Big Pharma, the FDA and Breast Cancer: Putting Patients Before Profits

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A Real Change in Breast Cancer...

- Public health over private profit at FDA
- Understanding and eliminating environmental causes of cancer
- Create awareness that systemic injustices lead to disparities in breast cancer
Webinar Goals:

- Learn about the history and the intended role of the FDA
- Understand the inherent conflict of interest between pharmaceutical company shareholders and the needs of patients (as it relates to new breast cancer drugs)
- Know the action steps you can take to make a difference
FDA MISSION

- Protect public health
  - Safety and efficacy of drugs and medical devices

- Advance public health
  - Speed innovations that make medicines more effective, safe and affordable

- Inform the public about medicines and foods
  - Make science-based, accurate information accessible
Brief History of the FDA

Food and Drug Administration Act of 1906

Required drugs meet official standards of strength and purity, defined as adulterated and misbranded, and prohibited the shipment and distribution of misbranded and adulterated drinks, drugs and foods.
Brief History of the FDA

Federal Food, Drug and Cosmetic Act of 1938

Marks the birth of the modern FDA

Required proof of safety before the release of a new drug
Brief History of the FDA

Durham-Humphrey Amendment, 1951

Explicitly defined prescription vs. over the counter drugs.

Prescription drugs must carry the statement, "Caution: Federal law prohibits dispensing without prescription."
The Kefauver-Harris Amendment of 1962

In response to Thalidomide and birth defect in thousands of babies born in Western Europe.

Required drug manufacturers to prove to FDA the effectiveness of their products before marketing them.
Brief History of the FDA

Accelerated Approval Process, 1992

In response to HIV epidemic

 Allows FDA to judge drugs using a surrogate endpoint instead of their effect on survival. Further clinical trials must be submitted, but drug is initially allowed to enter market.
FDA Structure and Organization

- Advisory Committee Structure
  - 49 committees and panels to obtain independent expert advice on scientific, technical and policy matters
  - Medical Committees
  - Drugs Committees
    - Reproductive Health Advisory Committee
    - Oncologic Drugs Advisory Committee
FDA Drug Approval Process

Preclinical testing

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Purpose</th>
<th>Time</th>
<th>New Drugs Approved</th>
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<tr>
<td>Laboratory and Animal Studies</td>
<td>Assess safety and biological activity</td>
<td>Year 1-2</td>
<td>100% of INDS</td>
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<tr>
<td>20 - 100 Healthy Volunteers</td>
<td>Determine safety &amp; dosage</td>
<td>Year 3</td>
<td>70% of INDS</td>
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<td>Evaluate effectiveness &amp; side effects</td>
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<td>Year 6-8</td>
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IND: Investigational New Drug
NDA: Non Disclosure Agreement
Drug Approval Process: Pre-Clinical Phase
Drug Approval Process: Phase I

Phase 1

20 – 100 Healthy Volunteers

Determine safety & dosage

Year 3

FILE IND

70% of INDS
Drug Approval Process: Phase II

Phase 2

100-300 Patient Volunteers

Evaluate effectiveness & side effects

Year 4-5

33% of INDS
Drug Approval Process: Phase III

Phase 3

1,000-3,000 Patient Volunteers

Verify effectiveness & monitor adverse long-term use

Year 6-8

27% of INDS
Accelerated Approval Process

Permits the FDA to issue a limited, or conditional, approval of a new drug that is intended for a “serious or life-threatening” disease and for which there is an “unmet” medical need.
Surrogate Endpoint

A measure of effect of a certain treatment that may correlate with a real clinical endpoint but doesn't necessarily have a guaranteed relationship.

Example: the shrinking of a tumor to determine proof the drug is working, yet the result (tumor growth) does not guarantee overall survival.
Big Pharmaceutical Companies
Shareholders vs. Patients
Big Pharma and Lobbying
Close ties between the FDA and pharmaceutical companies
BCAction’s position on new drugs

Approval should only be given if the drug:

1) Improve overall survival;
2) Improve quality of life; OR
3) Improve access by costing less than already available drugs
Case study: Avastin
Case study: Avastin

Approved for use and shown to be effective in treating colon, lung, kidney and brain cancers
Case study: Avastin

Severe side effects in some patients:

- Very high blood pressure
- Bleeding and hemorrhage
- Development of perforations in various organs
- Heart attack or heart failure
Case study: Avastin

Accelerated approval

- Granted conditional accelerated approval by FDA in 2008
- ODAC voted 12-1 to recommend disapproval in July 2010
- FDA agreed with ODAC and removed breast cancer as indication for Avastin in December 2010
- New Advisory Panel will review manufacturers appeal June 2011
Case study: Avastin

Costs

• Treating a breast cancer patient with Avastin costs about $90,000 a year
• Insurers will cover much of this cost as long as it is approved for use in breast cancer patients
• Genentech (owned by Roche) stands to lose $500 million to $1 billion if the FDA decision isn't turned around
• Genentech has a program to give financial aid to patients with incomes less than $100,000
Case study: Avastin

Upcoming FDA meeting on June 28-29

- Lobbying by Genentech
- Continued disapproval would lower drug utilization
- Doctors may continue to prescribe Avastin "off-label"
Actions: What can you do?

- Support women’s health organizations who do not take money from pharmaceutical companies
  - Our Bodies, Ourselves
  - National Women’s Health Network
  - Breast Cancer Action

- Standby for BCAction’s E-Alert on the FDA’s ruling on June 28th and 29th

- Contact BCAction to find out how you can become a Consumer Representative on an FDA Advisory Panel
More questions? Contact us!
Email: info@bcaction.org
Toll-free: 877-2STOPBC

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