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

ARMS#

13202

5 - SUMMARIES

[redacted]

HISTORY AND PHYSICAL EXAMINATION

[redacted]

MedWatch #13202
2/4,5/99 JAH
Ex#2 pg 3 of 49

Date 11/17/98 Hour A.M. P.M.

Order of Recording

HISTORY:

1. Chief Complaint
2. History of Present Illness
3. History of Past Illness
   a. childhood
   b. adult
   c. operation
   d. injuries
   e. allergies drug reaction
4. Family History
5. Social History
6. Systemic Rev.
   a. General
   b. Skin
   c. HEENT
   d. Neck
   e. Respiratory
   f. CV
   g. GI
   h. GU
   i. Gynec.
   j. Locomotor
   k. Neuro-psychiatric

PHYSICAL:

1. General
2. Skin
3. Eyes
4. Ears
5. Nose
6. Mouth
7. Throat
8. Neck
9. Chest
10. Heart
11. Abdomen
12. Genitalia
13. Lymphatic
14. Blood Vessels
15. Locomotor
16. Extremities
17. Neurological
18. Rectal
19. Vaginal
20. Diagnosis

SIGNATURE

CC: (R) UQ pain; ↓ renal function

HPI: This is a 22yo wf c̄ 2y h/o renal failure, came in for (R) UQ pain, colicky, radiated to the back, started ≈10 days ago.
Pt. denies fever, vomiting, though she states she had nausea for the last day and 5 liquid greenish stools (11/1
She was seen in her PCP's office and a set of blood exams was done, showing ↑ BUN and creatinine, high ESR and proteinuria.
Pt. had a similar pain 2½ y ago. At that time she was found pregnant. Serum pregnancy test done now in her's PCP's office ~~showed~~ was ⊖.

PMHx: ~~Triphasic~~
~~Not~~ significant

Meds:
Triphasic
Phensafe
Advil → 4 tabs
Motrin

Social Hx: tabacco ⊕ (1pk/d, 5y) ETOH ⊕

Family Hx: M, F healthy
Daughter (2y) epilepsy
⊕ ↑ M, ⊕ CAD, ⊕ ovarian CA (grandparents)

ROS: ↑ thirst, polydipsia, polyuria

Physical exam: young over weight pt. in no acute distress.

Vitals: BP: 114/80 HR 80 RR 16 T° 98.4°

Skin: ⊖ rashes, ⊖ lesions, ⊖ petechiae

HEENT: PERRLA, EOMI, pink, moist oral mucosa, clear throat.

Neck: supple, ⊖ lymphadenopathy, ⊖ bruits, ⊖ JVD

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[redacted]

[redacted]

HISTORY AND PHYSICAL EXAMINATION

[redacted]

Date	Hour	A.M. P.M.

MedWatch #13202
2/4,5/99 JAH
Ex#2 pg 4 of 49

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SIGNATURE

CV: RRR, S_1, S_2 nml., ⊖ G/M/R

Lungs: CTA, nml. breath sounds

Abdomen: obese, ⊕ BS, ⊖ G/R, ⊕ T in RUQ
Murphy sign ⊕, ⊖ HSM, ⊖ palpable kidneys
⊖ masses, ⊕ (R) CVA tenderness

Rectal: ⊖ hemorroids, nml sf. tone, ⊖ masses, brownstool guaiac

Extremities: ⊖ e/c/c, palpable pulses, ⊖ e/tend of hands

Neuro: A + 3XO, nonfocal.

Labs: UA: pH 5, Leuk. ⊖, protein ++, blood ⊖, SPG 1010
⊖ B, ⊖ G

14.1 > 13.9 / 40.5 < 167 / 87 ESR 75 142 | 108 | 45 / 5.1 | 20 | 4.9 <

~~Echo~~ Renal US: Nml (R), (L) kidneys. No signs of obstruction.

