Obstetrics & Gynecology Devices Panel

FDA advisory committee meeting

December 11, 2008

Recent regulatory developments

Recent regulatory developments

- Public Health Notification

  use of surgical mesh for vaginal repair of pelvic organ prolapse

- Fetal Monitoring Workshop

- New Labeling Requirements for Male Condoms

Public Health Notification

Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

- issued October 20, 2008
- >1000 Medical Device Reports (MDRs) since 2004
- nine manufacturers

Serious Complications: TV Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and SUI

- Most frequent complaints
  - erosion through vaginal epithelium
  - infection
  - pain
  - urinary tract symptoms
  - recurrence
- Also reported
  - perforation of bowel, bladder, and blood vessels
  - vaginal scarring

Serious Complications: TV Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and SUI

FDA recommendations to physicians:

- obtain training for mesh placement technique
- be vigilant for adverse events (including infection & perforation)
- inform patients
  - mesh is permanent
  - complications may occur
  - add'l surgery may be needed
  - risks related to erosion through vaginal epithelium, impact on quality of life
- provide patient labeling, if available

FDA-NIH workshop (Nov 10th):

fetal monitors & computer-assisted diagnosis

Purpose #1

Gather ideas on how to identify and differentiate categories of EFM/CAD devices and the corresponding levels of evidence needed for validation.

FDA-NIH workshop (Nov 10th): *fetal monitors & computer-assisted diagnosis*

Purpose #2

Discuss how currently available databases might be used to verify/validate intrapartum EFM/CAD algorithms

FDA-NIH workshop (Nov 10th): *fetal monitors & computer-assisted diagnosis*

attendance/participation

- MFMs, labor mgmt
- industry
- biostatisticians
- other stakeholders

FDA-NIH workshop (Nov 10th):
fetal monitors & computer-assisted diagnosis

Outcome

- break-out sessions
- website
- summary
- next steps

Male Condoms made from NRL

New Labeling Guidance

Male Condoms made from NRL
New Labeling Guidance

- initial history
- FDA review of literature
- 2005 proposal
- public comments
- 2008 final rule

Male Condoms made from NRL
New Labeling Guidance

initial history

- 2000 statute, PL 106-554

  FDA to re-examine condom labeling
- 2000 inter-agency workshop
- 2001 begin review of literature,

  develop implementation plan

Male Condoms made from NRL
New Labeling Guidance

FDA review of literature

- Used 2001 workshop report as initial building block
- Limited scope to male condoms made from NRL
- Developed two-tier perspective for looking at condom effectiveness

Male Condoms made from NRL
New Labeling Guidance

FDA considered……

- Physical properties of condoms,
- Condom slippage and breakage during actual use,
- Plausibility for STI-risk reduction attributable to condoms (transmission vectors),
- Evaluations of condom effectiveness against STIs by other federal agencies, and
- Clinical data re: condom protection against STIs.

Male Condoms made from NRL
New Labeling Guidance

Group 1 STIs

- HIV/AIDS
- Gonorrhea
- Chlamydia
- Trichomoniasis
- Hepatitis B Virus

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Group 2 STIs

- Syphilis
- Genital HSV
- Genital HPV
- Chancroid

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- 2005 proposal
  - two-tier concept of effectiveness
  - warnings about nonoxynol-9
- Public Comments
- Label Comprehension Study

Male Condoms made from NRL
New Labeling Guidance

2008 final rule

- issued last month
- defers response on N9, synthetic male condoms, female condoms
- effective January 9, 2009

condom labeling: outside retail pkg

Important Information:

- *Latex condoms do not completely eliminate the risks of pregnancy and sexually transmitted infections (STIs).*
- *To get the most protection from a latex condom, use one correctly every time you have sex. Please see directions for use inside the package.*
- *There are many STIs. A latex condom can reduce the risk of STI transmission to or from the head of the penis. However, some STIs can also be spread by other sexual contact. For additional information on STI protection, please read the information inside the package.*
- *If you believe you have an STI, contact a health care provider. For more information on condoms or STIs, contact a health care provider or public health agency.*

condom labeling: pkg insert

Degree of STI Protection

Latex condoms reduce the risk of transmitting STIs by providing a barrier against the source of the infection.

Latex condoms are most effective against STIs such as HIV infection (AIDS) and gonorrhea that are spread by contact with the head of the penis.

Latex condoms are less effective against STIs such as Human Papillomavirus (HPV) and herpes. These STIs can also be spread by contact with infected skin that is not covered by the condom.

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Next Steps

- letter to industry
- article in FDA Consumer
- partner with other public health agencies
- address other condoms not covered

Outgoing Panel Members

- Marcelle Cedars, MD
- Elizabeth George

Open Public Hearing

- two OPH sessions
- added perspective
- encourage questions

Thank you!