

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

ARMS#

11915



5 - SUMMARIES

000001

Date Dictated: 09-15-97

Med. Rec. No: [REDACTED]

Patient's Name: [REDACTED]

DISCHARGE SUMMARY

Date of Admission: 06-13-97

Date of Discharge: 06-20-97

CHIEF COMPLAINT: Progressive weakness in both lower limbs and both upper limbs and shortness of breath.

HISTORY: The patient is a 47 year-old right-handed African-American female. She has been having progressive weakness in the four limbs, plus respiratory problem in the last three months for unknown etiology.

PAST HISTORY: The patient has had no past history of any medical problem prior to this problem.

FAMILY HISTORY: She has a strong family history of high blood pressure and arthritis.

MEDICATIONS: The patient's medications at the time of admission were Carnitine, vitamin B2, Lasix, and potassium chloride.

PHYSICAL EXAMINATION: Her general examination at the time of admission was within normal limits, except diminished breath sounds bilaterally on the lung examination and holosystolic murmur on the cardiovascular examination. Neurological examination - mental status, she was alert and oriented times three. Language function was intact. Cranial nerve examination - optic nerve, full visual field, no cuts. Cranial nerves III, IV and VI - extraocular muscles were intact. No nystagmus or diplopia. Cranial nerve VII intact. Cranial nerves VIII, IX, X, XI and XII intact. Motor examination - she has motor power of +3 throughout the right side and 3-over the left side. She is weaker in the proximal muscles bilaterally. Deep tendon reflexes were +1 throughout, downgoing toes. Cerebellar function examination was intact. Gait - she is unable to walk.

LABORATORY STUDIES: She had sodium of 142, potassium 3.6, chloride 100, HCO3 32, BUN 8, creatinine 0.5, glucose 114. She has CPK of 13,524 at the time of admission. LDH 2,330. Magnesium 1.6. Amylase less than 30. SGOT 322. SGPT 200.

HOSPITAL COURSE: The patient was admitted to the Neurology Service, was started on a high amount of intravenous fluids. The patient was started on prednisone 40 mgs. q.d. Chest x-ray was done and showed cardiomegaly. Previously the patient had muscle biopsy done by Dr. [REDACTED] and the results were pending. Gastroenterology was consulted. The patient had swallowing study and they decided that the patient can eat soft food.

Date Dictated: 09-15-97

Med. Rec. No: [REDACTED]

Patient's Name: [REDACTED]

DISCHARGE SUMMARY

Discharge Summary Continued... Page 2

She had mild dysphagia. The patient improved slightly while she was in the hospital and she was seen by both Physical Therapy and Occupational Therapy. The patient was discharged to rehabilitation hospital on prednisone 20 mgs. q.d. with weaning of prescription, Prilosec 20 mgs. q.d. prescribed by Gastroenterology, Levocarnitine oral solution 500 mgs. b.i.d., heparin subcutaneously, vitamin B2 60 mgs. q.d., Lasix 80 mgs. q.d. and intravenous fluids. The patient was given instructions to follow up with Dr. [REDACTED]. Her neurological examination did not show big changes at the time of discharge.

[REDACTED] M.D.

Dictated By: Dr. [REDACTED]

DT: 09-18-97

DEPARTMENT OF NEUROLOGY [REDACTED]

000003

IC IN 7

DATE

ADMISSION DATE

6 17 91
MONTH DAY YEAR

DISCHARGE DATE

6 20 91
MONTH DAY YEAR

M

N

DIAGNOSES THIS ADMISSION (ABSOLUTELY NO ABBREVIATIONS)

LIST THE CONDITION ESTABLISHED AFTER INVESTIGATION TO BE CHIEFLY RESPONSIBLE FOR OCCASIONING THE ADMISSION OF THE PATIENT TO THE HOSPITAL

1 *Prinzemycinopathy*

LIST ADDITIONAL CONDITIONS/DIAGNOSES THAT EXISTED AT THE TIME OF ADMISSION AND WERE EITHER TREATED OR ALTERED THE COURSE OF TREATMENT

