



Engaging with FDA for Better Lung Cancer Treatments

August 6, 2013
American Lung Association

Agenda

- Background on FDA's initiative
- Patient & survivor views
- How can you share your thoughts?
- Other opportunities
- Lung cancer research
- Q&A

Background



Erika Sward

*Assistant Vice President, National
Advocacy*

Supporters



Boehringer
Ingelheim

Lilly Oncology

Project Origins

Prescription

Drug

User

Fee

Act



Patient

Focused

Drug

Development

Initiative

Patient-Focused Drug Development Initiative (PFDDI)

- Designed to provide a “more systematic approach to obtaining patient perspective on the disease severity and the currently available treatments for a set of disease areas.”
- September 2012: FDA releases a request for comments on which diseases the Initiative should focus



Patient-Focused Drug Development Initiative

The Lung Association:

- Reached out to patients, family members and advocates, who submitted 1800 comments (thank you!)
- Filed national comments
- Behind-the-scenes meetings with FDA
- Testified at public meeting



Patient-Focused Drug Development Initiative

- Chronic Fatigue Syndrome
- HIV



Lung Cancer

- Narcolepsy
- Alpha-1 antitrypsin deficiency
- Breast cancer
- Chronic Chagas disease
- Female sexual dysfunction
- Fibromyalgia
- Hemophilia and other heritable bleeding disorders
- Idiopathic pulmonary fibrosis
- Irritable bowel syndrome, gastroparesis, and gastroesophageal reflux disease with persistent regurgitation symptoms on proton-pump inhibitors
- Neurological manifestations of inborn errors of metabolism
- Parkinson's disease and Huntington's disease
- Pulmonary arterial hypertension
- Sickle cell disease

June 28 Meeting at FDA

- Included panel of FDA staff, 2 panels of current or former lung cancer patients
- Discussed FDA questions
- You can watch a recording here:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm353273.htm>



Questions for Lung Cancer Patients

- Disease symptoms and daily impacts that matter most to patients
- Patients' perspectives on current approaches to treating lung cancer
 - When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life vs. improving the symptoms you experience because of your lung cancer?
 - What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer?

Let's hear from some of the patient panelists!



Denise



Susan



Kathleen

How Can You Participate?



Participate in a survey

Deadline - August 15th

www.lung.org/pfddi

How Can You Participate?

Submit comments to the public docket

Deadline: August 26, 2013



How Can You Participate?

Spread the word!

- Share with family, friends
- Share with your cancer support group
- Share on social media
 - #lungcancer

