

**TRANSCRIPT OF:**  
**EPHEDRA EDUCATION COUNCIL TELECONFERENCE**

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MR. AKER: Good afternoon, and welcome to the media briefing sponsored by the Ephedra Education Council. This is Colburn Aker, PR Counsel for the group. The Ephedra Education Council is an educational organization sponsored primarily by the Ephedra Committee of the American Herbal Products Association, which represents Ephedra manufacturers.

The purpose of today's call is to review the facts surrounding the untimely death of Baltimore pitcher Steve Bechler, and to address the unsubstantiated reports that he may have been consuming a dietary supplement containing Ephedra.

Today the Ephedra Education Council, within the past hour or so, issued a statement in this matter. It was distributed by a U.S. news wire, but we can fax it or email it to participants in today's call, if you wish to call one of the following two numbers. The local calls in Washington, D.C. area is (202) 789-1447, 789-1447. If you're long distance you may call this toll-free number, (877) 846-6324, (877) 846-6324. Both of those numbers reach the Ephedra Education Council for a copy of our statement. Later today, it will be posted on our web site, which also can be a valuable source for background information on Ephedra. The address of that web site is [www.ephedrafacts.com](http://www.ephedrafacts.com), [www.e-p-h-e-d-r-a-facts.com](http://www.e-p-h-e-d-r-a-facts.com).

On today's call are three experts on the subject of the science and policies surrounding Ephedra. The gentleman who just spoke is Dr. Carlton Colker, first name spelled C-a-r-l-o-n, Colker, C-o-l-k-e-r. He is an MD, CEO, and medical director of Peak Wellness, Inc., Peak, P-e-a-k Wellness, Inc. He's also an expert on weight loss research and sports nutrition, and Ephedra. Also joining us today is Dr. Richard Kreider, Richard spelled in the normal manner, Kreider is K-r-e-i-d-e-r. He is a Ph.D., professor, and chair of Exercise and Sports Nutrition Laboratory in Baylor University, also an expert on sports nutrition and research. And finally on the panel today is Wes Siegner, first name Wes, W-e-s, last name Siegner, S-i-e-g-n-e-r, who serves as general council and a spokesperson for the Ephedra Education Council.

We will, of course, take questions after opening comments by each of our participants. And now that you know who we are, we hope that you will tell us who you are prior to asking the questions, please state your name and the media outlet that you represent. We will ask that you state that and let others ask questions. We aren't operating with any sort of cuing system today, so we'll try to give everybody the opportunity to ask their question, and then return for additional questions, if you wish. We're prepared to stay on as long as necessary to answer all your questions.

At this point I would like to thank you for your participation in the call. The next voice you will hear will be that of Wes Siegner, who will serve as moderator for today's news briefing.

Wes?

MR. SIEGNER: Thank you, Colburn.

Good afternoon. Our purpose today is to bring some balance to the coverage of this story, by focusing on the facts and not the speculation. As Colburn pointed out the EEC exists to assure consumer access to safe products that help consumers lose weight. The clinical data, the gold standard for assessing safety supports the safety of these products for weight loss. On the call today, as Mr. Aker pointed out, we have experts in science and medicine who can address the latest scientific data on the safety and benefits of Ephedra. The EEC represents manufacturers, but we also speak for our customers who number in the millions, and who do not have a voice in this debate. Recent coverage has unnecessarily alarmed, confused, and scared them from using a product that is benefiting many of them today. Getting the science right, and reported correctly is personally important to American consumers. Most need all the information they can get to lose weight, and improve their health, diet and exercise is not successful as a solo practice for most of these people. It is, we all agree, the best way to lose weight, but lots of these Americans can't do it by diet and exercise alone. With nearly two of every three Americans overweight, our nation is facing an epidemic that's estimated to cost us about \$100 billion a year in increased medical costs.

In short, misinformation in the media can have serious consequences to America's health crisis. The speculation such as we've seen in this case is the worst reason to reach judgments about any product including Ephedra. So is the failure by the media to inform the public of the risks versus benefits of any product, taking aspirin, as an example, more than 16,000 deaths a year occur from its use, mostly through consumer misuse or abuse. But, no one proposes banning aspirin from the lockers of athletes. It would be wrong to deny its use or Ephedra's use to millions who have used it for years, and have used it safely and responsibly.

So let's review the facts of this case. We can all agree that this is a tragedy to the family, that's not an issue here. What we're trying to do is focus on whether this has any implications for Ephedra. At this point we have no solid evidence that Steve Bechler actually consumed Ephedra. We need to wait for the tox tests to establish that fact. We have evidence that if he did take Ephedra that it might have contributed to his death. Several other risk factors apparently existed that could have contributed. The bottom line is, we don't know, and nobody knows exactly what caused the death. The facts need to come out, and what the medical examiner is saying at this point is basically a preliminary and personal opinion, not an opinion based on the facts.