2

3

4

5

LIST ANY CONDITIONS/DIAGNOSES THAT COMPLICATED TREATMENT

6

7

8

9

LIST SIGNIFICANT OPERATIONS/PROCEDURES

1 *Echo*

2

3

4

TO BE COMPLETED BY MEDICAL RECORDS

USE BLACK

BALLPOINT PEN ONLY

DISPOSITION: HOME EXPIRED AMA OTHER FACILITY

FACILITY NAME

DISABILITY: TOTAL PERMANENT PARTIAL PERMANENT UNDETERMINED
 TOTAL, TEMPORARY PARTIAL, TEMPORARY NONE

EXPECTED LENGTH OF DISABILITY

EXPECTED DATE OF RETURN TO WORK

PROGNOSIS:

GOOD

POOR

UNCERTAIN

DISCHARGE ORDERS

PATIENT TO BE DISCHARGED ON

6 20 91
MONTH DAY YEAR

PRIMARY STAFF PHYSICIAN AT DISCHARGE

DISCHARGE MEDICATIONS AND TREATMENT

- prednisone 20 J x3 -> 10 x 5 - stop
- prilata 20 J qd
- levo carnitine oral slt 500 J B 30
- Hepant 5-c.
- vit B 2 50 J qd

TYPE OF DIET

REGULAR
 SPECIAL

ACTIVITY INSTRUCTIONS

NONE
 SPECIAL

FOLLOW-UP APPOINTMENTS

- out this week 10-11-91 qd
- Lasix 80 J qd
- IV. Phlebot.

Rx ATTACHED Rx GIVEN PT /FAMILY

TRAN

Date

000004

[Redacted]

6/20/91

DATE

CH

CH

9/15/97

DICTATION DATE

PATIENT DISCHARGE DATA SUMMARY

MRN: [REDACTED] NAME: [REDACTED] ADATE: 06/13/97 DDATE: 06/20/97
ATTENDING PHYSICIAN: DR. [REDACTED] MD
FIN CLASS: [REDACTED] DISCHARGE DISP: [REDACTED]

DIAGNOSES:

[REDACTED] MYOPATHY NEC
[REDACTED] HYPOSMOLALITY
[REDACTED] ALKALOSIS
[REDACTED] HTN HEART DIS NOS NO CHF
[REDACTED] DIARRHEA
[REDACTED] NAUSEA WITH VOMITING
[REDACTED] DYSPHAGIA
[REDACTED] DISORDER PHOS METABOLISM
[REDACTED] DISORD MAGNESIUM METABOL

PROCEDURES:

I AGREE WITH THE DIAGNOSES AND MAJOR PROCEDURES LISTED ABOVE.

SIGNATURE: _____
DR. [REDACTED] MD

DATE: _____

DATE 07/09/97 TIME 10:56 ACCT [REDACTED]

000005

HISTORY and PHYSICAL

10 JUN 77

Date: 6/13/77

Source: IPD OPD

Obtained by: _____ Service: Neurology

Referring physician / Institution: _____

Staff physician / contact #: _____

Pt's contact(s) phone # (s): _____

MRN: _____

Name: _____

DOB: _____

CHIEF COMPLAINT(S):

Weakness - unable to walk
in 303

HISTORY OF PRESENT ILLNESS

47 y/o (M) c h/o progressive weakness
over last 3 mos. - T prox muscles
Lumbar etc, then arm weakness

Progressive dyspnea on exertion

Severe headg of dizziness off/on.

Now ↑ to 3x/2 (waking)

Now unable to walk

unable to lift arms.

SOB / weak

MEDICATIONS (dosages / frequency)

Carbamazepine

Vit B₁₂

Lasix 50mg 2 Am

KCl 40mEq qd

TAG Met

PAST MEDICAL / SURG Hx

(Arthritis)

- over last 3 mos,
work up c muscle bx

EMG

(See last results)

FAMILY Hx (Relationship)

DM / Htn / CA / Tb / Other

Arthritis
HTN

LIFESTYLE

ETOH

Smoking

Drugs

STD risks

OCCUPATIONAL Hx

DRUG/LATEX(Rubber Product)/CONTRAST AGENT DATE

REACTION:

AKDA

TRAVEL Hx (date)

000006

REVIEW OF SYSTEMS * (Line through symptom if negative; circle if positive; Label section heading and symptom at right and describe.)

