

# **The Voice of the Patient**

A series of reports from the U.S. Food and Drug Administration's (FDA's)  
Patient-Focused Drug Development Initiative

## **Lung Cancer**

**Public Meeting: June 28, 2013**

**Report Date: December 2013**

Center for Drug Evaluation and Research (CDER) and  
Center for Biologics Evaluation and Research (CBER)  
U.S. Food and Drug Administration (FDA)

## Table of Contents

<b>Introduction</b> .....	<b>3</b>
Overview of lung cancer and its treatment .....	3
Meeting overview .....	4
Report overview and key themes .....	4
<b>Discussion Topic 1: Most significant symptoms of lung cancer and their impact on daily life</b> .....	<b>6</b>
Most significant symptoms associated with lung cancer .....	6
Impact of lung cancer on daily life .....	8
<b>Discussion Topic 2: patient perspective on treating lung cancer</b> .....	<b>8</b>
Perspectives on cancer treatments .....	9
Perspectives on supportive care and non-drug therapies.....	9
Considerations on treatment decisions.....	10
Perspectives on a hypothetical treatment scenario .....	12
Other considerations on lung cancer treatment .....	12
<b>Summary of comments submitted to the docket</b> .....	<b>13</b>
Submitted comments on most significant symptoms .....	14
Submitted comments on cancer treatments and supportive care therapies.....	15
Submitted comments on the impact on daily life.....	15
Submitted comments on treatment decision making .....	15
<b>Conclusion</b> .....	<b>16</b>
<b>Appendix 1: Meeting Agenda and Discussion Questions</b> .....	<b>17</b>
<b>Appendix 2: Meeting Panel Participants</b> .....	<b>19</b>
<b>Appendix 3: Meeting Polling Questions</b> .....	<b>20</b>
<b>Appendix 4: Sample Benefit-Risk Framework for Lung Cancer</b> .....	<b>23</b>

## Introduction

On June 28, 2013, FDA held a public meeting to hear perspectives from lung cancer patients about their disease, its impact on their daily life, and currently available therapies. From this meeting, we sought to gain insights from patients that can help further inform the therapeutic context of the disease, which is important for the advancement of drug development tools and the assessment of drug products.

FDA conducted the meeting as part of its [Patient-Focused Drug Development initiative](#), an FDA commitment under the [fifth authorization of the Prescription Drug User Fee Act](#) (PDUFA V) to more systematically gather patients' perspectives on their condition and available therapies to treat their condition. As part of this commitment, FDA is holding at least 20 public meetings over five years, each focused on a specific disease area. More information on this initiative can be found at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

## Overview of lung cancer and its treatment

Lung cancer is a disease caused by uncontrolled growth of abnormal cells in the tissues of the lung. Lung cancer cells can spread (metastasize) to almost any other part of the body, such as to the brain or bones. Lung cancer has been broadly categorized into two main types: small cell and non-small cell lung cancer (NSCLC). NSCLC makes up about 80-85 percent of lung cancer cases. The American Cancer Society estimates that each year in the United States there are more than 228,000 new cases of lung cancer (both small cell and NSCLC) and almost 160,000 deaths from lung cancer, making it the leading cause of cancer death in the country for both men and women.

Patients in the early stages of lung cancer often do not experience any symptoms, and the cancer can grow for years before symptoms are felt. When symptoms do appear, they typically include shortness of breath, coughing, pain, weight loss, and fatigue.

Lung cancer treatments fall into two main categories:

- Therapies to cure, reduce the size of tumor, or control the spread of disease include surgery, radiation therapy, chemotherapy, and molecularly-targeted therapies. The standard of care depends on the type and stage of the cancer. Surgery is usually performed in early stages of cancer, and it may be curative in some cases. Radiation therapy may be used in early states as a curative therapy, often in combination with surgery or chemotherapy, or in lower doses as a palliative therapy for patients with more advanced disease. Chemotherapy drugs are designed to kill cancerous cells or stop them from dividing. Targeted therapies are drugs optimally used only for specific individuals whose tumors have a particular molecular defect. Each therapy has its own set of side effects, including serious risks.
- Palliative or supportive care therapies are used to improve or manage symptoms of the disease or side effects of treatments. Examples include supplemental oxygen, pain medications, steroids, and non-drug therapies such as breathing exercises.

## Meeting overview

This meeting provided FDA the opportunity to hear directly from patients, patient caretakers, and other patient representatives about patients' experiences with lung cancer and its treatment. Discussion focused on two key topics: (1) disease symptoms and daily impacts that matter most to patients, and (2) the patient perspective on treatment of this condition. The questions for discussion were published in a [Federal Register](#) notice to announce the meeting. See *Appendix 1* for the agenda and discussion questions. For each topic, a panel of patients and patient representatives (*Appendix 2*) shared comments to begin the dialogue. Panel comments were followed by a facilitated discussion inviting comments from other patients and patient representatives in the audience. The discussion was led by an FDA facilitator; a panel of FDA staff (*Appendix 2*) asked follow-up questions. Participants who joined the meeting via live webcast were able to submit comments, which are included in this summary. In-person and web participants were periodically invited to respond to polling questions (*Appendix 3*),<sup>1</sup> which provided a sense of the demographic makeup of participants, as well as of how many participants shared a particular perspective on a given topic.

Approximately 15 lung cancer patients and 15 patient representatives (including family members and representatives from patient support or advocacy organizations) attended the meeting in person. Approximately 25 patients participated through the live webcast by answering polling questions or by submitting comments. In-person and web participants included men and women living all over the country, across the spectrum of disease stages. It was noted, however, that the in-person participants represented a higher proportion of women, patients diagnosed more than five years ago, and patients whose cancer is currently in remission as compared to the overall lung cancer patient population. Because the potential for an imbalanced representation of patients was considered before the meeting, several in-person participants gathered input in advance of the meeting from other lung cancer patients, such as support group peers, and shared those perspectives throughout the discussion.

To supplement the input gathered at the meeting, patients and others were encouraged to submit comments on the topic to a [public docket](#),<sup>2</sup> which was open until August 28, 2013. Approximately 45 comments were submitted to the public docket, the majority by individual patients.

More information, including the archived webcast and meeting transcript, is available on the meeting webpage (<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm353273.htm>).

