Women’s Health, Emergency Contraception and the FDA

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Women’s Health Includes

- Conditions:
  - Unique to women or a subgroup of women
  - More prevalent in women
  - More serious in women
  - For which risk factors are different for women
  - Where the intervention/care is different
Emergence of Women’s Health Issues

- Ovarian Cancer
- Breast Cancer
- Osteoporosis
- Heart Disease
- Breast Implants
- Clinical Trials
- AIDS
- Mental Health
- Toxic Shock Syndrome
- Menopause
FDA’s Mission

- Regulated products are:
  - safe and efficacious
  - honestly, accurately and informatively represented
  - in compliance with laws and regulations
FDA’s Mission

Regulatory agency with jurisdiction over $0.25 of every consumer dollar.
So where does Emergency Contraception Fit In?

- Plan B emergency contraception: Approved in 1999 as a prescription product for all women of childbearing potential
- Manufacturer sought non-prescription status (over-the-counter, OTC) in 2003
Emergency Contraception should be Common Ground

- Prevents unintended pregnancy
- Does not cause abortion
- Only connection to abortion is that it can prevent the need for one
- Is very safe
- Needs to be taken soon (within hours) to be most effective
Recommendations come through review chain at CDER, final decision reached

Evaluate by appropriate review divisions

Outside Scientific Advisory Committee convened, questions posed by FDA

Reviews completed, recommendations by reviewers
Points of change

- Advisory Committee (FDA has many precedents of not accepting recommendations)
- Reviewer level
- Other professional management level
- Center Director
- Commissioner
Timeline for Plan B

- **Dec. 2003**: Advisory Committee meeting
  - 23-4 vote in favor of OTC status
  - Unanimous vote regarding safety
- **May 2004**: Center Director sends “non-approvable” letter requesting 2-tier prescription/non prescription status
- **Summer 2004**: Company resubmits
- **Winter 2005**: Expected decision based on usual timelines
- **August 2005**: FDA Commissioner determines need to open for public comment and possible rulemaking on issue of 2-tier status
Decision making for Health Policy

- Must be based on scientific and medical evidence
- Must promote health

This Decision Did Neither
Where do we go from here?

- Bringing Emergency Contraception OTC is the first test for the new Acting Commissioner of independence and priority on science
- We must insist that FDA and all health agencies base decisions on science and medical evidence
- We can’t risk the credibility of FDA as “gold standard” for safety and effectiveness of drugs, medical devices, and biologics
Resources for Information and Action

- **FDA information** about emergency contraception:  

- **Reproductive Health Technologies Project**: [http://www.rhtp.org](http://www.rhtp.org)  
  Back Up Your Birth Control Campaign  
  1-888-NOT-2-LATE

- **Union of Concerned Scientists**  
  Scientist Statement on Scientific Integrity  
  [http://www.ucsusa.org/scientific_integrity/](http://www.ucsusa.org/scientific_integrity/)  
  On February 18, 2004, over 60 leading scientists—Nobel laureates, leading medical experts, former federal agency directors, and university chairs and presidents—signed the statement, voicing their concern over the misuse of science by the Bush administration.