NEW ASTHMA OUTCOME MEASURES AIM TO MAXIMIZE INVESTMENTS IN RESEARCH, MAY HOLD KEY TO REDUCING DISPARITIES IN CHILDREN WITH ASTHMA

WASHINGTON, D.C., March 2, 2012 – Newly proposed asthma outcome measures will help standardize and improve results from the hundreds of millions of dollars the National Institutes of Health (NIH) spends annually to study asthma, according to the Merck Childhood Asthma Network, Inc. (MCAN), the nation’s only organization focused solely on childhood asthma. Even though years of research have led to groundbreaking improvements in better understanding and managing asthma, MCAN noted that the inability to compare results across many studies has hindered the nation’s efforts to find long-term solutions and reduce childhood asthma disparities.

This set of proposed outcome measures, published as a supplement to the March issue of the Journal of Allergy and Clinical Immunology, will be officially released at the annual meeting of the American Academy of Allergy Asthma & Immunology (AAAAI) in Orlando on March 3. NIH and other agencies will consider these outcomes in future clinical research initiatives later this year, which according to MCAN will permit the comparison of results across many large federally supported studies.

“For years, researchers, clinicians and others have worked to close the wide gap between the treatment that is recommended for children with asthma and the treatment most of them receive. We’ve struggled with an inability to make ‘apples to apples’ comparisons with research outcomes that could lead to improvements in management,” said Dr. Floyd Malveaux, Executive Director of MCAN and former Dean of the College of Medicine at Howard University. “This move towards standardization is a huge step in the right direction. It paves a way to reducing disparities in asthma management and treatment, especially for the most vulnerable children among us.”

In 2010, several federal agencies, non-governmental organizations and industry representatives gathered in Bethesda, Md., to identify how the nation might overcome the lack of outcomes standards in asthma clinical research. The meeting was organized by several NIH institutes, including the National Institute of Allergy and Infectious Diseases; the National Heart, Lung, and Blood Institute; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; and the National Institute of Environmental Health Sciences, as well as the Agency for Healthcare Research and Quality and MCAN. The report of the meeting recommended a standardization of outcome measures that these federal agencies will consider implementing in the coming months.

The proposed measures will allow more effective data sharing, enhance development of new prevention and treatment strategies, and eventually lead to improvements in the quality of asthma care. Dr. Malveaux also noted that there is great potential for increased ability to duplicate successful interventions in some of the country’s neediest communities, identify areas for cost reduction and, through data-sharing, reduce disparities in the communities hardest hit by asthma.

Although other endpoints may be proposed by researchers, the NIH has identified seven outcome categories that are important in clinical studies. These categories include:

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- **Symptoms**: Asthma symptoms are used to assess the impact of interventions on health outcomes. Although current tools have shortcomings, the report reviews key instruments and encourages further development of new ones.

- **Exacerbations**: Future studies will report exacerbations or worsening of asthma requiring the use of systemic corticosteroids.

- **Biomarkers**: The report identified ten biomarkers relevant to disease progression and response to treatment, with particular emphasis on reporting multi-allergen screening.

- **Lung Function**: Lung function outcomes are of central importance for future asthma clinical research, and spirometry and bronchial reversibility measures are considered key in diagnosing and determining disease severity.

- **Quality of Life**: Measures of asthma’s impact on a patient’s life as essential for characterizing patient populations and assessing the benefits or harms of specific asthma interventions; no core measures have been identified to date.

- **Asthma Control Questionnaire Results**: Several questionnaire instruments, including the Asthma Control Questionnaire (ACQ) and Asthma Control Test (ACT), were identified.

- **Healthcare Utilization and Costs**: Collecting and reporting information on healthcare utilization, intervention resources and indirect impact of asthma will be encouraged so that costs can be calculated and cost-effectiveness analyses can be conducted across several asthma studies.

The final outcomes standards report entitled “Asthma Outcomes in Clinical Research: Report of the Asthma Outcomes Workshop” is available online at [www.jacionline.org](http://www.jacionline.org). The press conference at the AAAAI annual meeting will be webcast live on Saturday, March 3 from 2 to 3 p.m. ET at [www.facebook.com/MedPageToday](http://www.facebook.com/MedPageToday) (click on the LiveStream link on the left). MCAN provided financial support for the 2010 NIH Outcomes Workshop and follow-up activities.

**About Childhood Asthma**
Asthma is the single most common chronic condition among children. In 2009, one in every 11 children – 7.1 million – had asthma, a number that has grown steadily over the 1997-2009 time period. It is also costly. The nation spends between $8 and $10 billion alone on treating childhood asthma, more than any other childhood condition. Additionally, indirect costs which include missed school days and lost wages for a parent or care giver who is caring for a child, approach $10 billion annually. While asthma affects children in every community across the country, low income and minority children bear the heaviest burden of the disease and its consequences, including death. Compared with white non-Hispanic children, data reported in 2009 indicate that asthma is nearly twice as high among Puerto Rican children and twice as high in African-American children.

**About the Merck Childhood Asthma Network**
The Merck Childhood Asthma Network, Inc. (MCAN) is a non-profit, 501(c)(3) organization established to address the complex and growing problem of pediatric asthma. Funded by the Merck Company Foundation, and led by Floyd Malveaux, MD, PhD, a nationally recognized expert in asthma and allergic diseases and former Dean of the Howard University College of Medicine, MCAN is specifically focused on enhancing access to quality asthma care and management for children in the United States. For more information, visit [www.mcanonline.org](http://www.mcanonline.org).

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