## Report overview and key themes

This report summarizes the input provided by patients and patient representatives who participated in the meeting. It also includes a summary of comments submitted to the docket, beginning on page 13. The report reflects the content of this meeting and is not meant to be representative in any way of the views and perceptions of any specific group of individuals or entities. There may be symptoms or treatments used for lung cancer or other aspects of the condition not mentioned in the report.

---

<sup>1</sup> The polling questions were intended as a discussion aid only. Polling results should not be interpreted as being representative of the overall lung cancer patient population.

<sup>2</sup> A *docket* is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. More information can be found at [www.regulations.gov](http://www.regulations.gov).

The meeting underscored both the wide diversity in patients' experience with lung cancer, the side effects of treatment, and the impact the disease can exert on patients' lives. A number of key themes emerged from the meeting:

- Patients find it difficult to distinguish between symptoms of the disease and side effects of cancer treatments. Fatigue, breathing difficulties, and chronic pain were identified as the most significant symptoms affecting patients' daily lives. Other symptoms described included cognitive effects (e.g., "chemo brain"), sleep difficulties, persistent cough, voice hoarseness, anxiety, depression, and cachexia (weakness and wasting of the body). The effects of lung cancer treatment can continue long after the treatment has stopped.
- Participants clearly appreciated and are encouraged by the advances in lung cancer treatments. However, the meeting reiterated the tremendous toll that treatment takes on patients and their families. Patients take a range of medications to manage their symptoms and treatment side effects, with mixed effectiveness. Many value the benefits they see in non-drug therapies, such as diet changes, vitamins and supplements, acupuncture, yoga, and supportive interaction.
- The impact lung cancer has on patients' lives varies widely, from "a normal life" to debilitating. The impact depends on a number of factors, including the disease manifestation, side effects of treatments, treatment requirements, and other responsibilities in the person's life.
- Lung cancer treatment decisions are highly individual and personal. Participants described a number of factors, including personal circumstances (age, overall health), responsibility for families, available treatment options, the impact of treatment on the body, pressures by loved ones to seek certain treatments, and financial considerations. When asked to discuss the tradeoffs, a majority appeared to value *prolonging life* above all other factors. However, many other participants indicated that preserving *quality of life* is equal in importance or more important than the chance of prolonging life.
  - Those who indicated that **prolonging life** is of higher priority tended to focus their comments on being young and otherwise healthy, being less affected by symptoms or side effects, having children to care for, valuing even the small chance of becoming a "survivor," or their hope to see better treatments or a cure in the future.
  - Those who indicated that preserving **quality of life** is of higher priority tended to focus their comments on their advanced age, their experience with debilitating symptoms or treatment side effects, the terminal nature of their condition, or their desire to end life peacefully.
  - Regardless of their current perspective on the tradeoffs between prolonging life and preserving quality of life, participants acknowledged that **priorities may change** over time, for instance, when the disease or suffering progresses. Participants described the difficulty in making decisions to stop (or not to begin) treatment, especially because of perceived pressure "to do whatever it takes." They stressed the importance of patients being fully supported by family and loved ones in their treatment decisions.

The patient input generated through this meeting and docket comments strengthens our understanding of the burden that lung cancer and its treatments have on patients, the various ways that patients try to manage their symptoms and side effects, and the range of considerations patients take into account when making difficult treatment decisions. FDA staff will carefully consider this input when advising sponsors on their drug development programs and when assessing products under review for marketing approval. For example, *Appendix 4* shows how this input may support our benefit–risk assessments for products under review. This input may also be useful to the drug development process more broadly, for example, by identifying potential areas of unmet need for lung cancer patients, or by informing development and qualification of new outcome measures (e.g., relating to pain) in clinical trials.

## **Discussion Topic 1: Most significant symptoms of lung cancer and their impact on daily life**

The first discussion topic focused on patients’ experiences with the symptoms of their conditions and the resulting impacts on their day-to-day lives. In particular, FDA was interested in hearing about the specific activities that are important to patients, which they can no longer perform at all or as fully as they would like because of their lung cancer.

Four panelists provided comments to start the dialogue. The panel included: a woman who was diagnosed with Stage IV lung cancer sixteen months prior and works full time; a woman diagnosed with bronchioloalveolar carcinoma in 1999 and currently in remission, who shared her own perspective as well as the perspectives of peers in her support group whom she interviewed; a patient advocate and cancer survivor whose last surgery was 13 years ago, who shared her individual perspective and her broader perspective based on her experience working with patients; and a patient advocate who spoke on behalf of a cancer patient who was too ill to travel.

The panel’s testimonies provided a vivid picture of what it is like to live with lung cancer. They described their or their loved ones’ challenges with their diagnosis and their experiences with treatment. They also described the impact lung cancer has on day-to-day life, and for some, their life since treatment. In the facilitated discussion, many patients and representatives in the audience indicated, by a show of hands, that their or their loved ones’ experiences were reflected in the comments shared by the panelists. A few indicated that their experience somehow differed from what was expressed by the panel; these participants were encouraged to share their own perspectives in the facilitated discussion.

### **Most significant symptoms associated with lung cancer**

Many participants recognized that there are very few early symptoms or warning signs of lung cancer. Reflecting on her experiences with patients, one advocate expressed “surprise with how nebulous the symptoms are.” Some described being in an advanced stage of lung cancer when diagnosed. A few described being “incidentally” diagnosed, for instance, after having a chest X-ray for some other reason.

Participants stressed the difficulty in distinguishing between symptoms of the underlying lung cancer and the side effects of lung cancer treatment. However, noting the importance of clearly identifying symptoms such as pain and fatigue to drug development and evaluation, FDA asked patients to distinguish between these two causes of symptoms, if possible.

In response to a polling question (Question 7 in *Appendix 3*), fatigue, shortness of breath, and chronic pain were identified as the most significant symptoms affecting patients’ daily lives. Participants also

described a number of cognitive symptoms as having a significant impact on daily life. As one said, “it's difficult to decipher which is more difficult, the physical challenges or the mental challenges [associated with lung cancer].” Participants’ comments on these and other symptoms are described below.