GENERAL

appetite
fatigue
 weight loss

fever
 diaphoresis
 rigors

DERMATOLOGIC

rash / skin lesions

GI

nausea / vomiting
 bowel habits
 incontinence
 Hx of 1) ulcer and/or bleed
 2) pancreatitis
 melena
 bright blood per rectum
 jaundice

HEENT / Neck

Δ in acuity
 hearing loss
 vertigo / dizziness /
 lightheadedness

CARDIOPULM

new cough
 chronic cough
 Δ in character
 hemoptysis
dyspnea
 orthopnea / PND
 chest pain

HEMATOLOGIC

Easy bruising > 2 cm
 Bleeding from gums
 epistaxis
 transfusion history

BREASTS

mass / discharge / pain

NEPHRO / UROLOGIC

burning
 hesitation
 frequency / nocturia
 incontinence
 hematuria

REPRODUCTIVE

G ___ P ___ A ___
 Δ in menstrual periods
 discharge

NEURO / PSYCH

new headache
 Hx of depression (depressed
 mood / anhedonia / sleep dis-
 turbances / crying spells /
 suicidal ideation)
 Hx of other psychiatric illnesses

EXTREMITIES

edema (bi / unilateral)
 claudication
 arthralgias

EXAMINATION

VITALS

Temp _____ ° C (oral/rectal)
 BP _____ / _____ mm Hg (supine) _____ / _____ mm Hg (standing)
 Pulse _____ / min (supine) _____ / min (standing)
 Respiratory rate _____ / min

GENERAL DESCRIPTION

* (For sections that follow, describe all pertinent positive and negative findings)

Neck / HEENT

thyroid
 lymph nodes
 carotid bruits

CHEST

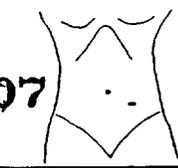
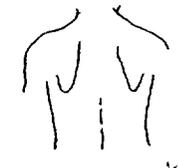
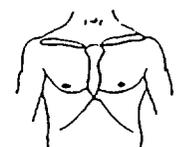
Chest wall / Back
 Lungs *dim bases - gd diaphragmatic excursion*
 Breasts

HEART

PMI (location / character / size)
 heart sounds (Rhythm / S1,2,3,4)
murmurs *IV/VI prolapsic S5m*
 JVD

ABDOMEN

scars organomegaly
 distension masses
 bowel sounds hernia(s)
 tenderness



000007

Ad 0 x 3. ment. intact

EXAMINATION (continued) Cran. intact - 4mm

RECTAL

anus (lesions / tone)
masses
prostate
guaiac

gd cervic. muscle strength
gd fecal strength/sound

Table with 2 columns: muscle exam, R/L. Rows include D, B, T, WE, FE, IP, Q, PFIE.

GENITALIA

Male: lesions / discharge
Female: pelvic / lesions / discharge

EXTREMITIES

deformities / atrophy
pulses

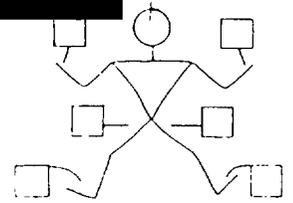
NEUROLOGIC

Mental status
Cranial nerves
Motor
Sensory
Reflexes
Cerebellar
Gait

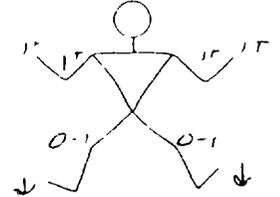
Sens - intact to CT, PP, V, T, prop

ocular - orthostatic

no gross lesions



PULSES (0-4)

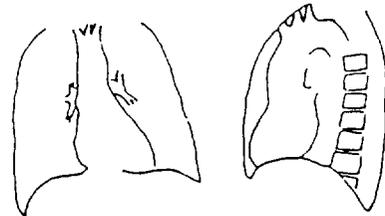


REFLEXES (0-4)

LABORATORY DATA

X-RAYS (date/time) / OTHER STUDIES

Table with 3 columns: Na, Cl, BUN; K, HCO3, Cr; Hgb, MCV; Hct, RDW; pO2, pCO2, HCO3 (calc); % sat, pH, FIO2. Includes handwritten values and notes like 'Glu: 114', 'WBC: 11', 'neut: 78'.



