

Scenario #1:

Case background: You are a 25-year old woman [or husband of such a woman] with a 2-year old child. Following your pregnancy, you experienced severe post-partum depression. You were prescribed the anti-depressant Prozac, and responded well to this therapy. After 6 months of treatment, you were weaned off the drug, and have had no further episodes of depression. Lately, you have been feeling a bit "down" again, and a friend suggested you try the TrueHope product. You have not noticed much difference, aside from some mild diarrhea initially, and so you have continued to increase your dosage to 18 caplets¹. You feel "fine" at this dose, but haven't noticed a huge change otherwise.

You are anxious to become pregnant with your next child, but are not anxious to repeat your experience with post-partum depression. Your doctor has suggested restarting the Prozac, but you aren't sure what you want to do.

Question #1: Are there any dangers for me using Prozac during the pregnancy?

Answer:

Question #2: Is it OK for me to continue to use the EMPower formula during pregnancy?

Answer:

Question #3: Will EMPower prevent me from getting depressed after this pregnancy?

Answer:

Question #4: Can I take EMPower together with an antidepressant? Will that hurt the baby?

Answer:

Question #5: Should I tell my doctor I'm taking EMPower? [Ask near the end to give the triage person time to ask if you have done so.]

Answer:

Other information if asked: You are not suicidal or homicidal. Some mild decrease in appetite, and sleep is a bit more troubled than usual. Mild guilty rumination, but you can usually talk yourself out of such things. You still find happiness in life, and you feel a bit more tired than usual, but think this is probably due to having an active 2-year old and less sleep. You are presently taking Materna², a pre-natal vitamin supplement in addition to your EMPower. You have not told the doctor you are using EMPower.

Did the TrueHope Assistant:

- ❖ Ask about other medications or supplements?
- ❖ Ask if you have discussed EMPower with your doctor?
- ❖ Suggest discussing medication/supplement safety with your doctor?
- ❖ Make assertions about EMPower's effectiveness in treating post-partum depression?

¹ Current EMPowerplus dosage is listed as Vitamin A, 960 IU per 3 tablets; thus 18 tabs x 960/3 = 5760 IU. The 5000 IU of Materna raise the dose to > 10,000 IU per day. See: http://www.truehope.com/_empowerplus/empIngredients.asp, accessed 9 January 2004.

² Materna contains 5,000 IU of Vitamin A (as acetate) per daily dose. Nissen, David (ed). *2004 Mosby's Drug Consult*. Entry "Materna", Table 1.

Commentary on Scenario #1

This scenario tests a number of aspects of TrueHope's triage and advice:

TrueHope's materials presents a negative spin on standard psychiatric medications—for example, they have produced a document entitled "A Report on the Use of Psychiatric Medications Their Safety and Efficacy" [sic], with the sub-heading "Providing a Detailed Meta-Analysis"³. Despite the title, the document in question is not a meta-analysis. It is a collection of adverse drug reactions (ADR) and statistics which aim to demonstrate that standard psychiatric medications are both dangerous and often lacking in efficacy. For example, the document's summary opines:

- ❖ "hundreds of studies suggest that further research is needed on the safety of psychiatric medications";
- ❖ "ADRs [adverse drug reactions] are a major cause of illness and death";
- ❖ "Addiction and withdrawal have become huge problems for many patients using psychotropic medications";
- ❖ "The efficacy of these medications is also being questioned by many psychiatrists and especially by the patients using them".

Prozac is one anti-depressant with a well-established track record of safety for pre-natal use—it has shown no teratogenic effects, and follow-up has shown no behavioral problems in exposed infants up to age seven. One limited study showed some risk of prematurity, but this was not confirmed. Peri-natal agitation and jitteriness, has been reported in case studies, but animal data is non-supportive⁴.

In contrast, the dose of EMPower reported by the patient contains 6,400 IU of Vitamin A per day⁵ (in addition to the 5,000 IU Vitamin A she is receiving via her pre-natal supplement). Vitamin A is a known human teratogen, though the minimum teratogenic dose is not known.

One drug reference states that "[s]afety of amounts exceeding 6000 Units of vitamin A daily during pregnancy has not been established at this time."⁶ The American College of Obstetricians and Gynecologists recommends no more than 5000 IU daily⁷. Rothman et al. do not express worries at a dose below 10,000 IU⁸, and the CDC concurs⁹.