- **Fatigue or lack of energy** received the greatest number of responses to the in-person and web polling question. One participant described not being able to walk without feeling “like I was lifting up weights.” Participants generally attributed their fatigue to their cancer treatment. As one noted, “[during chemotherapy], all I did was sleep... I had no energy to do anything... it's very debilitating.” A web participant described how the severe fatigue “came at specific points following the chemo cycles and then went away before the next cycle.”
- Shortness of breath, wheezing, or other **breathing difficulties** received the second highest number of responses to the polling question. Participants attributed these symptoms to both the underlying condition and to treatment, particularly removal of lung tissue during surgery. One web participant described how 15 years after treatment “I often have to stop talking, draw in some deep breaths, and begin my speech again.” A few other participants noted, however, that they were not affected by symptoms associated with removal of part of their lung.
- Some participants discussed **chronic pain**, including pain at the tumor site, “frozen shoulder” or rotator cuff issues, neuropathy, and pain in other parts of the body. Most comments concerning chronic pain were attributed to surgery, chemotherapy, or radiation. As one described a loved one’s experience, “Because of peripheral neuropathy from the chemotherapy, she had a lot of numbness in her feet, which caused her one day to fall, and because of the radiation, she also had fairly brittle bones, so she ended up with a [fracture] that required surgery [and it resulted in chronic pain thereafter].”
- Although not asked as part of the polling question, many described **cognitive impairment**, including unclear thinking, memory lapses, and problems with concentration and focus. As one participant described, “I walk into a room to do something and then I forget why I was there.” These participants generally associated these symptoms with chemotherapy (“chemo brain”) and noted that the negative impacts were still present even years after the treatment stopped. As one commented, “I was never as sharp again after chemo, even factoring in aging.”
- A few described **anxiety** (including “scanxiety”) or **depression**. One participant believed that depression is “a symptom that people don't like to talk about, but... most people I talk to have it... I think [it should be] defined as a symptom, and it certainly should be treated.”
- A few commented on insomnia or other **sleep difficulties**, which they primarily associated with the underlying symptoms, for example, as a result of breathing difficulties. One believed her sleep disturbances were the result of the spread of cancer to her adrenal gland.
- **Other health effects** cited by in-person and web participants included persistent cough, cachexia (general wasting of muscles and skin), pain and discoloration of the hand), osteopenia, allergy and asthma issues, sinus infections, postnasal drip, and bad breath.

A few participants who are currently in remission described how their **symptoms have receded** or their functioning has returned. As one participated described, “I'm missing a third of my lungs, but... that lung function has principally come back.”

## Impact of lung cancer on daily life

Participants shared a variety of experiences regarding the impact of lung cancer and its treatment on daily life, including the following:

- The impact that fatigue has on their **ability to manage** their work, families and households, including, “getting up and ready in the morning,” “making it through a day of work,” and “having the energy to take care of [my children].”
- The barrage of **doctors’ appointments, scans, and treatment**. For example, an advocate described a typical “scan day” experienced by a friend on targeted therapy. She described how treatment controlled her schedule and her choices (e.g., when to sleep, what to eat), spent her energy, and occupied her thoughts (e.g., “think[ing] of all the possible outcomes of my scan”).
- The need to **give up work and hobbies** as disease progresses. As one described her mother’s experience: “Work was really what kept her going, and to not be able to do that really brought her down in a major way.”
- **Living with uncertainty**. Participants described worrying about suffering, risks from treatment (e.g., “radiation causing another cancer”), and “running out of time to do everything that I want to do.” As one participant summarized, “It’s difficult managing dying with living.”
- **Identity as a “sick person.”** One participant commented that the visible side effects of treatment, such as hair loss and skin rashes, served as a constant reminder of her illness. Another commented on the *invisibility* of the disease: “Because my tumors are invisible and I look healthy, people tend to forget that I’m sick... it feels like they just don’t care anymore.”
- **Strong stigma** associated with lung cancer and smoking. As one participant commented, “I don’t think that any other cancer [patients get asked the question], ‘How did you get it?’”

A few participants, particularly those in remission, said that although they have lower lung capacity or experience some bothersome side effects, it is “**a small thing**” **compared to surviving**. One participant described a friend who had her lung removed but “views herself as having no real limitations [even though] she can’t climb stairs [and] can’t be as active as she would like to be.”

## Discussion Topic 2: patient perspective on treating lung cancer

The meeting’s second main discussion topic focused on patients’ perspectives on therapies used to treat and manage their lung cancer. Participants shared their, or their peers’ or loved ones’, experiences with a wide variety of treatments. According to a polling question, most participants had experience with chemotherapy and radiation; many also had experience with surgery or targeted therapies.

Five panelists provided comments to start the dialogue. Panelists included a man recently diagnosed with Stage IV lung cancer who had just finished his first chemotherapy cycle; a young mother currently on a targeted therapy with stable disease and no symptoms; a woman diagnosed with Stage II NSCLC who underwent surgery and chemotherapy and has been free of cancer for three years; a woman, now in remission, who fought two bouts of cancer (Stage II, then Stage IIIA) and who used treatments that



“hit me with everything”; and an advocate who focused her comments on an elderly family member’s decision not to undergo cancer treatment.

## Perspectives on cancer treatments

Participants were clear in their appreciation for current treatments for lung cancer. They expressed their belief that recent treatment advances have significantly improved their chances of survival, as well as their quality of life while battling the disease.

Participants did, however, describe several downsides of treatment, summarized below.

- **Chemotherapy** or radiation and chemo combined: Chemotherapy was the most commented upon treatment, and participants reiterated the debilitating effect chemotherapy had on them, even years after treatment. As one patient commented, “I thought [the chemotherapy] might kill me all on its own... it was the most difficult time in my life and I thought the end was near.” In addition to the side effects of chemotherapy, such as fatigue, described in the Topic 1 discussion, hearing loss and ringing in the ears were also mentioned.
- **Surgery:** Those who commented on the downsides of surgery focused on chronic pain that sometimes lingered for years after surgery, including neuropathy, muscle and joint stiffness, and scarring and pain at the scar site. They also commented on the loss of lung function. (These symptoms are described in more detail in the Topic 1 discussion.) One panelist commented that post-surgical steroid injections can help to significantly reduce post-surgical pain.
- **Targeted therapies:** Those who commented on molecularly-targeted therapies noted that although the side effects are generally less severe than for other cancer treatments, patients have to be on these therapies “for the remainder of our lives or until we stop responding to that drug.” They also expressed concern about losing response or building up resistance to treatments, thereby losing options (“what happens when I use everything up?”). As one participant commented, “I can deal with having lung cancer and living with a chronic illness, I just need to know that there is a drug out there without a resistance that will allow me to live a normal life expectancy, like diabetes and AIDS.” A web participant described low testosterone, contributing to unnecessary fatigue, as a side effect of a targeted therapy.
- **Radiation:** Those who commented on radiation expressed concern about resulting weakness (“brittle bones”), which has resulted in further injury and chronic pain. One participant believed the radiation caused excessive mucus, particularly when exposed to smoke: “If I’m exposed to [smoke], I feel like I can’t breathe... like I’m drowning in mucus.” One expressed concern about the risks of excessive radiation causing another cancer.

