Exhibit 35

Cara R. Welch, Ph.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. UNDETERMINED QUANTITIES OF 1,3-DIMETHYLAMYLAMINE HCl (DMAA), Defendant, and HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT, Claimants.	Civil Action No. 1:13-cv-13675- WBH-JCF

Deposition of Cara R. Welch, Ph.D.

Washington, D.C.

Tuesday, November 29, 2016

9:30 a.m.

Reported by: Laurie Donovan, RPR, CRR

Job No: 114996

Deposition of
CARA R. WELCH, Ph.D.

Held at the offices of:
U.S. Department of Justice
Consumer Protection Branch
450 Fifth Street Northwest
Room 6400-South
Washington, DC 20001

Taken pursuant to notice, before Laurie Donovan, Registered Professional Reporter, Certified Realtime Reporter, and Notary public in and for the District of Columbia.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:
United States Food and Drug Administration
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By: Joshua Davenport, Esq.

ON BEHALF OF THE DEFENDANTS:
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By: Jack Wenik, Esq.

EXAMINATION INDEX

E X H I B I T S

(Exhibits continued)

Cara R. Welch, Ph.D.

P R O C E E D I N G S

CARA R. WELCH, Ph.D.,

having been first duly sworn, testified upon her oath as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. WENIK:

Q Dr. Welch, I know you've been deposed once before, but let me give you preliminary instructions which you may already have heard.

As you can see, we have a court stenographer who is taking down the testimony, so when I ask you a question, we need a verbal answer. Just saying "uh-huh" or a facial expression or a nod won't work, so we need you to give an oral answer.

If I ask anything, and particularly if I've mispronounced a scientific term of art or you don't understand a question, by all means, ask me to rephrase it. Otherwise, I'll assume you heard the question and understood it.

Periodically your lawyer may object to a question. The way it works in this context as opposed to a court of law, we don't have a ruling on the objection. You put it on the record and

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you give an answer after the objection is interposed. Unless you are instructed not to answer a question, you should answer the question.

If at any point in time you want a break, just let me know. I don't think we're going to be here the whole day. Your report is fairly narrow, so I assume we'll be out of here hopefully pretty quickly.

Any questions for me before we begin?

A No.

(Exhibit 1 was marked for identification.)

(Exhibit 2 was marked for identification.)

(Exhibit 3 was marked for identification.)

BY MR. WENIK:

Q So with that being said, I've placed three documents in before you. Welch Exhibit 1, for the record, is the deposition notice in this case.

Have you seen this before?

A No.

Q All right. The one question I have

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is -- lawyers formally issue these things to schedule a deposition, if you will.

And looking at your Exhibit 2, which is your expert report, just take a look at that for a moment, and confirm -- I believe your signature appears on page 14 of the document.

(Witness peruses document.)

THE WITNESS: Yes.

BY MR. WENIK:

Q And the last two pages of the document are Exhibit 1, which is your reference list.

Do you see that?

A Yes.

Q And I've actually separated out and marked as a separate exhibit your Exhibit 2 to your report, which I've marked as Deposition Exhibit 3, which is simply your CV.

Do you see that?

A Yes.

Q All right. So getting back to the deposition notice, the Exhibit 1, the one question I have for you is -- what I've asked in there or what my firm has asked in there is that if there's anything new that you're relying on; in other

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words, any new study or treatise or textbook that you haven't cited in that exhibit list to your report, which we've marked as Welch Exhibit 2, if there's anything new, we've asked for the production of that today.

Is there any new material that you wish to cite or rely on in this matter to support your opinions?

A No.

Q Thank you.

All right. So other than any discussions with your lawyer, which I'm not interested in, could you tell me what you did to prepare for today's deposition.

Did you review any documents, did you talk to any of your colleagues or peers?

A I did not talk to any of my colleagues. I reviewed my expert report, Exhibit 2. I reviewed some sections of the Federal Food, Drug and Cosmetic Act.

Q All right. So let me discuss a little bit about some of your prior expert witness work.

So if I turn to your Exhibit 2, on page 13 you have a brief section here entitled

"Testimony in the last four years," and you list two citations to two court cases.

