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October 28, 2016

Gary H. Gibbons, M.D.
Director
National Heart, Lung and Blood Institute
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Gibbons:

The American Lung Association appreciates the opportunity to submit comments to the National Heart, Lung and Blood Institute (NHLBI) regarding the National Chronic Obstructive Pulmonary Disease (COPD) Action Plan.

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The organization represents lung disease patients, their families, loved ones and caregivers.

The American Lung Association works to prevent COPD and better the lives of those who have this disease. COPD has been increasing in prevalence and is the third leading cause of death in the United States.[1] During 2007-2010, around 8.5 million adults had been diagnosed with COPD.[2] However, this may represent underdiagnoses of the true burden as more than 18 million had evidence of impaired lung function.[3,4] This is of great concern to the American Lung Association as too many individuals are unaware they are living with a progressive, chronic illness. When detected and treated early, COPD can be controlled.

Raising the visibility of this preventable and treatable disease must be a national imperative. The American Lung Association supports the NHLBI's efforts to create a National COPD Action Plan and respectfully submits these comments to ensure the Action Plan identifies the appropriate strategies and resources to improve patient health outcomes and reduce the burden of COPD. The American Lung Association's comments address the general framework of the Action Plan and each goal.

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General Framework
The American Lung Association supports the Action Plan's aim to strengthen and enhance COPD health education, research and clinical care in order to improve prevention, early detection, diagnosis and treatment for patients. In light of the proposed Action Plan, the American Lung Association provides the following general comments:

1. The American Lung Association is concerned that the Action Plan does not establish clear accountability. We recommend that tasks be assigned to specific entities with clearly defined and actionable roles, and proposed timeframes for completion. This would provide an opportunity to establish a clearer assessment of the infrastructure required to advance the Action Plan's goals.

2. The American Lung Association is concerned that not all activities are aligned with their respective objectives under each goal. Some activities are more associated with other objectives or goals and should be moved to facilitate plan implementation.

3. The American Lung Association is concerned that there is no mention of a specific definition of COPD for purposes of guiding the proposed data collection and research that is to be undertaken. An agreed upon working definition is essential to provide the foundation for the identified data collection efforts.

4. The American Lung Association welcomes the Action Plan's references to tobacco consumption as a risk factor for COPD and the Action Plan's statement that smoking cessation, as a therapeutic intervention tool, should be a fully reimbursable program to COPD patients who qualify. However, availability of smoking cessation treatments as an integral component of the prevention and management of COPD is not sufficiently prominent in the Action Plan. In addition, access to smoking cessation programs should be available to patients without barriers and without qualifying factors. The dominant cause of COPD is smoking, and mortality from COPD has risen progressively in recent decades.[5] Quitting smoking, supported by tobacco cessation medications and programs, is the best method a smoker can use to reduce their risk of COPD and improve their health outcomes.

Goal 1
Goal One, as written, is to help people with COPD, their families and caregivers to recognize the disease through risk and symptom awareness, early detection, and diagnosis, as well as to empower these groups to best manage their health. This is to be accomplished through increasing access to reliable COPD information that is culturally and linguistically competent as well as expanding outreach communication campaigns and partnership development.

However, the objectives, as written, seem to place more emphasis on the methods of communication than on the content of the information. In light of the patient-centric aims of Goal One, the Action Plan should draw clearer distinctions between public awareness campaigns and patient education, which, have different purposes and outcomes as well as potentially different

stakeholders for engagement. Awareness campaigns for the general public are best used to improve risk reduction, increase early detection, reduce stigma and increase hope. Patient education, on the other hand, is more specifically geared to improving patient-provider communication and health outcomes as well as increasing patient engagement and self-efficacy. Objectives specific to patient education should be included in Goal One as part of its aim to empower patients, caregivers and families.

Furthermore, Goal One proposes that existing networks engage in reviewing, updating and creating additional COPD information sources (objective 1.1.). It is unclear whether this objective proposes to create a uniform set of materials. In light of Goal One's aim to ensure the creation of high quality, effective, and readily accessible resources, it would not be necessary or desirable to ask stakeholders to collaborate on a uniform set of materials. Rather, each organization is best entrusted to create and disseminate resources tailored to its own unique audience.