www.lung.org/pfddi



Other Opportunities for Lung Cancer Survivors & their Families



Carly Hamburger

Manager, Adult Lung Health Education

Lung Association Resources



www.mylungcancersupport.org

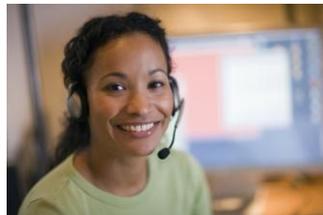
Lung Association Resources



connection.lung.org



www.lung.org/my-ffa



**Call the Lung HelpLine at
1 800 LUNGUSA or 1 800 586 4872.**

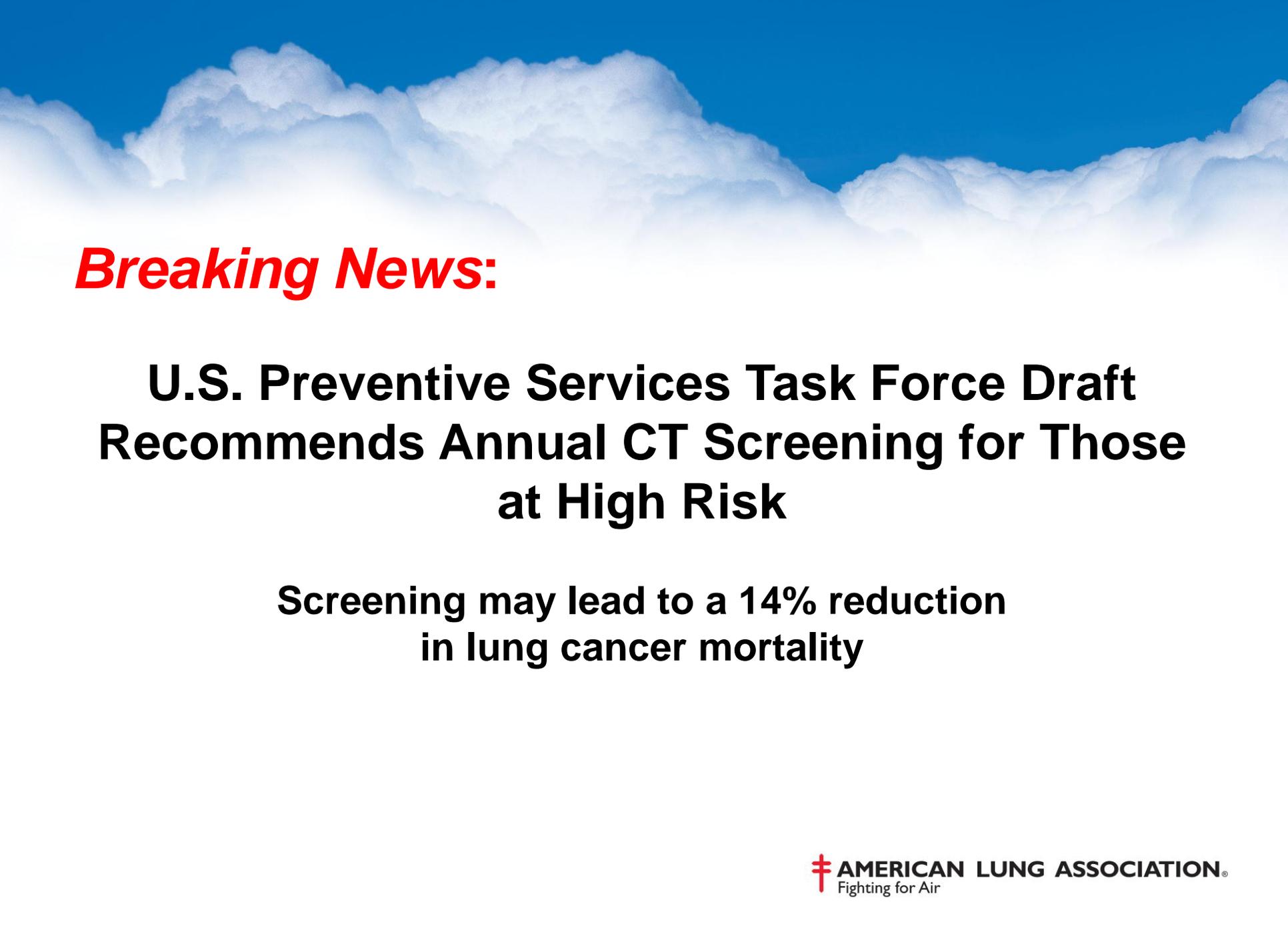
AMERICAN LUNG ASSOCIATION.
Fighting for Air

Lung Cancer Research



Susan Rappaport

Vice President, Research and Health Education



Breaking News:

**U.S. Preventive Services Task Force Draft
Recommends Annual CT Screening for Those
at High Risk**

**Screening may lead to a 14% reduction
in lung cancer mortality**

Lung Cancer Screening

High risk defined as those:

- 55 through 79 years old, and
- current or former smokers who have quit within the past 15 years.
- Smoking at least 30-pack years – a “pack year” is smoking an average of 1 pack of cigarettes per day for 1 year.



The American Lung Association Supports Lung Cancer Research



Lung Cancer Discovery Award

- Supporting investigators focusing on
 - novel approaches to improving clinical methods for the early detection of lung cancer
 - developing novel medical treatments
 - advancing current treatment options

Lung Cancer Discovery Award

- \$850,000 in research expenditures
- Nine current awardees throughout the country

Studies currently being funded include:

- validating biomarkers to determine who will respond to lung cancer treatment;
- improving personalized treatment for lung cancer
- identifying the mechanisms by which tobacco leads to lung cancer

Supporters



Boehringer
Ingelheim

Lilly Oncology



Questions? Comments? Ideas?

PFDDI@lung.org

www.lung.org/pfddi



We will breathe easier when the air in every
American community is clean and healthy.

We will breathe easier when people are free from the addictive
grip of cigarettes and the debilitating effects of lung disease.

We will breathe easier when the air in our public spaces and
workplaces is clear of secondhand smoke.

We will breathe easier when children no longer
battle airborne poisons or fear an asthma attack.

Until then, we are fighting for air.