Do you see that?

A Yes.

Q So let me take the first case, so United States versus Krueger. What type of case was that? Was that a criminal case, civil case, regulatory proceeding? What kind of case was that?

A This was a criminal case.

Q And in what context did you testify in that case?

A My testimony was speaking to a particular ingredient, that it was excluded from the definition of a dietary supplement according to Section 201(ff)(3) of the Act. It was not used as a dietary supplement or a food prior to being authorized for investigation as a new drug. The ingredient was Sibutramine.

Q And in that case, the Krueger case, were you testifying as an expert witness or as a fact witness?

A As an expert witness.

Q And was that on behalf of the government

or on behalf of the defendant?

A That was on behalf of the government.

Q All right, and you list here that you testified at trial. Was there an expert report that was prepared in that matter as well?

A Yes.

Q And did you prepare that report?

A Yes, I did.

Q All right, and then we have another case listed here, United States versus Cole.

What type of case was that, Doctor?

A That was a civil case. My testimony was on current good manufacturing practices of the dietary supplement products produced by this firm.

Q Actually, I should go back to the first case. When you testified in the Krueger case, were you an FDA employee at that time?

A I was, yes.

Q All right, and in the Cole case, similarly, were you an FDA employee at that time?

A I was, yes.

Q All right, and you testified as an expert in the Cole case rather than a fact witness; is that correct?

A Yes, as an expert.

Q Okay, and did you prepare an expert report in that matter?

A Yes, I did.

Q So the good manufacturing practices that you testified about in the Cole case, did any of that have anything to do with DMAA? And I assume you understand what I'm referring to when I say "DMAA."

A I do understand. It did not have anything to do with DMAA.

Q Okay.

I'm looking at Exhibit 3, which is the CV, your CV.

A Yes.

Q And I'm just looking at the professional experience blocks.

So you have one block from February 2016 to the present and one block from January 2015 to February 2016, and you have still another block there of January '14 to February 2016. All these of those blocks list your professional experience in one capacity or another with the Food & Drug Administration.

Do you see that?

A Yes, I do.

Q So just turning your attention to the earliest block on page 2, which is a January 2014 to February 2016 block, one of the bullet points that you have here in your CV, you refer to having prepared expert witness testimony regarding dietary supplement labeling and GMP compliance with dietary supplement manufacturing.

Does this pertain to any of the two cases we've just been talking about, or is this something else?

A I -- that refers to the Cole case.

Q Okay, and in the next block, I'm looking at the January '15 to February 2016 experience block, and you have a number of bullet points, and in the next to last bullet point in that block, you talk again about preparing expert witness testimony regarding dietary supplement labeling and GOP compliance.

Was that also in the Cole matter, or was this a different case?

A I believe that is referring to the Krueger case.

Q Okay, and then in the most recent professional experience block, the February 2016 to the present, again you have a number of bullet points, and I'm looking at the third one, and you talk again about preparing expert witness testimony and testified regarding dietary supplement regulations.

Is this referring to a third matter that we haven't already discussed, or is this referring to one of the two cases you've already talked about?

A I'm sorry. This most recent block is referring to the Krueger case. The previous block is probably referring to the Cole case or other expert testimony or expert witness reports that I've prepared for cases that didn't necessarily go to trial.

Q I see. So in addition to the Krueger case and the Cole case, you may have prepared some expert witness reports, but you weren't deposed or testified; is that what you're saying?

A Correct.

Q Okay. Did any of those other expert witness reports -- other, obviously, than Exhibit

2 -- have anything to do with DMAA?

A No. I have not prepared an expert report having to do with DMAA, before this one.

Q Okay.

Now, staying for the moment on your experience regarding testimonial activities and expert activities, I note from your CV and your expert declaration that you served for a number of years in different capacities with the Natural Products Association; is that right?

A Yes.

Q In that capacity with the Natural Products Association, did you prepare expert reports or serve as an expert witness in any case?

A No.

Q Have you ever served as an expert witness on behalf of a dietary supplement company?

A No.