I'll leave it to Dr. Colker and to Dr. Kreider to discuss what we know are the inconsistencies and the known science, and to explain why in their views this death, based on what they know about Ephedra, could not be related to Ephedra. Also, we know that there are other parties involved in this case, and I think we need to be understanding and aware that other parties may have their own reasons for wanting to blame Ephedra, to avoid the implications that they might have had some play in this issue. All of the scientific research, in terms of the clinical data today, supports the safety of Ephedra. We issued a press release and findings of scientific clinical studies back in September. There are over 55 clinical studies supporting the safety, and the benefits of Ephedra products, and not a single serious adverse event was reported

in any of those studies, even though thousands of study subjects, people used Ephedra in those studies.

Ephedra is popular because it works, and because people need help losing weight. Health policy should be based on the science, and the presumption that educated consumers will act responsibly in matters involving their own health. They have the right to make their own choices, and to consume products that are proven safe by science, and to decide based on the science, and the experts, what products they should be taking. The rushing to the judgment about Ephedra is bad public policy, and does more harm than good to consumers, and the American public.

The last thing I would like to say is that we are weeks away from knowing a lot more about the science in a very objective way than we are right now. There has been a lot of controversy surrounding this product. We all know that. What is really needed is a comprehensive objective -- sorry, somebody's got a radio on? Thank you. We're waiting for the Rand Report, which is an HHS-NIH study that will give us an objective look at the state of the science behind Ephedra at this moment, and also provide direction for future research to get us to the finish line and answer the remaining questions. And with that, I'd like to open it up to Colburn, would you like Dr. Colker or Dr. Kreider to make statements?

MR. AKER: Yes, if they are able to do so, and want to do so, we welcome them. Just, I think we want to make it as short as possible, so we can get to questions.

MR. SIEGNER: Okay. Dr. Colker.

DR. COLKER: Hello, everybody, and thanks for joining us, and basically what I'll say is I think, just to encapsulate some of the things that Wes Siegner said, I really speak from the scientific and research standpoint, and not so much on behalf of manufacturers. But, I'll say that certainly the science and the research is supportive of the fact that Ephedra consumption is safe and effective when taken as directed, and by individuals appropriate to do so. I think that's the important thing to keep in mind, that that's where the science directs us. And so when we focus on the facts and not the fears, as Mr. Siegner said in so many words, then certainly we take our lead from the government, and from Tommy Thompson. And so far it's been that Ephedra, and Ephedra-based products should be in the hands of the responsible Americans, and that's where they remain. Certainly, that is consistent with the science, and the research certainly doesn't point to incidents of horrible, fatal tragedies. They haven't been seen in research. And certainly, if you look at the adverse event reports, I will only say that, we know that they are non-scientific, but if you look at the relative paucity of adverse event reports relative to the very, very large number of individuals that have taken Ephedra, literally billions of doses have been given, that is really only supportive of the things that we've seen in the research, and only reflective of, again, the safety and efficacy relative to individuals that take the products as directed, assuming that they're individuals that are appropriate to do so.

I'll end with that statement.

MR. SIEGNER: Dr. Kreider?

DR. KREIDER: Yes, this is Dr. Rick Kreider, I'm the director of the Exercise, Sport, and Nutrition Lab, Center for Nutrition, Exercise, Preventive Health Research at Baylor University. I'm also president of the American Society of Exercise Physiologists. I've worked with athletes for about 20 years in strength conditioning, nutrition, so I have experience with both the scientific, as well as applied, practical viewpoints. Before I begin my opening comments, I'd like to say that I have no affiliation whatsoever with any supplement companies, or the Ephedra Council. I'm viewed as an honest, and clear opinion about the science of nutritional supplements, at least from people who take supplements and the industry. If you look at the research, as has been mentioned, the studies show that Ephedra, when taken appropriately, is safe, and is effective in promoting weight loss. We know -- we well know the signs and affects of excessive exercise in the heat, and how that can impact heatstroke. In my view, too much attention has been placed on the potential role of Ephedra in this case, rather than the clear and obvious factors associated with the tragic death of Mr. Bechler. Media reports have indicated that Bechler came to camp overweight, he was distraught about being overweight. A manager of the Orioles, and other officials, talked to him about this the day before he collapsed. He was unable to participate in about 60 percent of the conditioning drills. It was hot, humid, he hadn't been eating for a couple of days. And he had a history, evidently, in high school of having heat stroke, or heat illness.

You have to evaluate the proper training of the athlete, evaluating the fitness of the athlete before they got to camp, and monitoring and intervening when he showed signs of dizziness and fatigue that this unfortunate incident could have been prevented. There's no evidence that Ephedra is related to this from a physiological and from pharmacological impact, the impact of Ephedra on temperature is minimal, and therefore it could not have been a primary factor, in my view, in this instance.

Lastly I'll tell you that it's my view that comments about nutritional supplements and exercise should be based on science, not on anecdote.

Thank you.

