

Truehope Nutritional Support Ltd
Conference Call with Co-Founder David Hardy
September 5, 2007

Mr. Jared Hardy: Hello everyone and welcome to another Truehope Conference Call. Welcome, David Hardy.

Mr. David Hardy: Thank you.

Mr. Jared Hardy: Today we will be discussing the question “How safe is EMPowerplus?” A lot of people are interested in this question and we hope we will give you the answers today. So how would you answer that question?

Mr. David Hardy: Well to begin with I think a discussion of safety is discussion of relative risk because no food intake is completely safe. There is always the risk of allergy and allergic reaction and in the 35,000 people we have in our database at Truehope, we have had two people that I know of, that have had an allergic reaction to the grape seed extract. One of them knew that that was a problem; he knew that grape seed extract was in the product but he took it anyway and sure enough he had a reaction to the product and so he couldn't tolerate it. So that is always an issue and of course therefore a caution would be that if you have a reaction to the product that is showing some kind of allergic reaction, you need to stop it and not take it. Of course that would be true with anything, whether it be peanuts in your diet or whatever. Of course everyone knows that peanuts is a huge allergic problem that poses far more threat than anything encountered taking this supplement.

Mr. Jared Hardy: The people who have had allergic reactions, you would say, is a fraction of a percent.

Mr. David Hardy: Well, 2 out of 35,000, that's not a very high percentage.

Mr. Jared Hardy: Very small percentage.

Mr. David Hardy: The chances are probably better of getting struck with lightning.

Mr. Jared Hardy: Of course, EMPowerplus is not manufactured in peanut facilities or anything like that. It is completely free of those allergens for those who have those concerns. Good manufacturing practice keeps all the ingredients quarantined until they are tested thoroughly for those kinds of things.

Mr. David Hardy: Exactly. Of course there has been a lot of study, far more than most people are aware of. Far more than most doctors would be aware of in terms of the safety of all of the ingredients used in EMPowerplus. The Institute of Medicine and other groups around the world have said what is determined to be a safe upper limit and you, Jared, might tell our listeners what is meant by safe upper limit. What does that mean in science?

Mr. Jared Hardy: This is a less known fact, I guess. There are safe upper limits that have been set by the Institute of Medicine, Food and Nutrition Board in the United States. They are updated periodically and what that board tries to do is bring together all the science that has been published on each of the nutrients. These nutrients have been used for decades so there are a lot of scientific studies that have been done. Thousands and thousands of them. So they take all of these studies and look at any reports of adverse effects, any side effects. High levels, low levels, and they come up with not only recommended dietary allowances but also upper intake levels and that is defined as the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals.

Mr. David Hardy: So that means that you would expect to take the supplement then without any risk of seeing any kind of adverse event, even a minor one like slight headache, diarrhea, or anything.

Mr. Jared Hardy: Exactly. Nothing. Absolutely nothing. Now if you can market a drug for which you had a safe upper intake level, and until a person took that much, they would have no, absolutely no, adverse reactions, you would have something there.

Mr. David Hardy: No drug offers a no-side-effect range like that.

Mr. Jared Hardy: It's just a night and day difference between drugs and nutrients that way.

Mr. David Hardy: So the safe upper limit is certainly not the limit above which you would expect to have serious adverse events or die, it is just that you might have the potential at some level above the upper limit to begin to see a minor side effect.

Mr. Jared Hardy: Yes. They call it the tolerable upper intake level. They don't want to tolerate any side effects at all in these. But of course many of these nutrients have been used therapeutically and they are often used under care of a physician at levels much higher than the upper limit. Like any drug, after the upper intake level, which we sometimes call the upper limit, it just needs to be monitored carefully, like any drug, for possible side effects. They are very conservative in setting these limits so that in most cases it is just the most minor effect, the very first effect that shows up. It might be slight diarrhea.