A/P:

(R) UQ pain: Will ✓ gallblader US R/O acute cholecystitis. Will follow WBC

Renal failure: Will check urinary sediment c̄ Dr. [redacted] (Nephro consult) Repeat SMA-6 in am.

[redacted]

[redacted]

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[redacted]

[redacted]

CONSULTATION

REPORT

I have interviewed & examined patient and dictated a proposed following consult

dWatch #13202
4.5/99 JAH
EX#2 pg 11 of 49

Pat [redacted]

Date Requested: 11/17/98 [redacted]

CONSULTANT: Dr [redacted] Nephrology REQUESTOR: Dr [redacted]

REASON FOR CONSULTATION REQUEST: ↑BUN/cr

Pt seen with & note dictated by Dr [redacted]

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REPORT:

IMPRESSION:

(1) ACUTE RENAL FAILURE: with Nephrogenic Diabetes insipidus, probably 2° PhenSafe Diet Supplement (one of the many ingredients)

RECOMMENDATION:

(1) Hold all other meds except for Triphasyl
(2) Continue p.o. fluid intake
(3) ✓ ADH levels
(4) we will do literature search of all the ingredients in "PhenSafe" ... it contains a lot of "naturopathic" and herbal-type ~~meds~~ ingredients.
(5) Rev labs in AM ... if she is getting worse, we will recommend renal Bx.

Date of Consultation: 11/17/98 Signature of Consultant: [redacted]

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(Original – Patient Record • Copy – Consultant)

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CONSULTATION
REPORT

MedWatch #13202
2/4,5/99 JAH
Ex #2 pg 12 of 49

[redacted]

Date Requested: 11/17/98

CONSULTANT: Dr [redacted] Nephrology REQUESTOR: Dr [redacted]

REASON FOR CONSULTATION REQUEST: ↑ BUN/Cr

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REPORT:

Discussion: Pt is a 22 y.o. w.f. c̄ severe RQ pain since 11/8/98 & ↑ BUN/Cr (29/3.1) since 11/11/98 & even more ↑ levels on 11/16/98 (43/4.9). The pt. has no previous lab work measuring her renal function. The pt. had 1 UA performed ~~since~~ in the hospital which was an extremely dilute urine c̄ sp G 1.005, protein ⊖, trace blood, & no casts of any type. To obtain a more concentrated urine, an intranasal dose of desmopressin was given to the pt & a repeat UA was performed. This UA also was dilute c̄ sp G of 1.004 & absent casts of any type; however, this urine was also associated c̄ a S_{Na} of 146. This low sp G, high ~~SNa~~ S_{Na} combined c̄ the pt's 4 week h/o polydipsia, ↑ thirst, & polyuria suggest a nonosmotic urinary water loss 2° to diabetes insipidus; which in this case is nephrogenic b/c of unresponsiveness to ADH dose. The pt's ARF is improving c̄ this pm. BUN/Cr ↓ to 36/4.4. The pt's use of NSAID's does raise possibility of AIN or prerenal failure 2° to ↓ PGE_2 production; however the pt. had no ~~muddy brown casts~~ WBC casts or hypovolemic changes. The absence of RBC casts also R/o

Date of Consultation: 11/17/98 Signature of Consultant: [redacted]

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CONSULTATION
REPORT

MedWatch #13202
2/4,5/99 JAH
Ex# Z pg 13 of 49

Patie[redacted]

Date Requested: 11/17/98

CONSULTANT: [redacted] Nephrology REQUESTOR: Dr [redacted]

REASON FOR CONSULTATION REQUEST: ↑ BUN/Cr

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REPORT: an acute glomerulonephritis. The polydipsia, ↑ thirst, + polyuria initiated at the time when the pt. began taking a "natural" diet supplement PhenSafe 1 month ago. This is an OTC weight reducing supplement composed mainly of St. John's Wort (hypericin), Sida Cordifolia, Licorice, Ginger, Cayenne, Mustard, Bioperine (piperine (ff pepper)) + ? ChromeMate, + various other vitamins. Many of these are "naturally occuring" substances with ? uses, actions, + adverse effects.

