

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

ARMS#

13099



5 - SUMMARIES

000001

[REDACTED]

PATIENT NAME: [REDACTED]
MEDICAL RECORD #: [REDACTED]
ADMISSION DATE: 07/02/98
DISCHARGE DATE: 08/05/98
ATTENDING PHYSICIAN: [REDACTED]

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DISCHARGE SUMMARY

DISCHARGE DIAGNOSIS:

AXIS I: 1. Schizophreniform disorder.
2. Steroid abuse.
3. Marijuana abuse.
4. Stimulant (ephedrine) abuse.
5. Rule out substance induced psychotic disorder.

AXIS II: Deferred.

AXIS III: 1. Hypertension.
2. Insomnia -- improved.

AXIS IV: Psychosocial stressors -- moderate -- divorce of parents, concerns about father's failing health, pressures of school, pressures related to sense of need to care for mother, pressures related to relationship with girlfriend.

AXIS V: GAF: Current at the time of admission 20, highest in past year 60 to 65, current at the time of discharge 40.

MedWatch #13099 Investigation
Exhibit# 1 Part 12 of 13
4-5 March 1999 GM

HISTORY: Please see the attached admission evaluation.

MENTAL STATUS EXAMINATION: Please see the attached admission evaluation.

PHYSICAL EXAMINATION: Please see the attached admission physical examination.

LABORATORY STUDIES: Urine screen for drugs of abuse at admission was positive for cannabinoids. Serum chemistries were within normal limits including a cholesterol of 128 with an HDL fraction of 36, giving a total cholesterol HDL ratio of 3.5 with an estimated CHD risk of 0.5 times average. Serology was non-reactive. CBC was within normal limits except for minor elevations in hemoglobin and hematocrit at 17.5 and 50.4. Urinalysis was normal. Thyroid function tests were within normal limits including a TSH of 1.99 and a T7 o 4.2

PSYCHOLOGICAL TESTING: Zung depression scale at the time of admission was 53 which is in the range of mild to moderate depression. Mini mental status examination was 28/30.

More extensive psychological testing was not done at this time related to the clear and obvious psychotic nature of the patient's symptomatology.

[REDACTED]

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HOSPITAL COURSE: Following admission, the patient was placed on the intensive treatment unit in the context of his severely psychotic state. Initial efforts were directed at obtaining information on the patient relative to better understanding the identity of the substances he was taking. These were eventually obtained and the substances contained ephedrine compounds as well as dehydroepiandrosterone. This is particularly relevant in that the patient had not believed that he was taking anabolic steroids.

We, initially attempted to have this unfortunate young man on the adult unit, but the level of his psychosis, was such as to make this not possible. He was therefore, transferred, to the intensive treatment unit. It is noted that I did talk with Dr. [REDACTED] who had known the patient from in the past, but had not seen him for several years. Dr. [REDACTED] had been [REDACTED] pediatrician for at least several years.

As noted, [REDACTED] was very psychotic at the time of his admission with virtually no insight into the obvious and significant psychotic nature of his clinical state. He was agitated and frightened, and in this context, did not want to stay in the hospital or accept medications despite the obvious clinical needs. The patient's mother and grandmother had a very difficult time accepting the need for treatment and in this context, a Temporary Detention Order was obtained as it was not felt to be clinically prudent or responsible to allow discharge with the attendant risks given the clinical state. The patient, in this context, did have a TDO hearing which involved a lawyer privately retained by the family. The patient, in the TDO hearing, was found to meet [REDACTED] commitment criteria and was, therefore, committed to treatment. It is noted that both before the TDO was obtained and at the time of the TDO hearing and subsequently, I offered to transfer [REDACTED] to whatever facility the patient's family wished if that facility was willing, of course, to accept him. Despite their difficulty accepting his need for treatment, the family at no point requested that he be transferred to another facility.

As noted, the patient's mother and grandmother had a very difficult time accepting the need for treatment, although they did come in, especially mother, for a number of family meetings, and worked with us more closely. It is noted, however, that we did learn subsequently, that mother had called the insurance company asking the insurance company to de-certify the patient's stay, according to them, hoping that would, then, lead us to discharge the patient.