Even the nutritional reviewer for one of TrueHope's clinical trials, Dr. Catherine J. Field, indicated that "I did strongly recommend that pregnant women or women who are considering pregnancy not take the supplement."¹⁰ To our knowledge, no subsequent data have mitigated these concerns, though TrueHope has altered the formulation on more than one occasion—perhaps Dr. Field would be less concerned with the current mix.

³ Document is listed "Copyright TrueHope Nutritional Support Ltd.", July 23, 2003.

⁴ Ward, RK et al. "Benefits and Risks of Psychiatric Medications During Pregnancy". American Family Physician, Vol. 66, No. 4, August 15, 2002.

⁵ Purity studies carried out by the Schizophrenia Society of Ontario found that EMPower contained 17% more than the labeled amount of Vitamin A; if applied to this case and formulation, the patient could be receiving at least 6739 IU from EMPower alone—personal communication.

⁶ Mosby's Drug Consult 2003 Edition, "Vitamin A", Ref #002429, on-line edition.

⁷ American College of Obstetricians and Gynecologists: Vitamin A Supplementation During Pregnancy. Committee Opinion No. 196, Washington, DC, ACOG, January 1998. Cited in Smith CS and VanAndel R. "Pregnancy and north american lifestyles: Exercise, work, and diet in pregnancy". *Clinics in Family Practice*. Vol. 3, No. 2, June 2001.

⁸ Rothman KJ, Moore LL, Singer MR, Nguyen U-SDT, Mannino S, Milunsky A "Teratogenicity of high vitamin A intake." *N Engl J Med* 333:1369-1373 (1995).

⁹ Oakley GP Jr, Erickson, JD. "Vitamin A and Birth Defects" (Editorial). *N Engl J Med* 333:1414-1415 (1995).

¹⁰ Email message from Field, Catherine J. to Marvin Ross, Wednesday, August 01, 2001 5:13 PM, copy in authors' possession.

Despite the issues involved in excessive Vitamin A consumption in pregnancy, there is anecdotal evidence that TrueHope Assistants either ignore or are unaware of them¹¹.

Scenario #2

Case background: You are a 26-year old man who was diagnosed with Bipolar Affective Disorder 2 years ago. In retrospect, you have been suffering from manic episodes two or three times a year since you were 21. You were finally diagnosed after your family became concerned when you ran up \$10,000 worth of credit card bills (despite being unemployed) and went without sleep for four nights.

At diagnosis, you were hospitalized, and placed on lithium carbonate therapy with an antipsychotic (Seroquel). You responded very well to the treatment, and have had no further manic episodes since your diagnosis. You take lithium 300 mg in the morning and at noon, and 600 mg at night—the antipsychotic was discontinued following stabilization. You had one minor episode of depression about 1 year ago, which was managed with short-term use of Paxil. This resolved after a few months, and you remain on lithium therapy only. You have held a job for the past 18 months (a personal record) as a shipper-receiver, and things are going well for you.

Question #1: I've heard about EMPower. Can your product help my bipolar disorder?

Answer:

Question #2: If I start EMPower and feel good, can I stop my lithium?

Answer:

Question #3: If I decide to stop the lithium are there any risks to doing so?

Answer:

Question #4: Do I need to stop the lithium, or can I use both EMPower and lithium?

Answer:

Other information if asked: You have not talked to your doctor about EMPower. You have a very strong family history of bipolar [an uncle and brother]. Your diagnosis is Bipolar I, if asked.

Did the TrueHope Assistant:

Commentary on Scenario #2

EMPower insists that they will not tell a patient to stop medication. However, information may be presented in a way which may disincline a patient to follow their physician's advice.

Bipolar disorder is a recurrent illness in 80-90% of patients¹². Stopping effective lithium therapy in a bipolar patient is not necessarily a benign choice—some data initially suggested that patients who formerly responded to lithium may not do so if they discontinue it and then attempt to restart¹³. More recent reviews dispute this¹⁴.

¹¹ Personal communication.

¹² Hopkins HS, Gelenberg AJ: Treatment of bipolar disorder: How far have we come? *Psychopharmacol Bull* 30:27–37, 1994.