Her presentation is ARF c̄ nephrogenic diabetes insipidus – a presentation that can be seen with certain agents such as demeclocycline. I suspect one of the ingredients in "PhenSafe". Her last dose of PhenSafe was on 11/13. She has a normal renal u/s except ↑ renal echogenicity. Her urine sediment is bland. She has no other obvious cause for ARF c̄ NDI (she has not taken demeclocycline, foscarnet, cidovir or any other agent).
Will follow closely.

Date of Consultation: 11/17/98 Signature of Consultant: [redacted]

[redacted]

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CONSULTATION
REPORT

MedWatch #13202
2/4,5/99 JAH
Ex#2 p14 of 49

Patie[redacted]

Date Requested: 11/17/98

CONSULTANT: Dr [redacted] Nephrology REQUESTOR: Dr [redacted]

REASON FOR CONSULTATION REQUEST: ↑BUN/cr

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REPORT: cc: abdominal pain
↑urinary frequency

HPI: 22 y.o. w.f. who is presenting with ↑ BUN/cr since 11/11/98. The pt. visited her PCP 10 days ago c/o RUQ pain. The pain was constant, radiating to the (R) lower back. The pt. denies any pain radiating to her (R) lower quadrant. She reports ↑ pain on 2 occasions in the past week and a half after drinking 2-3 beer. She denies any associated vomiting or diarrhea. The pt visited [redacted] on 11/8/98 c similar pain where she was given fluids + Percocet & D/c'd. On 11/11/98 she visited her PCP who found the pt. to have a BUN/cr of 29/3.1 & a UA significant for pr⁻: 2+ & sp G: 1.010. A repeat BUN/cr on 11/16 was 43/4.9 c UA pr⁻ (−) & sp: 1.015. The pt. denies dysuria or frank hematuria. Pt does report polyuria, waking "every hour" at night starting 1 month ago. At this time the pt. began taking a "natural" diet pill phen-sate (from [redacted]). She states this pill ↑ her thirst & ↑ her urinary frequency; however, she stopped this drug 2 weeks ago. Pt. reports that before starting phen-sate her urine was yellow-orange & not cloudy, and now she states that since starting the drug it has been totally clear. The pt. also

Date of Consultation: 11/17/98 Signature of Consultant: [redacted]

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CONSULTATION
REPORT

MedWatch #13202
2/4,5/99 JAH
Ex#2 pg 15 of 49

Pati [redacted]

Date Requested: 11/17/98

CONSULTANT: Dr [redacted] Nephrology REQUESTOR: Dr [redacted]

REASON FOR CONSULTATION REQUEST: ↑BUN/cr

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REPORT: reports significant NSAID use in the past month. She states having taken Advil 4 times/day when her abd. pain ↑ in the past month. On other occasions in the past month she took 2 Aleve for the pain. She also reports using in the past ~~using~~ Motrin or Ibuprofen for menstrual pain. She denies any other drug use, other than oral contraceptives (Triphasil) and the percocet given to her in the ER. Pt. denies HA, dizziness, tinnitus, vertigo, or diarrhea. She has visited [redacted] 4 times in the last 2 years with similar abd. pains. On 11/3/98 she had a WBC: 14000 Spreg: ⊖ & PLT: 167,000.

PMH: (L) ovarian cyst (1997) G1 P1 (1996)

Med All: NKDA

MEDS: Triphasil, percocet, "phen-Soft", NSAID

FH: grandfather: CAD, DM; grandmother: abo Pin; Father: healthy; Mother: healthy; daughter: epilepsy.

SH: smoker: 1 ppD × 6 yrs; ETOH: social: 2-3 beers; Denies illicit drug use.

ROS: negative unless otherwise noted

GI: Reports having nausea in the past 2 weeks & vomiting. ↓ appetite in the last week & half.

