

# PALs United for Lung Health Advocacy Roundtable at CHEST

Collaborating to Raise the Profile of Lung Disease  
and Advance Better Patient-Centered Solutions

October 6, 2018

Marriott Rivercenter | San Antonio, TX



**PALs**  
**UNITED**



Patient Advocacy Leaders  
United for Lung Health

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### Overview

The PALs United for Lung Health Advocacy Roundtable was held on October 6, 2018 in San Antonio, Texas in concurrence with the American College of Chest Physicians (CHEST) Annual Meeting. In total, 24 lung health advocacy leaders and other stakeholders from organizations throughout the U.S. participated in the Roundtable event (see Appendix A for a list of registered attendees). The meeting was developed by the Patient Advocacy Leaders Summit (PALS) in collaboration with the PALs United for Lung Health Steering Committee.

The convening was intended to carry forward the engagement that began at the inaugural PALs United for Lung Health event held in Washington, DC in October 2017 which continued at the Advocacy Roundtable held at CHEST in Toronto in October 2017 and was further advanced at the American Thoracic Society International Conference in San Diego in May 2018. Roughly half of the Advocacy Roundtable registrants attended one or more of these previous meetings.

Key objectives of the Advocacy Roundtable were to:

- Build upon the engagement started at the inaugural PALs United for Lung Health event held October 23, 2017 in DC, to further coalesce and collaborate around common goals to raise the profile of lung disease and advance patient-centered solutions relating to access to care, services and innovations in lung health.
- Address biomarkers across lung health, in particular, how biomarkers are and will be used to determine what treatments will work best for people with lung cancer, COPD, asthma and other lung diseases. Examine examples and identify how the lung health community can collaborate to help ensure the promise of delivering treatment based on biomarker testing can be fully realized.
- Further assess and prioritize action steps and implementation strategies identified at the PALs United for Lung Health Roundtable May 20, 2018 at ATS, to enable lung health leaders to work collectively in raising the profile of lung disease and advancing patient-centered solutions.

### Welcoming Remarks

The meeting began with opening remarks by Deborah Bryan, President and CEO (retired) of the American Lung Association of North Carolina. Ms. Bryan welcomed guests and thanked PALS sponsors and the PALs United for Lung Health Steering Committee for their support. She introduced event co-moderators Tonya Winders, President and CEO, Allergy & Asthma Network and President, Global Allergy & Asthma Patient Platform; and Jamie Sullivan, Vice President of Public Policy & Outcomes, COPD Foundation, who both helped put this Advocacy in context of the previous events. Rudy Anderson, Senior Director, Development, CHEST and Associate Executive Director of CHEST Foundation, provided a welcome on behalf of CHEST/CHEST Foundation.

## Spotlight Topic – Innovation and Biomarkers in Lung Health



Featured speaker for this Advocacy Roundtable was national lung health thought leader, Barry Make, MD, who is Co-Director of the COPD Program and Director, Pulmonary Rehabilitation, and Respiratory Care, and Chair of the Faculty Appointment, Promotion and Periodic Evaluation Committee at National Jewish Health. He is Professor of Medicine in the Division of Pulmonary Sciences and Critical Care Medicine at National Jewish Health and the University of Colorado School of Medicine.

Dr. Make addressed biomarkers across lung health, focusing on how biomarkers are and will be used to determine what treatments will work best for people with lung cancer, COPD, asthma and other lung diseases.

Dr. Make gave an overview of personalized medicine, with the universal management goal of physicians and patients being treating:

- The **right** patient
- With the **right** treatment / medication
- At the **right** time in the course of the disease
- To achieve the **right** outcome

Current understanding of lung disease has changed previously held beliefs. COPD, asthma and lung cancer are not single, homogeneous diseases. With specific lung health examples, Dr. Make discussed how we can better understand the differences between patients, and better utilize personalized medicine, through phenotypes, endotypes and biomarkers.

- **Phenotype** – The composition of observable characteristics or traits, such as morphology, development, biochemical or physiological properties or behavior.
- **Endotype** - Subgroup of a disease characterized by a specific biological pathway (pathophysiologic mechanism) that explains the observable properties of a phenotype.
- **Biomarker** – A defined characteristic that is
  - measured
  - an indicator of
    - normal biological processes,
    - pathogenic processes, or
    - responses to an exposure or intervention, including therapeutic interventions.