## Perspectives on supportive care and non-drug therapies

Participants described a variety of supportive care therapies used to manage their symptoms. In response to a polling question (Question 9 in *Appendix 3*), in-person and web participants reported using, in highest frequency: breathing, exercise or relaxation techniques, pain medications, dietary supplements or diet changes, and supplemental oxygen. Although not discussed in detail, specific off-label treatments mentioned by participants included pregabalin for neuropathy and leg pain,

testosterone replacement (which “adequately manages fatigue”) and steroids to manage surgery pain. A few participants commented that non-drug therapies, such as yoga and acupuncture, were helpful in managing their pain, fatigue, and breathing problems.

Many participants commented on the importance of paying strong attention to personal care, including staying hydrated, “sneaking” in naps, getting physical exercise, maintaining a healthy diet, using air and water filters, and “learning to say no.” Many also commented on the benefit they or loved ones found in maintaining a positive attitude (e.g., “not giving in,” focusing on the “mind-body connection,” “refusing to let it define me”), as well as “faith and prayer.”

### **Considerations on treatment decisions**

A key topic of discussion focused on understanding the factors that patients take into account when making decisions about using cancer treatments. Acknowledging that there are many important considerations in patients’ decisions, we were particularly interested in understanding how patients consider specific factors such as the potential benefit of treatment, likely side effects, potential serious risks of treatment, and how the drug is administered.

The discussion underscored that lung cancer treatment decisions, particularly decisions related to more aggressive cancer treatments, are highly personal and influenced by a number of factors, described below. For most, these decisions are very difficult and patients’ priorities and decisions may change as experiences or situations change.

#### ***Prolonging Life vs. Preserving Quality of Life***

When asked which factors are *most important* to decisions about using cancer treatments (polling question 10 in *Appendix 3*), the factors “how long the therapy would *probably* prolong life” and “how long it could *possibly* prolong life” received the most responses by in-person and web participants. Those who indicated that **prolonging life** is a higher priority to them tended to focus their comments on: being young and otherwise healthy, having children to care for, being less affected by lung cancer symptoms or treatment side effects, or their hope for better treatments or a cure in the future. The following examples illustrate their perspectives:

- “I’m willing to pay any price [and endure any amount of pain] to stay alive... It’s easy for me because I’m young and otherwise healthy, and I have two little girls... I just hope that there will be enough options that work to get more years of parenting in.”
- [At the time of my metastasized recurrence], I knew I was in the fight for my life, and I looked at my doctor and I said, ‘Hit me with everything you have. I’m 48, I’m healthy... and in very, very good shape.’”
- “[I] hope to live long enough for the development of new treatment options.” [web participant]

However, other participants described **quality of life** as being equal to or more important than the chance of prolonging life. These participants tended to focus their comments more on their experience with debilitating symptoms or the disabling effect of chemotherapy, their advanced age, or their desire to end life peacefully. The following examples illustrate their perspectives:

- “If I [ever needed] chemotherapy again, I don't think I would do it” because “it totally disabled my life... I couldn't accept that it was killing everything else... there was no quality of life.”
- “[My father-in-law] and his wife are both very at peace with this decision [not to undergo any cancer treatment]... He would rather enjoy his peaceful life for as long as he can. It's not one single factor, but the combination of factors: the effectiveness of treatments, the side effects, the inconvenience and his overall health status [at age 79, and with emphysema].”

Regardless of their current perspective on these tradeoffs, participants acknowledged that **priorities may change** over time as the disease progresses or on the basis of the person's experience with treatment or personal factors. For example, an advocate recalled a conversation she had with a woman who, “got to the point where the chemotherapy was so debilitating that she couldn't get out of bed. She and her husband had plans to go on a cruise... so she made the choice to go off treatment [because she wanted to regain some quality of life].”

Similarly, participants reiterated how decisions to **not undergo treatment or to stop treatment** are particularly difficult. They described how “there is so much pressure to do whatever it takes” from the patient's family, friends, and even doctors. As one participant explained, “it happens too often where patients are having toxic treatments in the last few weeks of their life because they didn't have ... help in the decision-making process to understand when to transition to more of just a palliative care.” Participants stressed that patients should be fully supported in these decisions.

### ***Other considerations***

Participants raised a number of other issues that factor into their overall perspectives on treatments, including:

- **Deciding on specific treatments.** Participants commented that once the decision to undergo cancer treatment is made, it may be easier to make choices about specific treatments. As one participant said, “[Comparing] risks associated with the medications is irrelevant because they all have very serious side effects.”
- The **options available** to the patient, for example, whether a patient has the right genes or tumor mutations and how they have responded to different treatments.
- The recent **advancements in targeted treatments**, which has “inspired people to hang on until that next [treatment].” As one participant explained, “You do see people who have been through multiple lines of therapy and then all of a sudden they were tested for a mutation [to be a candidate for targeted treatment] and now their lives have transformed.”
- **Access to supportive care**, from the very beginning. One participant described a study showing how supportive care offered alongside active treatment extended both the quantity and quality of life in patients. She indicated that supportive care doesn't have to mean “that I'm giving up and I'm not going to try to beat this.”
- **How the drug is administered.** When asked through a polling question, most participants rated “how the drug is administered, such as how long the treatment takes, whether it requires

hospitalization, required doctor visits, etc.,” as the *least important* factor in their decision making. However, a few described how this factor has been an important consideration in their or their loved one’s case.