Pharmacologically, [REDACTED] was begun on a treatment regimen that initially involved Haldol. He was, then, begun on olanzapine hoping to use an atypical anti-psychotic agent with fewer side effects. He was also started on Verapamil SR 180 mg p.o. q.d. by recommendation of internal medicine consultation to treat

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persistent high blood pressure. That high blood pressure had been known prior to his admission. The patient did continue to show significant difficulties with psychotic thinking and agitation and, at times, would engage in bizarre behaviors such as pulling down the smoke detectors in the building or smearing the walls with orange chalk. In the context of helping him diminish agitation, we did re-introduce a small dose of Haldol as a typical anti-psychotic agent to augment the olanzapine. It was found that even with the use of Cogentin, he had difficulties with dystonia above five mg. We, therefore, held the dose of the Haldol at five mg with the addition of Cogentin two mg b.i.d. Eventually, the olanzapine was increased to 15 mg p.o. q.d.

Repeatedly during the course of his hospitalization, we did attempt to transition him to the adult unit or at least into adult unit treatment activities such as group or activity therapies. For a long period of time, he would have a lot of difficulty with the stimulation of the adult unit, either being unable to tolerate the session itself or to show behavioral decompensation following the experience.

Eventually, however, the patient did begin to show clinical improvement and ultimately, we were able to transfer him to the adult unit prior to his discharge. By that point in time, he was able to tolerate a group session for an hour without either needing to leave to decrease stimulation or having the stimulation activate him to the point that he was being disruptive, intrusive, and quite loose in associations.

It was noted that despite the behavioral improvements seen, [REDACTED] did, even at discharge, continue to show abnormalities of affect, primarily a flattening of affect and clear formal thought disorder with, at times, quite significant loosening of associations and predicative identification. Ego boundaries, often, were quite deficient and [REDACTED] ability to differentiate his own issues from those raised by other individuals in the group was often poor.

During the course of his hospitalization, we also involved [REDACTED] in some of the chemical dependency dual diagnosis tract activities. He accepted the fact that the ephedrine and steroids he was using at the gym were detrimental to him and he also began to address his heavy marijuana use. It is noted that at the time of his admission, he considerably down played the marijuana use, but as his hospitalization continued, he was more open about this. It is noted that he never did get to the point, while an inpatient, where the chemical dependency dual diagnosis team felt that he could tolerate or appropriately utilize AA or NA meetings. He does maintain, however, that he will not be utilizing these substances following his discharge from the hospital. The family is much more aware of his use of these substances now and also seems committed

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to "protecting his brain" by having him not utilize these substances.

It is noted that at the time of his admission, the clinical hope was that the patient's presentation represented primarily a psychotic decompensation directly related to the drugs used including the ephedrine and the steroids. The patient's lengthy time of recovery and his residual symptoms suggest, however, that longitudinal experience with this patient may well suggest that the substances used more unmasked an underlying psychotic diastasis.

It is noted that this patient did have limitations on his insurance coverage and he was, in fact, kept in the hospital beyond the dates of exhaustion of his benefits as a free care patient. We were hoping in this way, specifically, to avoid the necessity of transferring him to a longer term public facility and to optimize his chance of successfully transitioning to the community.

The family did select [REDACTED] M.D. to follow [REDACTED] after discharge. I did discuss the case with Dr. [REDACTED] who will see the patient within two days after discharge. I have emphasized repeatedly to the family the importance of his staying on medications. It is somewhat unclear whether the family is, in fact, committed to this course of action. The importance of substance of abuse avoidance, obviously, was also stressed. Finally, [REDACTED] does state a wish to return to school with the fall semester which is really only a few weeks away. I have strongly encouraged him to do this only in the context of approval from Dr. [REDACTED]. I have significant doubts about [REDACTED] ability to be able to deal with an academic situation until and unless he has further clinical improvements.

It is noted that the family has assured us that they have recruited help to allow [REDACTED] to have continuing support and supervision within the home until it is clear that the transition has been successful.

[REDACTED] does deny suicidal ideation or intent at the time of discharge.

