

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

ARMS#

13370



5 - SUMMARIES

000001

[REDACTED]

[REDACTED]

CASE SUMMARY

DATE OF ADMISSION: 02/03/99

DATE OF DISCHARGE: 02/10/99

SYNOPSIS OF HISTORY AND PHYSICAL:

This is a 19-year-old Caucasian male who was admitted through the emergency room because of extreme agitation. Clinical symptoms were consistent with manic state and in addition he showed significant psychotic symptoms reflecting his delusional religious beliefs and auditory hallucinations in that he was hearing voices from television that was "Sending messages from God." Apparently this is his first episode of a psychotic state most likely triggered by the use of massive amounts of Megaphorma over the counter food supplement.

LABORATORY DATA AND X-RAY FINDINGS:

At the time of discharge valproic acid was 64.5 mcg per meal. Chemistry profile essentially within normal limits. CBC within normal limits. Total T3 155 mg percent, T4 8.6 mcg percent and TSH 1.3.

HOSPITAL COURSE:

On admission the patient was put on a regular diet and given close observation. For the first few days he had to be given Haldol injections p.r.n. due to his psychotic agitated state and he also needed seclusion on occasions due to his inappropriate behaviors. At one point he was given one to one observation due to his inappropriate behaviors including constant walking into other patients bedrooms. In terms of medications to address his manic symptoms he was given Depakote up to 500 mg t.i.d. and Risperdal 2 mg b.i.d. However, because of his complaints of palpitations and other clinical symptoms reflecting the side effects of Risperdal he was given Zyprexa 5 mg q.h.s. The Depakote dosage was reduced down to 500 mg b.i.d. when the blood level of valproic acid was over 120 mcg per meal. During the last 24 hours before discharge he was relatively stable in terms of his affect showing clear insight as to his need for taking medications. Incidentally, at the time of discharge he showed some evidence of side effects from his previous use of Haldol including akathisia.

DISCHARGE INSTRUCTIONS:

Diet regular. Activities no restrictions.

DISCHARGE MEDICATIONS:

Depakote 500 mg b.i.d. and Zyprexa 5 mg q.h.s.

FINAL DIAGNOSIS (ES):

Axis I: Bipolar disorder, manic with psychotic features.

000002

PT. [REDACTED]

M.R.# [REDACTED]

PHYSICIAN: [REDACTED]

M.D.

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CASE SUMMARY

Job [REDACTED]

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Exh 65



CASE SUMMARY

Axis II: Not determined.  
Axis III: Not applicable.  
Axis IV: Not determined.  
Axis V: GAF upon discharge 70.

CONDITION ON DISCHARGE:

Prognosis is fair.

FOLLOW-UP:

The patient will be seen within the next two weeks for outpatient follow-up.



D: 02/10/99  
T: 02/11/99

000003

PT-- [REDACTED]

M.R.# [REDACTED]

CASE SUMMARY

PHYSICIAN: [REDACTED] M.D.

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Complaint/Injury F/U DET-0833  
3/24,25,30/99 ABP Exh. 64



HISTORY AND PHYSICAL EXAMINATION

DATE OF ADMISSION: 2-4-99  
06/14/98

CHIEF COMPLAINT:

[REDACTED] a 19-year-old Caucasian male was admitted through the emergency room because of extreme agitation and confusion.

HISTORY OF PRESENT ILLNESS:

Reportedly, he was relatively fine up until a couple weeks before this admission when he began to experience increasing agitation, hyperactivity and severe insomnia. Reportedly, he was sleeping no more than 1-2 hours a night in the past couple weeks, became extremely hyperactive, constantly running around aimlessly, talked nonstop from subject to subject in rapid succession to such an extent that what he was trying to talk about was hardly intelligible. He rambled on and on about death, etc. On admission, he talked rather fast from subject to subject, often times making little sense. He was highly agitated and was not able to sit still in his chair during the interview. He states that he "keeps hearing voices about death in my head." They say I should believe in myself like that "God is coming down to take over my destiny", etc. and that "I get messages through T.V. about God's will", etc. Evidently he was given a certain over-the-counter food supplement named "Megaform" which apparently contained a certain herb named Ma Huang which has a high concentration of ephedrine (in addition, he also has been taking a food supplement names "Calorad" and Viagra on a daily basis.) He states that he has been using Viagra so that he could be with his girlfriend "all the time."