Q On behalf of a pharmaceutical company?

A No.

Q Have you ever personally -- and I'm only interested in your professional capacity. I'm not interested if you had a divorce or a car accident or anything like that. Have you ever been a

defendant or a plaintiff in a litigation in your professional capacity, either as part of the NPA or as part of the FDA?

A No.

Q Now, in these two matters that we're referring to, the Krueger case and the Cole case, it sounds like only one of them you actually testified in a court of law, and that would have been the Krueger case; is that right?

A Yes.

Q And in that case, the Krueger case, do you recall whether the judge in that case made a ruling qualifying you as an expert in a particular subject area?

A I don't recall.

Q What was the subject area of expertise that you recall testifying about in the Krueger case? And I mean more general than the specific report. Was it organic chemistry? Was it regulations? Was it something else?

A It was dietary supplement regulations.

Q Okay.

Now, basically, as I read your CV, it looks like you were first employed by the Federal

Food & Drug Administration in January of 2014; is that correct?

A Yes.

Q So would it be fair to say then that you had no involvement at all with any of the inspections that occurred at Hi-Tech Pharmaceuticals in Georgia?

A Correct.

Q And did you have any involvement with any of the analysis or testing of any of the products that were seized pursuant to those inspections?

A I had no involvement.

Q Have you interviewed anyone from Hi-Tech Pharmaceuticals since you became an employee at the FDA?

A No.

Q All right. So when was it -- let me back up a bit.

I assume as far as being an expert in this case, the case we're sitting at today, you're not being compensated in any fashion other than your, whatever salary you make from the FDA; is that right?

A Correct.
Q Okay. So when was it, roughly, if you can recall, that you began to serve as an expert in this case as opposed to an FDA official, if you will?
A I believe I started drafting my expert report for this case in November or December of 2015.
Q And who made the decision that you would serve as an expert in this case?
A I don't know.
Q Now, as part of your preparing your expert report and your testimony today, did you consult with any of the other experts that have been -- I'll use the word "retained" -- in this matter by the government?
MR. DAVENPORT: Objection to the form of the question.
You may answer.
THE WITNESS: No.
BY MR. WENIK:
Q Have you reviewed, as part of your expert analysis in this case, any of the deposition transcripts of any of the expert

depositions of either the government's experts or the defendant/claimant's experts?
A No.
Q Have you reviewed any of the expert reports of either the government's experts or the defendant/claimant's experts?
A I have not reviewed any of the government's expert reports. I don't believe I've reviewed expert reports of the claimants.
Q Okay, and this declaration that we have in front of us, the report/declaration, Exhibit 2, does that document contain all of your opinions and conclusions in this matter?
A Yes.
Q Having looked at that and having prepared for this deposition, is there anything in the document, in Exhibit 2, that you wish to modify or change or amend in any fashion?
A No.
Q Okay. Let's move on to your CV which I've marked as Exhibit 3.
Is this the most current version of your CV, or has there been a new version with perhaps different, I don't know, achievements or

publications or what-have-you since you prepared this one that was attached to your report?
A I believe this is the most recent CV I've prepared.
Q Okay, and does this CV list all of your -- I'm looking now at page -- they're not numbered, but beginning of the fourth page and going onto the fifth page, you have a section called "Scientific Publications."
Does this list all the articles that you've published, this CV?
A I might have a more recent publication. I haven't checked.
Q Okay, and what subject matter might that more recent publication be on?
A I believe we've prepared a manuscript, the dissertation topic from my grad school work, graduate school work.
Q What was that topic? What was your dissertation?
A It was on the chemistry and pharmacology of kinkeliba, a West African medicinal plant. We have two publications. I believe one of them has been prepared and submitted.

