Risk Communication Advisory Committee Meeting: Communicating Information about Risks of Prescription Products and Vaccines used during Pregnancy

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U.S. Food and Drug Administration

- One of the oldest U.S. consumer protection agencies
- FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation
- Speed innovations that make medicines more effective, safer, and more affordable
- Regulates the manufacturing, marketing and distribution of tobacco products
- Fosters development of medical products to respond to deliberate and naturally emerging public health threats
- Part of the Department of Health and Human Services
- FDA annually regulates over $1 trillion worth of products

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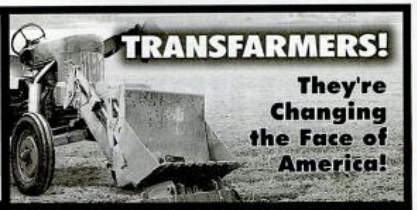

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MORE PHOTOS –See Page 3

U.S. Evidentiary Standard for Approval

- A product approved must:
  - Demonstrate **substantial evidence of effectiveness/clinical benefit** (21CFR 314.50)
  - Clinical benefit:
    - The impact of treatment on how patient feels, functions or survives
    - Improvement or delay in progression of clinically meaningful aspects of the disease
- Evidence of effectiveness [PHS Act, 505(d)]
  - Evidence consisting of adequate and well –controlled investigations on the basis of which it could fairly and responsibly be concluded that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in the labeling
- Adequate safety information must be included in the application to allow for appropriate risk benefit analysis [FD&C 505(d)(1)]

Pregnancy and Product Approval

- Drugs approved for adult populations
  - Efficacy established in non-pregnant patients supports efficacy in pregnancy
  - Dosing and safety may be different
- Pregnant patients have access to an approved therapy once the product is approved in adults
- Drugs intended to treat a pregnancy-specific indication or condition must be studied in pregnant populations (e.g., eclampsia, pre-term labor)

FDA and Prescription Product Labeling

- Provides a summary of essential scientific information needed for the safe and effective use of a drug
- Written for the health care provider, not for the patient
  - Pregnancy information in FDA product labeling intended for the prescriber is focus of this AC
  - However, many patient materials are derived from FDA labeling
  - Prescribers and pregnant patients benefit from clearly communicated information in prescription product labeling
- Must be informative, accurate, and neither promotional in tone nor false or misleading
- Must be updated when new information becomes available

Pregnancy and Lactation Labeling Rule (PLLR)

- Published on December 4, 2014, and requires manufacturers of prescription drugs and biological products (OTC products are not subject to this rule) to comply with the rule beginning June 30, 2015
- Intended to improve the communication of information in labeling related to pregnancy, lactation, need for pregnancy testing, contraception, and effects on fertility
- Since June 30, 2015, over 500 products have labeling that complies with PLLR format
- Future PLLR submissions anticipated:
  - 2018: approximately 450 products
  - 2019: approximately 800 products
  - 2020: approximately 300 products

Assessment of FDA Implementation

- Review lessons learned from the first 500 PLLR labeling conversions
- FDA seeking advice from the RCAC
  - What is working well?
  - What is not working so well?
  - What improvements can we make?
  - How are we doing overall?
- We hope to use your advice to implement any recommendations in advance of the first cohort of required PLLR conversions in June 2018

Agenda Day 1

- FDA review of the Pregnancy and Lactation Labeling Rule and the labeling revision process
- Guest speaker presentations
  - Physicians' Perspective of the New Pregnancy and Lactation Labeling: Survey Results; Jennifer Namazy, M.D.
  - Communicating Risk in an Environment of Uncertainty; Michael Greene, M.D.
  - Prescribing for Pregnant Patients: Progress Report; Katherine Wisner, M.D., M.S.
  - Communication: ACIP Recommendations and Vaccine Uptake by Pregnant Women; Laura Riley, M.D.
  - Communicating Teratogen Information Effectively: The Teratogen Information Service Perspective; Beth Conover, APRH, CGC
- Open Public Hearing
- Guest speaker presentations
  - A Patient Perspective: PLLR—A Modern Day Medical X Factor; Jamie Zahlaway Belsito
  - Pregnancy and Lactation Labeling: A Law and Ethics Perspective; Kayte Spector-Bagdady, J.D., Mbioethics
  - PLLR from an Industry Perspective; Traci J Lee, Pharm.D.

Agenda Day 2

- Open Public Hearing
- Clarifying Questions
- Committee Discussion
  - Discuss how factors impact healthcare provider decision-making and patient counseling
  - Discuss how effective PLLR has been in conveying safety evidence in pregnancy that is useful in benefit-risk decision making
  - Discuss your interpretation of certain phrases currently used in PLLR
  - When there is limited evidence suggesting a safety signal in pregnancy, discuss criteria that should prompt FDA to communicate this information

Acknowledgements

- Guest Speakers
- FDA RCAC Staff
- Members of the RCAC Planning Committee
- Members of the RCAC

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RIO AGONY AT WIFE'S CANCER DEATH

SEE PAGES 12 & 13

WILLS & KATE'S 8lb 3oz PRINCESS

Pictures: ARTHUR EDWARDS

Happy family . . . beaming Kate, Wills and baby leave hospital

Sleeping cutie

By EMILY NASH and JAMES SEAL

WILLS and Kate's new daughter makes her first public appearance yesterday — and serenely snoozes through it.

The 8lb 3oz Princess of Cambridge, less than two hours old, greeted the world cradled in her mum's arms and wrapped in a shawl. Earlier, brother George, left, waved to well-wishers as he arrived to meet his sister in London.

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