

JUST THE FACTS

MORE THAN

26

MILLION AMERICANS HAVE
ASTHMA¹

ASTHMA

IS THE LEADING
CHRONIC ILLNESS IN CHILDREN¹

MORE THAN

50

MILLION AMERICANS
EXPERIENCE ALLERGIES
EACH YEAR¹

16

MILLION AMERICANS
HAVE COPD²

ASTHMA AND ALLERGY

More Than **100** Medicines in Development for Asthma, Respiratory Allergies, Other Breathing Diseases

Breathing is a simple act that most people don't ever have to think about. But, for the millions of Americans suffering from respiratory diseases—such as asthma or respiratory allergies—breathing can be a life-threatening struggle.

Respiratory diseases are a major health burden in the U.S., particularly chronic diseases like asthma and chronic obstructive pulmonary disease (COPD). Together, these two diseases affect more than 40 million people in the U.S. with various allergies combined affecting more than 50 million people every year.¹ Respiratory allergies affect 10 percent of children under the age of 18.³ Many of these diseases can have a tremendous impact on a patient's day-to-day functioning, and some can be life-threatening.

Today, 130 medicines are in development by America's biopharmaceutical research companies to help the millions of Americans affected by respiratory diseases.⁴ For this report, we are examining respiratory diseases that are not infectious or cancer. All of the medicines are in clinical trials or awaiting review by the U.S. Food and Drug Administration (FDA):

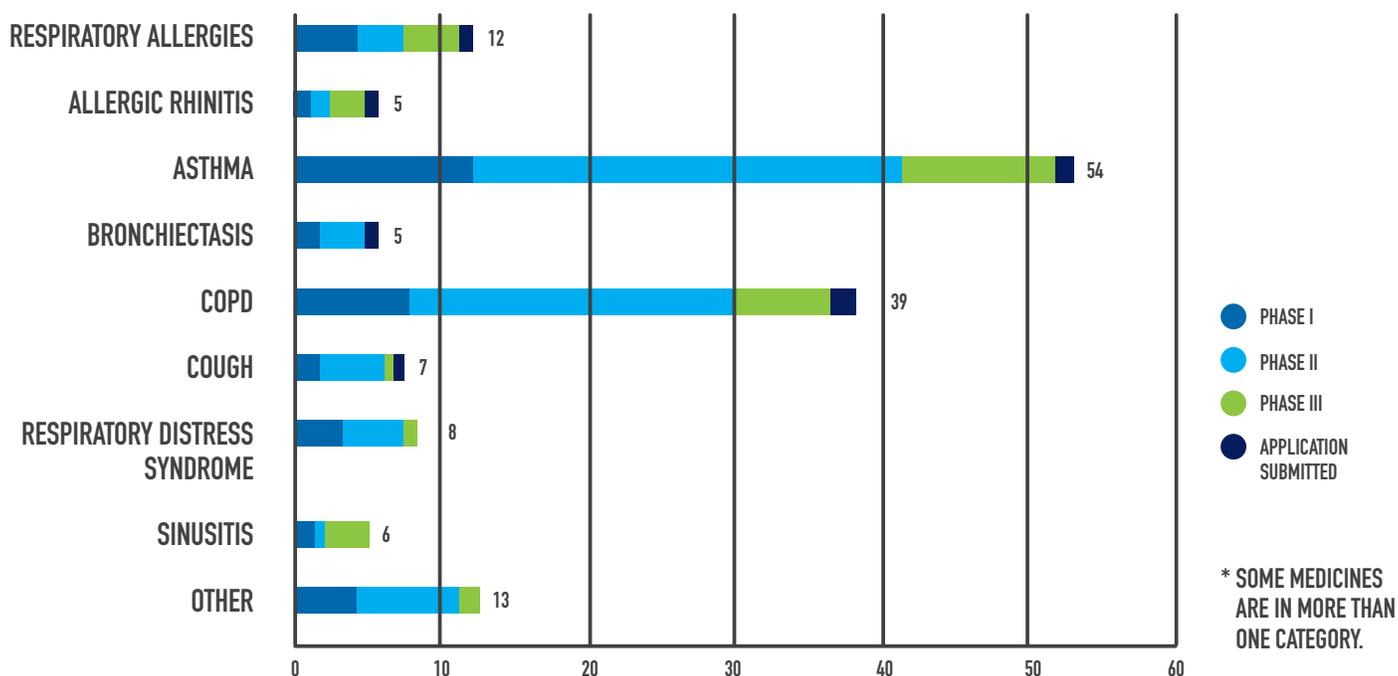
- **54** for asthma, a condition causing hyperreactivity of the airways of the lungs resulting from inflammation in the air passages caused by genetic, environmental factors, or both. It is the most common chronic condition among children in the U.S., with more than 6 million children and 20 million adults affected.¹
- **39** for COPD, a group of diseases that cause airflow obstruction to the lungs that interferes with normal breathing. COPD includes emphysema and chronic bronchitis that can lead to limitations in the ability of patients to work, exercise and perform normal activities. About 16 million Americans are affected by COPD.²
- **12** for allergies with respiratory symptoms, such as peanut allergies and allergies to grass pollen. Allergies result when the immune system reacts to an allergen, such as tree pollen, dust mites or food. Allergies are the 6th leading cause of chronic illness in America.¹
- Other diseases covered in the report, include allergic rhinitis, bronchiectasis, cough, respiratory distress syndrome and sinusitis.

