U.S. FOOD & DRUG ADMINISTRATION

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

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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

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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

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Patient Network Web site

Provides information on

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

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

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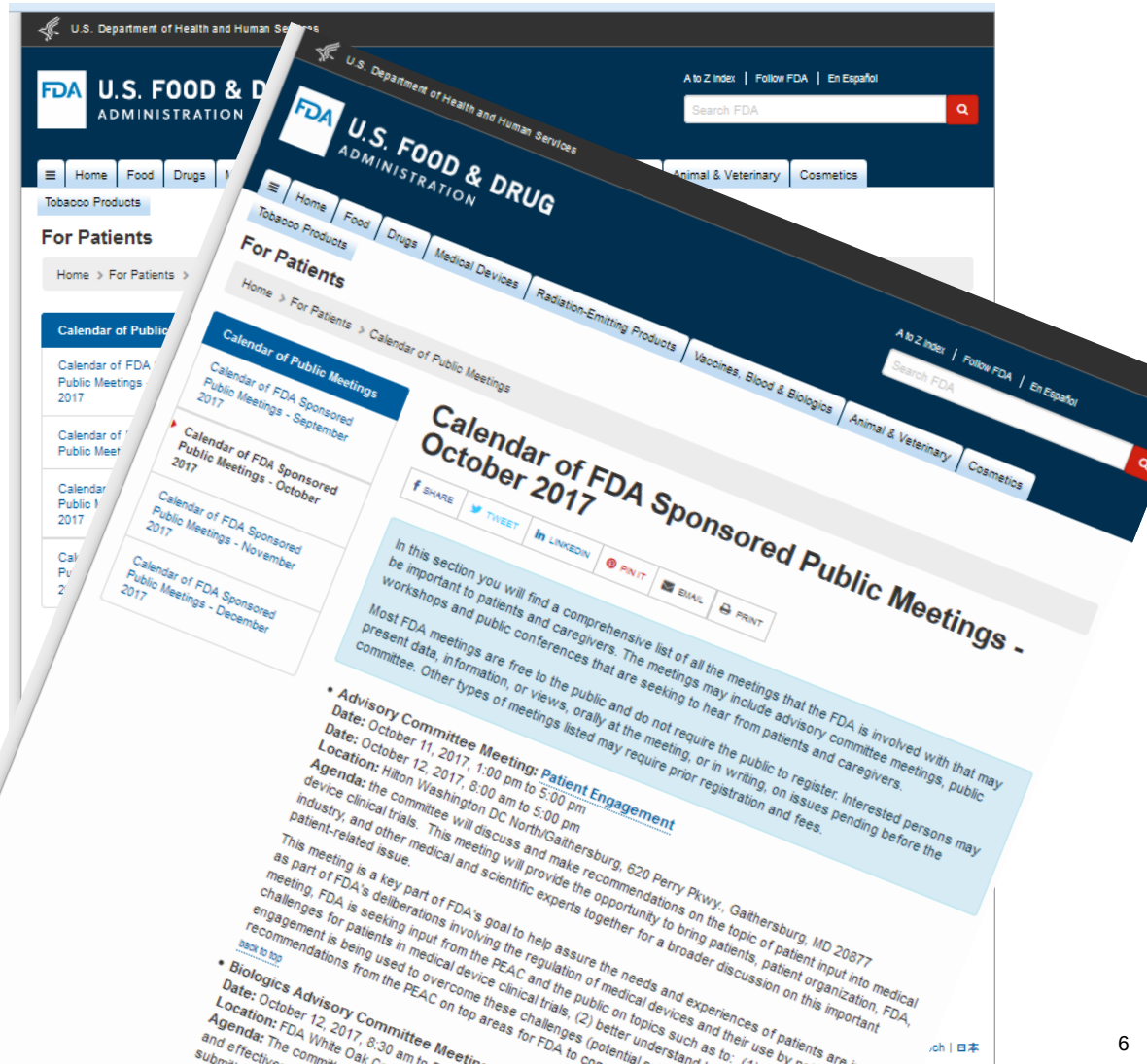
Public Meetings