Continuing with lithium clearly decreases the risk of suicide in mood disorders¹⁵, and lithium is indicated for the prevention of future manic and depressive phases¹⁶.

Thus, lithium discontinuation seems not to preclude its future effectiveness, but does expose the patient to the risks of relapse. Lithium efficacy does not tend to decrease with time¹⁷. In short, discontinuation may not be in this patient's best interests, and may have significant risks.

Scenario #3

Case background: You are the parent of a 10-year old boy with a diagnosis of ADHD. Your son takes Ritalin 10 mg in the morning and in the afternoon. He has done well on this medication: he was previously getting in the 40% range in classes; he now gets 80%. His behavior at home is better, and his sleep and appetite are OK.

Three days ago, you heard about EMPower, and a friend gave you some tablets to try, since you aren't sure you want your son to need to take a "drug", and the EMPower is "natural". You are continuing to use the Ritalin.

You're using a dose of 5 caps of EMPower. However, for the last 24 hours, your son has been complaining of a bad headache, he threw up, and he feels warm.

Question #1: Is this a normal reaction?

Answer:

Question #2: Could the EMPower be causing this?

Answer:

Question #3: Should I stop EMPower?

Answer:

Question #4: Anything else I should do?

Answer:

Other information if asked: Your son's temperature is 38.9 degrees C. This is the worst headache of his life. His neck is sore and a bit stiff. He's had two episodes of shaking chills. You have not seen a doctor. His physician does not know he is taking EMPower.

Did the TrueHope Assistant:

¹³ Maj M, Pirozzi R, Magliano L. "Nonresponse to reinstated lithium prophylaxis in previously responsive bipolar patients: prevalence and predictors." *Am J Psychiatry* 1995;152:1810-11.

¹⁴ Kleindienst N. *Eur Arch Psychiatry Clin Neurosci* 01 JUN 2003; 253(3): 120-5; see also Baldessarini RJ. *Harv Rev Psychiatry* 01-MAR-2002; 10(2): 59-75

¹⁵ Tondo L, Hennen J, Baldessarini RJ. Lower suicide risk with long-term lithium treatment in major affective illness: a meta-analysis. *Acta Psychiatr Scand* 2001;104:163-72.

¹⁶ Keck PE Jr, Welge JA, Strakowski SM, et al: Placebo effect in randomized, controlled maintenance studies of patients with bipolar disorder. *Biol Psychiatry* 47:756-761, 2000

¹⁷ Maj M. *Bipolar Disord* 01 Jun 2003; 5(3): 180-8

- ❖ Ask if the patient was feverish?
- ❖ Ask regarding neck stiffness?
- ❖ Ask regarding shaking chills?
- ❖ Tell the parent to get prompt medical attention?

Commentary on Scenario #3

A common pitfall in diagnosis is "premature diagnostic closure"—a situation in which the mind is made up "too soon", and further information is not sought.

Not all matters that present for TrueHope telephone triage will necessarily involve true psychiatric issues. In this case, the EMPower and Ritalin use may deceive parents and triage. The patient is at potential risk for infectious meningitis. Urgent medical consultation is indicated.

Scenario #4

Case background: You have a long history of depression, and have been treated with a variety of medications. Some medications have worked for a while (Paxil – it stopped working after about 6 months), some did not help (Zoloft, Celexa), and others were stopped for side effects (Luvox, Effexor, Prozac). You quit your medication, and quit seeing your psychiatrist. You have been trying EMPower for the last 3 weeks. At first, you felt a bit better. You're on the 18 caplets, but it "doesn't feel like it's working anymore".

Question #1: My doctors have told me for years that I'm "depressed". None of the pills they've tried have worked for very long, and the side effects are terrible. Is this the sort of thing your group works on?

Answer:

Question #2: I feel really guilty about calling. You see, a friend of mine tried out your product—she has fibromyalgia and chronic fatigue syndrome—but didn't really feel much different. The pills were pretty expensive, so he/she told me that if I wanted to, I could buy them off him/her. She told me I should really call in if I'm going to do the program, but I just didn't have the energy, so I'm sorry to just dump all this on you. But, I started taking the pills—I'm up to 6 pills with every meal. Is that an okay dose?