Dr. Make provided an overview of specific types and uses of biomarkers with detailed illustrations in COPD and asthma. Specific Biomarker Types are:

- Molecular – blood, urine, sputum
- Histologic – tissue
- Physiologic – blood pressure, pulmonary function test
- Radiologic – lung cancer size, emphysema on chest CT scan

Dr. Make highlighted the work of the COPD Biomarker Qualification Consortium (CBQC), a program of the COPD Foundation, in qualifying new biomarkers and clinical outcome assessments in COPD. The CBQC is a collaborative public-private partnership, aiming to undertake regulatory qualification [FDA/EMA] of emerging biomarkers and clinical outcome assessments to facilitate the development and approval of novel treatments for COPD. The goals of the Biomarker Qualification Program are to:

- Qualify biomarkers and make supporting information publicly available
- Facilitate uptake of qualified biomarkers in the regulatory review process
- Encourage the identification of new biomarkers to be used in drug development and regulatory decision-making

Dr. Make shared some of the lessons learned to date from the work of the CBQC:

- The qualification process is expensive and time consuming (~5 years from start to approval).
- Public/private consortia represent a strong mechanism to do this work.
- Requires strong partner commitment and engagement.
- A strong governance and organization “hub” (e.g. the COPD Foundation) can facilitate progress.
- The voices of patients matters to all involved.

He reiterated how Biomarker Development takes a village and collaboration with involvement from key stakeholders including: Academia, Federal Partners, Regulatory Agencies, Patient Groups, Foundations and Professional Societies, Industry, Consortia.

Areas to consider as this work moves forward include:

- Fostering research in clinical aspects of biomarkers, phenotypes and endotypes that are important to patients
  - Discovery
  - Validation
- “Qualifying” with the community
  - FDA
  - Pharma
  - Academic
  - Patients
- Implementation
  - Education – patients, providers
  - Electronic medical record incorporation

Collaboration and implementation are critical!

## Opportunities to Move the Needle

Co-moderators Tonya Winders and Jamie Sullivan led an interactive discussion following Dr. Make's presentation. The focus of this segment was on identifying opportunities for action, as well as ways to collaborate and engage across the entire lung health spectrum.

### Raising the Profile of Lung Disease – Tonya Winders

Tonya Winders addressed the issue of raising the profile of lung disease; specifically how can we work together to engage all the stakeholders in order to collectively raise the profile of lung disease? She identified a couple opportunities that generated robust discussion amongst the audience.



- **Increase NIH Funding** - The National Heart, Lung and Blood Institute (NHLBI) budget delegates only 10% to lung and 90% to heart and blood diseases, even though chronic respiratory disease is 3rd in global mortality.
- **Build Awareness** – Stigma exists regarding lung health, which calls for awareness to be raised and positive messaging employed to overcome. Look for burden of illness statements that address lung health as a whole, but can be made more specific per a certain condition. Focus on the connection between lung health and overall health across the lifespan (i.e., the lung health/total health connection).

Specific action items were proposed and discussed:

- **Consider a campaign** that all lung health advocates can rally around. Some examples (all of which could be linked to personalized medicine):
  - One Size Does Not Fit All (in lung health)
  - Shortness of Breath is Not Normal
  - Chronic Cough is Not Normal
  - It's Time for Your Annual PFT (Pulmonary Function Test)
  - Taking it to the Street – Living with Lung Disease (Pulmonary Rehab, Education)
- **Utilize planned awareness events** to collectively and collaboratively raise awareness (e.g., World Lung Day (9/25), National Asthma Month, etc.)
- **Share resources** with other partners to help amplify and enhance the collective voice.
- **Consider Drafting Principles** broad enough to span lung health that all can support. Ms. Winders shared 6 principles included in *A Charter to Improve Patient Care in Severe Asthma*, as an example.
  - Principle 1 – I deserve a timely, straightforward referral when my severe asthma cannot be managed in primary care.
  - Principle 2 – I deserve a timely, formal diagnosis of my severe asthma by an expert team.
  - Principle 3 – I deserve support to understand my type of severe asthma.
  - Principle 4 – I deserve care that reduces the impact of severe asthma on my daily life and improves my overall quality of care.

