to medication is important**
- **Access to medication is not ALL that's important**

Asthma's Impact on the Nation Data from the CDC National Asthma Control Program



What is asthma?

Asthma is a chronic disease that affects the airways in the lungs. During an asthma attack, airways become inflamed, making it hard to breathe. Asthma attacks can be mild, moderate, or serious — and even life threatening.

Symptoms of an asthma attack include:

- Coughing
- Shortness of breath or trouble breathing
- Wheezing
- Tightness or pain in the chest

We don't know for sure what causes asthma, but we do know that attacks are sometimes triggered by:

- Allergens (like pollen, mold, animal dander, and dust mites)
- Exercise
- Occupational hazards
- Tobacco smoke
- Air pollution
- Airway infections

There's no cure for asthma. People with asthma can manage their disease with medical care and prevent attacks by avoiding triggers.

1 in 11
children
has asthma

1 in 12
adults
has asthma

Is asthma really a problem?

Yes. Asthma is a serious health and economic concern in the United States. It's expensive.

- Asthma costs the United States \$56 billion each year.
- The average yearly cost of care for a child with asthma was \$1,039 in 2009.

In 2008, asthma caused:

- 10.5 million missed days of school
- 14.2 million missed days of work

It's common.

In 2010:

- 18.7 million adults had asthma. That's equal to 1 in 12 adults.
- 7 million children had asthma. That's equal to 1 in 11 children.

It's deadly.

- About 9 people die from asthma each day.
- In 2009, 3,388 people died from asthma.

National Center for Environmental Health
Division of Environmental Hazards and Health Effects



OF COURSE PEOPLE WITH ASTHMA WANT ACCESS TO AFFORDABLE MEDICATIONS—BUT WHAT THEY REALLY WANT IS:

Not This



This



THEY WANT TO LIVE LIVES NOT LIMITED BY THEIR HEALTH

TO LIVE THAT LIFE WITHOUT LIMITS, PEOPLE WITH ASTHMA RELY ON A COMBINATION OF MEDICINES, DEVICES, AND LIFE STYLE MODIFICATIONS



THE GOOD NEWS IS THE PRICE OF MANY OF THESE MEDICATIONS IS DECLINING IN THE WAKE OF GENERIC SUBSTITUTIONS

New generic Singulair could save asthma sufferers big bucks

Consumer Reports News: August 06, 2012 05:37 PM

Asthma and allergy sufferers who take Singulair (montelukast) will soon be able to slash their medication bills. Late last week, the Food and Drug Administration approved the first generic version of the popular drug. And within the first year or so, the monthly cost of the generic is expected to drop to half or less of the \$180 retail price tag of brand-name Singulair.

If you're one of the millions of people who take Singular, you're probably wondering when you will see the price tumble even further on the generic. The short answer is, it's uncertain.

Sometimes it can take several months following a generic approval before consumers see substantial price reductions. This happens because often, only one generic manufacturer has been allowed to produce the drug in the first six months, so there is no competition to drive the price down. But with Singulair, the price drop should happen sooner since the FDA granted 10 manufacturers the right to make a generic version. At least one of the 10 has already started shipping its generic to pharmacies, and the others will likely soon follow.

Montelukast, the generic name of the medication in Singulair, helps reduce asthma and allergy symptoms by blocking substances in the body called leukotrienes that can trigger inflammation and constrict airways. The most common side effects of the drug include fever, headache, cough, diarrhea, runny nose and sinus infections.

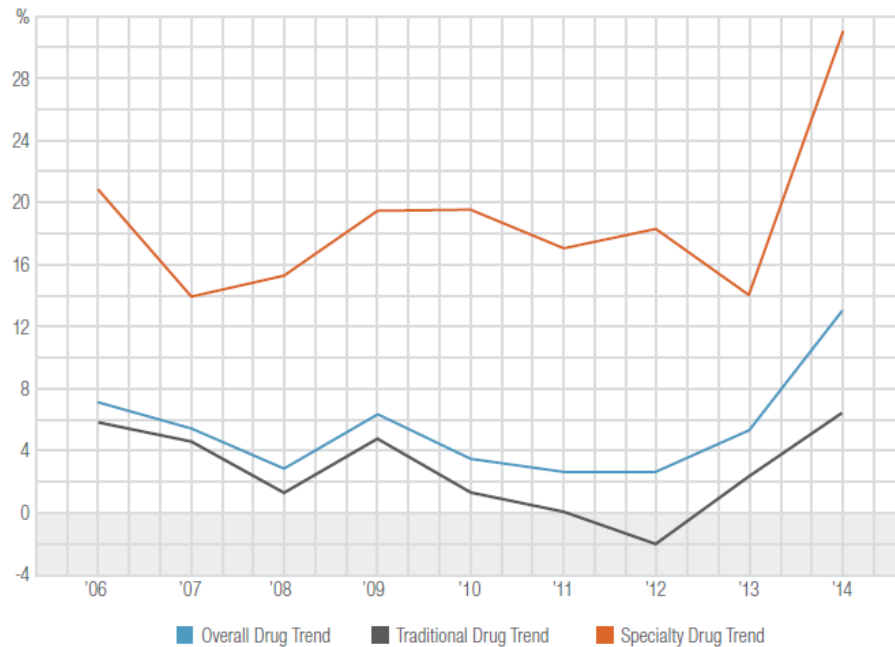
In rare cases, the medication can also cause serious side effects. Contact your doctor immediately if you experience any of these while taking montelukast: mood changes, such as aggression, depression, or hallucinations; a feeling of "pins and needles" or numbness in the arms or legs; a rash; flu-like symptoms; or severe pain and swelling of the sinuses.