Mr. David Hardy: In some cases they have even set this upper limit at a level, I understand, where there has been no indication of a side effect.

Mr. Jared Hardy: Sure.

Mr. David Hardy: Even at levels higher than that, people haven't seen adverse effects.

Mr. Jared Hardy: There are many, many examples of that. They are very, very conservative. The reason that they can say that this level that they have set, the upper intake level, is likely to pose no risk at adverse health effects is because they are very conservative in setting these limits. I've studied each of the nutrients in EMPowerplus extensively to know how they set the upper intake level for that nutrient. In many cases they will have a report in the scientific literature of -- let's choose one -- folic acid, there is some concern at 5000 mcg per day. There has been a report in the scientific literature and so they are very, very careful and very conservative. They have dropped that level down to one-fifth, so the upper intake level is 1000 mcg per day for folic acid.

Mr. David Hardy: So there is a safety factor of five times that before they ever saw an adverse event.

Mr. Jared Hardy: That is why they can say that it is likely to pose no risk. Again, if you had a drug in that category, you would have something very unique in the field of treatment.

Mr. David Hardy: Let me make some broad observations and then let's go into discussion as to the safe upper limit of each of the ingredients in EMPowerplus and just talk about that for a minute. First of all I would just like to pose the idea that because every ingredient in EMPowerplus has been used safely for 40-100 years, that means that these ingredients have all been used either included in our diet or as a food additive, like boron, that was used for years and years, decades, at levels far above what the safe upper limit is as a food additive. As a result, because it posed no known risks in that event, it is assumed by scientists to be extremely safe and it is my submission to this discussion that the use of all of these ingredients for a period of time of the minimum is 40 years and some in the excess of 100 years of use, is the best indicator of safety that you can possibly get. Some people challenge that. I know that I have been challenged on that statement, Oh, you need scientific investigation, you need a special study to study safety; and I just say, "Well, look. The drugs that are studied for safety, like Vioxx and some of the anti-depressants and the atypical antipsychotics, when they were put on the market, they were deemed to be safe with known risks only. But obviously that is not true because within a few years of use, Vioxx was shown to kill numerous people because the side effects were unknown. That is true of the antidepressants where the known risks of increasing the risk of suicide for instance, were not reported or were not known until it became into common use. The use of these products for 40-100 years safely without reported events, is in, my view, better than any small study that could be done however carefully conducted scientifically that there is safety in these elements.

Mr. Jared Hardy: The double blind studies are just a few weeks. There is no way that they can test for long-term safety that way in humans.

Mr. David Hardy: Right. So the relative risk then of taking EMPowerplus is so significantly different than even the most minor medication. Even over-the-counter medications like Aspirin, for instance, or Tylenol. The relative risk of taking those products is much, much greater in terms of

having an adverse event because they still cause death and they still cause liver compromise. Those kinds of problems taken within the safe upper limit or even above, with nutrients has not been noted. We get a situation where the negative events of taking natural health products for instance in a period of their entire use, over the years, is less than the negative events, for instance, of taking eating peanuts in a single year. It puts it into perspective and you could see the relative risk is just minuscule here, and it is well proven. It is not that this is unstudied stuff, it is well proven. For instance, recently, John Hopkins University evidence based practice center in Baltimore Maryland was asked to prepare for the agency for healthcare research and quality US Department of Health and Human Services, a study of articles, these are double blind studies, I understand, done on nutrients; and they have found over 10,000 articles in references and pared that down to what was relevant to them. But the conclusion that they came to on safety was that “consumption of multivitamin supplements for prolonged periods (1 to 8 years) appears to be safe. We found no reports of major, life-threatening adverse effects, and no evidence of increased mortality in groups consuming multivitamin supplements.” That is a pretty sweeping statement but very significant after having looked at the results of 10,000 studies. “A similar general conclusion”, they said, “can be reached for single nutrient supplements.”