## Collaborating to Raise the Profile of Lung Disease and Advance Better Patient-Centered Solutions

- Principle 5 – I deserve not to be reliant on oral corticosteroids.
- Principle 6 – I deserve to access consistent quality care, regardless of where I live or where I choose to access it.
- In all this collaborative work, align with partners around **social media strategies/tactics and messaging**.

### Advancing Patient-Centered Principles – Jamie Sullivan

To supplement the discussion about communications and messaging to raise the profile of lung disease, Jamie Sullivan then addressed advancing patient-centered principles. Her focus was on specific Policy Levers that can help us achieve change on a large scale and also move us toward personalized medicine. Some of the Policy Levers Jamie highlighted include:



- FDA/Patient Engagement Opportunities
- Centers for Medicare and Medicaid Services (CMS) (e.g., readmission penalties to hospitals)
- NIH Funding
- Delivery Systems
- State Health Policies

Ms. Sullivan talked about how important it is to talk about and promote wins, and then led an interactive discussion with the audience about recent wins at the state and federal levels. Some of the wins identified were:

- Non-medical switching (IL/ME)
- Step therapy - state wins / federal bill
- CMS Changes - adequate Durable Medical Equipment (DME), peak flow testing and monitoring
- NIH - +\$2billion in 2019; greater increase pursued for 2020
  - NHLBI - Dr. Gary Gibbons heads
- COPD National Action Plan report language connected to an appropriations bill

### How to Make it Happen: Next Steps for Action

The final session, moderated by Tonya Winders and Jamie Sullivan, was designed to move toward consensus on action steps. The items below were identified as opportunities for future collaboration/engagement of those in the PALs United for Lung Health Network.

- **Develop a central collaboration calendar/portal** where advocates can post news of Hill Days, Awareness Events, key issues, resources etc. so others can share, potentially piggy back on efforts and overall better leverage the collective work going on in lung health advocacy.
- **Utilize planned awareness events** to collectively and collaboratively raise awareness (e.g., World Lung Day (9/25), National Asthma Month, etc.)

- **Develop consensus statements/guidelines** around issues of mutual concern for all to use in advocating for lung health. An environmental scan of lung health advocacy organizations' policy priorities would help identify common issues.
- **Consider hosting an Innovations & Biomarkers in Lung Health webinar** to allow others who were not at this event to learn more on this topic.
- **Convene future PALs United for Lung Health events** – Consider a national event (more policy focused) and another event at a Medical Congress, like ATS or CHEST with a spotlight issue/subject matter expert and time to further ongoing PALs United for Lung Health work.

*This event has been developed by **PALS** and the **PALs United for Lung Health Steering Committee**:*

Name	Organization	Title
Rudy Anderson	CHEST Foundation	Associate Executive Director
Deborah Brown	American Lung Association	Chief Mission Officer
Deborah Bryan	PALS Advisory Board, American Lung Association-NC	Advisory Board Member, President & CEO (Retired)
Mike Cohen	PALS Advisory Board, MJC Health Solutions	Advisory Board Member, Principal
Anne Easter	Patient Advocacy Leaders Summit	Director
Jamie Sullivan	COPD Foundation	Vice President of Public Policy & Outcomes
Tonya A. Winders	Allergy & Asthma Network	President and CEO and President, Global Allergy & Asthma Patient Platform



*This **PALs United** event is part of the **PALS (Patient Advocacy Leaders Summit)** program, which involves patient advocates from around the country who are committed to improving health and healthcare in our communities. PALS is guided by the PALS Advisory Board comprised of advocacy leaders from across the country who help ensure that PALS is *By Advocates, For Advocates*. PALS was developed by GlaxoSmithKline (GSK) in 2002. GSK has authorized The AIDS Institute exclusive rights to implement PALS, and provided a portion of the funding for this event. Funding was also provided by AbbVie.*



## Photo Gallery