DISCHARGE PLAN:

1. Psychiatric follow-up is arranged with [REDACTED] M.D. with first appointment on Friday, 08/07/98 at 9:30 a.m.
2. Medical follow-up will continue with [REDACTED] M.D.
3. Regular diet.
4. Activity ad lib.
5. Medications: Verapamil SR 180 mg p.o. q.a.m. number 30 with no refills, olanzapine five mg tablets three tablets (15 mg) p.o. q.h.s. number 100 with no refills, Cogentin two mg one p.o. b.i.d. number 60 with no refills, Haldol five mg one

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- p.o. q.h.s. number 30 with no refills.
6. A copy of the patient's discharge packet will be sent to Dr. [REDACTED] and to Dr. [REDACTED]
 7. Continue monitoring of potential return to substance abuse, particularly in this patient's case marijuana, will be necessary, although the patient, at this point in time does state his intent to not engage in use of these substances again.
 8. As noted above, I have recommended that the patient not attempt a return to school until released to do so by Dr. [REDACTED]

8/7/98
Date Signed

[REDACTED]
Associate Professor
Department of Psychiatric Medicine

[REDACTED]
Clinical Associate Professor
Department of Internal Medicine

[REDACTED]
D: 08/05/98
T: 08/06/98
[REDACTED]

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such as writing on hospital walls, and with saliva, writing on the windows. He demonstrates, at times, a very intense affect and acknowledges that he is, at times, feeling very overwhelmed by his thoughts and his emotions.

The patient has denied clear suicidal or homicidal ideation.

The patient has expressed fears of developing diabetes and he also expressed beliefs that he is being "watched." He also reportedly has had a lot of preoccupation with a man named [REDACTED]. Apparently, this is the uncle of his girlfriend who he has only met briefly only on a couple of occasions.

It is noted that, reportedly, that the patient's biological father is currently on dialysis related to renal difficulties for diabetes. He, apparently, just began the dialysis on Saturday.

The patient, apparently, lives with his mother and younger brother. His parents are divorced. It is unclear to me how long they have been divorced. The patient's father is reportedly an alcoholic. Otherwise, the patient's mother denies known family history of psychiatric illness.

DEVELOPMENTAL HISTORY: The patient is the older of two siblings with a 15-year-old brother. He, apparently, is going to [REDACTED] having done reasonably well in high school. He reportedly did not do particularly well in his studies this last semester. He does have a girlfriend, who reportedly, is in fact, not pregnant.

At this point in time, the patient is unable to provide me with further developmental history.

MEDICAL HISTORY:

MEDICATIONS: None.

ALLERGIES: The patient denies.

SURGERIES: The patient denies.

MEDICAL ILLNESSES: The patient reportedly has a history of high blood pressure. At the time of his admission to this facility, his temperature has seemed to be slightly elevated at 99.8. Pulse is normal at 82, blood pressure shows some increase in systolic pressure at 160/82.

The patient's primary care physician is [REDACTED] M.D., a pediatrician with whom I have spoken.

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MENTAL STATUS EXAMINATION: The patient, on mental status examination, is seen to be a large young white male, who is 6'2 and a half inches tall, and 240 pounds. He is seen to have very intense affect. Clinical interview is very difficult because he is resistant to answering questions and in fact, tends to "reverse the tables" and repeatedly ask similar questions. He expresses doubt that individuals are who they present, expressing doubt that I am a physician or that the nurse, in fact, is a nurse. He is oriented to person, time, place, and situation to my exam, although nursing staff has told me that other times, he seems not fully oriented. He is resistant to doing further mini mental status examinations such as specific memory testing, calculations, or proverb interpretations. His general level of intellectual functioning would be judged to be in the normal range. The patient is not able to provide a coherent mood statement. His affect is energized, intense, and somewhat paranoid. He, reportedly, has been having sleep disruption. He tells me his appetite has been good. I could not clarify with him whether he has gained or lost weight. He does acknowledge his involvement in the gym and that he has been taking preparations related to body building which he acknowledges includes caffeine and ephedrine. He denies use of steroids to me. He has admitted to marijuana use to the nurse, but denied drug or alcohol abuse to me. The patient is seen to have elements of a formal thought disorder with thought blocking and distraction during the clinical interview when he seems to be responding to internal stimuli. He, at times, has been seen by staff to be talking to apparent individuals who are not there. He does acknowledge that he feels he is being watched and he states that he has seen an individual who is watching him who he acknowledges others do not see. He is, however, unable to clarify why he believes this is happening. He has expressed delusional beliefs related to his father and his girlfriend as noted in the HPI. He denies homicidal or suicidal ideation. He has demonstrated some aggression here pushing through staff people when they try to appropriately direct him on the unit and being inappropriate with a nurse as noted in the HPI. He displays current significant impairments in judgment and insight. He has no known history of suicidal or homicidal behaviors.