Any use < 30
Alk ph. 7.2
Ca 9.7
mg 1.7
PO 4.7

Serum 322
SGPT 200
Tbili 0.4
AT 11 5/10/97
pH 24

(Circle: room air / nasal cannula / ventimask / intubated / other:

Urinalysis: Clear - 1.025 - 6.0 - mod blood - 3RBC 3epithelial

Additional chemistries / ABG's

Prox

Muscle bx 5/8/97: L.P. surge ↑
mild regenerating myopathy
muscle fiber degeneration + regeneration

EMG 4/10/97. Active diffuse myopathy pattern involving proximal + intermed. muscle
Bil. mod-severe med an mononeuropathy equiv
Suggestion periph. polyneuropathy

PREVIOUS / BASELINE LABS (date)

EKG's (recent and baseline / dates)

CK 13,504
SGOT 322
LFT 2330
pH 5.28, an
mg 1.0
Free T3 2.8
TST 2.0

Shred (0+0) 4/103 - (+) myoglobinuria
C diff
(4/10) Sjogren's Abs 0
(4/11) Scl 0.3 hyp-neg

CKR 5/197. mild
Card. myopathy
MVI 6-3 2/97
- origin dist L4/L5 + L5/S1
Lat bulge of L4, L5 + L5/S1
left
drum reu
compression

000008

ASSESSMENT and PLAN

47y10 (R) is progressive muscle weakness, progressive cardiac murmur, dyspnea, and angedly, elevated LFT's



gross storage dz
myositis / necrotizing myopathy

no cholelithiasis

no CHF

no GI deterioration / involvement

D-Dimer
V tri capacity / S115 } m. add d
recomm
SICG

3rd rate
myoglobin urine
CK, LDH
LFT's

on anti CD course

phosdo - watch urine pH - keep > 5.0
by date / give Lasix

Abundant: Hx renal w/ phosdo

As noted to pt care to CR on able to walk, Pt has a known myopathy & generalized weakness. dysphagia, hx CHF, xdiarrhea. Her diarrhea has been & it is unclear if heart problem is due to worsening myopathy or 2nd to fluid loss. Pt also has ± CHF. Pt also has low blood pressure. (The above was reviewed)

HOUSE OFFICER (signature) _____
DATE 6/13/77

STA _____
DATE 6/13/77

I have examined plus - Dr. _____

(The signature above indicates that I have reviewed physical herein, and agree with its contents, as

000009.)

[Redacted]

[Redacted]

DATE

[Redacted]

Audit Box

→ CONSULTATION

Responsible/Referring Physician. [Redacted] CODE

MRN SUFFIX

Referring Resident [Redacted] CODE

NAME

Division Neuro Unit [Redacted] Room [Redacted]

TO: CONSULTANT Shiff DIVISION Speech LOCATION _____

REASON FOR CONSULTATION

- Patient Should Be Seen On Floor
- Patient May Be Seen In Clinic
- Transportation
- ISOLATION/PRECAUTIONS
- Service Transfer
- Ambulatory
- YES
- NO
- Dual Service
- Wheel Chair
- Consultation
- Litter

myofascial & weakness

SIGNATURE / TITLE

CONSULTANT'S REMARKS: First Consult Second Consult Subsequent Consult

47yo f admitted a progressive weakness also bloating
c EACH meal plus having diarrhea during or immediately p
each meal for the past month. - I am unable to test pt's
hearing at this time. CRAL-MOTOR EXAM: WNL - Pt. swallows
air c swallow attempts & frequently burps immediately p swallow

Speech & language are wnl. Voice tends to be soft but can be
made louder when requested.