Answer:

Question #3: I'm running out of pills, so that's partly why I called. Plus, at first I felt okay, but It "doesn't feel like it's working anymore". I can't eat, I can't sleep, I feel like crying all the time. I don't know what to do.

Answer:

Question #4: Should I stop the Empower?

Answer:

Question #5: Do I need to see a specialist in depression?

Answer:

Question #6: Can I get more pills from you?

Answer:

Other information if asked: you have 2 past suicide attempts: once you took a month's worth of Zoloft, and two years ago you swallowed two bottles of Extra Strength Tylenol. You are taking no other medications at the moment. You have not discussed EMPower with your family doctor, and you have not spoken with a physician recently (though you will readily agree to do so if advised). Your psychiatrist recommended a course of ECT, but you've been reluctant to try this, and so haven't had contact with him for 9 months—you didn't plan on going back. Your depression has been worsening, and you are actively contemplating suicide. You have told no one about this.

Did the TrueHope Assistant:

- ❖ Ask if the patient had ever been suicidal?
- ❖ Ask if the patient was actively suicidal?
- ❖ Ask regarding any other medications or supplements?
- ❖ Ask if the patient has told his doctor about EMPower?
- ❖ Tell the patient to get prompt medical attention?
- ❖ Encourage the patient to see a "depression specialist"?
- ❖ Encourage an increase in dosage?
- ❖ Insist on a more thorough history before giving advise and/or suggesting more pills.

Commentary on Scenario #4

Suicide is a well-known risk of many mental illnesses, including bipolar disorder, unipolar depression, and schizophrenia (all of which TrueHope purports to treat). Changes in clinical status require that suicidality be re-assessed.

This patient had a relatively significant past suicide attempt, in that acetaminophen overdose has significant morbidity and mortality. The failure of multiple treatments can increase a patient's feeling of despair, and the psychiatrist's intention to consider ECT suggests a serious, treatment-resistant depression.

Scenario #5

Case background: You have recently [9 months ago] been diagnosed with multiple sclerosis (MS) after having double vision, numbness in your right hand, and a positive MRI scan. You've also been kind of "panicky" your whole life, though that's gotten a bit worse since the diagnosis of MS.

You have a friend who used EMPower for her depression, and you're wondering if EMPower would help you since MS is a "brain disease" like depression.

Question #1: Does your company have anything that's been shown to help multiple sclerosis?

Answer:

Question #2: [Ask this immediately if the Assistant asks you about other medications. Otherwise, bring this up after your MS questions have been answered.] I've been taking clonazepam for quite a few years, and I've heard it's addictive. Is this true?

Answer:

Question #3: I've been thinking I should stop the clonazepam. What do you think?

Answer:

Question #4: If I did choose to stop the clonazepam, should I just stop taking them?

Answer:

Other information if asked: You take clonazepam 0.5 mg three times a day, for 4 years for your anxiety/panic symptoms. You are also on Betaseron (interferon B 1b) for your MS. You drink about 5 bottles of beer a day (though will admit to more on the week-end). You've not discussed EMPower with your neurologist or family physician, nor have you discussed your drinking or desire to stop clonazepam—a doctor at a walk-in clinic just gives you a prescription for the clonazepam every month, since you find yourself a bit "jumpy" without it. You've had two MS "relapses" in the last 9 months, which responded to high dose IV prednisone in hospital. You have never attempted suicide, are not depressed or suicidal, but do have an increase in anxiety and 4-5 panic attacks per week.

Did the TrueHope Assistant:

- Ask regarding any other medications, alcohol, or supplements before making recommendations regarding MS?
- Ask if the patient has told his doctor about EMPower?
- Caution the patient against abrupt benzodiazepine discontinuation?
- Urge them to seek medical help for anxiety, depression, or substance use issues (including stopping the clonazepam)?
- Assess regarding suicidality?

Commentary on Scenario #5

Abrupt discontinuation of benzodiazepines can be life-threatening, since seizure is a very real risk. The concomitant excess use of alcohol potentially suggests addiction and/or untreated depression or anxiety. The additional stress of a serious, chronic, potentially fatal illness is a risk factor for worsening depression and/or anxiety. It is also a risk factor for suicide. Steroids have been implicated in worsening psychiatric illness.