Mr. Jared Hardy: And you can be assured that in a large study like that, prepared for a government agency, they are also very conservative in the way that they say things. So when they say “no reports”, that means they have researched it all and there are no reports.

Mr. David Hardy: Because of this low level risk factor, you can see why various groups like the Fraser Institute has suggested that it is hardly worth the money or the time to regulate natural health products because the relative risk of taking these products is much lower than even taking Tylenol or Aspirin. It, in some ways, doesn't make sense spending a lot of money to go to the bother of regulating extensively these products.

Mr. Jared Hardy: It would make more sense to put that money towards regulating Aspirin, say, or peanuts.

Mr. David Hardy: Exactly.

Mr. Jared Hardy: As far as life costs go.

Mr. David Hardy: Let's turn now to the discussion of the safe upper limits in the ingredients of EMPowerplus. Of the 36 ingredients, practically all of them, but not all, are within the safe upper limit. Now is that a concern?

Mr. Jared Hardy: That is a very good question. And we want to be clear and upfront about this issue. We've talked about how the upper limits are established and hopefully that gives you some idea. We will go through 4 nutrients that are above the upper limit set by the Institute of Medicine and give you the reasons why EMPowerplus exceeds those levels.

Mr. David Hardy: This is, you are talking about, at a loading dose (15 capsules per day), because at the label levels (7-8 capsules per day), only two of them, I think, are above the upper limits. Is that correct?

Mr. Jared Hardy: That is correct. This is 15 capsules per day.

Mr. David Hardy: One of them is niacin. So tell me about niacin.

Mr. Jared Hardy: Like, as usual I guess, the Institute of Medicine chooses the earliest thing that pops up as people take more and more of a nutrient, they choose the first effect whether it be just a headache, or in this case it's called skin flushing. That is a tingling or itching, reddening of the skin on the face, arms or chest.

Mr. David Hardy: Like blushing.

Mr. Jared Hardy: Like blushing, yeah. That is what people reported. That is about how bothersome it is. It feels about like that.

Mr. David Hardy: In 35,000 people in our database, there really haven't been any reports of flushing with niacin, but yet it is above the level where they say that might occur. Is there anything that is mitigating that?

Mr. Jared Hardy: Yes there is. It is important to understand these nutrients have different forms.

There are lots of different kinds of chemicals and when you take chemistry you understand you can change just a tiny little bit in the chemical, and it changes the properties of that chemical a lot. You add a little thing here or there, that is the case of niacin. There is a form of niacin called nicotinic acid and it has been used a lot therapeutically to treat people and that is the form of niacin that has ever been reported. The only form of niacin ever reported to show a flush at levels greater than 50 mg per day, it is the lowest ever reported level. EMPowerplus contained 90 mg but in a different form, this is niacinamide and it has never been reported, according to the Institute of Medicine that niacinamide has been associated with flushing effects. So, they set the upper limit according to nicotinic acid, just to be safe.

Mr. David Hardy: Which we don't use.

Mr. Jared Hardy: In EMPowerplus, it's a non-issue.

Mr. David Hardy: So that becomes a non-issue . Another one is magnesium and we are above the safe upper limit of magnesium.

Mr. Jared Hardy: Yes. There are a few issues here, and I will get you to speak to some of it. The Institute of Medicine states this: "A few studies have noted mild diarrhea and other mild gastrointestinal complaints in a small percentage of patients at levels of 360-380 mg/day of magnesium. That is magnesium by itself. I will get you to talk to that issue in a second. They say: "However, it is noteworthy that many other individuals have not encountered such effects, even when receiving substantially more than this UL of supplementary magnesium." I might add, these reports are substantially more than the levels of 15 capsules of EMPowerplus -- so grams of magnesium. There is an issue of balance here. That is what I would like you to speak to.