ASSETS: The patient does have an involved family. He is in school and apparently, until recently, has done reasonably well in school. He does have an established relationship with Dr. [REDACTED] as his primary care physician.

IMPRESSION:

- AXIS I:
1. Psychotic disorder, NOS.
 2. Rule out substance induced delusional disorder.
 3. Rule out steroid use.
 4. Rule out marijuana abuse.
- AXIS II: Deferred.

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- AXIS III: 1. History of high blood pressure.
2. Recent insomnia.
- AXIS IV: Psychosocial stressors -- moderate -- divorce of parents, pressures of school, concerns about father's health.
- AXIS V: GAF: Current at time of admission 20, highest in the past year undetermined, but reportedly, in solid range of at least 70.

ESTIMATED LENGTH OF STAY: One week to 10 days.

INITIAL TREATMENT PLAN:

1. Admit to safety and security of inpatient unit. We, initially, attempted to integrate this patient on the adult unit, but issues of agitation and inappropriate behaviors led to the need to place him on the ITU.
2. We have attempted to give this patient "space" on the ITU despite his, at times, inappropriate and somewhat aggressive behaviors because he is currently able to be alone on that unit and have "the run of the unit."
3. We have offered the patient medication including Haldol as an anti-psychotic agent and Ativan as an anti-anxiety agent. He did refuse those medications through last night, but this morning, did agree to accept the medications. We did not attempt to force medications with this individual.
4. Physical examination per [REDACTED]
5. Regular diet.
6. Activity ad lib as noted above.
7. Expand data base with information from Dr. [REDACTED] -- the patient's CBC was within normal limits and Dr. [REDACTED] will fax us serum chemistries as soon as they become available.
8. Comprehensive urine drug screen.
9. Individual psychotherapy aimed initially at establishing rapport, clarifying history especially about substance abuse, and helping the patients recover from psychotic denouncement.
10. Group psychotherapy when the patient is adequately improved to provide supportive holding milieu and to evaluate the patient within an interpersonal setting.
11. It is noted that the patient's mother wishes to remove the patient from the hospital. It is my clinical judgment that the patient's psychotic illness and the social inappropriateness displayed in the hospital is such that this is inappropriate and clearly not in the patient's best interest. It is my clinical experience that individuals who are this psychotic tend to lose their ability to sustain control in the context of their disordered perceptions and, ultimately, begin to act on those perceptions in ways that are in broad sense, injurious to themselves. Within this context, I offered to transfer the patient to any other psychiatric hospital that the mother wished. If this was not agreeable, I felt that discharge at this point, would

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- constitute negligent care on my part, and would place this patient at risk. I, therefore, stated that I did feel the need to request an ECO, and if the [redacted] pre-screener was in agreement, the patient would then need a TDO hearing, where of course, both the patient and the family would be present and the patient would be represented by legal counsel. The special justices had informed us that they would not be doing hearings today as it is a court holiday. Nonetheless, I did have the social worker call each of the three area special justices to see if they would be available to do a hearing expeditiously today despite the fact that by law the patient on an ECO can be held for 72 hours. None of the three special justices were able to meet this request.
12. While I believe, at this point, the patient's best interest would be served by taking medication which would, hopefully, speed the rate of recovery from this psychotic denouncement, I do not intend to force medications in that his level of agitation has, to this point, been containable with the structure of the unit and psychosocial support by staff.
 13. Follow-up care will need to be arranged once a course of clinical improvement is established.

[redacted]
[redacted]
Medical Director

7/7/98
Date Signed

Associate Professor
Department of Psychiatric Medicine

Clinical Associate Professor
Department of Internal Medicine

[redacted]
D: 07/03/98
T: 07/03/98
[redacted]