IMPRESSION: - Dysphagia - mild
- GI distress

RECOMMENDATIONS:
1- Soft diet
2- Pt. is to be in full upright position for meals
- up in a chair if possible. Thanks,
3- GI Consult -

Date 6-13-97

Dr. Name [Redacted]

Dr. Code [Redacted]

REVENUE CENTER [Redacted]

ENCOUNTER CODE ICD - 9 CM [Redacted]

CONSULTATION CLASSIFICATION:

Check One

- LIMITED
- INTERMEDIATE
- EXTENSIVE
- COMPREHENSIVE
- COMPLEX

ADDITIONAL DX ICD - 9 CM [Redacted]

ADDITIONAL DX ICD - 9 CM [Redacted]

000010

Responsible/Referring Physician _____ CODE _____
 Referring Resident: _____ CODE: _____
 Division Neuro I.P.D. Unit _____ Room _____

TO: CONSULTANT _____ DIVISION _____ LOCATION _____
 Patient Should Be Seen On Floor
 Patient May Be Seen In Clinic
 REASON FOR CONSULTATION
 Transportation
 Isolation/Precautions
 Service Transfer
 Ambulatory
 YES
 NO
 Dual Service
 Wheel Chair
 Consultation
 Litter

SIGNATURE / TITLE

CONSULTANT'S REMARKS: First Consult Second Consult Subsequent Consult

47 y/o PMHx of Myopathy. Unknown etiology, microscopic colitis, abnormal
 LETS, CHF, S/P cholecystectomy admitted to you weakness & inability
 to walk. weakness progressive got worse over last 3 months. Progressive SOB
 on exertion. Double cr. walking - GI consulted. Unable to walk & raise arms
 on exertion. Pat. unable to stand. cough P COP PND & orthopnea. When exert gets tired
 5-6 breaths, w/ short of breath. Sleeps on one pillow. Edema feet + legs as dependent. 120/80 mm.
 APD med - carvedilol, Lasix, KCl, Toprol 4/97
 Social - non smoker, non alcohol. dd Test - ANP - DNTA PK
 Anti SmG, Ach: 4/1
 2/96 - normal S.FE.
 4/97 EMG - myopathy
 Bilat. calpal tend. S40T = 322, S6PT = 26, B1 =
 ? Polyneuropathy. ALK P. - 72, Amylase < 30
 ALK = P BC = 3, moderate B
 Met. history - ms. necrosis, hyper 5/30 CPK = 1350
 ? metabolic LBN = 2330
 ? cardiomyopathy S40T = 322
 ? CHF, thyroid

Physical Exam: obese, 37, 98/min, 130/70/4/pulsing flat @ SOB. comfortable.
 Chest - CTAB/L, good air entry.
 CVS - Tachy S1 + S2 + ESM 4/6, P S3 + S4.
 Abd - scars +, soft, BS + @ abd + systole, mild epigastric tenderness.
 Ext - Edema ++, D. Pedis +.
 CNS - proximal ms. weakness +.
 Breast Exam Ext

IMPRESSION: GI already consulted.
 1) Agree 2D Echo, CXR showed (observed myopathy but not
 2) Magnesium replacement & Electrolyte correction
 3) Serum albumin.
 4) Daily weight
 5) Heparin SQ
 6) Daily electrolyte & fluid replacement as reqd
 7) Heparin SQ
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Date 6/13/97
 Dr. Name _____
 Dr. Code _____
 REVENUE CENTER _____
 CONSULTATION CLASSIFICATION:
 LIMITED
 INTERMEDIATE
 EXTENSIVE
 COMPREHENSIVE
 COMPLEX
 ENCOUNTER CODE ICD - 9 CM
 PRIN DX FOR SERVICE ICD - 9 CM
 ADDITIONAL DX ICD - 9 CM
 ADDITIONAL DX ICD - 9 CM

000011

DATE

CONSULTATION

MRN
SUFFI

NAME

Responsible/Referring Physician:

Referring Resident

CODE

Division

TO: CONSULTANT

DIVISION

LOCATION

REASON FOR
CONSULTATION

- Patient Should Be Seen On Floor
- Patient May Be Seen In Clinic
- Transportation

ISOLATION/PRECAUTIONS

YES NO

- Service Transfer
- Dual Service
- Consultation
- Ambulatory
- Wheel Chair
- Litter

Pt. of Dr. [redacted] to discuss her
myopathy. Admitted to [redacted] on [redacted]

