Perspective from HHS Offices and Programs on Women’s Health: FDA Perspective

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OVERVIEW

- Introduction to FDA Office of Women’s Health (OWH)
- Impact of research
- How we communicate results to women
FOOD & DRUG ADMINISTRATION

- Regulatory Agency
- Oldest Consumer Protection Agency
- Oversight & regulation of over $1 trillion worth of products annually
- ~ $0.25 of every consumer dollar spent
- NOT a research agency
ROLE OF FDA

- Regulatory oversight of many products:
  - Pharmaceuticals
    - Prescription & OTC
  - Vaccines, blood products
  - Medical devices
  - Food (not meat)
    - Dietary supplements
  - Veterinary products
  - Cosmetics
  - Inspections at ports, research facilities
Why Does FDA Have An Office Of Women’s Health?

- Women were not adequately included in clinical drug studies
- Lack of understanding of sex/gender differences
- 1994 – FDA OWH created by Congressional mandate

1992 GAO Report

United States General Accounting Office
Report to Congressional Requesters

October 1992

WOMEN’S HEALTH
FDA Needs to Ensure More Study of Gender Differences in Prescription Drug Testing

1992 GAO Report
FDA OWH
Mission

- Protect and advance the health of women through policy, science, and outreach
- Advocate for inclusion of women in clinical trials and analysis of sex/gender effects
1. Influence Regulatory Decision Making & Policy

2. Translate Regulatory Science for Consumers
1. Influence Regulatory Decision Making & Policy

- Funding opportunities ***
- Scientific Collaborations
- Scientific Meetings
Awarded ~$20 million research funds (FY1994-2008)
  Intramural  ~$13.4 million
  Extramural  ~$4.5 million
  Demographic/Critical Path ~$2 million

~$14 million to FDA Centers & OC for RESEARCH

Awards for 1-2 year studies
Max $100,000/year
RESEARCH AGENDA

Determined by:

- Congressional mandates
- FDA mission
- FDA priorities – e.g., safety
- Internal Advisory Council
- Strategic planning & needs assessment
- Advocacy concerns
RESEARCH PRIORITIES

- Participation of women in clinical studies submitted to FDA, including IT infrastructure*
- Sex/gender differences in FDA-regulated products*
- CVD*
- Pregnancy
- FDA-regulated product specific areas:  
  - Condoms, breast implants, oral contraceptives, etc.

* Congressional mandates
REGULATORY IMPACT

**Regulations**
- Pregnancy Labeling Rule
- Mammography Quality Standards Act (MQSA)

**Guidances for Quality & Safety**
- Guidance for on Labeling for Combined Oral Contraceptives
- Guidance for Industry & FDA Saline, Silicone Gel, and Alternative Breast Implants
- Guidance on Bone Sonometer PMA Applications
- Guidance on Safety Pharmacologic Studies for Assessing the Potential for Delayed Ventricular Repolarization by Human Pharmaceuticals ICH S7B
- Guidance for Industry on Pharmacokinetics in Pregnancy-Study Design, Data Analysis, & Impact on Dosing & Labeling
- Guidance on QT Prolongation During Drug Review
- Guidance for Industry: Non-Contraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms & Vulvar & Vaginal Atrophy
- Draft Guidance on Male Condom Defects

**Product Labeling**
- Effects of Echinacea: Labeling Recommendations for CYP 450 Substrates
- Effects of St. John’s Wort: Labeling Recommendations for Oral Contraceptives
2. Translate Regulatory Science for Consumers

- Consumer health information
- ~50 different topics
- English & Spanish
- Electronic outreach to ~3,000 organizations

- Received FCIC Consumer Choice Award (2004)
  - #1 requested source of health information in federal government
OWH Thanks Our Previous Partners

"I was impressed by OWH’s ability to stimulate grassroots involvement…"

Phil Schneider, President National Association of Chain Drug Stores (NACDS) Foundation
Take Time To Care “MY MEDICINES”

- Collaboration with 60 national organizations, led by NACDS
- Reached >30 million consumers
- AMA endorsed as a tool and model for reducing medication errors
- Received APHA Pinnacle Award
Menopause & Hormone Therapy (MHT) Campaign

- Congressional Mandate result of WHI findings
- Partnered with all DHHS agencies & 26 national organizations
- Raise public awareness about the risks and benefits of menopausal hormone therapy

Nearly 100 Million messages delivered to Peri-menopausal and Menopausal Women
NEW Medication Booklets
First-of-a-Kind for All FDA-approved Products

- Birth Control
- Cholesterol
- Depression
- High Blood Pressure
- HIV/AIDS
- Menopause
- Smoking Cessation

http://www.fda.gov/womens/medicinecharts/default.htm
General Information about Pregnancy Exposure Registries

- What is a pregnancy exposure registry?
- How can you participate in a pregnancy exposure registry?
- What should you expect when you participate?
- Learn more about taking medicines while you are pregnant
- See list of pregnancy exposure registries

- About 50% of all U.S. pregnancies are unplanned.
- Many women enter pregnancy with medical conditions that require medical treatment.
- New medical problems may develop or old ones may worsen due to pregnancy.
- It is common for pregnant women to take medication during the critical period of fetal development because
  - The woman is unaware of her pregnancy.
  - It may be medically necessary to continue treatment throughout pregnancy.

In response to these facts, FDA began requiring some pharmaceutical manufacturers to conduct pregnancy exposure registries. The results of these studies will provide pregnant women and their health care providers' better understanding of drug effects on fetal health. FDA/OWH developed a master directory of pregnancy registries to aid pregnant women who are taking medications to participate in these important studies.
OWH Mission:
Protecting and Advancing the Health of Women