Mr. David Hardy: Absolutely. It is an important issue and it is an issue that has been talked about by people who have studied these ingredients over many years; particularly the US Department of Agriculture who have noted that, when these elements are in balance with one another, the likelihood of any toxic reaction is greatly lessened. So when you put magnesium in balance with calcium, which is a known balance, and the standard balance is a 2:1 level or even up to a 1:1

level of magnesium to calcium, and it seems like when those two ingredients are in balance, and they also have to balance with phosphorus of course, that those adverse events just don't occur. magnesium taken all by itself is much more likely to create the adverse event that they would use in establishing an upper limit than something in EMPowerplus where these elements are balanced. That is true of other things as well. For instance, zinc and copper, which would be our next discussion. We can exceed at the loading dose the level of zinc but the reason that they set that, of course, once again, is because too much zinc can have the effect of creating what appears to be a copper deficiency when it is not in the proper balance with copper and when you put those two elements in balance, once again, you don't see a problem even at much, much higher levels. So the issue is that the balance of the supplement is extremely important and it is an extremely important issue in terms of possible reactions and side effects as well because you just don't see those side effects. Another interesting thing is that taking a relatively high level of certain nutrients that are in balance can actually bring a potential imbalance in your diet into balance. For instance, if you are taking too much, well let's go back to the area of copper. Let's say you are taking too much copper and you really do have too much copper in your diet and it is creating a problem, that has been identified for instance in certain cases of Schizophrenia, that there seems to be too much copper in the diet. But when we provide and come in and provide more copper, you would think that would create a toxic issue, but it doesn't because we have a balancing level of zinc and when you combine those two, and add a abundance of copper but probably a deficiency of zinc in the diet, it actually brings your total diet into what the body can tolerate and makes it so that the toxic issue that you were experiencing with copper is no longer there. We have seen that definitely in terms of copper and we have seen that in terms of things like iron, where you can, some people are sensitive to high levels of iron can tolerate our supplement because the balance of the other elements in conjunction with the iron actually make it so that iron imbalance and negative affects is not present.

Mr. Jared Hardy: You are talking about hemochromatosis.

Mr. David Hardy: Exactly.

Mr. Jared Hardy: So certain people who use EMPowerplus become less sensitive to iron as a result.

Mr. David Hardy: Exactly. It appears that the balance of the ingredients makes them less sensitive to the abundance of iron or over abundance of iron.

Mr. Jared Hardy: That's wonderful. So, we've talked about niacin. We've talked about magnesium a little bit. We've acknowledged the risk there of mild diarrhea, but it is a lot less likely to occur because of the balance of nutrients. You've mentioned zinc. It is interesting to note that the Institute of Medicine, looking through the literature, found no reports of adverse effects from zinc until 60 mg/day and there is less than that in EMPowerplus. So just going by that alone, zinc is fairly safe, but the balance issue is the real issue at hand and EMPowerplus has plenty of copper, so it is not an issue. The final one would be folic acid. Could you talk about that a little bit?

Mr. David Hardy: Well, folic acid of course is an element that can mask a vitamin B12 deficiency. And once again you have to have vitamin B12 and folic acid in a particular balance, and we have that ideal balance. According to the literature we have an absolute ideal balance. We have a very high level of vitamin B12 but we also have a reasonably decent level of folic acid. Of course, folic acid has so many positive benefits that that is one element that is likely to be deficient because it is so readily cooked out of foods and so supplementing is really the only effective way to get a decent amount of folic acid. But when you combine those two, of course it is not an issue and the safe upper limit of folic acid was set because it has a potential to mask a vitamin B12 deficiency, and obviously with EMPowerplus it is not an issue because we have plenty of vitamin B12 there would not be a B12 deficiency, nor could there be because both elements are present and in balance.

Mr. Jared Hardy: So if a person had a B12 deficiency before, they won't anymore.

Mr. David Hardy: It is not an issue. You can see why, in these cases, that when being review by ethics committees, they don't have a concern because there is no evidence in science that any of

these levels, even where they appear to be above the safe upper limit, would be of any concern whatsoever.