Q Okay.
Does the CV list all of your professional positions that you've had since you obtained your Ph.D.?
A Yes.
Q All right. When you worked at the Natural Products Association -- actually, let me back up.
What's your understanding of what the Natural Products Association is?
A The Natural Products Association is a trade association representing the natural products industry. They represent retailers, manufacturers, product manufacturers, and ingredient suppliers of products such as dietary supplements, cosmetics, home care products and foods.
Q All right. Is it commonly known by the acronym of "NPA"?
A Yes, it is.
Q Are you familiar with an entity NNPA?
A I'm not familiar with NNPA.
Q Okay.
When you were employed at the Natural

Products Association, did you know an individual named Dr. Daniel Fabricant?
A Yes.
Q And how did you come to know Dr. Fabricant?
A He hired me.
Q And did you report to him?
A Yes, I did.
Q Was Dr. Fabricant responsible for bringing you to the FDA in January of 2014?
A Yes.
Q And when you first began with the FDA in January 2014, did you report to Dr. Fabricant?
A Yes.
Q Was he your direct supervisor, or was there some intermediary between you and him?
A I believe he was my direct supervisor.
Q Okay.
Is it true that your husband also works for the FDA? Is that correct?
A Yes, it is.
Q And in what capacity is he employed with the FDA?
A He is a new drug reviewer for the Center

for Drug Evaluation and Research, CDER.
Q All right. How long has he held that position?
A I believe he was hired in -- I'm sorry. His current position?
Q Yes.
A Two or three years. He was hired in 2010.
Q By the FDA?
A Yes, at FDA.
Q What did he first do at the FDA?
A He was a regulatory project manager, I believe is what they call it, for CDER.
Q Did he ever work on the dietary supplement side of the FDA, for lack of a better word?
A No.
Q And does he have the same surname, Welch, or does he go by a different professional name?
A He goes by Welch.
Q All right. So I'm looking now at your --
MR. DAVENPORT: Are you done with

Exhibit 3?
MR. WENIK: I may come back to it.
MR. DAVENPORT: Okay. All right. Just for organizational purposes.
MR. WENIK: That's all right.
BY MR. WENIK:
Q I'm looking at your expert declaration, paragraph 8, which is on page 5, and in paragraph 8 on page 5 of Exhibit 2, your expert declaration, you talk about some of the things you did for the Natural Products Association.
Do you see that?
A Yes.
Q And one of the things you listed as one of your responsibilities was "drafting scientific opinions, position papers, and comments in response to regulatory decisions."
Do you see that?
A Yes.
Q All right. Did you draft, when you were at the NPA, any position papers regarding DMAA?
A No, I do not believe so.
Q Did you draft any scientific opinions when you were at the NPA regarding DMAA?

A No, I don't believe so.
Q And did you draft any comments when you were at the NPA regarding DMAA?
A No, I don't believe so.
Q All right. Let me drill down a little bit.
So when you're referring to a scientific opinion versus a position paper, what is the difference between those two documents? What is a scientific opinion as compared to a position paper?
A A scientific opinion would be a review of the scientific information at our disposal, putting forth an opinion based on purely scientific position.
A position paper, how I'm referring to it here, is a position that is accepted for NPA's use, so it's a position of NPA on a topic. I think it could be broader than just scientific topic. It could be a regulatory topic or other topic.
Q And when you craft or draft these sorts of documents, was there a level of review separate and apart from yourself for these position papers

and scientific opinions?
A Yes.
Q Who would conduct that review?
A Depending on the nature of the position, if it were purely scientific, it would certainly be reviewed by committees from the Association. We had different committees. One committee in particular at NPA reviewed my work. It was called ComPLI, Committee on Product Labeling Integrity of regulatory decisions.
If it were a broader position paper, it would certainly be reviewed by management, legal, likely, and depending on the acceptance of the position, it would be reviewed certainly by the board of directors' executive committee and possibly by the entire board of directors.
Q Putting DMAA aside for the moment, did you have any role in drafting either a scientific opinion or a position paper for the NPA regarding synthetic ingredients generally as dietary supplements?
A That position -- that topic was part of our comments, which is not a scientific opinion or a position paper, but the association's comments

in response to the July 2011 draft new dietary ingredient guidance from the FDA.
Q And did you take the position that a synthetic could be a dietary ingredient under DSHEA?
Do you understand when I say "DSHEA," I mean Dietary Supplement Health and Education Act?
A I understand DSHEA, yes.
The Association's position was synthetic ingredients should be considered to be dietary ingredients.
Q Has your thinking on that particular topic changed since you've become a member of the FDA?
MR. DAVENPORT: Objection to the form of the question.
You can answer.
THE WITNESS: To that particular position, not necessarily. My thinking has expanded, but ultimately I still believe synthetic ingredients can be dietary ingredients.
BY MR. WENIK:
Q Let me drill down a little bit more.