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/



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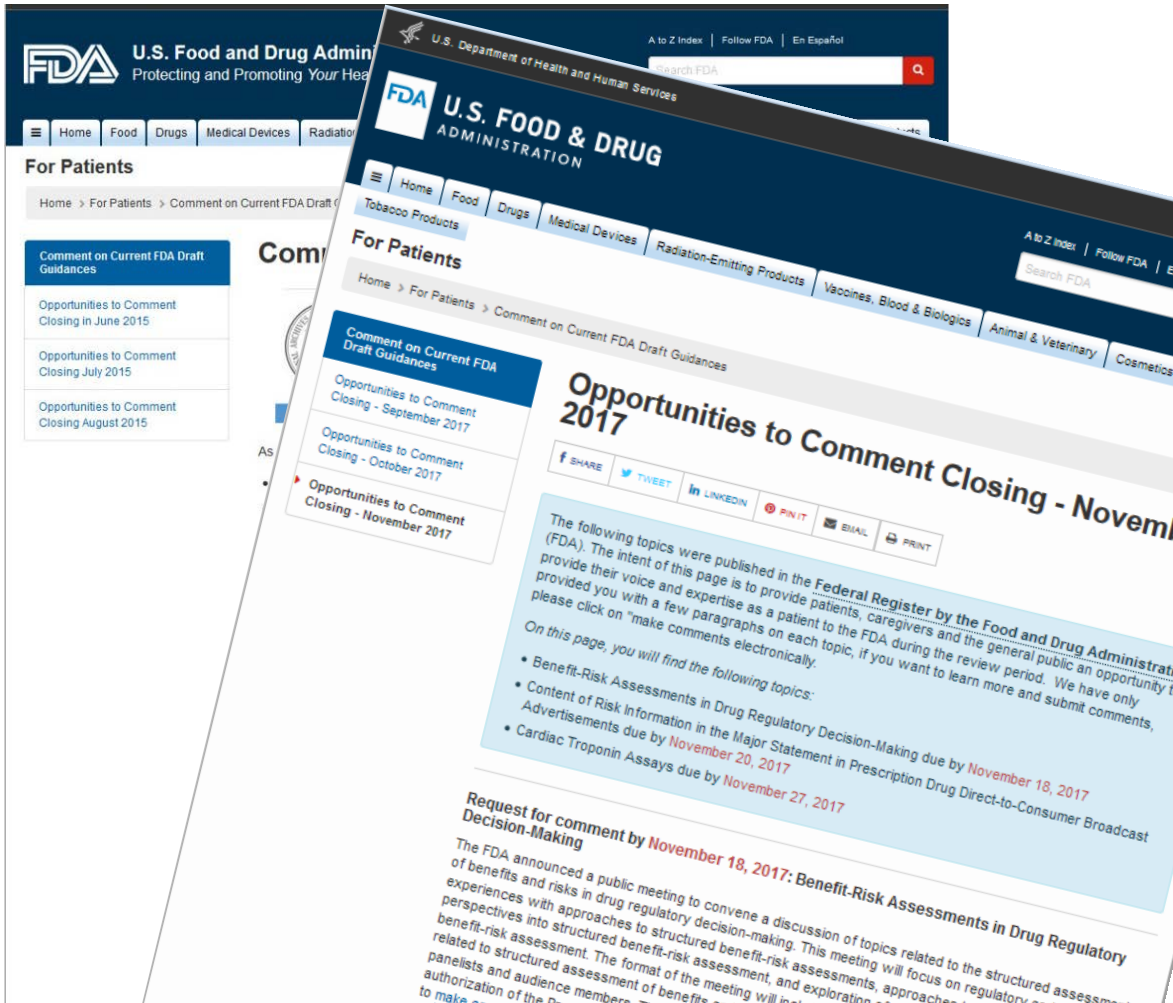
Submit comments through the Federal Register

Submit comments

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- Submit comments about draft guidance documents

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



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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

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This *bi-weekly* newsletter from the Food and Drug Administration (FDA) Office of Health and Constituent Affair 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.

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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

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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

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MedWatch Program: What to Report In

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


Drugs


Medical Devices


Biologics


Cosmetics


Combination Products


Special Nutritional Products

www.fda.gov/medwatch

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MedWatch Program: How To Report?

- Online using FDA Form 3500B: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.homehttps://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

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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

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Thank you!