

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

ARMS#

13187



5 - SUMMARIES

000001

[REDACTED]
DISCHARGE SUMMARY

medWatch Report #13187
Follow-Up Adverse Report #88
Thomas S. Donaldson 01-11-99
Exhibit: 3 page 3 of 4B

PATIENT NAME: [REDACTED]

MEDICAL RECORD #: [REDACTED]

DC MR #: [REDACTED]

ADMISSION DATE: 09/12/98

DATE DISCHARGED: 09/15/98

PHYSICIAN: [REDACTED] MD

PRINCIPAL DIAGNOSES:

Acute pancreatitis, idiopathic - remote possibility caused by Minocycline

SECONDARY DIAGNOSES:

10/19 later - found she was on an "Herbal med"

OPERATIONS/PROCEDURES:

Memo Date: January 11, 1999
Subject: F/U Adverse Report/
To: Dorothy L. Usher, ASCSO
From: Thomas S. Donaldson, MD
Exhibit No: [REDACTED] of [REDACTED]

SUMMARY: 56 year-old-female admitted through the Emergency Room with abdominal pain and amylase level of 1,296. Treated initially with NPO and IV fluids. Amylase was checked daily and dropped to 1100 the following day and continued to drop to 605 and on the fourth day 186. Clear liquids were instituted about 36 hours before discharge and were tolerated quite well. She was having some pain on the day before discharge, relieved by a Fleets Enema. She had a bowel movement and was feeling markedly improved on the fourth morning and felt ready to go home.

She has been on Minocycline for many months, if not a couple of years, for acne rosacea. This is listed as a possible cause of pancreatitis, although I did informally consult with one of the gastroenterologists who felt that usually if that had been the cause it would have occurred within the first few weeks and hence, it seems unlikely.

Other lab data included a slightly low calcium of 8.4 and subsequently 8.6. Albumin was 3.0, FBS 145, however, with IV running. Overnight fasting triglycerides only 105 and I am not sure that is totally valid with the acute illness and hypertriglyceridemia on long term basis remains to be ruled out although I doubt it will be the case.

Hemoglobin was 16.3 on admission, WBC 13,300 with 90 segs. Lytes essentially normal. AST was 60 on admission and then normal, ALT 38, alk phos, bilirubin normal. Albumin was 4.1 on admission.

Upper abdominal ultrasound showed negative for cholelithiasis and did indicate "probable fatty infiltration within the liver". Pancreas was felt to be somewhat full, but without focal lesion or surrounding inflammatory change. EKG was normal.

At discharge, she will avoid fatty foods for the next couple of days and then progress her diet. Recheck on a prn basis initially. She will continue her same Premarin daily I believe at 1.25 mg. I did advise her to remain off Minocycline for the time being, although likely could resume that later cautiously.

DISCHARGE SUMMARY

ORIGINAL

000002

DISCHARGE SUMMARY - Page 2

PATIENT NAME: [REDACTED]

MEDICAL RECORD # [REDACTED]

Follow up in my office in one month for annual GYN exam. Will check 12 hour fasting lipid profile and FBS, calcium, albumin, ALT in a couple of days before.

[REDACTED]

cc: [REDACTED] MD
[REDACTED] MD

DD: 09/15/98

TD: 09/15/98 12:34 [REDACTED]

[REDACTED]

medWatch Report #13187
Follow-Up Adverse Report
Thomas S. Donaldson 01-11-99
Exhibit: 3 page 4 of 48

Memo Date: January 11, 1999
Subject: F/U Adverse Report/Duluth, MN
To: Dorothy L. Olson, ASCSO
From: Thomas S. Donaldson, CSO TSD
Exhibit No: page of

**DISCHARGE SUMMARY
ORIGINAL**

000003



HISTORY AND PHYSICAL

PATIENT NAME: [REDACTED]

ROOM #: [REDACTED]

MEDICAL RECORD #: [REDACTED]

DATE OF ADMISSION: 09/12/98

DC MR #: [REDACTED]

PHYSICIAN: [REDACTED] MD

CHIEF COMPLAINT: Abdominal pain.

