July 12, 2000
Minutes of the Nonprescription Drugs Advisory Committee

Topic: Labeling and Re-marketing Issues on the Today Sponge®, Allendale

The meeting was held at the Holiday Inn, Bethesda, MD.. Prior to the meeting, the members, consultants and guests had reviewed background material from the FDA and from Merck. In order for the public to be informed, the background material was also available on the Dockets page the day before the meeting. There were approximately 75 persons in attendance. The meeting started at 1 p.m. and ended at 5:30 p.m.

Attendance:
NDAC Members Present: Acting Chair, Louis Cantilena, Jr. M.D., Ph.D., Richard Neill, M.D., Edward Krenzelok, Pharm.D., Edwin Gilliam, Ph.D., Julie Johnson, Pharm.D., Donald Uden, Pharm.D., Henry Williams, M.D. , George Blewitt, M.D. (non-voting)

NDAC Members Absent: Hari Sachs, M.D., Francis Lam, Pharm.D., Eric Brass, M.D., Ph.D.,

Consultants: Jodi Lerner, M.D., Michael Green, M.D., Jaime Davidson, M.D. (consumer representative)

FDA Participants Robert DeLap, M.D., Ph.D., Charley Ganley, M.D., Linda Katz, M.D., Ling Chin, M.D., Claudia Karwoski, Pharm. D., Gloria Chang, R. Ph.

Open Public Hearing:
The following individuals made statements:

1. William Smith, SIECUS (Sexuality Information and Education Committee)
2. Amy Allina, National Women's Health Network
3. Donna Richmond, Vice President, Association of Reproductive Health Professionals
4. Armand Lione, Ph.D., President, Associated Pharmacologists & Toxicologists
5. Lizza Gonzales, The Alan Guttmacher Institute
6. Elizabeth Arndorfer, NARAL (National Abortion and Reproductive Rights)
7. William Soller, Ph.D., Consumer Health Products Association (CHPA)

3630m

Overview of Allendale's Presentation:
Elizabeth B. Connell, M.D., Professor Emeritus, OBGYN, Emory University School of Medicine discussed the sponge as an option for women. Mary Delaney, MS, Research Associate, Brigham & Women's Hospital, Harvard gave a presentation on Toxic Shock Syndrome and the Today Sponge. Roberta Geidner Antoniotti, President and CEO, Planned Parenthood of Maryland, discussed the relative Public Health Need for the Today Sponge. Forrest Greenslade, Ph.D., Intercare 21st Consulting, presented information on Communicating Effectiveness Data for the Today Sponge. R.J.Staab, Ph.D., Chief Scientific Officer, Allendale presented the overview of the issues of the Today Sponge.

Overview of FDA Presentations
Ling Chin, M.D., MPH, Medical Officer, DOTCD, described the history and chronology of the Today Sponge. Claudia Karwoski, Pharm.D., Safety Evaluator, DDRE 1, OPDRA gave a safety review. Gloria Chang, R.Ph., Interdisciplinary Scientist, DOTCDP, discussed the labeling issues. Charley Ganley, M.D., Director DOTCD, gave the charge to the committee.

Committee Discussion:
Allendale Pharmaceuticals plans to resume marketing of the Today Sponge®. The agency has requested that the sponsor revise the currently approved carton label so that it conforms to the Drug Facts format. The agency has also proposed revisions to the package insert. The information provided to the committee included the currently approved labeling (designated 1991 labeling) and the proposed revised labeling (designated 2000 labeling).

1. Given the material provided in your briefing packages and presented today, does the revised labeling adequately convey the risks associated with the use of the product?

   Yes= 9 No=1 (toxic shock needs more)

2. The current carton label does not include information on the efficacy of this product. Should the carton label include efficacy information so that the consumer will have this information available at the point of purchase?

   Yes=9 No=1

The no vote qualified the vote with the following explanation: if you do not add efficacy about other products than it is not very useful information.

There was a suggestion that a simple statement on the carton would be easier to understand about efficacy than the complex table. For instance, it was proposed that a sentence should be added on the external label that said that this method was not as effective as the pill or IUD but as favorable as the condom, spermacidal jelly etc.

a. If yes, should this kind of information be required of all OTC contraceptive products?

Yes=10 No=0

3. Are there other aspects of the labeling that should be revised?

The committee suggested that the revised label needed information on what to do if the sponge comes out. There should also be information on what happens if you use it several days in a row. The outside label might not need information about hand washing but more about helping a consumer know more about the product' efficacy. Some felt that the information that it must be left in place for six hours after intercourse was not obvious enough information. Also that there should be a stronger warning about not using during menses. Some felt that since a consumer would take one or two sponges from a box that they each should have certain key information. Bilingual labeling was recommended.

4. Please provide comments on the type of post-marketing surveillance for adverse events the sponsor should conduct (e.g. active collection, follow-up reporting and analysis of cases of difficult sponge removal, provisions in place to facilitate adequate adverse event reporting)?

Regarding the sponsors 24-hour – 7 day hot line service. Many felt the sponsor needed to have a more evolved plan; they suggested that the company not hire individuals but perhaps contract with a strong nursing service. There should also be information on how an MD reports problems. It was pointed out that the sponsor can collect consistent quality data if they hire an appropriate service to respond to consumer questions, problems and medical advise given.

A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

I certify that I attended the July 12, 2000 meeting of the Nonprescription Drugs Advisory Committee and that these minutes accurately reflect what transpired.

Sandra Titus 8/20/00

Sandra Titus, Ph.D. Date
Executive Secretary, NDAC

Louis Cantilena 8/21/00

Louis Cantilena, M.D., Ph.D. Date
Acting Chair, NDAC