- Wanting to find “the most effective treatment with the **least damage to my healthy cells.**”
- **Other factors** described included: quality of the medical team, whether the treatment is merely taken as a “precaution,” and whether there is a possibility of treatment or dose adjustment.

### **Perspectives on a hypothetical treatment scenario**

In order to gain patient insight on the types of issues that FDA has to consider in its review of lung cancer treatments, participants were asked to consider a hypothetical chemotherapy drug, Drug X. (See Q13 in *Appendix 3* for the full scenario.) When added to a standard of care treatment regimen, Drug X was shown to prolong survival by two months on average, but it was associated with more bothersome side effects and more uncommon but serious toxicities.

Participants’ thoughts on this scenario generally aligned with their perspectives shared earlier in the discussion with respect to prolonging survival versus preserving the quality of life. Many participants commented that the **modest gains might be worth the risks**, for a number of reasons, including: the hope that “I’m going to be in the smaller sample that will [survive longer than average];” “never forego[ing] effective treatment due to fear of side effects;” the reality that the fatal disease forces the choice between “dying of lung cancer or liver failure;” and “the hope of [living long enough to see] another drug in the future.”

A few, however, believed that the potential gain in **survival time is “not enough”** to outweigh the risks and downsides of the drug. As a web participant commented, “Gaining months without quality is not worth it for me.”

Participants raised a number of other thoughts or questions regarding the scenario. Some said that they would want to **know more about the risk**, such as how it could be monitored and whether it is reversible and what damage can be caused by the risks. For example, upon clarification by FDA that some patients who experience severe liver toxicity may die, one participant said, “I didn’t know that and I try to keep up with all of the information. [Information like that] has to be clearly spelled out.” One participant asked whether dose adjustments could be made if adverse effects were found.

A few participants said they would want to **know more about the benefit**. They commented on the challenges of framing the drug’s benefit based on average effect. One participant expressed concern about “drugs that fall off quickly because their overall survival was minimal when, in fact, probably for some they might have been a very powerful drug.”

### **Other considerations on lung cancer treatment**

Throughout the meeting, participants spontaneously raised a number of other considerations that they believed are important relating to lung cancer drug development or treatment more broadly:

- The challenges associated with diagnosis. For example, one participant described the “emotional rollercoaster... from an initial diagnosis of follicular thyroid cancer... to [a diagnosis] of non-small cell lung cancer.”
- The importance of genetic testing as early as possible to support treatment decision making, the need for more research into whether targeted therapies can be used at earlier diagnostic stages, and the need for more clarity in treatment guidelines on how to use targeted therapies. As one commented, “[Six years ago,] although targeted therapy was around at that point, I couldn't really get anybody to check me for any of the biomarkers because I was a IIIA, I wasn't a IV.”
- The need for patients to clearly understand the short- and long-term goals of treatment, particularly for treatments that delay tumor progression but are not expected to cure.
- The need to ensure that physicians truly understand patients’ needs, including understanding “what quality of life means to the patient and which of the possible treatment options might best preserve those qualities of life [for that individual patient].”
- The need to acknowledge cost as a factor in people’s decision making and access to treatment.
- The importance of early and routine follow-up after diagnosis and treatment, to ensure that cancer doesn’t advance or metastasize unnoticed.
- The need to increase patients’ awareness of the opportunity to participate in clinical trials, particularly for targeted therapies and particularly for patients in smaller cancer centers, and the need to ensure that clinical trials enroll patients across the spectrum of disease or with comorbid conditions.
- Patients’ desire for more “transparency” in the individual outcomes of clinical research. As one commented, “If a clinical trial [tests for] mutations, then the patient deserves that information.”
- The need to continue to address smoking.
- The opportunity to coordinate efforts to understand and address the complex symptoms (e.g., fatigue, pain) that are so common in a wide range of chronic disease areas.

## **Summary of comments submitted to the docket**

Approximately 45 comments were submitted to the public docket that supplemented the Patient-Focused Drug Development meeting on lung cancer. The majority were submitted by individual patients or their loved ones. By their descriptions, lung cancer patients who submitted comments to the docket ranged from 4 weeks to more than 17 years since diagnoses, with the majority diagnosed within the past three years. The majority described themselves as Stage III or IV. A few commented on behalf of a person who had passed away from the disease.

The submitted comments largely supported the perspectives shared by participants at the June 28 meeting. They also provided additional context to supplement the meeting input. The following is a summary of comments provided through the docket on the symptoms associated with lung cancer or

cancer treatments, and decisions on treatment. Particular focus is placed on experiences or perspectives not addressed in detail at the meeting.<sup>3</sup>

### Submitted comments on most significant symptoms

The submitted comments largely supported the perspectives shared by the meeting participants that breathing difficulties, fatigue, and chronic pain can have a significant impact on lung cancer patients' daily lives. A brief summary of the input on symptoms is described below.

- **Shortness of breath** was identified as a significant symptom by about 20 commenters, most often attributing the symptom to loss of lung tissue and reduced lung capacity. A few described specific challenges with stairs, walking long distances, physical activity, and household chores. For example: "I can walk seven miles, but three flights of stairs is challenging;" and "I can't walk down a long corridor ... without uncontrolled panting."
- **Fatigue** was identified by about 15 commenters. Although most appear to attribute fatigue to treatment, one commenter attributed it to his condition, stating that his fatigue was his first indication that something may be wrong with his health.
- Although not discussed in detail at the meeting, about 10 commenters said that they had **difficulty falling or staying asleep**, which they generally associated with pain, difficulty breathing, persistent coughing, or anxiety.
- About 10 commenters described **chronic pain**, including "neuropathy," "nerve bundle pain," and pain in the chest cavity. One described not being able to walk or do any activity for longer than 10 minutes without severe [back] pain." Another described how the "[metastasized] cancer destroyed some disks in my back... nerve endings were destroyed and being pressed on, which made the pain worse [and had] no feelings in the legs."
- **Persistent cough and voice hoarseness** were mentioned to a greater degree in the submitted comments than in the meeting.
- A few described severe **anxiety or depression**, for example, anxiety attacks that occur during periods of shortness of breath. A study submitted in one comment suggests that many patients "conceptualize emotions and attitudinal orientation as symptoms of NSCLC."
- **Other symptoms** included COPD, acid reflux, severe anxiety and memory issues.
- A few commented being "**totally asymptomatic**" or "**having fully recovered.**"

---

<sup>3</sup> Because the Patient-Focused Drug Development initiative focuses on lung cancer symptoms, impacts and treatments, comments pertaining to these topics are the focus of this report. The comments to the docket covered a range of other important topics related to lung cancer such as early detection, personalized treatment, and endpoint development. Although not described in the report, these comments were reviewed by FDA.