MR. SIEGNER: Okay. I guess we're ready to field any questions that people have. If you could just state your name and then address the question to whomever you'd like to have it answered by.

CALLER: Wes.

MR. SIEGNER: Sure.

CALLER: Yes, this is John Morgan from the Baltimore Sun. You and your speakers have stressed the importance of taking the medication as directed. What is your position on the notion that it be restricted to prescriptions where medical advisors could presumably go through the requirements and the risks, and needs to be careful about the directions. Is that something you would oppose or support?

MR. SIEGNER: Well, let me be clear that we're not trying to cut doctors out of medical decisions. But, weight loss decisions are decisions that we think are appropriately handled by consumers. Obviously, the public health decision of whether something is prescription or over-the-counter relates to a public health decision about the safety of products, and Dr. Colker and Dr. Kreider can speak to this more as experts. But the clinical data, as we've been told by experts, supports use over-the-counter. That means that the consumer is able to say, look, I need to lose some weight, I can read the label and determine if this product is appropriate for me. And, therefore, I have a safe and beneficial product that is not going to incur the huge costs that can be associated with a medical examination and prescription product.

The short answer is, we are not in favor of prescription status because we don't think the science supports that.

CALLER: Thank you.

MR. SIEGNER: No problem.

CALLER: I have a question for Wes. This is Suffolk County Legislator John Cooper. Wes, as you know, I was the author of the legislation that banned the sale of all dietary supplements containing Ephedra in Suffolk County. And I had a couple of questions for you. How do you respond to the data that came out of the American Association of Poison Control Centers database, their 2001 Annual Report, that showed that products containing Ephedra counted for 64 percent of all adverse reactions to herbs in the U.S., although those products represented only .82 percent of the herbal products sold in the U.S.?

MR. SIEGNER: It's an interesting study. The best thing to do when you get a study like that is to talk to people who are really experts in poison control and collection of such data, which the authors of this study, I think, would admit they aren't. As a matter of fact, the authors have all disclosed that they're working for plaintiffs' attorneys in various lawsuits against the industry. But, as I understand from the experts, and there's several letters to the editor to this effect already, this is a study that doesn't say what the authors' say it says. You know, you could treat the data basically as you want, and make the case that Ephedra is the safest of the herbs. But the bottom line is, the poison control experts will make it clear in subsequent letters that they mishandled the data, and that you can't make conclusions about relative risk based on data like this.

CALLER: Thank you. And another point that was made by one of the speakers, I'm not sure who, was that a claim that there had never been a single serious adverse event related to ingestion of Ephedra supplements, and over the past six months in Suffolk County, we've heard much testimony from medical professionals to the contrary.

MR. SIEGNER: I would say, that was me and I was talking about the clinical data. In the clinical studies, if you take the world clinical studies relating to Ephedrine or Ephedra, and again clinical studies are the gold standard in determining safety because you have a group of people taking the active product versus a group taking a placebo, and therefore you can compare the rates of adverse events. In those types of studies, there has never been a single report of a

serious adverse event.

CALLER: May I ask a question please? This is --

DR. KREIDER: Can I interject one point to Mr. Cooper. You mentioned the poison study.

MR. SIEGNER: Could you identify yourself, please?

DR. KREIDER: This is Dr. Kreider.

MR. SIEGNER: Thank you, doctor.

DR. KREIDER: Sorry. I was a co-author to a letter that just went to respond to that analysis of the poison data. There are significant statistical concerns and interpretation concerns regarding that study. In my view, it was a poorly done study, and it's not good science. For example, they indicated that only .82 percent of all herbs sold are actually Ephedra when, if you look at Nutrition Business Journal data, it clearly shows that it's a much higher percentage of that. In addition, when you compare the number of supposed adverse events of Ephedra, they actually were a lower percentage than several other herbs. So I think that the conclusions were unfortunate and not a proper evaluation of the data.

DR. COLKER: This is Dr. Colker, I'll support that also saying that I would really even not call that a study per se as much as I would call it a paper that analyzed existing data, again relating back to what Mr. Siegner said, it's quite clear in the scientific, in the medical research community that we rely on true clinical studies in which we take a product and dispense it to subjects in perhaps a double blind placebo controlled, and we prospectively look at the results from there. And this was not that type of study. This was a retrospective data analysis, if you will, and certainly not a clinical study.

MR. SIEGNER: It's also true that if you look at aspirin in this context and did an analysis of the aspirin data, you would assume that aspirin is probably the most dangerous thing that ever existed, and it would be banned immediately.