Goal One also states to increase the effectiveness of outreach communications (objective 2). The metrics, if any, from the evaluation research to be conducted (objective 2.1.3) should integrate patient-centric measures to determine the scope and health impact of the outreach efforts.

In objective 3.3., what is the defined scope of 'support' that the objective aims to provide all 50 states and the District of Columbia regarding COPD education efforts? Is the 'support' financial, operational, advisory, or, materials? Additionally, will the 'support' be from the NHLBI, other agencies (federal and/or nonfederal), or, a combination?

Lastly, there should also be an incorporation of patient and community feedback from these patient education and awareness efforts, as a way to enrich subsequent communications with information tailored to patient needs.

Goal 2

Goal Two has an emphasis on clinician education. However, the Goal is narrower in scope than its corresponding objectives. The objectives are to create national guidelines of care, develop a clinical decision tree, create a patient self-management tool and increase access to care. We recommend that Goal Two be revised to have more emphasis on improving clinical practice.

National Guidelines of Care

Similar to our comments in Goal One—where we recommend that existing networks continue creating COPD health information tailored to their unique audiences—guidelines created by professional societies, rather than by a national authority, may more readily address and adequately represent patient needs with up-to-date scientific advances.

Credentialing

In objective 1.1.4., the Action Plan calls for a certification program that will support a trained workforce, including primary health care providers, in the medical evaluation, management, and treatment of people at risk for or diagnosed with COPD. It is important to note that any such credentialing program should emphasize a well-defined set of skills and training objectives that

will clearly address the needs of COPD patients. We recommend a careful examination of existing training and certification programs to identify specific needs and gaps before calling for the development of something new.

Self-Management Tools

Objective 4 provides for a patient-centric COPD management tool. The proposed objective, as written, is unclear. The Action Plan can and should define the key components of an effective COPD management plan. Stakeholders should all be encouraged to disseminate and promote the use of COPD management plans to their own audiences. Specifically, it is not necessary nor desirable to propose creating one tool that should alone be implemented.

Access to Care

Objective 5 is to improve access to care for people with COPD, particularly for those in 'hard-to-reach' areas. The American Lung Association acknowledges that more efforts to increase access to underserved and rural communities are necessary. We believe that "hard-to-reach" should be clarified to ensure that all underserved populations are supported with the specific aim of reducing disparities in the burden of disease.

The objective continues by proposing the development of a comprehensive public health strategy to match respiratory care resources to each patient's respiratory care. However, it does not describe the framework of approach nor the key stakeholder entities that should be involved in that process to ensure proper adoption and implementation of access to care initiatives. Given the significant challenges surrounding patient access to care, perhaps objective 5 should be a critical objective within Goal 5 and tailored to the findings from Goal One, Two, Three and Four, respectively.

Clinical Decision Tools

Objective 3 states to develop clinical decision trees and other tools to ensure high-quality care for people with COPD. However, activity 3.2 is more appropriately placed under objective 5, since it promotes the collaboration among health plans to ensure providers are knowledgeable, trained and adoptive of COPD diagnostic tools. Consequently, interchanging activity 3.1 with objective 3 would then create a more aligned objective.

<u>Goal 3</u>

Goal Three urges promotion of data collection from multiple sources, analysis and dissemination of findings, as well as the development of new infrastructures and alliances to address data needs.

The American Lung Association proposes that primary care providers' collection and reporting of COPD surveillance data to state and local health departments (objective 1.1.2.), should be an institutionalized practice rather than voluntary to ensure consistency in data gathering and continued engagement of providers. Additionally, this will provide the opportunity to ensure that any clinical care recommendations derived from data collection and analysis are continually tailored to patient populations.

The Action Plan encourages studies that assess the efficacy, risks, and costs of existing and new models of detection, care and treatment for people living with COPD (objective 2.2). The American Lung Association proposes that studies also be conducted to assess the extent of access to existing models as well as the challenges or opportunities for integration of new models of detection, care and treatment into the health care system, including, challenges related to patient access and cost-sharing.

Lastly, objective 1.2.2 (utilization of aggregated data to describe how COPD and related prevent, care and treatment programs influence health and morbidity) may be more aligned with objective 1.3 which analyzes the collected data to understand public health trends.