## **Submitted comments on cancer treatments and supportive care therapies**

The submitted comments described a range of experiences with surgery, radiation therapy, chemotherapy, and targeted therapies. Their perspectives generally aligned with those shared by meeting participants. In addition to fatigue and chronic pain (described in Topic 1), commenters described a number of other specific side effects. These included susceptibility to pneumonia and other lung infections, increased blood pressure, loss of appetite and weight loss, diarrhea, nausea, rash, and dry skin, hair, and nails. One commented that the side effects “are significant and somewhat overwhelming... [given] the fact that the therapy [considered palliative in his case] is... intended to increase my life expectancy only by a few months.” A few commented on effects, such as vocal cord problems, tinnitus, and dry mouth, that have remained long after treatment concluded.

Commenters identified a number of prescription medications or therapies that they take in addition to the cancer treatments, including pain medication, sleep aids, inhalers, steroids, antidepressants, and anxiety medications. They offered mixed reactions regarding the effectiveness of these medications, including “not at all,” “a quick fix,” “manageable,” and “excellent.” A few said that these medications present their own downsides, for example: “To put it bluntly, some of the side effects [of the medications I take to manage the side effects of cancer treatments] make me avoid [those] meds.”

Many commenters described in detail a number of non-drug therapies, including diet changes, vitamins and supplements, acupuncture, breathing techniques, meditation, cancer support groups, and “engaging in life.” These commenters generally believed that these therapies are very helpful in reducing pain, controlling treatment side effects, increasing energy, and helping with breathing.

The most common symptoms that commenters identified as not being addressed as well as they would like included shortness of breath, pain, stamina, dry mouth, coughing, and headaches.

## **Submitted comments on the impact on daily life**

The submitted comments largely echoed those of the meeting participants regarding the impact that lung cancer, particularly its treatment and side effects, has had on patients’ day-to-day life. The commenters described a range of impacts, from “amount[ing] to nothing in the big picture” and “living a normal life,” to “time consuming” because of treatment, to debilitating because of the side effects (“can’t do anything for yourself”).

A few commenters described in detail the impact that lung cancer and its treatment has on the patient and his or her family. Specific impacts included: having to travel long distance for treatment, frequent doctor’s visits, financial burdens from not being able to work, fear of losing health insurance, requiring assistance from family to maintain the household or to go to doctor’s appointments, and not being able to leave the house because of diarrhea. One commenter noted that “pain affects every aspect of my job as a nurse and limits my ability to perform my job to the fullest extent.”

## **Submitted comments on treatment decision making**

The submitted comments reiterated the complex tradeoffs that patients must weigh when making choices about treatment. Similar to the meeting input, many commenters appeared to weigh

“prolonging life” as most important. The following quotes supplement the perspectives shared at the meeting:

- “There didn’t seem to be any choice for me... I thought I would find a way to deal with [side effects] as they arose.”
- “I don’t mind putting up with side effects if the treatment is working.”
- “Most of the lung cancer patients I know are currently undergoing treatment or contemplating the need for additional treatment in the future... Overwhelmingly [they] have had the attitude that they wanted to prolong life as long as they reasonably could, so that when new treatments come available, they would (or will) be able to take advantage of them.”

However, many other commenters appear to place equal or greater weight on preserving quality of life, describing their desire to “to be able to function and enjoy the life I am living.” Some described the difficult balance often required to weigh prolonging life versus preserving quality of life, as well as the reality that priorities and decisions change over time. The following quotes illustrate these perspectives:

- “If I was sick, weak, and bedridden I would seriously consider stopping treatments. However, I am none of the above and will continue to fight like hell to survive.”
- “I am 100% in favor of living. I am also 100% in favor of quality of life. If treatments are going to prevent me from participating in living, then I would need strong proof that after treatment my life would improve. If this were not the case, then I would probably decline the treatment.”
- “Of course prolonging life is more important than the side effects I currently experience. However, I will have to consider the benefits if I do any further chemo... I have been told that the next types of chemo will have harsher side effects.”
- “We all want options... including the option to change our minds and end treatment. We want to be in charge of our own risk-balancing, quality of life, and life-extending treatment options.”

Other factors identified included: exploring non-pharmaceutical options first, the doctor’s advice, and financial considerations.

## Conclusion

The input received through the lung cancer Patient-Focused Drug Development meeting and the public docket underscores the devastating nature of this disease. It also shows how individual the experience is, depending on the patient’s disease manifestation, the treatment options that are available to them, their experiences with treatment, their personal circumstances, and their values. FDA is grateful to the patients, caretakers, and advocates who courageously shared their experiences and perspectives on lung cancer through the Patient-Focused Drug Development initiative. This effort has enabled us to obtain, in a systematic way, patients’ points-of-view on the severity of lung cancer, its impact on daily life, and available treatment options. We recognize that patients have a unique ability to contribute to our understanding of the broader context of this disease, which is important to our role and the role of others in the development of safe and effective drug therapies for lung cancer.