... within the first year or so, the monthly cost of the generic is expected to drop to half or less of the \$180 retail price tag of brand-name Singulair.

BUT THERE IS A TSUNAMI COMING

COMPONENTS OF OVERALL DRUG TREND

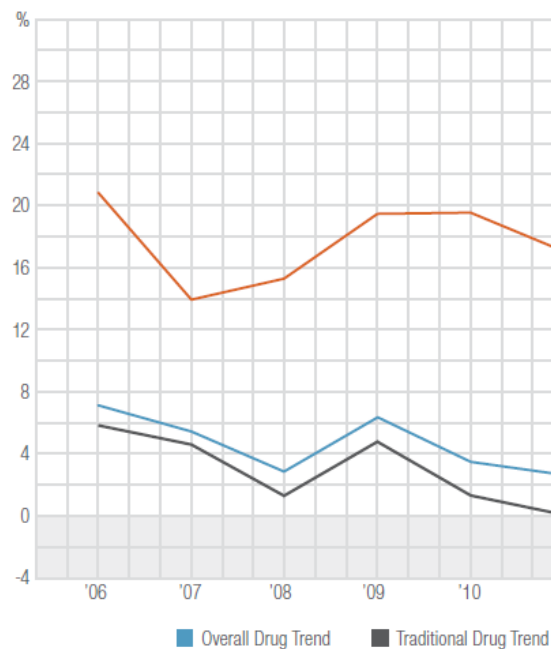
EXPRESS SCRIPTS 2006-2014



BUT THERE IS A TSUNAMI COMING

COMPONENTS OF OVERALL DRUG TREND

EXPRESS SCRIPTS 2006-2014



HEALTH POLICY BRIEF

WWW.HEALTHAFFAIRS.ORG

1

HealthAffairs

Robert Wood Johnson Foundation

Health Policy Brief

NOVEMBER 25, 2013

Specialty Pharmaceuticals. Complex new drugs hold great promise for people with chronic and life-threatening conditions. The drugs are also a driver of spending growth.

WHAT'S THE ISSUE?

Specialty pharmaceuticals are a rapidly growing share of total drug expenditures by public and private health plans. These drugs, typically used to treat chronic, serious, or life-threatening conditions, such as cancer, rheumatoid arthritis, growth hormone deficiency, and multiple sclerosis, are often priced much higher than traditional drugs. Total costs can be in the thousands of dollars a month and can exceed \$100,000 a year for some products. There are usually few if any low-cost generic equivalents.

These high costs represent an increasing burden on payers, including governments and employers. Because health plans often require substantial cost sharing for specialty drugs, there is also a large impact on patients who need such medicines. Some are concerned

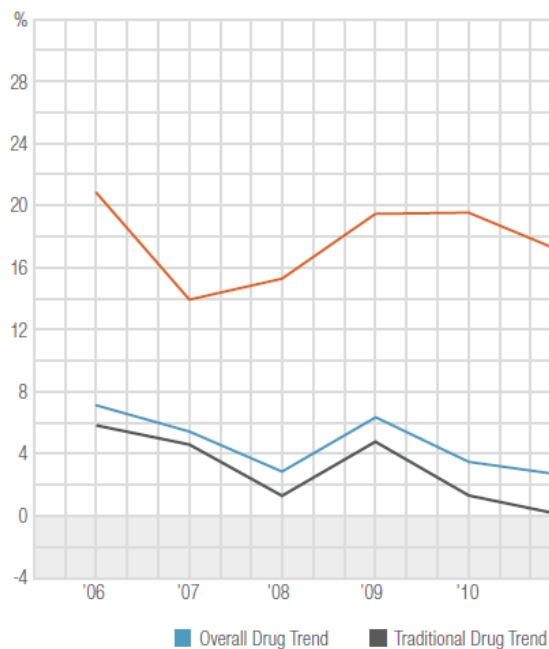
cases, companion diagnostic tests are used to identify patient subpopulations in which the specialty product generates a differential response, either negative or positive. As a result, specialty products have stimulated diagnostic research. Given the level of investment, this means that patients and payers can expect continued innovation and research to develop such medicines and companion diagnostics in the future.