Pt. reports that she has lost weight, but does not know how much. [redacted]

Date of Consultation: _____ Signature of Consultant: [redacted]

cont'd →

[redacted]

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[redacted]

CONSULTATION
REPORT

MedWatch #13202
2/4,5/99 JAH
Ex#Z 16 of 49

Patient [redacted]

Date Requested: 11/17/98

CONSULTANT: Dr [redacted] REQUESTOR: Dr [redacted]

REASON FOR CONSULTATION REQUEST: ↑ BUN/Cr

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REPORT: ROS: neuro: Pt reports feeling ↑↑ somnolence over the past month, sometimes finding it very hard to wake up.
Ext: Reports having "cold, clammy" hands over the past month

PE: Young, pleasant female, laying supine c̄ ↓ movement.
VS: BP 140/92 (supine) / 138/90 (standing: 1 min) / T: 98.6° / HR: 82 / RR: 20 / 96% (RA)

HEENT: PERLA/EOMI. Neck supple. ∅ JVD. ∅ carotid bruits. ∅ lymphadenopathy. Pink, moist oral mucosa.
CHEST: Normal expansion. Clear Bilat Breath sounds.
CV: RRR. S_1-S_2 nl. ∅ c/m/g
Abd: Nondistended. BS (+). Severe tenderness elicited over deep palpation of RUQ. Tenderness is elicited all along the (R) inferior costal margin. Tenderness elicited over (R) lower back c̄ palpation & fist percussion.
Ext: ∅ edema. 2+ bilat. pedal pulses. Palmar surface of hands cool & moist to touch.
Neuro: A & O x 3. Nonfocal. Strength +5/+5. CN I-XII intact
Skin: ∅ lesions. Adequate turgor.

LABS: 146 / 5.1 | 108 / 23 | 36 / 4.4 | 72 — 10.9 | 12.9 / 37.1 | 178 — Ca: 1.22 — Mg: 2.5 — Phos: 5.6 — AlkP: 111 — AST/SGOT: 16 — Total bili: 0.4

(11/8) BUN/Cr: 29/3.1 (11/16): 43/4.9 USG 11/11: No hydronephrosis ∅ obstruction / (11/17): No cholecystitis / ↑ tenderness

Date of Consultation: 11/17/98 Signature of Consultant: [redacted]

[redacted]

(Original – Patient Record • Copy – Consultant)

OTHER CONSULTATIONS

[redacted]

CONSULTATION
REPORT

[redacted]

Patient Addressograph

Date Requested: 8-22-98

CONSULTANT: Dr. [redacted] OB/GYN REQUESTOR: [redacted]

MedWatch #13202
2/4,5/99 JAH
Ex2 pg 38 of 49

REASON FOR CONSULTATION REQUEST: LLQ Abd pain

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REPORT:

HPI: Pt is a 21 y.o. G2P1011 c̄ LMP 8/6/98 presents c̄ 1 day h/o LLQ. Pt has a 13 mo of LLQ thought to be 2° to a cyst (pe pel a) but s̄ adequate w/u. Pain intermittent – on for 4 days, gone for weeks, back for 1 day, etc. Characterized pain as sharp + stabbing. Tonight, pain has radiated to RLQ + to back. Pain not related to menses, activity, position, or activity. Not relieved or worsened by an means. Has not taken any pain meds. Also c/o worsening of pain p̄ intercourse. ⊖ Fever/chills/N/V/Diarrhea. ⊖ unusual vag discharge. ⊖ Dysuria

PMH ∅ MeDS – ∅ OCPs. P. Gyn Hx
BSurg Hx ∅ Allergies – NKDA ⊖ STD/PID

OB Hx – 1 NSVD ~ 1½ yrs ago.

SOCIAL – ⊕ tob ~ 1 PPD ⊕ occ. Ato[redacted] ⊕ [redacted] marijuana use. [redacted] in years

Date of Consultation: 8-22-98 Signature of Consult[redacted]

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[redacted] (Original – Patient Record • Copy – Consultant)