PAST PSYCHIATRIC HISTORY:

Premorbidly, he was hyperactive, energetic, outgoing and socially engaging, but at the same time he was highly anxious and he tended to worry about "things that have yet to happen." It appears that he was seen by a psychiatrist outpatient approximately one week ago and was put on various psychotropic agents which names are not clear at this time, but without any therapeutic effect.

SOCIAL HISTORY:

He was born in town as the middle child in a family of three children. He completed high school and he states that he was an A/B student. He is planning to start college. He states that his early childhood and teenage life experiences have been rather uneventful. He denies substance abuse or alcoholism.

PAST MEDICAL HISTORY:

Unremarkable.

ALLERGIES:

He states that he is allergic to PENICILLIN.

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X.R.#/RX. [REDACTED]

DR [REDACTED] M.D.

COPY

HISTORY AND PHYSICAL EXAMINATION

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Exh 61

## HISTORY AND PHYSICAL EXAMINATION

### FAMILY HISTORY:

His father may have had at least two hospitalizations because of psychiatric reasons. Notably, he has had panic attacks.

### REVIEW OF SYSTEMS:

**GENERAL:** Free of complaints.  
**HEAD, EYES, EARS, NOSE and THROAT:** Free of complaints.  
**RESPIRATORY:** Free of complaints.  
**CARDIOVASCULAR:** Free of complaints.  
**GASTROINTESTINAL:** Free.  
**GENITOURINARY:** Free.  
**ENDOCRINE AND METABOLIC:** Free.  
**NEUROLOGICAL:** Free.

### PHYSICAL EXAMINATION:

**VITAL SIGNS:** Blood pressure 138/80, pulse rate 80, respirations 18, temperature 98.4.  
**HEAD, EYES, EARS, NOSE AND THROAT:** Free.  
**NECK:** Supple. Thyroid gland not enlarged.  
**CHEST:** Externally clear. No rales or wheezing to auscultation.  
**HEART:** Regular sinus rhythm with no murmurs.  
**ABDOMEN:** Flat and soft. No hepatosplenomegaly. Bowel sounds within normal limits.  
**EXTREMITIES:** Free.  
**NEUROLOGICAL:** Gait within normal limits. Cranial nerves II through XII bilaterally intact. No gross motor or sensory deficits. Deep tendon reflexes bilaterally brisk and equal. Babinski sign absent.  
**SKIN:** Free.

### MENTAL STATUS EXAMINATION:

The patient is alert and coherent and is oriented to time. However, he tends to be distracted rather easily and often times seemingly unable to comprehend the questions given. His speech is rather pressured and fast. Psychomotor activity is markedly increased. Affect is expansive. Mood is anxious and euphoric. He admits to severe insomnia hardly sleeping at all in the past week. He denies panic attacks or autonomic hyperactivity. Thought process is characterized by flight of ideas. He shows gross religious and grandiose delusions and also admits to florid auditory hallucinations. Judgement and insight completely nil.

### DIAGNOSTIC IMPRESSIONS:

Axis I	Bipolar disorder, manic, with psychotic features. Most likely triggered by the use of "Megaform".
Axis II	Not determined.
Axis III	Not applicable.
Axis IV	Not determined.
Axis V	GAF on admission 30.

000005

PT. [REDACTED]

M.R.#/RM. [REDACTED]

DR. [REDACTED] H.D.

COPY  
2

HISTORY AND PHYSICAL EXAMINATION  
 Complaint/Injury F/U DET-0833  
 3/24,25,30/99 ARP Exh B2

HISTORY AND PHYSICAL EXAMINATION

TREATMENT PLAN:

The patient will be treated on a combination of Depakote and Risperdal.

D 02/04/99  
T 02/04/99

000006

COPY  
3

HISTORY AND PHYSICAL EXAMINATION

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Exh 62

[REDACTED] a 19-year-old Caucasian male, was admitted through the emergency room for the second time in 2-1/2 weeks because of acute agitation. Clinical symptoms at the time of admission was manic psychotic state.

LABORATORY DATA AND X-RAY FINDINGS:

Chem profile was essentially within normal limits. Lithium level at the time of discharge was 1.0 mEq/L, carbamazepine level 5 mcg/ml. CBC and urinalysis were essentially within normal limits. Urine drug screening was negative.