Goal 4

Goal Four's emphasis is on advancing research to further examine the contributing risk factors and underlying mechanisms of COPD, and the development and personalized medicine for COPD based on this research.

LDCT Screening

Goal Two (objective 4.6) and Goal Four (objective 1.2.2.1.) collectively reference new diagnostic tools, such as computerized tomography, for detecting COPD among those at-risk for the disease, including nonsmokers and those being screened for lung cancer. At least 8.6 million Americans are considered high risk for lung cancer and are recommended to receive screening with low-dose computed tomography (LDCT).[6] And in 2016, an estimated 224,390 new cases of lung cancer are expected to be diagnosed.[7]

Opportunities for detection of COPD may be enhanced due to the recommendation for LDCT screening for lung cancer. This may also identify previously undiagnosed COPD, given the smoking histories of those eligible for screening. Follow-up lung function testing should be incorporated into protocols, and executed before any invasive work-up approaches are carried out.

Research

The Action Plan provides an opportunity to create a research agenda to improve the quality of COPD detection and diagnostic technologies. The American Lung Association proposes that the research agenda include addressing a fundamental challenge in COPD research: why half of regular smokers do not develop COPD is not known. This is an important research question and we urge that genetic research into this question be included as part of this plan.

Goal 5

Goal Five seeks to translate policy, educational and program recommendations into legislative, research and public health care efforts.

The American Lung Association acknowledges the need for oversight to ensure proper implementation and evaluation of the proposed Action Plan. The opportunity to have both federal and nonfederal partners included as representatives of the proposed collaborative oversight

entity (objective 1.1.) strongly facilitates coordination and engagement efforts across a range of stakeholders. The American Lung Association proposes that patient advocates also be included as member representatives to ensure that the Action Plan continually remains patient-centric throughout each Goal's progress, developments and successes.

The American Lung Association appreciates the NHLBI's proposal to create a COPD resource guide and undertake related activities to include the awareness of funding opportunities (objective 2). The American Lung Association proposes an emphasis on promoting increased federal and other funding for COPD research in light of the Action Plan's research aims.

In Goal Five's objective 3, the Action Plan proposes the development and implementation of COPD quality measures into national care delivery. Here, the objective includes defining, validating and disseminating quality performance measures for the COPD continuum of care, including, pulmonary rehabilitation. However, this Goal does not include oxygen therapy or tobacco cessation programs. Additionally, in light of Goal Five's aim, perhaps this objective may also be more aligned with that of Goal Two's objective 3, which seeks to develop clinical decision tools based on clinical quality measures.

Conclusion
The American Lung Association appreciates the NHLBI's efforts to establish a National COPD Action Plan and thanks the NHLBI for the opportunity to comment on the Action Plan.

The American Lung Association supports the Action Plan's overall goals of empowering patients, families and caregivers; improving clinical quality care; promoting research; gathering data to better understand COPD; and, developing a centralized, collaborative entity to oversee implementation of the Action Plan. The American Lung Association respectfully requests the NHLBI to address our comments to help mobilize the appropriate measures and resources that will assist with improving health outcomes and reduce the burden of COPD with a patient-centric focus that the Action Plan aims to uphold.

Sincerely,

Harold P. Wimmer
National President and CEO

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[2] Centers for Disease Control and Prevention. National Health Interview Survey, 2007-2010 and 2014. Analysis by the American Lung Association Epidemiology and Statistics Unit using SPSS Software.

[3] Tilert T, Dillon C, Paulose-Ram R, et al. Estimating the U.S. Prevalence of Chronic Obstructive Pulmonary Disease Using Pre- and Post-Bronchodilator Spirometry: The National Health and Nutrition Examination Survey (NHANES) 2007–2010. *Respiratory Research*. 2013; 14(1):103.
[4] United States Census Bureau. Population Estimates, 2007-2010.
[5] US Department of Health and Human Services. *The Health Consequences of Smoking - 50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA; 2014.
[6] The National Lung Cancer Screening Trial Team. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. NEJM, August 4, 2011; 365(5):395-409
[7] Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2016. *CA: A Cancer Journal for Clinicians*. 2016:1-24.