HISTORY OF PRESENT ILLNESS: This is a 56-year-old female admitted through the emergency room with pancreatitis.

History is that she had a "strong, dull ache" across the epigastrium beginning around noon today with minimal nausea and no vomiting, somewhat crampy in nature, i.e., would get worse but never go away. No bowel habit change or melena or yellow stool. Had one similar attack about ten years ago overnight and nothing since.

PAST MEDICAL HISTORY: Surgery - says she had a hysterectomy with a Stamey some time in the 1990s and tonsillectomy in the 1990s. Illnesses - aware of no chronic illness other than rosacea. She is not aware of any high triglyceride; however, she was told by her dermatologist that her cholesterol was up in 7/98, and she was going to have that checked out further by myself. Meds - Minocin for rosacea and Premarin.

ALLERGIES: IV contrast dye for CT scan when she had a migraine once caused hives apparently.

FAMILY HISTORY: Not aware of diabetes or high cholesterol.

medWatch Report #13187
Follow-Up Adverse Report *MD*
Thomas S. Donaldson 01-11-99
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SOCIAL HISTORY: Works at the coding center.

SYSTEM REVIEW: Respiratory - initially said no dyspnea or cough but then says she does get cough and wheezing at times, not currently. CV - no chest pain. GU - no symptoms.

OBJECTIVE: She is alert, pleasant, appears very comfortable, in no distress. Not diaphoretic, color okay. Vital signs in ER showed a BP of 147/98, pulse 82, temp 36, resp 20. Eyes - PERLLA. Mouth negative. Neck - no masses. Carotids and thyroid normal. Lungs are clear. Heart - NSR, no murmur or gallop. Tones normal. Rate 96. Breasts - no masses. Axillae negative. Abdomen - slightly distended, but she says that is her usual appearance. Minimal tenderness to deep palpation. Epigastrium - no guarding, no mass. No lower abdominal tenderness. Extremities - no edema. Calves nontender. Skin benign. Neurologic - speech is normal, no obvious deficits. Moves all fours.

Old chart is not on floor for review.

Memo Date: January 11, 1999
Subject: F/U Adverse Report [REDACTED]
To: Dorothy L. Olson, ASCSO
From: Thomas S. Donaldson, CSO TSD
Exhibit No: page of *MD*

HISTORY AND PHYSICAL
ORIGINAL

000004

HISTORY AND PHYSICAL - Page 2

PATIENT NAME: [REDACTED]
MEDICAL RECORD #: [REDACTED]

I am told by ER physician that abdominal ultrasound was negative for gallstones.

Hemoglobin 16.3, MCV 88, WBC 13,300, 90% segs. ALT is normal. SGOT is 60, bilirubin, alk phos normal. Amylase 1,296.

IMPRESSION:

1. Acute mild pancreatitis, uncertain etiology.
2. History of rosacea, on Minocin.

PLAN: Will continue NPO and IV fluids. Will try to avoid nasogastric suction at this time. Will need to check triglycerides down the line when she has recovered from this.

Possible etiology of this pancreatitis could be her Minocycline as pancreatitis is in deed listed as an adverse reaction to the drug. Will check with her dermatologist on Monday to see if he has seen this.

[REDACTED] MD

cc: [REDACTED], MD
[REDACTED], MD

DD: 09/12/98
TD: 09/12/98 10:53 [REDACTED]
[REDACTED]

medWatch Report #13187
Follow-Up Adverse Report [initials]
Thomas S. Donaldson 01-11-99
Exhibit: 3 page 11 of 10

Memo Date: January 11, 1999
Subject: F/U Adverse Report [REDACTED]
To: Dorothy L. Olson, ASCSU
From: Thomas S. Donaldson, CSO [initials]
Exhibit No: page of [initials]