Innovative Medicines in the Pipeline

Medicines in the development pipeline today aim to build on the progress made by existing treatments, and many use novel approaches to treat respiratory diseases, adding new treatment options available to patients. Among the 130 medicines in development are:

- A potential first-in-class medicine in development for **asthma**, blocks TSLP, an immune system messenger protein that is critical in the development and persistence of inflammation of the airways. It is believed that by blocking TSLP, the release of pro-inflammatory proteins by immune cells will be stopped, resulting in the prevention of asthma exacerbations and improved asthma control.
- A medicine in development for **COPD** targets the lung inflammation associated with the disease. The medicine is an antagonist of the chemokine receptor (CXCR2) that can potentially reduce inflammation in COPD by inhibiting the activity of white blood cells (neutrophils) in response to lung tissue damage. When over-activated, these blood cells can result in additional tissue damage by releasing proteases, stimulating mucus secretion and other negative lung events.
- Nut allergies can cause an anaphylactic response that leads to difficulty swallowing and shortness of breath. A combination therapy in development for **peanut allergies** pairs an oral desensitization immunotherapy that is designed to help protect patients from severe allergic reactions when exposed to peanuts and a monoclonal antibody that inhibits signaling of IL-4 and IL-13 cytokines. These two cytokines (immune system proteins) are believed to be major drivers of type 2 inflammation, a systemic response that may play a role in reactions to allergens. The monoclonal antibody was recently approved in the U.S. to treat asthma as a single agent.

Medicines in Development: Asthma, Respiratory Allergies and Breathing Diseases



A New Era for Asthma Treatment

Throughout most of his life, every time he took a breath, Gilberto (Gil) felt like there was a belt tightening around his chest. Diagnosed with severe asthma at age two, Gil faced extreme difficulty performing basic activities like sleeping and sometimes even speaking, as well as constant anxiety that a life-threatening asthma attack could be moments away.

One day, this worry became reality. A year ago, Gil nearly lost his life to an attack that came so suddenly and painfully that he and his family began to prepare for the worst.

Little did Gil know, in the years leading up to his asthma attack, researchers were hard at work on a new type of treatment that would change the course of both his asthma and his life. René was one of those researchers, devoting her life's work to the development and launch of biologic treatments for respiratory conditions like Gil's.



Recent advancements in biologic medicines for asthma has allowed for what René calls “the kind of precision that can allow us to provide the right medicines to the right patients.” Incidentally, the “right patient” in this case was Gil, who began treatment, under the guidance of his physician, about a month after his latest life-threatening attack.

The first night, Gil slept without waking up from shortness of breath for the first time in years. Today, the change has been so profound that it feels like he has been given a new pair of lungs. One of the most rewarding moments came when recent breathing tests revealed normal lung function—something a severe asthma patient could only dream of just a few years ago.

“The new treatment has given me my life back, and more importantly, it’s given me back to my family,” says Gil.
“Without innovation, I wouldn’t have the life I’m living today.”

Benefiting Patients

“The Asthma and Allergy Foundation of America encourages people with asthma to be active participants in their healthcare. The 130 medicines in development for respiratory diseases, like asthma, represent revolutionary new choices for these patients and gives them an opportunity to find the treatments that work best for their individual needs and preferences. These new therapies are the product of years of pioneering research aimed at expanding our understanding of chronic conditions and improving quality of life for millions of patients. We’ve reached a pivotal point in asthma research with advances in personalized and patient-centric medicines, and we’re excited about the hope these treatments will offer to people living with asthma.”

—Kenneth Mendez, President and CEO, Asthma and Allergy Foundation

Personalized Medicine in Treating Respiratory Diseases

Advancements in science and technology have changed the way we define disease, develop medicines and prescribe treatments. Armed with a greater understanding of disease biology, it has become evident that a patient's response to treatment—with respect to both safety and efficacy—is different for each patient. The promise of personalized medicine is to get the right treatment to the right patient at the right dose the first time through the use of molecular biomarker tests and targeted therapies. Personalized medicine, sometimes referred to as precision or individualized medicine, uses an individual patient's unique information about genes, proteins and environment in disease diagnosis and treatment for that patient.

In both asthma and COPD, the role of genetics and phenotypes (an individual's physical reaction or clinical expression resulting from the interaction of its genes with the environment), are offering hope that personalized medicine can play a key role in diagnosing and treating respiratory diseases. By determining a patient's specific genotype and phenotype, a personalized approach in diagnosis and treatment could be more effective for patient's by offering better-targeted therapies.

How Environmental Factors Affect the Lungs

Allergic reactions occur when the body's immune system reacts to a foreign substance. In asthma, allergens or other irritants enter the lungs triggering an asthma attack that results in the swelling and narrowing of the airways. The most common triggers include: pollen, mold spores, dust mites and animal dander. But public health concerns such as tobacco use, outdoor air quality, climate change and obesity can also affect lung health and respiratory diseases.

Tobacco smoke is the leading cause of preventable disease and death in the U.S.⁶ and is a leading driver for COPD. Outdoor air pollution, such as smog and particle pollution are a greater challenge for children, older adults and people who already have a lung disease. The buildup of greenhouse gases is creating warmer temperatures, which increases the risk of smog and particle pollution, especially in the summer months. Obesity, which affects 93 million Americans,⁵ is a risk factor for the development of asthma, the worsening of asthma symptoms and poor asthma control.⁶

New scientific advances are expanding our understanding of respiratory disease biology, helping biopharmaceutical researchers conduct the research needed to reduce the destructive toll of asthma, COPD, respiratory allergies and other respiratory diseases. This research can help find new and better treatments for patients.

Sources:

1. Asthma and Allergy Foundation of America
2. National Heart, Lung and Blood Institute, National Institutes of Health
3. Johns Hopkins University, Asthma and Allergy Statistics
4. Number of medicines obtained through public government, and industry sources, and the Adis Insight database; current as of January 16, 2019.
5. American Lung Association
6. U.S. Centers for Disease Control and Prevention