## Appendix 1: Meeting Agenda and Discussion Questions

---



# Lung Cancer Public Meeting on Patient-Focused Drug Development



June 28, 2013

---

7:30 – 8:30 am	<b>Registration</b>
8:30 – 8:40 am	<b>Welcome</b> Patricia Keegan, MD <i>Director, Division of Oncology Products II, Center for Drug Evaluation and Research (CDER), FDA</i>
8:40 – 8:50 am	<b>Overview of FDA’s Patient-Focused Drug Development Initiative</b> Theresa Mullin, PhD <i>Director, Office of Strategic Programs (OSP), CDER, FDA</i>
8:50 – 9:00 am	<b>Background on Lung Cancer and Treatment Options</b> Sean Khozin, MD, MPH <i>Division of Oncology Products II, CDER, FDA</i>
9:00 – 9:10 am	<b>Overview of Discussion Format</b> Sara Eggers, PhD <i>Office of Program and Strategic Analysis, OSP, CDER, FDA</i>
9:10 – 9:40 am	<b>Panel #1 Comments: Topic 1 (see Appendix)</b> A panel of patients and patient representatives will provide comments to start the discussion.
9:40 – 10:10 am	<b>Large-Group Facilitated Discussion: Topic 1</b> Patients and patient representatives in the audience are invited to add to the dialogue.
10:10 – 10:25 am	<b>Break</b>
10:25 – 10:55 am	<b>Panel #2 Comments: Topic 2 (see Appendix)</b>
10:55 – 11:45 am	<b>Large-Group Facilitated Discussion: Topic 2</b>
11:45 – 12:15 pm	<b>Open Public Comment</b>
12:15 – 12:30 pm	<b>Closing Remarks</b> Theresa Mullin, PhD <i>Director, OSP, CDER, FDA</i>

## Discussion Questions

### Topic 1: Disease symptoms and daily impacts that matter most to patients

- 1) For context, how long ago was your diagnosis of lung cancer? Is your cancer currently in only one area of the lung or has it spread to other parts of the lung or outside of the lungs?
- 2) Of all the symptoms that you experience because of your lung cancer, which 1 to 3 symptoms have the most significant impact on your daily life? (Examples may include pain, cough, shortness of breath, fatigue, voice hoarseness.)
- 3) Are there specific activities that are important to you but that you cannot do at all, or as fully as you would like, because of lung cancer? (Examples may include sleeping through the night, climbing stairs, household activities.)

### Topic 2: Patients' perspectives on current approaches to treating lung cancer

- 1) Are you currently undergoing any cancer treatments to help reduce or control the spread of your lung cancer? Please describe.
  - a) What do you consider to be the most significant downsides of these treatments? (Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)
  - b) How do these downsides affect your daily life?
- 2) What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your lung cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as breathing techniques).
  - a) What specific symptoms do your treatments address?
  - b) How well do these treatments manage these symptoms?
  - c) Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?
- 3) When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your lung cancer?
- 4) What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer? In particular:
  - a) What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)
  - b) How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite, fatigue, diarrhea, rash.)
  - c) How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)

## **Appendix 2: Meeting Panel Participants**

### **Patient Panel 1, Topic 1**

- Kathleen Skambis – Patient
- Susan Warmerdam – Patient
- Lorren Sandt – Patient Advocate, Caring Ambassadors Program
- Sheila Ross – Patient

### **Patient Panel, Topic 2**

- Denise Hogan – Patient
- Stephanie Haney – Patient
- John Ryan – Patient
- Karen Arscott – Patient
- Shelley Fuld Nasso – Patient Advocate, National Coalition for Cancer Survivorship

### **FDA Panel**

- Patricia Keegan, Division of Oncology Products II (DOPII), CDER
- Gideon Blumenthal, DOPII, CDER
- Dickran Kazandjian, DOPII, CDER
- Shakun Malik, DOPII, CDER
- Robert Le, Office of Cellular, Tissue and Gene Therapies (OCTGT), CBER
- Paivi Miskala, Study Endpoints and Labeling Development, CDER
- Theresa Mullin, Office of Strategic Programs, CDER

## Appendix 3: Meeting Polling Questions

The following questions were posed to in-person and web meeting participants at various points throughout the June 28, 2013, Lung Cancer Patient-Focused Drug Development meeting. Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

### Demographic Questions

1. Where do you live?
  - a. Within Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
  - b. Outside of the Washington, D.C. metropolitan area
  
2. Have you ever been diagnosed as having lung cancer?
  - a. Yes
  - b. No
  
3. What is your age?
  - a. Younger than 30
  - b. 31 – 40
  - c. 41 – 50
  - d. 51 – 60
  - e. 61 – 70
  - f. 71 or greater
  
4. Are you:
  - a. Male
  - b. Female
  
5. What is the length of time since your diagnosis?
  - a. Less than 1 year ago
  - b. 1 years ago to 2 years ago
  - c. 2 years ago to 5 years ago
  - d. More than 5 years ago
  - e. I'm not sure
  
6. Which of the following best describes your current condition?
  - a. My cancer is localized and has not spread outside my lungs
  - b. My cancer has spread (metastasized) to the rest of my body
  - c. My cancer is currently in remission
  - d. I'm not sure

### Question for Topic 1

7. Of all the symptoms you have experienced because of your lung cancer, which do you consider to have the most significant impact on your daily life? **Please choose up to three symptoms.**
- Pain, such as chest pain, or shoulder pain
  - Shortness of breath, wheezing or other breathing difficulties
  - Coughing, or coughing up blood, phlegm, and mucus
  - Loss of appetite or weight loss
  - Voice hoarseness or other impacts on speaking
  - Fatigue or lack of energy
  - Depression or anxiety
  - Other side effects of cancer treatments
  - Other symptoms not mentioned

### Questions for Topic 2

8. Have you ever undergone any of the following cancer treatments to help reduce or control the spread of your lung cancer? Include any current treatment.
- Chemotherapy
  - Radiation therapy
  - Surgery to remove the tumor(s) or any part of the lung
  - Targeted drug therapy
  - Other
  - I have not undergone any cancer treatments
  - I'm not sure
9. Besides your cancer treatments, what therapies have you taken to manage any symptoms you have experienced because of your lung cancer or your lung cancer medications? Check all that apply.
- Pain medications
  - Supplemental oxygen
  - Steroids
  - Breathing, exercise or relaxation techniques
  - Dietary supplements or diet changes
  - Complementary or alternative therapies, such as massage, acupuncture
  - Other therapies
  - I am not doing or taking any therapies to treat symptoms

10. Of the following factors, which two would you rank as most important to your decisions about using treatments to help reduce or control the spread of your lung cancer? Please select up to two responses. *We acknowledge that there are many other important factors in these decisions.*
- Whether the treatment is expected to help relieve the symptoms I experience because of my cancer
  - The small but significant risk of serious side effects, such as blood clots or kidney failure
  - How long the treatment would probably prolong my life
  - How long the treatment could possibly prolong my life (for longer than expected)
  - The expected side effects of the treatment, such as nausea, loss of appetite, etc.
  - How the treatment is administered, such as how long the treatment takes, whether it requires hospitalization, required doctor visits, etc.
11. Of the following factors, which one would you rank as least important to your decisions about using treatments to help reduce or control the spread of your lung cancer? *We acknowledge that there are many other important factors in these decisions.*
- Whether the treatment is expected to help relieve the symptoms I experience because of my cancer
  - The small but significant risk of serious side effects, such as blood clots or kidney failure
  - How long the treatment would probably prolong my life
  - How long the treatment could possibly prolong my life (for longer than expected)
  - The expected side effects of the treatment, such as nausea, loss of appetite, etc.
  - How the treatment is administered, such as how long the treatment takes, whether it requires hospitalization, required doctor visits, etc.

