

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

13345



5 - SUMMARIES

**000001**

Handwritten: taped 2/3/99 (6)

(STAMP)

NAME LAST, FIRST, MI

MR NUMBER D.O.B. SEX

PHYSICIAN M.D. Preop 2/2/99

### HISTORY AND PHYSICAL RECORD

ADMISSION DATE

**MEDICAL HISTORY**  
(Order of recording)

- 1 CHIEF COMPLAINT
- PRESENT ILLNESS
- PAST HISTORY
  - childhood
  - adult
  - operations
  - injuries
- 4 FAMILY HISTORY
- 5 SOCIAL HISTORY
- 6 SYSTEMIC REVIEW
  - general
  - skin
  - head, eyes, ears, nose, throat
  - neck
  - respiratory
  - gastro-intestinal
  - genitourinary
  - gynecological and menstrual
  - locomotor
  - neuro-psychiatric

CC: Missed AB

HPI: Patient's LMP was a light one and it was also late. The little bit of bleeding she had started on November 3, 1998. She was seen in the office on January 4, 1999. Her initial OB exam demonstrated a fundus about 9 weeks consistent with her dates. Since that time the patient has felt excessively tired and just not well. US today demonstrated her 9 week dead intrauterine fetus. She is admitted for D & C.

PMH: She's never had any kind of surgery, illness or injury. She is a Gravida 3 now Para 2, now SAB 1, living children 2 ages 2 and 3. Had asthma in the sixth grade but has had no trouble since.

FH: Mom and dad are alive and well. Brothers and sisters are alive and well. One grandfather died of cancer, one aunt died of cancer. No diabetes no heart disease in her family.

ALLERGIES: None

MEDICATIONS: Only prenatal vitamins right now however, the patient did take during the first 4 weeks of her pregnancy something called Magic Herb which contains Ma-haung along with some Chromium Picolinate and Licorice and Ginseng and some other things that are unfamiliar to me. She was also taking Siberian Ginseng root.

**PHYSICAL EXAMINATION**  
(Order of recording)

- 1 GENERAL
- 2 SKIN
- 3 LYMPHATIC
- 4 EYES, EARS, NOSE, THROAT
- 5 MOUTH
- 6 NECK
- 7 CHEST
- 8 HEART-BLOOD VESSELS
- 9 ABDOMEN
- 10 GENITALIA
  - Vaginal
  - Rectal
- 11 LOCOMOTOR
- 12 EXTREMITIES
- 13 NEUROLOGICAL

SH: The patient has sons ages 2 and 3. She has also started taking care of another child just recently. Her husband is a trucker and is away all week long except for weekends. She does not smoke, she does not drink.

O: VITALS: Wt 150 lbs. BP 110/70, Heart rate is 64 and regular. She's alert. Right now, of course, she is tearful and upset. This was a wanted pregnancy but she is appropriate in her demeanor.

GENERAL: She looks tired.

HEENT: Normocephalic, TMs are both normal. PERRL, Posterior pharynx normal.

NECK: Without masses or adenopathy, voice is normal.

CARDIOPULMONARY: LUNGS are clear to auscultation. No rales, rhonchi or wheezes.

No mummur, rub, gallop or click. No JVD, peripheral edema, or hepatojugular reflux.

ABDOMEN: Demonstrates a palpable uterus, 2 cm. above the pubis anteriorly. Fetal heart tones were not heard.

PELVIC/RECTAL: Were not repeated at this time.

**DIAGNOSTIC IMPRESSION**

SIGNATURE AND DATE

medWatch Report #13345  
Follow-Up Adverse Report  
Thomas S. Donaldson 03-19-99  
Exhibit 6 page 01 of 27 TSD

over

000002

## HISTORY AND PHYSICAL RECORD

Preop cont.

LABS: are pending at this time, CBC and STAT V. We cancelled the prenatal panel. Her blood type is AB+, she is rubella positive. Last pap January 4, 1999, it was wnl but there were very many WBC's.

ASSESSMENT: 1. Missed AB  
2. Possible connection with over the counter herbal preparations. Remains to be investigated.

PLAN: I have spoken with Dr. [REDACTED] who will do the D & C for her tomorrow at her request. Her alternative is to wait a couple of weeks and see if she passes it on her own and this is unacceptable to her.  
She is instructed not to have anything by mouth after midnight tonight.

T2-3-99 [REDACTED], M.D. [REDACTED]

ADDENDUM: ROS was missed:

In general the patient has been feeling excessively tired and sick but she can't really put her finger on it any more than that.

HEENT: She denies headaches, sore throat, runny nose, trouble swallowing.

CARDIOPULMONARY: Denies SOB, Chest pain, wheezing, cough, palpitations.

GI: Denies abdominal bloating, cramping, diarrhea or abdominal pain.

GU: Specifically denies vaginal burning, itching, discharge or bleeding.

MUSCULOSKELETAL: ROS Is negative.

[REDACTED] M.D. [REDACTED]

medWatch Report #13345  
Follow-Up Adverse Report  
Thomas S. Donaldson 03-19-99  
Exhibit 6 page 02 of 02 TSD  
22 [REDACTED]

000003