Scenario #6

Case background: You are a woman with a diagnosis of fibromyalgia. You have seen the TrueHope website, and are calling to find out about EMPower for treating your condition.

Question #1: Can your product help my fibromyalgia?

Answer:

Question #2: How sure are you that this works? I've tried a lot of different things, and not much has worked very well. I don't have a lot of money, so I don't really want to start something that my insurance won't cover unless it's got a good chance of working.

Answer:

Other information if asked: Other than your fibromyalgia, you have been told you have irritable bowel syndrome (IBS). You've been tried on a variety of antidepressants over the years [Prozac, Paxil, Wellbutrin, Zoloft] but without much change. You're currently taking Effexor XR 75 mg every morning, Elavil 25 mg at night, and Neurontin 300 mg three times a day. This has made you have a bit less pain and a bit more energy, but you're still quite restricted in what you're able to do. You are not suicidal. You are not depressed, though you are a bit discouraged by your disease. You've had to stop your work cleaning houses, and so your family is getting by on your husband's single income at a meat packing plant.

Did the TrueHope Assistant:

- ❖ Ask regarding any other medications or supplements before making recommendations regarding MS?
- ❖ Ask if the patient has consulted a doctor about EMPower?
- ❖ Make any reference to the double-blind trial on fibromyalgia?
- ❖ Discuss the 'need' to discontinue medication?

Commentary on Scenario #6

Little rigorous study has been carried out on EMPower—there is no published research on the treatment of the majority of the diseases which TrueHope claims to treat.

Dr. Bonnie Kaplan et al. published an 11-patient open-label study of bipolar disease in 2001¹⁸. Kaplan also collaborated in an open-label trial of 2 children in 2002¹⁹. Kaplan has indicated in a statement to the media that "[w]hile the participants in our research generally benefited mentally and remained healthy physically, the results are preliminary"²⁰.

A third "study" is a letter to the editor in *The Journal of Clinical Psychiatry* in 2003, describing a case series of 19 bipolar I and II patients treated in the author's private practice²¹.

It should also be noted that the composition of EMPower and its derivatives has changed over time, and this has implications for the existing research data. Despite numerous changes to the formula, TrueHope places great emphasis on the importance of the supplement's composition. Company founder Tony Stephen states on their website that "if we had missed just one thing in the formula, it wouldn't have worked. The odds were a billion to one"²²

Despite being convinced that the formula reflects a finely-tuned—and indispensable—combination, the company made a switch from the "SynergyQuad" formula to the "EMPower+" formulation in April 2000. The amount of 29 vitamins and minerals was altered, and an additional 7 products were added²³. The supplement's dose of Vitamin A was again altered in Summer 2001. The current formulation ("Empowerplus") began sales in about the Fall of 2002²⁴. Unfortunately, research conducted using past formulations is, of necessity, of limited value in assessing the current, different mix.

This difficulty is further complicated by variations in the exact composition of individual doses. Despite claims by David Gilbert, TrueHope's "Medical Liaison", that the supplement maker ensures "[a]ll manufacturing standards are rigorously maintained, as a manufacturing error would destroy years of work"²⁵, laboratory analysis conducted by the Schizophrenia Society of Ontario in fact found that sixteen of twenty-three measured ingredients²⁶ in EMPower+ varied from -25% to +70%

¹⁸ Kaplan, BJ, Simpson JSA, Ferre RC, et al. "Effective mood stabilization with a chelated mineral supplement: an open-label trial in bipolar disorder." *J. Clin Psychiatry* 2001;62:936-944.

¹⁹ Kaplan BJ et al. "Treatment of mood lability and explosive rage with minerals and vitamins: two case studies in children." *J Child Adolesc Psychopharmacol.* 2002 Fall;12(3):205-19.

²⁰ Quoted in Rutan, S. "No hearing in Ottawa for backers of vitamin supplement", *Edmonton Journal*, June 13, 2003, p. A13.

²¹ Simmons M. *J of Clin Psych* 64:3, March 2003, p. 338 [letter].

²² <http://www.truehope.com/aboutMessageStephan.asp>, as of November 14, 2003.