CALLER: If I might add -- this is John Cooper again -- the problem is that because of DSHEA, and I think that the problem really tracks back to DSHEA ultimately, because the dietary supplement such as Ephedra did not require any premarket safety testing, and of equal concern, because adverse events do not need to be reported to FDA, unlike with pharmaceuticals, we really don't have an idea of just how serious this problem is. I know two of my constituents, at least two of my constituents, that died after they ingested Ephedra supplements. But I've spoken to many other clinical experts across the country over the past six months that have told me their stories. But the problem is, no one really knows for sure. Everyone is aware of Metabolife International, and claims made by the president of that company to FDA that they had never received a serious adverse event report, but now it turns out that they had over 13,000 adverse events in their files that they had just never turned over. We really don't have an idea of just how serious this problem is. I know two of my constituents, at

least two of my constituents, that died after they ingested Ephedra supplements. I've spoken to many other experts across the country over the last six months that have told me their stories. But, the problem is that no one really knows for sure. Everyone is aware of Metabolife International, and claims made by the president of that company to the FDA that they had never received a serious adverse event report, now it turns out that they had over 13,000 adverse events in their files that they had just never turned over.

MR. SIEGNER: Do you have a question?

CALLER: Yes, so don't you believe that the ultimate problem really tracks back to DSHEA, and if we modified that law and required free market safety testing --

MR. SIEGNER: Let me answer that, and let me also thank you for coming on. But, we're trying to get questions from the press. The answer to that is, and we've been involved with supplement regulation for decades. DSHEA wasn't as dramatic a shift in law as people are claiming it is in the press right now. The fact was, DSHEA was necessary, because FDA was using an authority to keep supplements off the market that Congress had told the FDA repeatedly was not appropriate. And then the courts came out and ruled against FDA in several important cases, and used words about FDA's legal theories, such as Alice in Wonderland thinking. So in 1994 essentially Congress said, okay, let's make it very clear in a new law that FDA can't act this way. I'll agree with you that we need to do more enforcement with respect to supplements, and my view as a legal expert is authority exists, we need to get the resources to FDA. We have to have good quality products. We have to have labels and advertising that are meaningful. Nobody disagrees with that. It's a matter of enforcement. The authority is there, we can get there.

Thank you, again, John.

Do we have any questions from the press?

CALLER: Yes, this is Michael O'Keefe with the New York Daily News. Dr. Colker, you mentioned earlier that you want to take your lead from Tommy Thompson and from the science, and I just wanted to point out that Thompson was widely quoted yesterday -- in today's papers, actually, as saying, I wouldn't -- he told reporters, I wouldn't take Ephedra, would you? I think that was a direct quote. My question is, if Wes or anyone else wants to address this, do you worry that Bechler's death, regardless of where fault ultimately lies, is going to damage political support for the Ephedra industry, and for the supplement industry. My other question is, you made reference to 55 studies that you say are the gold standard and that have found that Ephedra is safe and effective. The San Diego Union Tribune on February 9th did a very interesting story where they address that, and they said that many of those studies were flawed, that research that was contrary to what researchers wanted to hear, what they wanted to find, was then discarded, or ignored. How much of this research can we really believe is accurate, and we can hold as a gold standard?

DR. COLKER: O'Keefe, being a local boy, I'll tell you I love your work, so I know the stuff that you do. But, I'll respond by first saying, I'm not a politician, so I won't respond in that



regard.

CALLER: Sorry, just let me make sure I understand who's talking.

DR. COLKER: This is Dr. Colker here.

CALLER: Thank you, Doctor.

DR. COLKER: But, I will say this, I really think that Tommy Thompson certainly -- he's the person that would be required to answer and qualify his statement. But, I think his actions speak for themselves, in the fact that he has been very prudent, and very patient in wanting to take very guarded steps, by not jumping to any premature conclusions or inaccurate conclusions. His desire to want to rely on the science and a careful analysis of the existing science I think should be commended. The very fact that the Rand Corporation was commissioned to do this overview, and careful look into each and every study that exists, and a compilation of that opinion into one position, I think should be commended, and we really look forward to the results of the Rand findings. And I think that's what really needs to be focused on, really his actions, and not perhaps a statement that he might have made, because someone does not want to take Ephedra, or wouldn't take Ephedra at a particular moment in time, I don't think that indicates -- it certainly doesn't indicate that he is against Ephedra. I think his actions speak for themselves.

And in response to the second part of your question, with regard to the case of the baseball player, this very, very unfortunate incident, which sort of reminds me, in a way, of the Cory Stringer incident, in which a professional athlete was -- that was, in this case, certainly overweight, possibly obese, and from what I understand may have had some other complicating issues, why he was allowed to push himself so far, I really don't have an answer. Perhaps there are other people that can answer to that. But, certainly, whether he was an individual that was taking the product at all, and whether it was involved in his -- whether it shows up in a toxicology or not is still premature to even say that. But even if it were to, I would have trouble accepting, as a physician, and as a scientist, that Ephedra played a role. From what I understand his core temperature was 108 degrees, which is enormously high. I mean, clearly this is a case of heat stroke, and there have been, and I think Dr. Kreider referred to it, or at least alluded to the studies on exercise, the Ball studies, and the studies in Canada, in which athletes have been pushed to incredible extremes, and certainly did not drop of heat stroke. And I think this is that coupled with the mass of studies out there, and scientific studies that we have out there to indicate that clearly taking Ephedra, Ephedra-based products as directed, and certainly by individuals appropriate to do so, following labels, guidelines, responsible label guidelines, does not lead to heat stroke.

