

# Partners In Progress: Cancer Patients and FDA

## Office of Health and Constituent Affairs: The Patient's Voice

November 13, 2017

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# Topics

- ❖ Patient Representative Program
- ❖ Patient Network Web Site
- ❖ Calls and Emails
- ❖ MedWatch Program

# Patient Representatives Program

## Roles

- Patient Representative
  - Patient representatives serve on advisory committee panels
- Patient Consultant
  - Patient representatives participate in divisional assignments
- Informal Role

<https://www.fda.gov/ForPatients/PatientEngagement/ucm412709.htm>

# Preparing Patient Representatives for Their FDA Roles

- Initial one-on-one orientation and (FDA 101) training by the Office of Health and Constituent Affairs staff
- Annual workshop (FDA 102)
  - Role of advisory committees
  - Drug and medical device review processes
  - How to prepare to participate in FDA meetings
  - Best practices from patient representative experiences
- Webinars for continuing education
  - Conflict of review issues
  - Understanding data sets
  - Clinical trial endpoints
  - Safety issues

# Patient Network Web site

Provides information on

- Public Meetings
- Draft Guidances Documents
- Newsletters
- Expanded Access

<https://www.fda.gov/ForPatients/>

# Public Meetings

## Attend public meetings

- Speak during the Open Public Hearing Session at Oncologic Drugs Advisory Committee meetings
- Participate in workshops and other public meetings.

<https://www.fda.gov/ForPatients/Calendar/>

U.S. Department of Health and Human Services  
FDA U.S. FOOD & DRUG ADMINISTRATION

Home > For Patients > Calendar of Public Meetings

### Calendar of FDA Sponsored Public Meetings - October 2017

In this section you will find a comprehensive list of all the meetings that the FDA is involved with that may be important to patients and caregivers. The meetings may include advisory committee meetings, public workshops and public conferences that are seeking to hear from patients and caregivers.

Most FDA meetings are free to the public and do not require the public to register. Interested persons may present data, information, or views, orally at the meeting, or in writing, on issues pending before the committee. Other types of meetings listed may require prior registration and fees.

- **Advisory Committee Meeting: Patient Engagement**  
**Date:** October 11, 2017, 1:00 pm to 5:00 pm  
**Location:** Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy, Gaithersburg, MD 20877  
**Agenda:** the committee will discuss and make recommendations on the topic of patient input into medical device clinical trials. This meeting will provide the opportunity to bring patients, patient organization, FDA, industry, and other medical and scientific experts together for a broader discussion on this important patient-related issue.  
 This meeting is a key part of FDA's goal to help assure the needs and experiences of patients are taken into account as part of FDA's deliberations involving the regulation of medical devices and their use by patients. In this meeting, FDA is seeking input from the PEAC and the public on topics such as to: (1) better understand challenges for patients in medical device clinical trials, (2) better understand the challenges for patients in medical device clinical trials, and (3) better understand the challenges for patients in medical device clinical trials. The committee's recommendations are being used to overcome these challenges (potential regulatory changes) for FDA to consider recommendations from the PEAC on top areas for FDA to consider.
- **Biologics Advisory Committee Meeting**  
**Date:** October 12, 2017, 8:30 am to 12:00 pm  
**Location:** FDA White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, MD 20910  
**Agenda:** The committee will discuss and make recommendations on the topic of patient input into medical device clinical trials.

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# Submit comments through the Federal Register

## Submit comments

- Open Dockets for Advisory Committee Meetings
- Submit comments about draft guidance documents

<https://www.fda.gov/ForPatients/CommentonGuidance/>

The image shows two overlapping screenshots of the FDA website. The top screenshot displays the 'For Patients' section with a list of 'Opportunities to Comment Closing' for June, July, and August 2015. The bottom screenshot shows a similar page for November 2017, featuring a list of topics for comment, including Benefit-Risk Assessments, Content of Risk Information, and Cardiac Troponin Assays. It also includes social media sharing options and a detailed announcement about a public meeting for Benefit-Risk Assessments in Drug Regulatory Decision-Making.