Mr. Jared Hardy: So you are talking about how studies could proceed on EMPowerplus. They go through an ethics board to review how safe they are.

Mr. David Hardy: That is right. All these safety issues are reviewed and EMPowerplus has probably been reviewed more as a particular supplement than any other supplement that is on the market by ethics committees for potential studies. Other concerns that often come up are, the heavy metals that people ask us why do we have nickel in our product? Well we have nickel which is normally considered a heavy metal. And chromium. Why do we have chromium? Well, the fact is that these heavy metals are essential elements and up to a certain level they are absolutely essential and we have those within safe upper limits where they pose positive benefits not negative benefits. All of these things have been well assessed. Our users, customers using EMPowerplus, can be very confident that indeed safety is an issue that has been addressed in EMPowerplus in every element, and like I say, these elements have all been used for 40-100 years at these levels or higher, without known risks.

Mr. Jared Hardy: Of course, nickel has an upper limit established by the Institute of Medicine and we are well within that.

Mr. David Hardy: Any of these elements can be overdone. Certainly, you know, zinc and selenium, these elements can become toxic if taken. Chromium, for instance, taken as chromium dioxide can be quite toxic but of course chromium dioxide isn't used in our supplement. There are other forms. The same can be said of germanium. Germanium dioxide has been shown to have some toxic effects, but we have proven that germanium sesquioxide, the organic form of germanium taken even at hundreds of times the level that is in EMPowerplus is safe with no reported adverse effects. Only positive really, because it shows powerful benefit in cancer and other kinds of things. So there are great benefits to these. The last thing that I would really like to bring up is the Institute of Medicine little chart that I have before me, that shows the risk of not

supplementing. I mean, often we think that we may be at risk if we take something, but what about the risk of not taking it. In this case, the case of EMPowerplus, the scientific evidence is overwhelming that if you don't supplement, you are actually at greater risk because the only safe level of taking these ingredients is an adequate level. If you are taking an inadequate level, Bruce Ames from the University of Berkeley, has shown that you actually can induce mutations and that 50% of the population is deficient enough that that is happening. They are actually inducing mutations in their enzyme systems in their body. That is not safe. Also it has been found that things like thiamine, where studies have been done, actually a deficiency kills brain cells. These are deficiencies that occur when you are only taking half of the RDA, which again, Ames has pointed out that 50% of the population are deficient enough in some of these elements to do that. So that is scary. The safe level is the adequate level. So taking EMPowerplus you can definitely argue is much safer than not taking it because taking the supplement puts you in the adequate level of intake.

Mr. Jared Hardy: Fills in the holes.

Mr. David Hardy: And fills in the gaps so you are not experiencing inadequate intake, nor are you experiencing excessive intake so you are now within the observed level of intake that is not causing any problems. So just denying someone a supplement isn't protecting them from harm in this case; because these nutrients are essential to the body and every function in it. Inadequate levels are dangerous and pose dangers that we are only now beginning to recognize and prove in science.

Mr. Jared Hardy: That is so crucial to understand. Another interesting thing I think that most people don't understand is the RDA. Which they call the "daily amount" on a label.

Mr. David Hardy: The Recommended Daily Allowance.

Mr. Jared Hardy: That gives you enough if you are one of the lucky ones to be in 97.5% of the population. They have set that actually as an estimated level that is adequate for 97.5% of the population. What about the other 2.5%? Even if they were shooting for that RDA, and hitting it

every day, they could still be inadequate in all these nutrients. In any one of these nutrients.

Mr. David Hardy: The RDA, too, is only the level that is effective in mitigating deficiency disorders that we are really familiar with. Certainly not optimizing performance in the body and I think the new research that is being done with EMPowerplus showing really jaw dropping experiences that these researchers and doctors are seeing in their patients using the EMPowerplus, is indicative that nutrition has a lot more value than we ever thought. Especially when it is put in a highly bioavailable form like EMPowerplus is, and where it is certainly in a form that is broad spectrum and covering all the potential deficiencies that someone might be experiencing.