HOSPITAL COURSE:

On admission the patient was put on a regular diet and was given Lithium carbonate 300 mg, t.i.d. and Tegretol 100 mg, t.i.d. along with Klonopin 1 mg, q.h.s. During the first 3 days after admission he was almost on a constant basis in seclusion and restrained because of extreme agitation and physical violence. He exhibited clinical symptoms reflecting auditory hallucinations and delusions as well as all the manic symptoms such as nonstop talking and hyperactivity. He also stayed awake 24 hours a day despite all the medications he was given including Haldol, p.r.n. and Ativan up to 6 mg, per day to control the agitation.

On the fourth hospital day he began to show gradual and steady reduction in his agitation and confusion and became more directable by the fifth day. At that point one to one observation was discontinued. In the meantime the patient was put on Risperdal 1 mg, b.i.d. on the second hospital day and the dosage was increased up to 2 mg, b.i.d. on the fifth hospital day. Tegretol dosage was changed to 200 mg, b.i.d.

On the sixth hospital day Ativan dosage was cut down to 1 mg, t.i.d. with no discernible reappearance of agitation. During the last 2 days before discharge he was relatively stable in terms of his affect and he showed no evidence of agitation. The patient was discharged on the 8th hospital day to be followed as an outpatient. At the time of discharge he still showed significant racing thoughts, inattention, and poor comprehension of his surroundings, however, it was deemed that he was well controlled enough to be treated as an outpatient. Discharge instructions:

DIET:

Regular diet.

PT: [REDACTED] DOB: [REDACTED]  
ACCT: [REDACTED] MR: [REDACTED]  
ADM: 02/28/1999 DC: 03/07/1999  
ROOM: [REDACTED] PSY

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CASE SUMMARY  
MEDICAL RECORD

000007 [REDACTED]

Complaint/Injury F/U DET-0833  
02/28/99 20/99 ARP FvH FZ



ACTIVITY:

No restrictions.

MEDICATION(S):

Risperdal 2 mg, b.i.d.; lithium carbonate 300 mg, q.a.m. and 600 mg, q.h.s.; Tegretol 200 mg, b.i.d.; Klonopin 0.5 mg, q.a.m. and 1 mg, q.h.s.

FINAL DIAGNOSES:

Axis I: Bipolar disorder, manic, with psychotic features.  
Axis II: Not determined.  
Axis III: Not applicable.  
Axis IV: Not determined.  
Axis V: GAF upon discharge 70.

PROGNOSIS:

Fair.

FOLLOW UP:

The patient will be seen in my office in 2 weeks for outpatient follow up.

D 03/07/1999 11:32 A  
T 03/12/1999 2:04 P  
cc: [Redacted]

MD



Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Exh [3]

PT: [Redacted] DOB: [Redacted]  
ACCT: [Redacted] MR: [Redacted]  
ADM: 02/28/1999 DC: 03/07/1999  
ROOM: [Redacted] SVC  
PSY

CASE SUMMARY  
MEDICAL RECORD

000008

CONSULTING PHYSICIAN: [REDACTED] MD

DATE: [REDACTED] TIME: [REDACTED]

REASON FOR CONSULTATION:  
Wound infection on the left arm.

HISTORY OF PRESENT ILLNESS:

This is a 19 year-old-male who was recently diagnosed to have a bipolar manic disorder. The patient was in the hospital about a month ago or so and subsequently he was doing well. He was on medication as an outpatient and he was following with the psychiatrist and was taking medication. Apparently the patient was admitted last night in an acute psychotic behavior. He was in a leather restraint and was very agitated.

Therefore full examination was not done; however, the examination of the left antecubital area revealed some recent scar mark and slight redness of the skin over it, but there were no areas of infection. The rest of the examination could not be done today because of his violent behavior. He will be checked at a later time.

IMPRESSION:

1. Infected left antecubital area on the skin.
2. Manic depressive illness with acute mania and probable schizophrenia.

The patient is being taken care of by Dr [REDACTED] I will follow up this patient on whenever necessary basis if any need arising for any medical treatment. The patient apparently did not have any other medical problems in the past except for some acne on the face. He was not taking any medications from me.

D 03/01/1999 1:29 P  
T 03/03/1999 3:17 P  
cc: [REDACTED] MD

PT: [REDACTED] DOB: [REDACTED]  
ACCT [REDACTED] MR: [REDACTED]  
ADM: 02/28/1999 DC: [REDACTED]  
ROOM: [REDACTED]

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000009

Complaint/Injury F/U DET-0833  
3/24,25,30/99 APP Exh E32

**CHIEF COMPLAINT:**

The patient was admitted through the emergency room because of extreme agitation and inappropriate behavior.