U.S. Food and Drug Administration  
Protecting and Promoting Your Health

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products

For Patients

Home > For Patients > Comment on Current FDA Draft

Comment on Current FDA Draft Guidances

- Opportunities to Comment Closing in June 2015
- Opportunities to Comment Closing July 2015
- Opportunities to Comment Closing August 2015

U.S. Department of Health and Human Services

U.S. FOOD & DRUG ADMINISTRATION

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For Patients

Home > For Patients > Comment on Current FDA Draft Guidances

Comment on Current FDA Draft Guidances

- Opportunities to Comment Closing - September 2017
- Opportunities to Comment Closing - October 2017
- Opportunities to Comment Closing - November 2017

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### Opportunities to Comment Closing - November 2017

The following topics were published in the **Federal Register** by the **Food and Drug Administration (FDA)**. The intent of this page is to provide patients, caregivers and the general public an opportunity to provide their voice and expertise as a patient to the FDA during the review period. We have only provided you with a few paragraphs on each topic, if you want to learn more and submit comments, please click on "make comments electronically."

On this page, you will find the following topics:

- Benefit-Risk Assessments in Drug Regulatory Decision-Making due by **November 18, 2017**
- Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements due by **November 20, 2017**
- Cardiac Troponin Assays due by **November 27, 2017**

### Request for comment by November 18, 2017: Benefit-Risk Assessments in Drug Regulatory Decision-Making

The FDA announced a public meeting to convene a discussion of topics related to the structured assessment of benefits and risks in drug regulatory decision-making. This meeting will focus on regulatory experiences with approaches to structured benefit-risk assessments, approaches to benefit-risk assessment. The format of the meeting will include panelists and audience members. To be eligible to participate in the meeting, you must be a member of the public and have a direct interest in the topics to be discussed.

# Patient Network Newsletter

A bi-weekly newsletter containing FDA-related information on a variety of topics, including:

- New product approvals
- Significant labeling changes
- Safety warnings
- Proposed regulatory guidances
- Opportunities to comment and other information important to patients and caregivers
- FDA public meetings



This bi-weekly newsletter from the Food and Drug Administration (FDA) Office of Health and Constituent Affairs is intended to inform patients and patient advocates of FDA-related information on new product approvals, significant labeling changes, safety warnings, notices of upcoming public meetings, proposed regulatory guidances and opportunity to comment, and other information of interest. [Subscribe](#) or [update your subscriber preferences](#).



## Patient Network News

from the FDA Office of Health and Constituent Affairs

Volume 7 | Number 18 | August 30, 2017

### Medical Product Safety

**Statement from FDA Commissioner Scott Gottlieb, M.D. on the FDA's new policy steps and enforcement efforts to ensure proper oversight of stem cell therapies and regenerative medicine**

One of the most promising new fields of science and medicine is the area of cell therapies and their use in regenerative medicine. These new technologies, most of which are in early stages of development, hold significant promise for transformative and potentially curative treatments for some of humanity's most troubling and intractable maladies. Recent advances in our basic knowledge of the pathways involved in tissue damage and regeneration have combined with remarkable progress in adult stem cell biology to put us at a genuine inflection point in the history of medicine. The prospect of clinical tissue repair strategies is a tangible reality. This promise is reinforced by the strong commitment of the investment and scientific communities in exploring the potential applications across a wide range of vexing diseases and conditions, such as cancer, Parkinson's disease, and diabetes, among many others.





# Calls and Emails

From

- Individual patients asking about clinical trials, expanded access, etc.
- Patient advocates with concerns for their patient community or questions about topics such as clinical trial design
- Physicians, industry, academics, etc. asking about expanded access, IRB requirements, etc.

Contact OHCA at: 301-796-8460 or

[PatientNetwork@fda.hhs.gov](mailto:PatientNetwork@fda.hhs.gov)

# MedWatch Program

What is MedWatch?

1. A way to send information *IN* to FDA



2. A way to get safety information *OUT* from FDA

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

# MedWatch Program: What to Report In

- Serious events
- Medication errors
- Product quality problems
- Potential for error



Drugs



Cosmetics



Medical Devices



Combination Products



Biologics



Special Nutritional  
Products

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

# MedWatch Program: How To Report?

- Online using FDA Form 3500B:  
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>  
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>
- Mail in FDA Form 3500B:  
<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf>
- Fax in FDA Form 3500B: 1-800-332-0178
- By Phone: 1-800-332-1088

# MedWatch Program: Safety Out

- Update the product label
- Request a change in the product's design, process, packaging, or distribution
- Request a product recall

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

**Thank you!**