²³ Polovoy T. Reinhold R. Ross M. "PigPills Inc. The anatomy of an academic and alternative fraud", E-book available on-line at www.pigpills.com, Appendix 5, p. 189.

²⁴ NEED REFERENCE

²⁵ Email message from Gilbert, David to Martin Ross, Saturday, August 04, 2001 2:30 PM, copy in authors' possession.

²⁶ Other ingredients were either present in amounts too small to be measured, or assays were deemed too expensive.

of the labeled amount²⁷. Such a finding is in keeping with the general level of poor standardization reported for many "natural health" products²⁸.

TrueHope's website indicates that "[t]o date, there have been four studies published using the Empowerplus formulation." However, their research page lists only three of these studies²⁹. The fourth (mentioned in earlier TrueHope literature³⁰) seems to be a single-patient case study, reporting benefit in fibromyalgia, published in 1999³¹.

Additional research data also exist—available only in abstract form, the only double-blind, placebo-controlled trial involving EMPower was conducted on 99 fibromyalgia patients at the University of Calgary. This trial showed little benefit and there was a large (34 patients) drop-out rate; the only period of benefit was seen during the open-label portion of the trial: i.e. benefit was only seen when the investigators and patients knew they were taking the supplement. The authors rightly concluded that "[t]he results of this study argue against nutritional deficiencies being a primary or important cause of [fibromyalgia]"³².

It is disturbing that, given the limited available research on EMPower, the company chooses not to mention the one available double-blinded, placebo controlled trial, and that this trial showed no benefit above placebo. Further, they continue to advertise on their website that they can treat fibromyalgia, while the best available data strongly suggest otherwise. They also continue to use data obtained from previous incarnations of the supplement as evidence for the current formulation, a scientifically dubious practice.

Scenario #7

Case background: You are calling about your spouse. You have heard that TrueHope can help with "mental problems". You've never thought your spouse had a "mental problem" before, but now your spouse has been up for three days without sleep, and has spent most of this time organizing and reorganizing the house: books on the shelves, clothes in the drawer, utensils by fine gradations of size, etc. They are quite irritable and snappy with you, and often talks "a mile a minute". She hasn't been eating very well for months, and now weighs about 105 pounds.

Question #1: Is this a mental illness? What's wrong with him/her?

Answer:

Question #2: What would you suggest?

²⁷ Anonymous. *Report by the Schizophrenia Society of Ontario on the Vitamin 'EM Power+'*, March 2002, p. 2.

²⁸ See, for example, Christine M. Gilroy CM, Steiner JF, Byers T et al. "Echinacea and Truth in Labeling" *Arch Intern Med*. 2003;163:699-704; Draves AH, Walker SE. "Analysis of the hypericin and pseudohypericin content of commercially available St John's Wort preparations." *Can J Clin Pharmacol* 2003;10(3):114-8; numerous assessments are available on-line at www.ConsumerLab.com.

²⁹ <http://www.truehope.com/research.asp>, emphasis in original, as of November 14, 2003.

³⁰ Information package to physicians from Synergy Group of Canada, Document Five – Fibromyalgia Case Study, dated July 20, 2001. The same study is mentioned in a radio interview by Anthony Stephen on American Freedom Network – Ryn Revis Technology Hour – October 26, 2002. See transcript in Polovoy T. Reinhold R. Ross M. "PigPills Inc. The anatomy of an academic and alternative fraud", E-book available on-line at www.pigpills.com, Appendix 7, p. 201-202.

³¹ *Journal of Musculoskeletal Pain*, vol. 7, number 4, 1999, pages 127-130

³² Kaplan BJ, Crawford S, Kennedee R. "A Randomized Controlled Trial of a Nutrient Supplement in the Treatment of Fibromyalgia" presented at American College of Rheumatology annual meeting, New Orleans, October 29, 2002.

Answer:

Other information if asked: Your spouse has never had a psychiatric diagnosis, and has never seen a psychiatrist. The spouse also has hepatitis C—a liver biopsy a year ago showed little change in the liver, and so no treatment undertaken at present. Liver function tests are normal.

If asked if your spouse takes any medication, say "she used to be, but quit three or four months ago. She's not taking anything right now. She's always hated taking pills."