**HISTORY OF PRESENT ILLNESS:**

He was brought in by his family members because of his extreme agitation and hyperactivity in the past week or so before this admission. On admission, it was reported that he did not sleep at all in the past four or five days before this admission, that he was so agitated that he could not sit still for any length of time, constantly pacing in and out of the house, doing inappropriate things such as gesturing into space, pushing things or throwing things, that he would talk nonstop from subject to subject in rapid succession, making very little sense as to what he was trying to say, that time and again he would make threatening gestures and behaviors, that he was completely unaware of his surroundings and of his own inappropriate behaviors, that he was laughing and giggling and making comments that reflected his grandiose ideas, that he was responding to objects in space as if he was conversing or communicating, that he was not able to answer any of the questions given, reflecting his lack of comprehension of the questions or lack of attention. He was in this hospital three and one-half weeks before this admission and was sent home on a combination of Depakote and Zyprexa. He was relatively stable during the first week after discharge but soon he began to show worsening of the clinical symptoms despite the fact that he was given medications on a regular basis although his mother questioned if he actually had taken his medications.

**PAST PSYCHIATRIC HISTORY:**

He had no previous psychiatric contact but evidently he became increasingly manic since a month or two before this admission and it appears that his problem may have got worse because of ingestion of large quantity of over-the-counter herb named "megaform" prior to this admission. The contents of the herb showed evidence that it had a high content of ephedrine.

**PERSONAL HISTORY, FAMILY HISTORY, MEDICAL HISTORY:**

Refer to old chart.

PT: [REDACTED] DOB: [REDACTED]  
ACCT [REDACTED] MR: [REDACTED]  
ADM: 02/28/1999 DC: [REDACTED]  
ROOM: [REDACTED] [REDACTED]

**HISTORY AND PHYSICAL EXAMINATION  
MEDICAL RECORD**

000010

Complaint/Injury F/U DEI-0833  
3/24,25,30/99 ARP Exh E-21

**REVIEW OF SYSTEMS:**

System review could not be done because of the patient's delusional state but it was not known that he had any outstanding medical problems at this time.

**PHYSICAL EXAMINATION:**

**VITAL SIGNS:** Within normal limits.

**HEAD, EYES, EARS, NOSE, THROAT:** Free of complaints.

**NECK:** Supple.

**CHEST:** Externally clear. No rales or wheezing to auscultation.

**HEART:** Regular sinus rhythm with no murmurs.

**ABDOMEN:** Flat and soft. No hepatosplenomegaly. Bowel sounds within normal limits.

**EXTREMITIES:** Free.

**NEUROLOGIC:** Gait within normal limits. Cranial nerves II-XII bilaterally intact. No gross motor or sensory deficits. Deep tendon reflexes are bilaterally hyperreflexic.

**SKIN:** Free.

**MENTAL STATUS EXAMINATION:**

The patient is alert but incoherent and also disoriented to time, place and person. His speech was rather fast and pressured. Psychomotor activity was markedly increased. Affect was expansive and fluctuating. Mood was irritable and euphoric. Notably he has not slept at all for the past five days. No evidence of weight change. No evidence of panic attacks or autonomic hyperactivity. Thought process is characterized by racing thoughts, flight of ideas and occasional looseness of association. He reveals evidence of florid auditory hallucinations and grandiose delusions. Judgement and insight are completely nil.

**IMPRESSION:**

Axis I: Bipolar disorder, manic, with psychotic features.

Axis II: Not determined.

Axis III: Not applicable.

Axis IV: Not applicable.

Axis V: GAF upon on admission was 25.

PT: [REDACTED] DOB: [REDACTED]  
ACCT: [REDACTED] MR: [REDACTED]  
ADM: 02/28/1999 DC: [REDACTED]  
ROOM: [REDACTED]

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HISTORY AND PHYSICAL EXAMINATION  
MEDICAL RECORD

000011 [REDACTED]

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Exh EZZ

**PLAN:**

On this admission, the patient will be tried on lithium carbonate and Tegretol along with neuroleptic medications.

D 03/02/1999 9:29 A  
T 03/03/1999 8:14 P  
cc: MD

PT: [REDACTED] DOB: [REDACTED]  
ACCT: [REDACTED] MR: [REDACTED]  
ADM: 02/28/1999 DC: [REDACTED]  
ROOM: [REDACTED]

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HISTORY AND PHYSICAL EXAMINATION  
MEDICAL RECORD

000012

Complaint/Injury F/U DET-0833  
02/28/99 00:00 APP EVH E23