I'll finish with that.

CALLER: Can I ask a question.

MR. SIEGNER: Certainly.

CALLER: I felt like someone else wanted to address my question before we move on?

CALLER: That's my question, as well, when we get back to the 55 studies question?

CALLER: Yes, please.

DR. KREIDER: This is Dr. Kreider. In science the best way we can make a decision, whether it's medicine or science, is based on clinical research studies, they provide information on safety, efficacy, not based on opinion, but based on statistical outcomes. When you get a series of studies showing similar results, in this case about 55 showing no significant adverse effect, and in most cases showing efficacy and weight loss, there's a preponderance of evidence, on the scientific standard of peer review that indicates that the evidence is showing some safety and efficacy. On other hand, we have anecdote that we can't substantiate. We don't know how much the media spin has impacted on people's perceptions that there may or may not be a problem. We have no way of documenting or evaluating the accuracy of the anecdote. And so what's happening is you're having some studies coming out evaluating the anecdotal evidence, versus the peer reviewed, clinical, double-blind, placebo controlled studies. In my view, scientifically you always base your opinion on the science, not on speculation.

MR. SIEGNER: This is Wes Siegner, in specific response to the San Diego article, you know, what's being reported there is basically some speculation that's been raised in some lawsuits. There are allegations being made in those cases that are perfectly understandable. If you accept them as true, and if you throw out three or five of the studies you still, as Dr. Kreider pointed out, have a consistency in these studies which is fairly amazing. And it's hard to -- I mean, you can't explain it other than to say that, well, this is what we know about the product. Are we saying that you can't do more research? No, you can always do more research. And I expect that when the Rand report comes out that's what they'll recommend, is some additional studies to kind of hone in on the questions that remain.

CALLER: Dr. Kreider, I was wondering if you could respond to those theories that Ephedra might have contributed to the deaths by driving up metabolic rates, heart rates, constricting blood vessels, and inhibiting cooling by sweat?

DR. KREIDER: The primary mechanism of Ephedra in what's called thermogenic supplements, is really somewhat of a misnomer. The results of studies show that generally if you take a recommended dose, up to 30 milligrams or so per dose of Ephedra containing supplement, that generally your total caloric expenditure increases from 2 to 10 calories per hour. Exercise increases caloric expenditure, depending on the intensity, from 600 to 1200 k-cals per hour. So from a thermogenic standpoint, an extra 5-10 k-cals of energy expenditure per hour, even if it was attributed, would have a meaningless affect on total core temperature. So the primary factor of the increased heat would be the exercise, and the environmental conditions the athlete was in, and whether the athlete was acclimatized.

We know the pathology of heat stroke. And generally people who are overweight, who are not in as good condition when they start exercising, when they're not heat acclimatized, in other words used to exercise in the heat, have more difficulty. There's no doubt about that. If

you add compounding considerations, that the person may have been trying to diet, and was restricting food intake and other things, those are primary factors, in my opinion. If you consider it as a bucket of full water, and try to say that maybe this was the last drop in the bucket that tipped it over, the bucket never should have been that full. The person should not have been pushed that hard. They should have had warning signs, and had some intervention before the person even got there to be sure that he was appropriately fit, and ready to participate in that type of condition.

So in my view, I don't see Ephedra as an additive, and as a primary factor here. I think the main factors, in my viewpoint, I've seen in the press reports, is that we had an athlete who unfortunately was pushed a little too hard, in a too hot and humid environment. His body wasn't ready to do it, and they didn't recognize that he was having that much problem. You know, when you work with athletes, it's a very intense situation, particularly when you're doing conditioning drills. And there's a lot of effort and pressure from the athletes themselves, that they put on themselves, as well as their peers and coaches, to keep sucking it up, and continuing on. And sometimes, unfortunately, athletes do that to their own detriment, and end up having problems. And I see that as the primary factor.

CALLER: Okay. Just to follow up, though, could you address the basal constrictor possibilities here?

DR. KREIDER: Ephedra, and Dr. Colker could probably talk to you about this. Ephedra is more of a basal dilator, and if anything, limiting -- the primary factor in my view on heat and exercise was the humidity, the humidity was fairly high that day. And the higher the humidity the more difficult it is to evaporate the sweat in an individual, when you don't evaporate, that's your primary way of losing heat when you exercise in a hot environment. So even if there was limited skin flow, assuming that that could happen, the primary mechanism of heat loss would be the evaporation of sweat. Given the fact that the humidity was so high, that probably is the major complicating factor, and why he couldn't regulate his temperature properly.

MR. SIEGNER: This is Wes Siegner, could I just remind people to identify themselves, and if the last questioner could just tell us who he was.