If asked what medication she was on, you inform them she was on Retrovir [Zidovudine/AZT] 300 mg twice a day, lamivudine (3TC) 150 mg twice a day, and Kaletra 3 tabs once a day for a diagnosis of HIV. Your spouse is a former IV drug user, and was diagnosed with HIV-1 two years ago when they had a bad case of "thrush" (oral yeast infection) that made swallowing very painful. He/she became quite despondent 3-4 months ago when told his/her CD4 counts were dropping (possibly due to poor medication compliance), and stopped taking his/her medications completely. Your spouse has been refusing to see his/her infectious disease specialist. Her weight has dropped from 150 pounds over the last year.

Did the TrueHope Assistant:

- ❖ Make a diagnosis? If so, what?
- ❖ Recommend EM Power therapy?
- ❖ Realize that the patient had HIV?
- ❖ Realize that the patient had hepatitis C?
- ❖ Identify the past prescribed HIV medication?
- ❖ Ask about liver function?
- ❖ Advise the patient to seek prompt medical attention?

Commentary on Scenario #7

This is not a clear-cut case of bipolar disorder; an HIV-induced mania is clearly in the differential diagnosis³³. In any case, no medical diagnosis has been made, and it would be inappropriate for a lay TrueHope Assistant to do so.

HIV medications have frequent interactions with multiple drugs and supplements, so caution is indicated³⁴. Liver disease, while not a key issue in this patient, must be considered in those with hepatitis. The presence of a previous AIDS-defining illness, poor medication compliance, and marked weight loss also suggest that this is an advanced case. Medical consultation is indicated to rule out medical causes of the patient's behaviour, establish a diagnosis, and begin treatment.

Scenario #8

Case background: You are calling about a seven-year old daughter [Susan], with diagnoses of ADHD and bipolar I. You stopped Lithium and Zyprexa therapy three months ago—you can't stand the idea of your daughter being on medication, even though her sleep and mood improved, and she did much better in her repetition of Grade 1.

³³ Robinson MJ "Practical psychopharmacology in HIV-1 and acquired immunodeficiency syndrome" *Psychiatr Clin North Am* - 01-MAR-2002; 25(1): 149-75.

³⁴ Hsiao AF. "Complementary and alternative medicine use and substitution for conventional therapy by HIV-infected patients." *J Acquir Immune Defic Syndr* 1 Jun 2003; 33(2): 157-65; Lesho EP. "Managing issues related to antiretroviral therapy." *Am Fam Physician* 15 Aug 2003; 68(4): 675-86.

Things got worse about a month after stopping the pills. You didn't do anything for another 4-5 weeks, but your daughter was really "out of control". A woman at your bipolar support group has been taking EMPower—she strongly suggested you try it. You were going to, but had to wait until payday to be able to afford it. Your acquaintance (her first name is "Joy" or "Joyce") offered to loan you a bottle, "But she told me I really need to do the whole program if I want this to work."

You are giving 12 pills of EMPowerplus per day, but her behaviour has not improved at all: she is generally depressed, moody, prone to rages, unable to concentrate, and sleep is becoming a distant memory. Her school work is suffering again.

Question #1: Things have been crazy at work, and Susan's behavior is just making it worse. We're almost out of pills. Is it worth it to keep going?

Answer:

Question #2: I'm at the end of my rope. Is there anything else I can do?

Answer:

Question #3: Does EMPower help with bipolar and ADHD?

Answer:

Question #4: How can I tell if she's maybe taking too much EMPower?

Answer:

Question #5: Could the problems she's having be because she's taking EMPower? [Or, "So the problems she's having aren't from the EMPower?"]

Answer:

Question #6: I dunno--even the Lithium and Zyprexa might be better than this. How much longer before I take her back to see the child psychiatrist?

Answer:

Question #7: If I decide to stop the EMPower, can I just quit?

Answer:

Other information if asked: No other medications. No allergies. No suicidal behavior. Strong family history of mental illness—1 uncle with bipolar, grandfather suicide, few aunts with depression.

Did the TrueHope Assistant:

- ❖ Assert that EMPower can treat ADHD and BAD?
- ❖ Encourage a return to the child psychiatrist?
- ❖ Indicate how to determine over-dosage?
- ❖ Indicate whether over-dosage was possible?
- ❖ Consider that EMPower might cause problems in this patient?