Payers are interested in steps they can take to control the contribution that specialty pharmaceuticals make to the growth in premium costs while ensuring that patients can access those drugs that will improve their health and quality and length of life. Biopharmaceutical manufacturers and patient advocates are concerned that restrictions on specialty pharmaceuticals could discourage research and harm patient care. Pharmacists are also concerned

BUT THERE IS A TSUNAMI COMING

COMPONENTS OF OVERALL DRUG TREND

EXPRESS SCRIPTS 2006-2014



HEALTH POLICY BRIEF WWW.HEALTHAFFAIRS.ORG

HealthAffairs

Health Policy

Specialty Pharmaceuticals. C...
drugs hold great promise for
chronic and life-threatening c...
drugs are also a driver of spe

WHAT'S THE ISSUE?

Specialty pharmaceuticals are a rapidly growing share of total drug expenditures by public and private health plans. These drugs, typically used to treat chronic, serious, or life-threatening conditions, such as cancer, rheumatoid arthritis, growth hormone deficiency, and multiple sclerosis, are often priced much higher than traditional drugs. Total costs can be in the thousands of dollars a month and can exceed \$100,000 a year for some products. There are usually few if any low-cost generic equivalents.

These high costs represent an increasing burden on payers, including governments and employers. Because health plans often require substantial cost sharing for specialty drugs, there is also a large impact on patients who need such medicines. Some are concerned

cases, co... identify p... specialty sponse, e... specialty research, means th... continue such med... the futur...

Payers to control m... costs wh... those dru... quality and length of life. Biopharmaceutical manufacturers and patient advocates are concerned that restrictions on specialty pharmaceuticals could discourage research and harm patient care. Pharmacists are also concerned

Medicines in Development

ASTHMA

PRESENTED BY AMERICA'S BIOPHARMACEUTICAL RESEARCH COMPANIES

2012 REPORT

Biopharmaceutical Research Companies Are Studying More Than 70 Medicines for Asthma

Asthma Prevalence in the United States

(Rate per 1,000)



Source: U.S. Centers for Disease Control and Prevention, National Center for Health Statistics.

24 million
American adults and children
suffer from **asthma**;
each day **40,000**
Americans miss school or
work due to **asthma**



More than 24 million Americans are affected by asthma, with prevalence increasing 12 percent in the last decade. Asthma is a narrowing of the airways to the lungs caused by inflammation in the air passages resulting from both genetic and environmental influences. It is the most common chronic condition in children and costs the U.S. economy an estimated \$56 billion each year in direct and indirect costs.

America's biopharmaceutical research companies are developing 74 medicines to treat or prevent asthma. All of the medicines are either in clinical trials or awaiting review by the U.S. Food and Drug Administration.

New medicines today in the pipeline offer hope of reducing the human and economic costs of asthma. Examples of some medicines now being tested to treat the disease include:

- A monoclonal antibody that inhibits eosinophils from accumulating in the lungs.

- A new inhalation therapy that harnesses the body's natural defenses in the airway against asthma.
- A medicine that blocks the pro-inflammatory effect of prostaglandin in allergic asthma.

The quest for new medicines is intense and financially risky. Each new medicine costs, on average, more than \$1 billion and takes 10 to 15 years to develop. But new scientific advances are increasing our knowledge, and researchers are using every tool at their disposal.

Advances in our understanding of diseases and how to treat them have allowed America's biopharmaceutical research companies to conduct the cutting-edge research needed to reduce the destructive toll of asthma.

Pfizer

THE GOAL AND PATH FORWARD

People with asthma will have access to effective medication at a reasonable cost

- Need policies that assures access to the most effective option *for each individual*
- Need research to *create a better map between individuals and therapies*
- Need patients to engage more effectively
- And we need to be careful, so that we do not stifle the R&D needed, to solve the access problem for those for whom there are not yet effective medications (at any cost)

SUMMARY

- Drug costs are a problem—and are likely to be more so in the near future
- Addressing that problem will require policy that assures that patients have access to the medications that are right for them
- That kind of “precision medicine” will require research
- Improving lives for people with asthma requires more than policy and research
 - Patient engagement is essential
 - Patients need support to engage
- Savings—from better outcomes—can help offset potentially higher medication costs

FOR MORE INFORMATION

- Contact me: Cary Sennett, MD, PhD, FACP: csennett@aafa.org
- Contact Meryl Bloomrosen, SVP for Policy, Advocacy and Research: mbloomrosen@aafa.org
- Contact AAFA: info@aafa.org or www.aafa.org