MR. : The last questioner did identify himself.

MR. SIEGNER: I'm sorry. I didn't hear it.

MR. : Just then to follow up, 71 percent humidity, which is I believe what it was around noon, is a very high level of humidity?

DR. KREIDER: Yes, any time you're getting in the 70, to 80, to 90 percent humidity. It was 71 at noon, during the day humidity is higher in the morning, and the afternoon, later afternoon times, the temperature is easier in the morning, but gets hotter during the midday and the humidity starts to go down. If it was 71 around noon, then you probably were almost 80 or so in the morning. And the higher the humidity, the body cannot evaporate the sweat. And that is the primary way that heat is lost when you exercise.

Concerning Ephedra and its effect on core temperature, I completely concur with Dr. Kreider in the sense that Ephedra can have only the most minimal and mostly undetectable effect on core temperature ever, ever, ever so slight, that it's seldom been picked up in research in terms of an increase in temperature. My understanding is that this individual had a core temperature of 108, that is, again, consistent with this heat stroke, and I don't see how Ephedra would be contributory.

DR. KREIDER: This is Rick Kreider again. The normal increase in temperature when you exercise, even when the body regulates itself, is usually a 2 to 3 degree increase. So, if you start off at about 98.6 degrees, it generally gets to about 101-102. What typically happens when the person is dehydrated, can't sweat enough, or it's too humid and sweat is not evaporated properly, is that over time there could be a rapid increase in temperature, and that's when it starts soaring in a very quick manner.

That's why it's extremely important to be climatized to heat, to have sufficient breaks, not do excessive workouts in the heat, retain hydration, and one of my concerns about this whole issue is that these primary factors prevent heat stroke from being overlooked, and the thought might be, well, if they'd just ban Ephedra supplements from athletes, then the problem goes away. When, in fact, there are many things that can be done to prevent the problem from getting so far.

CALLER: Can I ask a question?

MR. SIEGNER: Sure, go right ahead.

CALLER: My name is Penny Crabtree, I'm a reporter with the San Diego Union Tribune. I wanted to ask a couple of questions concerning the 55 clinical trials, one of which would be, I've talked to various researchers doing clinical research on the subject before, including Carol Boozer, and they all say, and I'm just curious with Peak Wellness myself, a few studies I've seen of theirs, you're studying people who are something like 17 people, 20 people, 30 people. No one has ever suggested that those studies are powered in such a way that it could ever show safety. Would you, for instance, the gentleman at Peak Wellness, do you think a study that looks at 17 people is powered enough to prove safety?

DR. COLKER: Well, again, I don't want to get into the semantics -- this is Dr. Colker, again, responding -- of prove or not prove. I mean, certainly what we've demonstrated in science is that our studies were certainly adequately powered to the point that we achieved statistical significance with the data that we presented. As far as Dr. Boozer, she can certainly respond to her own study, but I believe that was 167 participants over six months, and certainly she concluded that there were no serious adverse events were reported.

CALLER: But she also said in interviews that it was not a study that one could walk away and say it's a safety study. That it's not powered to prove safety.

MR. SIEGNER: I think actually Carol Boozer would say it is a safety study, but it

doesn't prove safety. You don't establish safety through one study. I mean, clearly the title of it shows that it is a safety study. The protocol was designed to assess the impact of Ephedra on heart functions, and people actually wore halter monitors to accumulate huge volumes of data on heart function.

CALLER: But she also says --

DR. COLKER: This is Dr. Colker. Just furthering that response, I mean, again, one does not set out to prove something with one study. But, again, a preponderance of all the studies that we have, we are always assessing tolerability when we do a study. And I think that's a point that should be made clear to the public in a balanced reporting is that there have been many, many, many studies, and we simply haven't seen the serious life-threatening adverse events. We haven't seen that in the research.

CALLER: This is Michael O'Keefe at the New York Daily News, again. Penny brought up a good point, and I've talked to Dr. Boozer as well, and she's also told me that her study, the last thing she wanted to say was that it proved that Ephedra was safe. But Penny did some very good reporting on this issue where, you know, I know the Ephedra Education Council and others have used the Boozer study as one of the gold standards, and Penny's story of February 9th, again, says that she was mixing up the group that was -- you know, that the people in the placebo group were actually getting pills with caffeine and Ephedra. And, again, we talk about a gold standard here, but it sounds like the science was done, in at least this case and some of the other ones that Penny wrote about, in a very sloppy manner.

DR. COLKER: This is Dr. Colker just responding to that. Again, I'm not here to defend Dr. Boozer, but I will say this much. Just like no person is perfect, no studies are perfect. And if you put everybody under a magnifying glass, you might find something that might have been done differently, or some such, but it does not invalidate any of these studies. These studies are credible, and important studies, and that's the fact.

CALLER: It wouldn't invalidate the studies if folks are questioning whether the studies were done in a responsible manner, all things reported?