Mr. Jared Hardy: Very good points. Do you think it is plausible to say that in reexamining the RDAs in the future, a group like the Institute of Medicine, might look at studies with EMPowerplus say and determine that the adequate amounts for people need to be higher because the new research is showing that if people don't have these amounts they can have serious illnesses.

Mr. David Hardy: And serious risk. There is no question. I think that that is a common feeling amongst a lot of scientists that the RDA really is not adequate and we need to move more towards the areas that we have moved to with animals, showing that higher levels are indeed incredibly beneficial.

Mr. Jared Hardy: And each person kind of needs to find their optimum level. Do the experiment themselves, you might say.

Mr. David Hardy: Exactly.

Mr. Jared Hardy: We know the safe boundaries. The safety is in getting out of the unsafe area of inadequacy for each person. Each person needs to kind of do the experiment of where their optimum level is at.

Mr. David Hardy: Exactly. When you recognize that these elements, too, are controlling so many functions in the body like growth of the nerve endings in your nerves to make them effective and

development, fetal development, and all of these things, the effective of these things in growth factors in the body all shows that this is powerfully beneficial. For instance we have proven in the animals that the use of EMPowerplus can actually grow endings on the end of a nerve and make an animal more functional because it is developing its neurons closer to the genetic potential. It is really significant and I'm sure that that is a factor in humans as well. That we are setting out to prove in the research that is being undertaken.

Mr. Jared Hardy: There is sometimes talk about risks of taking nutrients during pregnancy, during a baby's development. What would you say about that?

Mr. David Hardy: Well, there is never a time when you need more elements and more nutrients than you do when you are taking those nutrients from your body and giving them to a baby. So in animals of course, the animal industry where I have been involved in for 20 years, that was so evident. That is the time where you really needed to supplement heavily because the animals require it. It makes so much sense that EMPowerplus and supplements like that, can have so much powerful beneficial effect in pregnancy. You are not protecting a woman by having her not supplement something when she is in such dire need of it and the literature is so clear on that now. It is ludicrous to say, Don't take this because it may pose some remote or some unknown risk. When really the biggest risk is in not taking it.

Mr. Jared Hardy: How does EMPowerplus rate, how does it do for upper limit of pregnancy and lactation?

Mr. David Hardy: Taking EMPowerplus would be a very good supplement for pregnancy. I mean, it is certainly supplying all of the ingredients and, you might know Jared, you want to comment on your own question?

Mr. Jared Hardy: It turns out it is exactly the same as what we have discussed. Virtually the only risk is mild diarrhea from magnesium. The others have virtually no risk. That is for pregnancy and for lactation.

Mr. David Hardy: And the likelihood of that, once again, posing a problem when it is in balance

with the other elements is very, very slim.

Mr. Jared Hardy: It's just something to monitor, like you would monitor side effects of any medication. But it is a very, very minor thing. And very obvious thing to monitor.

Mr. David Hardy: Well I think we discussed a lot of what we need to discuss in relation to the safety, and once again, just in conclusion, the relative risk of taking EMPowerplus is certainly less risky than eating peanuts or taking Tylenol or Aspirin, and that puts it into perspective. That kind of says it all. So we hope that our discussion has given our listeners an idea of the fact that taking this supplement is extremely safe and in fact you are really increasing your safety by taking it because you are preventing the deficiencies that have been shown to be present by recent scientific research.

Mr. Jared Hardy: Thank you so much for the discussion today -- for the call. And thanks to our listeners. Once again, you can contact us at feedback@truehope.com or call us at 1-888-TRUEHOPE. There will be an audio archive of this conference call online and a written transcript as well available on mytruehope.net. We welcome your questions and comments and we'd love to have you listen in next time.