FDA Approval: Who’s Being Harmed & Who’s Being Helped?

Presented by:

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Agenda

• Overview of FDA approval process
• FDA approval of drugs and devices
• Substantially Equivalent Devices
• BCAction’s Position on FDA approval
• Ways you can get involved
Our Mission

*Breast Cancer Action carries the voices of people affected by breast cancer in order to inspire and compel the changes necessary to end the breast cancer epidemic.*
BCAction’s Strategic Priorities

(1) Putting Patients First
(2) Creating Healthy Environments
(3) Eliminating Social Inequities
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FDA Approval: Who is being Harmed And Who is being Helped?

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There are 3 kinds of lies:
Lies, damn Lies, and statistics
Objective Studies?

- Research shows that the source of funding influences study outcomes.
- When companies pay for studies, published results tend to reflect their financial interests.
Does FDA Approval = Safety?

Criteria for Approval of Prescription Drugs:

- Safe (over the short-term)
- Effective (compared to placebo)
- Lack of data on dangers is NOT sufficient

CAVEAT: companies pay for the studies but the FDA reviews the data
FDA Approval of Drugs

Safe and Effective does NOT mean

- Nobody will die from this drug
- Nobody will be harmed by this drug
- This drug is safe for long-term use
- This drug was tested on people of color
- This drug is more effective than other OR cheaper drugs on the market
What Medications Don’t Require FDA Approval

Criteria for Dietary Supplements and Compounding Pharmacies

- Not tested for Safety
- Not proven Effective
- Lack of data on dangers IS sufficient
FDA Approval of Medical Devices

- Reasonably Safe
- Reasonably Effective

OR

- Substantially Equivalent to other devices on the market – same use, similar materials--
  98% of devices are approved that way (510 k loophole)
Low Risk = Not tested
Moderate Risk (510k)
High Risk Medical Devices
(pacemaker, heart, infusion pump)
Example: Radiation Shield

- The Axxent FlexiShield Mini shapes the radiation beam. It is a flexible pad placed on the body, made of tungsten and silicone.
- It was cleared as substantially equivalent to a lead block attached to a tray.
- Recalled when tungsten was found in the women’s breasts.
Substantially Equivalent Devices

Mammography

- 3D mammography machines must be proven safe and effective

- Other mammography machines only need evidence they are substantially equivalent to those already on the market

- No clinical trials required. No inspections to make sure they are made correctly
Are these substantially equivalent?
Are these substantially equivalent?

Vitek TMJ implants

Dow silicone sheet

?
Are these substantially equivalent?
Studies for FDA are Short-term

But some products are used for years, such as Tamoxifen, Hormone Replacement Therapy, Osteoporosis drugs, breast implants, or mammography

Approval: Based on short-term studies, PERHAPS with requirement of later long-term studies
Breast Implants
Doctors Focus on Benefits

**Promise:** You’ll feel good about yourself

**Evidence:** Short-term subjective studies
Implant Complications

#1 - Capsular Contracture
FDA booklet
Necrosis in breast cancer patient with implants for one week
Breast Implant Studies

- Long term data MIA: 95% of women dropped out of some post-market studies, but FDA did not enforce study requirements

- Implant makers focused on good news: no breast cancer or lung cancer after 7-10 years!

- How many smokers get lung cancer at age 27? Cancer often takes 20-30 years to develop.
Avastin was approved for Stage IV breast cancer on the basis of delay in cancer progression – not long-term patient health.

YEARS LATER: After approval, studies showed women taking Avastin lived for a shorter amount of time with a worse quality of life because of stroke and perforations of gastrointestinal track.
Why are standards lowered?

Lobbyists: $$$

Lobbyists: device companies in every Congressional district

Lobbyists: Jobs/ innovation vs. Safety
Conclusions

- FDA approval does not mean safe for everyone
- Dietary supplements are tested only if they seem to be dangerous
- Drugs from compounding pharmacies are not tested for safety or effectiveness
- 95% of medical devices are approved without clinical trials
Conclusions

- When studies are required, they are short-term.
- FDA standards of safety for devices is less strict than for drugs, and FDA approval for drugs does not always mean they are safe.
- Let the buyer beware.
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BCAction’s position FDA Approval

Treatments should be:

● More effective
● Less toxic
● Less expensive
Accelerated Approval Process

- What is Accelerated Approval?
- Accelerated Approval vs. Compassionate Access
- Striking a balance
- Examples – Avastin, TDM-1
Surrogate End Points

● What are they?

● Common surrogate marker

● Progression free survival vs. Overall survival

● Limitations
What you can do

- **Individuals**
  - Empowered and engaged consumer/patient

- **Systems**
  - Collective power to influence and change regulatory systems
Review resources from presentation

- National Research Center for Women and Families [www.center4reserach.org](http://www.center4reserach.org)
- The Cancer Prevention and Treatment Fund [www.stopcancerfund.org](http://www.stopcancerfund.org)
- The National Women’s Health Network [www.nwhn.org](http://www.nwhn.org)
- Breast Cancer Action [www.bcaction.org](http://www.bcaction.org)
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Breast Cancer Action

Challenging Assumptions. Inspiring Change.

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