DR. KREIDER: This is Dr. Kreider. Can I add, the process for science is to do the study, submit it to peer review, and publish the work. And then after the article is published, then people have an opportunity to replicate or view the study in a particular way. That's the process. And what we do in science is look at peer-reviewed publications as the best indicator of quality of research. That paper was published in a quality journal, it was published by a quality researcher, and it replicates basic findings that had been done in many other studies. And so, yes, of course it would be nice to do larger studies with 10,000 patients, et cetera. Unless the United States Government and NIH step up to fund a study like that, they're just not going to get done. They're not done with any other -- many pharmacological studies. We have no data at that level.

CALLER: Could I ask Wes something on the 55 study situation?

MR. SIEGNER: Sure.

CALLER: And this is not wondering about the validity of the study particularly, but I was looking at the 55, and I assume the 55 studies are things that you've handed to the Rand and said, we believe this is our -- a strong case, and would you take a look at it. Is that correct?

MR. SIEGNER: I would be surprised if the Rand Corporation didn't know about each of these studies, but it was actually kind of flipped around. I mean, people were submitting studies to the Rand Corporation, and it was part of that outflow and people were also sending me studies, but that was a separate thing from Rand. But the Rand request for data inspired people to say, okay, I'm going to go out and give my data, whether it's published or not, and that's kind of what led to the realization that, wow, there's a lot of studies out there.

CALLER: And the 55 you're citing, did those go to the Rand?

MR. SIEGNER: Again, I would be surprised if they don't know about them, but I don't have a way to confirm until they publish a report whether they had all those studies or whether they considered them all.

CALLER: Well, what I wanted to ask you is, when I was looking at the 55, the citations, I think on the weight loss studies, nine to ten of them were from Arne Astrup in Denmark, and as you probably know that drug that he basically invented and sold to the manufacturer who makes that drug has been pulled, suspended by the Danish equivalent to the FDA because of serious side effects and death reports. And my understanding from looking at the Danish press reports, and I don't know personally, is there's even some bit of a probe going on with his financial ties to that manufacturer.

I was kind of curious when you're using, you're citing this data, these nine, ten studies of his as proof of safety, if the Danish FDA is saying, this is a prescription drug, and even as a prescription drug we're going to pull it until we do some more studies, because we've got some concerns, how do you kind of jive that with, I don't think it needs to be under prescription here?

MR. SIEGNER: Well, what I can say in terms of a review of the adverse event profile of the product in Denmark is that the -- I mean, it's not the safest product that exists over there. It's one of the safest. Again, I can't really get into the minds of the regulators in Denmark, but I suspect a lot of what they were seeing, press reports related to Ephedra, and pressure from that end. Again, what we're trying to focus on here is, what is the science here, what is the appropriate decision to make for American consumers.

CALLER: I think we're trying to focus on the science, too.

MR. SIEGNER: Let me just finish. Let me finish.

CALLER: But there's questions about the quality of the science.

MR. SIEGNER: The appropriate thing for consumers here is that they have options in

weight loss that are backed by science and that are safe to help them lose weight. That's really what we're trying to do.

CALLER: But isn't it also science you can trust, and there seems to be some question about that.

MR. SIEGNER: Well, again, you know, you can -- what you're focusing on are some allegations that are raised on maybe three studies, two studies, in a couple of --

CALLER: Actually, they're raised against a couple of research groups who have done more studies than that. And then there's the whole point of the Arne Astrup probe that's going on right now. And that's, by my count, about 20 of your 50 so far.

MR. SIEGNER: I don't think that -- first of all, there's not that many Astrup studies, and I know nothing about a probe there. There's never been a question in the peer-reviewed literature about the objectivity or quality of his research. You can talk to other geriatric researchers, such as Dr. Gray and his colleagues at Pennington Biomedical Institute. They have done extensive research on Ephedra Caffeine products, and Ephedrine Caffeine. Their opinions are in the public record. They believe that these products ought to be available for consumers because they're safe, and they're needed. And, those are the giants among the weight loss industry, and the weight loss academic research. I agree with Dr. Kreider and Dr. Colker, I mean, there's such a consistency here on the data done by various researchers. I mean, you're talking about probably 15 different research centers. You're saying that they're all fraudulent. I can't agree with that.

CALLER: No, I never said they were all fraudulent. I said there's been a question to wonder about the science.

MR. SIEGNER: That's the implication.

CALLER: This is Vickie Temper with the Los Angeles Times, and this is a question really for any of you or all of you. In the Bechler case, you all have made the point that he was overweight and possibly obese, and that this is a supplement marketed as a weight loss product. I was wondering how you square that. And also, Wes, what kind of warning labels the industry would support in terms of particularly the weight piece of it?

MR. SIEGNER: Sure. Dr. Colker, Dr. Kreider, you want to speak to the first part.