SIGNATURE

TITLE

CONSULTANT'S REMARKS:

First Consult

Second Consult

Subsequent Consult

See enclosed notes

Patient well-known to me from outpatient evaluation. I originally saw her for elevated "LFT's" few months ago. At this point I feel patient has no liver disease, but transaminase ↑ is solely due to muscle degeneration. Normality of liver is likely since: alk P, GGT, bili, albumin and USG are all normal. Patient does not have colitis as mentioned elsewhere in chart. Colonoscopy to ileum was normal; biopsies revealed "normal" mucosal inflammatory cells. Her GI ex could be 2° myopathy of gut, but myopathy of mouth & skeletal muscle together is rare. UGI / small bowel series recently was normal and did not suggest motility disturbance as of 5/7/97.

IMPRESSION:

However, symptoms have progressed. She could be having poor gastric

RECOMMENDATIONS:

emptying and "dribble" secondary to anal sphincter weakness, actually only incontinence. Would suggest nuclear gastric emptying study & rheumatology consult. R1-

Date 6/15/97

Dr. Name [redacted]

Dr. Code [redacted]

REVENUE CENTER [redacted]

CONSULTATION CLASSIFICATION:

- LIMITED
- INTERMEDIATE
- EXTENSIVE
- COMPREHENSIVE
- COMPLEX
-
-

ENCOUNTER CODE ICD - 9 CM

PRIN DX FOR SERVICE ICD - 9 CM

ADDITIONAL DX ICD - 9 CM

ADDITIONAL DX ICD - 9 CM

000012

15 JUL 97

DATE

Audit Box

CONSULTATION

Responsible/Referring Physician: Dr [redacted] CODE

Referring Resident: [redacted] CODE

Division: Neurology [redacted] Unit [redacted] Room [redacted]

MRN SUFFIX NAME

TO: CONSULTANT [redacted] DIVISION Pg 1/2 LOCATION [redacted]

- Patient Should Be Seen On Floor
- Patient May Be Seen In Clinic
- Service Transfer
- Dual Service
- Consultation
- Transportation
- Ambulatory
- Wheel Chair
- Litter

REASON FOR CONSULTATION

This case was initially referred to Toxicology/PCC on 7/9/97 by the Nephrology Service. 47 y/o African-American female who was admitted in early June to [redacted] Neurology service because of progressive muscle weakness, dysphagia, and diarrhea. Apparently, patient's symptoms began in February 1997, with the onset of diarrhea. Work-up included GI tract cultures, endoscopy and multiple biopsies (all negative), followed by empiric treatment for Clostridium difficile infection.

SIGNATURE TITLE

CONSULTANT'S REMARKS: First Consult Second Consult Subsequent Consult

In April 1997, patient began experiencing proximal muscle weakness and difficulty swallowing. An extensive work-up by Neurology, including immunologic, infectious and metabolic testing has not yielded an etiology for her myopathy. On 4/28/97, a deltoid muscle biopsy showed evidence of an active necrotizing myopathy without inflammatory changes. Tissue was sent to an outside lab for further testing which is pending. During her hospitalization in June/July 1997, patient was also diagnosed with hydronephrosis, requiring a ureteral stent placement and percutaneous nephrostomy. She was also found to have significant proteinuria with a creatinine clearance of 383 ml/min (normal 80-120). She has had significant elevations of CPK's (13,000 in May, 9,000 in June, 5,000 in July), as well as elevated LDH and aldolase. Liver function tests (SGOT/SGPT) have been slightly elevated (200-300 range). Since 4/23/97, she has been treated with corticosteroids which are being tapered. The diarrhea, muscle weakness, and dysphagia continue. Of toxicologic interest was the history of taking new dietary supplements purchased at [redacted] just prior to the onset of her initial symptoms:

- (#=total tabs taken).
- Dec 96/Jan 97: Root-to-Health: Formula for Circulation (#7), Root-to-Health: Formula for Arthritis (unknown #), and Dieter's Natural Tea/made in China (#34 teabags), Per-Form Perfect Herbal formula (#24).
- Feb 97/Mar 97: Juice Plus Garden Blend (#11), Juice Plus Orchard Blend (#5)
- May 97: Multi-Herb Formula (2 varieties, #9 & #7), Papaya chewable enzyme (a few tabs), went to local practitioner for IMPRESSION: colonic cleansing x 1.
- Jan-May 97: Sublingual Vitamin B12, B2, Trizyme enzymes (off and on).
- PMH: Hypertension, Arthritis in knees and back, L4-L5 disc dz
- RECOMMENDATIONS: Meds prior to onset of illness: Feb 97 Lozol, April 97 Lasix, Nov 97 Vasotec & HCTZD, Lodine, Anaprox, Robaxin, Flexeril, Darvocet, Vistaril
- Meds since onset of illness: Antacids, Tagamet, Cisapride, Immodium, Prednisone
- Occupation: Post Office EMPLOYEE Hobbies: None
- Family Hx: No neurologic or muscle diseases
- Social: No ETOH, or drugs of abuse

MEDICAL RECORD

DO NOT SEPARATE

If additional space is needed to report Consultant's Remarks,

Date 7-17-97

Dr. Name [redacted]

Dr. Code [redacted]

REVENUE CENTER [redacted]

CONSULTATION CLASSIFICATION: ENCOUNTER CODE

Check One

- LIMITED
- INTERMEDIATE
- EXTENSIVE
- COMPREHENSIVE
- COMPLEX
- [redacted]
- [redacted]

Professional Fee [redacted] PC

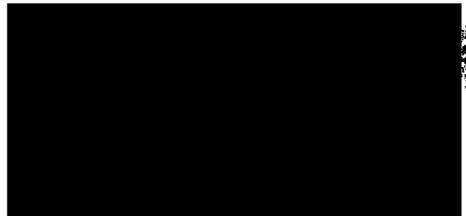
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EXH 1 8/12/97

Audit Box

CONSULTATION

DATE



Responsible/Referring Physician

CODE

MRN SUFFIX

Referring Resident:

CODE

NAME

Division

Neurology

Unit

Room

TO: CONSULTANT

DIVISION

Pg 2/2

LOCATION

Patient Should Be Seen On Floor

ISOLATION/PRECAUTIONS

YES NO

REASON FOR CONSULTATION

Patient May Be Seen In Clinic

Service Transfer

Dual Service

Consultation

Transportation

Ambulatory

Wheel Chair

Litter

Lab : ECHO: concentric LVH, EF55%

EMG: Diffuse, proximal and intermediate muscle myopathy, as well as, a median nerve mono-neuropathy.

Summary: 47 y/o African-American female with a 6-mo. history of diarrhea, proximal muscle myopathy, dysphagia, and recently diagnosed proteinuria, for which an extensive medical work-up to date has not established a clear etiology.

SIGNATURE

TITLE

CONSULTANT'S REMARKS:

First Consult

Second Consult

Subsequent Consult

Based on preliminary research, an environmentally associated or triggered myopathy related to dietary supplements, used by the patient just prior to the onset of her symptoms, should be considered in the differential diagnosis of her illness. It would, of course, be a diagnosis of exclusion.

Dietary supplement/nutritional products are not regulated by the FDA, therefore, their composition and effects are not well studied. These products contain mixtures of botanical constituents, chemicals, and adulterants. The imported products (Dieter's Natural Tea-mad in China) are of particular concern, since their ingredients are unknown and may have considerable lot variability.

The mechanism by which a non-infectious, environmentally associated myopathy/connective tissue disease can develop has not been clearly established and may be multi-factorial. (Love L. New Environmental Agents Associated with Lupus-like Disorders. Lupus 1994;3:467-471), (Love L, Miller F. Noninfectious Environmental Agents Associated with Myopathies. Current Opinion in Rheumatology 1993;5:712-718). This has been discussed with Dr. [redacted] & Dr. [redacted] the patient's Neurologists.

Additional questions remain:

- 1) Is this a dose-response effect?
 - 2) Why have patient's symptoms progressed in spite of cessation of product use?
 - 3) What role hypokalemia has played in this patient's myopathy since review of labs shows serum K has been less than 3.5 on several occasions. Some of these supplements may cause hypokalemia, e.g., Licorice (glycyrrhiza) which has
- IMPRESSION:** mineralcorticoid activity - and causes potassium diuresis.