Commentary on Scenario #8

The total "children's dose" established by TrueHope is 12 capsules of the current formulation. It is not clear how this maximum dose was established.

This scenario tests the TrueHope Assistants' willingness to exceed this dose. It also examines whether an Assistant will discourage a patient from returning to previously effective therapy.

It also explores whether an Assistant is open to the possibility that EMPower may worsen a problem, and whether over-dosage is even considered a theoretical possibility.

Scenario #9

Case background: You have been diagnosed with depression and generalized anxiety disorder. You were previously treated with Ativan 1 mg PO 3x per day as needed, and started on Paxil. Your Paxil was increased to a dose of 40 mg a day, and your mood and anxiety symptoms improved markedly. Your Ativan use decreased to 1 tablet once a week at most.

Not liking the idea of being on pills, you persuaded your doctor to try to wean you off the Paxil after some of your life stresses had resolved. Your anxiety and panic returned almost immediately, and you had to restart the Paxil. Your Ativan use is back down to 1 tab per week at most.

Hearing about EMPower, and wanting a "natural" alternative to the pills, you started the program. You felt fine on the recommended dose, and so weaned yourself off the Paxil. It has been two weeks since you stopped the Paxil, and now you are getting anxious and having panic attacks again. Your mood is also less good than it was.

Question #1: What's wrong?

Answer:

Question #2: What should I do?

Answer:

Other information if asked: No other medications. You have begun drinking 4-5 beer/day because this helps reduce the panic feelings. You are out of Ativan, and so are not using that any more either. You are not suicidal. You are beginning to wonder if you shouldn't restart the Paxil. Your mood swings and anxiety are causing problems in your marriage, and you're fighting with your spouse a lot more.

Commentary on Scenario #9

Truehope assistants often blame any adverse outcome of their program on "a drug interaction", or on "withdrawal from" or "addiction to" psychiatric medications. This scenario presents a situation in which drug withdrawal is very unlikely, since the patient experienced no symptoms immediately after discontinuing the drugs. Ativan addiction in this context is very unlikely, since few pills were being used, and no symptoms of panic or anxiety were seen until the SSRI (Paxil) had been stopped for two weeks. Symptoms of Ativan dependence, if present, would have occurred much sooner in the clinical course.

This scenario also tests whether the assistant will recommend return to a previously effective therapy, and whether other substance abuse issues will be considered (the increased alcohol use), along with psycho-social issues like marital strains caused by non-compliance with effective therapy.

Scenario #10

Case background: For the last several months, you have been feeling generally ill at ease, and unhappy. This occurs especially when you go home for family events. You've finally been able to admit to yourself that you were sexually assaulted by your step-brother (7 years older than you) from the time you were 11 to age 15 when he left home.

Other information if asked: You've always known this happened, but tried not to think about it. But, the memories are becoming more persistent since your step-brother was killed in a car accident 7 months ago. Your step-father wasn't around much, and your mother was a "wall-flower" type that was very non-assertive. The step-son pretty much ran rough-shod over her, and so you've never told your parents what happened. There were no other siblings at home. You have never seen a psychiatrist or been diagnosed with a mental illness. Your biological father died in a hunting accident when you were two years old. Your mother remarried when you were 11. Your mother is still alive at age 68, though tends to be a very "anxious" person. You don't know if she'd on medication. Your step-father died 5 years ago from a heart attack.

Your sleep has been disrupted, and you are having nightmares about your step-brother's assault. You become anxious, jumpy, and irritable whenever you go home to visit your mother. You insist upon sleeping in the living room on the couch "to be near mother's room" instead of upstairs in your own bedroom, but this is really to avoid the bad memories associated with your room. Your appetite is poor (you've lost 10 pounds—which you're happy about, but realize it means you're not eating well). You are not suicidal or homicidal.

Commentary on Scenario #10

Some psychiatric problems respond well to medication and minimal supportive therapy. However, other cases almost always require trained intervention by a practitioner skilled in talk-therapy and various cognitive techniques. This patient likely has Post-Traumatic Stress Disorder (PTSD), and would benefit from talking to a skilled psychiatrist, psychologist, or counselor. Referral for such care is indicated. Medication may also be appropriate.