DR. COLKER: This is Dr. Colker. I don't -- I certainly don't think that the fact that this individual was overweight does not mean that he -- that should not be taken to imply that somehow we believe that he shouldn't have been taking an Ephedra-based product. I think the problem is, number one, primarily whether he was pushed too hard, or certainly allowed to push himself too hard under conditions in which he shouldn't have done so. That's number one.

Number two would be the question as to whether he heeded the warning labels, given the fact that perhaps he may have had some medical conditions, be they a hypertension, or an asthma, perhaps he had some other medical problems that would be contraindicated on a given

warning label.

And, thirdly, whether the dosage was taken as directed. I think those are all questions that remain unanswered. But, again, let's go back to the idea that you don't have the toxicology report yet either, and so that's important too.

DR. KREIDER: This is Dr. Kreider. I would like to add, I think the point making about that Mr. Bechler was overweight reiterates that caution should have been implemented when doing conditioning in the heat and humidity, especially in the beginning of training. We know that the heat stroke pathology that people who are heavy, or overweight, not in as good condition, and particularly doing unusual dietary practices to make weight or lose weight are going to be at higher risk. And, therefore, precautions need to be taken to make sure that the athlete comes into camp well-conditioned, that you start training gradually so that you climatize your athletes, and so that you don't overpush people. Exercise can be very beneficial to most people. But in the wrong population, it can also be deadly, especially when you mix heat and overweight, and all those type of things.

So that is an important factor, I think, because those are precursors to heat stroke. And that's what I'm afraid is being missed in this coverage about his death, that these are things that can be done to prevent heat problems for athletes. Just because they're athletes doesn't mean they're healthy. And then, if you look at, find out yesterday that his parents indicated that evidently he had two episodes after playing basketball in high school, it may be that there is a pathology here that is underlying all of this, and usually once you have heat stroke once, it's much more prevalent that an athlete will have it again. And that history needs to be evaluated as well. So those are all warning signs, in my view, that this athlete needed some special observation and care before he was put in an excessive exercise situation.

CALLER: This is Michael O'Keefe with the New York Daily News again. Wes, you --

MR. SIEGNER: Michael, could I just answer the second part of the question?

CALLER: I'm sorry. Go ahead.

MR. SIEGNER: The second part of the question was with respect to the warning labels. There's been an industry standardized warning label since about '94, and if you take a look at that and compare it to what FDA proposed in 1997 as a regulation, it's really a matter of a few words. And the basic concept is we need to have a warning that is short enough that consumers will read it, and inform the consumer that the product is not meant for everybody. If you have certain medical conditions, or you're taking other prescription drugs you shouldn't take the product unless you're consulting with a physician. And our request, and the hope is that FDA will get out a warning label soon, this year if not some time in the next month or so.

CALLER: I have a question for Wes.

MR. SIEGNER: Sure, actually Mike O'Keefe had a follow up, too.



CALLER: Wes, just real quickly. We've been talking about -- I think the doctors have made an excellent point about Steve Bechler's weight, and maybe the condition he showed up in, maybe the fact that he was pushed too hard, I think those are all, I think, good questions to ask. You began your statement when you said that, people may be pointing to Ephedra to cover -- I don't want to put words in your mouth, but I think you said, to cover their own responsibility. Who were you speaking about? Who were you referring to?

MR. SIEGNER: Well, you know, there's always a concern in these cases that somebody is going to sue, regardless of the cause. I'm not saying that that's going to happen, but there's obviously an effort to keep certain people in the Orioles organization from talking to the press. I think you've probably experienced that. I don't know exactly what's going on there, but what I'm saying is, we don't want to see a rush to judgment on any of this. And let's let the facts come out, and then we can move from there. But with respect to Ephedra, again, the really important thing, in terms of facts is, let's get the Rand study out, see what the assessment is, of the clinical database, and of the adverse event reports that have been submitted and collected so far, and see what some organization that we all view as objective will say about the current state of the science, and where we need to go to get the answers.

CALLER: Thank you.

MR. SIEGNER: Sure.

I'm sorry, we had another question?

CALLER: Yes, this is Larue Faver (sp) from the Daily Bulletin. This for Wes. I was wondering if it's true that supplement manufacturing companies can no longer get product liability insurance for supplements containing Ephedra? It was something that was told to me, I want to clarify that.

MR. SIEGNER: Sure. There's been no secret that there have been some companies that have stopped marketing Ephedra-based products, and that insurance has played a role in that. It's a lot to do with what's happening with the insurance industry post 9-11, and also because of the economy. But, it is, and people recognize, much more difficult to get liability insurance for a whole range of things, including Ephedra.

Other questions?

Well, I'd like to thank everybody for participating, and Colburn, do you have any final comments?

MR. AKER: Again, the telephone number for additional information and interviews is local (202) 789-1447, long distance (877) 846-6324. Ask for Richard Price, and for background information consult [ephedrafacts.com](http://ephedrafacts.com).

Thank you for your participation today.

(End of event.)