Currently the plan is to more completely identify all product ingredients and research their potential effects with the **RECOMMENDATIONS:** assistance of Poison Control Center (PCC) staff [redacted]. The FDA will pick-up a sample of the Chinese Dieter's Tea to analyze ingredients. I have spoken with Dr. Love & Dr. Miller [redacted] at the FDA (authors of the articles referenced earlier). Dr. [redacted] and/or Dr. [redacted] will also contact them for further input into the case.

Date 7-17-97

Dr. Name

Dr. Cod

REVENUE CENTER

CONSULTATION CLASSIFICATION:

Check One

LIMITED

INTERMEDIATE

EXTENSIVE

COMPREHENSIVE

COMPLEX

Professional Fee

Fee

00014

MEDICAL RECORD

DO NOT SEPARATE

If additional space is needed to report Consultant's Remarks, continue on the Consultation Continuation -

EXH 1 M2
Memo dt'd. 8/12/97

[REDACTED]

7/16/96

Patient's case referred to toxicology/PCC by Nephrology service at [REDACTED] on 7/9/97. Patient is a 47-yr African American female who was admitted at the early part of June to [REDACTED] because of progressive muscle weakness, dysphagia, and diarrhea. Apparently, patient's symptoms began in February 1997 when she began experiencing significant diarrhea on a daily basis. This was extensively worked up with GI tract biopsies, cultures, and empiric treatment for Clostridium difficile infection. In April 1997, patient began experiencing proximal muscle weakness and difficulty swallowing. This problem was and is being worked up extensively by the neurology service. Patient has had a variety of immunologic, infectious, metabolic tests, all of which have not yielding significant explanation of her problem. A muscle biopsy showed active necrotizing myopathy but no inflammatory changes. Tissue was sent to an outside lab for lipid storage testing. This is pending. EMG showed evidence of diffuse proximal and intermediate muscle myopathy as well as a median mononeuropathy (Carpal Tunnel syndrome). During her hospitalization in June/July 1997 patient was also diagnosed with hydronephrosis, requiring a ureteral stent placement and percutaneous nephrostomy. She was also found to have significant proteinuria, with a creatinine clearance of 383 ml/min (normal 80-120). She has also had elevations of CPK (13,000 in May, 9,000 in June, decreasing to 5,000 in July). During the last several months she has been treated with corticosteroids, which are being tapered and nearly completed.

Of toxicologic concern was the history of taking new health food preparations purchased at [REDACTED] just prior to the onset of her initial symptoms:

Dec 96/Jan 97: Root-to-Health formula for circulation (7 tabs), Root-to-Health formula for arthritis (unk), and Dieter's Natural tea (made in China)(34 tea bags), Per-Form Perfect Herbal formula (24 caps).

Feb 97/Mar 97: Juice Plus Garden Blend (11 caps), Juice Plus Orchard Blend (5 caps).

May 97: Multi-Herb formula (two varieties, 9 + 7 tabs), Papaya chewable enzyme (a few tabs), went to local practitioner for colonic cleansing x1

Jan-May 97: Sublingual vitamin B12, B2, Triozyme enzymes (off and on)

PMH: hypertension, arthritis in knees and back

Meds prior to onset of illness: Lozol, Lasix, Vasotec
Lodine, Anaprox, Robaxin, Flexeril, Darvocet, Vistaril

Meds since onset of illness: Antacids, Tagamet, cisapride, Imodium, prednisone

Occupation: Post office employee

000015

Hobbies: none

Family Hx: no neurologic or muscle diseases

Social: No ETOH, or drugs of abuse

Selective abnormal Labs (7/10/97): see attached

CPK: 5196

Mg: 1.7

SGOT 204

SGPT 185

GGT 58

Summary: 47 yo African American female with 6 month history of diarrhea, progressive proximal muscle weakness, and recently identified nephrotic syndrome, etiology of which is unclear after extensive medical workup. Relationship of health food products mentioned above could be a possible explanation of this syndrome, based on our preliminary research, however further information must be gathered to complete our assessment.

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