## 12. Scenario Questions Asked During Facilitated Discussion:

What thoughts and questions come to mind when you read the following scenario?

- Drug X is a chemotherapy drug being developed for patients with metastatic non-small cell lung cancer
  - It was studied in a clinical trial comparing “standard of care” chemotherapy plus Drug X versus standard of care alone
- Clinical trial results showed that:
  - The addition of Drug X prolonged survival on average 2 months longer (median survival was 12 months on Drug X + standard of care, versus 10 months on standard of care alone)
  - In addition to toxicities related to standard of care chemotherapy, patients treated with Drug X had more diarrhea and rash, and had more rare but serious toxicities such as liver injury and lung inflammation

## Appendix 4: Sample Benefit-Risk Framework for Lung Cancer

### Introduction

Over the past several years, FDA has developed an enhanced structured approach to benefit-risk assessment in regulatory decision-making for human drugs and biologics.<sup>4</sup> The Benefit-Risk Assessment Framework involves assessing five key decision factors: *Analysis of Condition*, *Current Treatment Options*, *Benefit*, *Risk*, and *Risk Management*. When completed for a particular product, the Framework provides a succinct summary of each decision factor and explains FDA's rationale for its regulatory decision.

In the Framework, the *Analysis of Condition* and *Current Treatment Options* rows summarize and assess the severity of the condition and therapies available to treat the condition. This assessment provides an important context for drug regulatory decision-making, including valuable information for weighing the specific benefits and risks of a particular medical product under review.

The input provided by patients and patient representatives through the Lung Cancer Patient-Focused Drug Development meeting and docket comments helps further our understanding of the *Analysis of Condition* and *Current Treatment Options* for this disease.

The information in the top two rows of the sample framework for lung cancer, on the next page, draws from various sources, including patient and patient representative input from the Lung Cancer Patient-Focused Drug Development meeting held on June 28, 2013. This sample framework contains the kind of information that we anticipate could be included in a framework completed for a drug under review for lung cancer. This information is likely to be modified over time based on a further understanding of the condition or changes in the treatment armamentarium.

---

<sup>4</sup> Commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) include further development and implementation of the Framework into FDA's review process. Section 905 of the FDA Safety and Innovation Act also requires FDA to implement a structured benefit-risk framework in the new drug approval process. For more information on FDA's benefit-risk efforts, refer to <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

**Sample Benefit-Risk Framework for Lung Cancer: Analysis of Condition and Current Treatment Options**

Decision Factor	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition	<ul style="list-style-type: none"> <li>– There are more than 200,000 new cases and ~160,000 deaths from lung cancer every year.</li> <li>– Prognosis depends on the type and stage of lung cancer. The average 5-year survival rate for NSCLC is ~15%. Over 50% of patients are diagnosed at an advanced stage, once the cancer has spread (metastasized) to the brain, bones, and other areas.</li> <li>– Patients in early stages of lung cancer may not experience any symptoms. When symptoms do appear, they can include shortness of breath or difficulty breathing, coughing, coughing up blood, pain, weight loss, and fatigue.</li> <li>– Lung cancer and its treatment can have a significant impact on patients’ ability to manage work and family life and their overall quality of life. Many patients live with uncertainty, fear, anxiety, and depression.</li> <li>– See the <i>Voice of the Patient</i> report for a more detailed description of patients’ perspectives on lung cancer symptoms and impacts.</li> </ul>	<p>Lung cancer is a serious and life-threatening disease. It remains the leading cause of cancer deaths in the United States. It is a rapidly fatal disease, and prognosis is dismal. While symptoms vary depending of the type and stage of lung cancer, the disease and its treatment can have a debilitating effect on patients’ lives.</p>
Current Treatment Options	<ul style="list-style-type: none"> <li>– The standard of care depends on the type and stage of the cancer. In early stages, surgery in combination with radiation therapy and/or chemotherapy can potentially be curative. In later stages, these treatments may be used to shrink or slow tumor progression or prolong life.</li> <li>– FDA-approved chemotherapy treatments include cisplatin, paclitaxel, gemcitabine, docetaxel, pemetrexed, and others.</li> <li>– Molecularly-targeted therapies are aimed at treating patients with specific genetic changes. FDA-approved targeted therapies include crizotinib, erlotinib, and afatinib.</li> <li>– Patients can develop resistance to chemotherapy and targeted therapies drugs after extended use, making some treatments less effective over time.</li> <li>– Side effects and risks vary depending on the type of treatment and can have a significant impact on patients’ quality of life. Side effects of chemotherapy may include fatigue, nausea, nerve damage, cognitive impairment, hair loss, and increased risk of infection or bleeding. Side effects of targeted therapies may include rash, diarrhea, fatigue, high blood pressure, increased risk of bleeding, visual changes, lung injury, and liver injury.</li> <li>– Palliative or supportive care therapies include supplemental oxygen, pain medications, steroids, and non drug therapies such as breathing exercises and relaxation techniques.</li> <li>– See the <i>Voice of the Patient</i> report for a more detailed description of patients’ perspectives on lung cancer treatments and treatment decision making.</li> </ul>	<p>There is a continuing need for additional treatment options for lung cancer patients. While some effective treatments exist, they can only be potentially curative if the disease is diagnosed in early stages. Most treatments are toxic and their side effects can have a significant impact on patients’ daily lives. Emerging targeted therapies are promising for subsets of lung cancer patients.</p> <p>The potential development of resistance to chemotherapy or targeted therapies further supports the need for an expanded treatment armamentarium.</p> <p>Patients’ treatment decisions often require making difficult tradeoffs between increasing the chance to prolong life and preserving quality of life.</p>