So when you were drafting these scientific opinions and you're reviewing the science and you had these levels of review, before you would put your name to a document like that, if you will, what level of evidence did you need to see to issue a scientific opinion? Did it need to be uncontroverted, did it need to be a consensus, a reasonable degree of scientific certainty, some other standard that perhaps you operated under?
MR. DAVENPORT: Objection to the form of the question.
You can answer.
THE WITNESS: Scientific opinions need to be based on peer-reviewed published information. The full methodology, if it included methodological methods, would need to be clearly laid out for our review. It didn't need to be incontrovertible, but all of the evidence would be weighed equally.
BY MR. WENIK:
Q And I guess I should have asked this question much earlier, but would you consider yourself a scientist? Even though you are now

perhaps wearing a regulator's hat, would you still consider yourself a scientist?
A Yes.
Q All right. So going back to your CV, which is Exhibit 3, I'm looking at page 2, and I'm looking at the block where you talk about when you were a vice president for Scientific and Regulatory Affairs for the Natural Products Association.
A Okay.
Q And in the very last bullet point there, you talk about "integrated communication department with scientific and regulatory initiatives to ensure dissemination of information to the membership, response to media inquiries, and misleading scientific articles."
Do you see that?
A Yes.
Q What is a misleading scientific article?
A The dietary supplement industry has a lot of publications that are -- has a lot of articles that are published looking at the evidence behind the efficacy of their products, and there are times when the industry believes the

information is misleading, giving the impression the products aren't efficacious, when, in fact, they might be, or the information is not yet settled one way or the other. Those were often the types of articles we were responding to.

Q How about articles that dealt with safety; would those be in the same category of, quote-unquote, "misleading scientific articles" in addition to ones dealing with efficacy?

A They could be.

Q And would it be fair to say that you would review these articles with a skeptical eye?

A Yes.

Q Let's talk for a moment about the scientific method generally.

So you mentioned earlier peer review. What is the function of peer review?

A A peer review is an assurance that the information presented in an article is accepted by peers at the level peers would accept.

Q All right. So when we are talking about someone that publishes a peer-reviewed article, a study of one sort or another, is it part of the scientific method that a researcher begins with a

hypothesis of some sort? Is that typically the scientific method?

A Yes.

Q And as a scientist, is the goal of conducting a study to provide evidence that either proves or disproves that hypothesis?

A Yes.

Q And is it important to you as a scientist that the researchers that are conducting the study to prove or disprove the hypothesis be as free from bias as possible?

A Yes.

Q And is it common in your experience -- and you've worked now for a number of years both in the government and in a trade association -- for peer-reviewed research to be funded by a commercial entity of one sort or another, pharmaceutical company, dietary supplement company, or what-have-you?

A It is common, yes.

Q Does that in and of itself, that a study or a research paper is funded by a commercial enterprise of some sort, does that in and of itself, in your opinion as a scientist, detract

from its reliability?

A It's one piece of evidence.

Q And evidence toward what?

A One piece of evidence toward bias.

Q Can a study that's funded by a commercial enterprise be a legitimate study, producing legitimate results?

A Yes.

Q So when an entity -- and some research sponsored by governmental entities such as the NIH or the FDA, is that common in your experience?

A Yes.

Q So as part of the scientific method, is it inappropriate for the sponsor, be it a government entity or a commercial entity, to comment and give feedback on the research as it's being conducted? Is that in and of itself inappropriate?

MR. DAVENPORT: Objection to the form of the question.

You can answer.

THE WITNESS: I apologize. Can you repeat the question.

BY MR. WENIK:

Q Sure. Is it inappropriate, in your mind as a scientist -- and you are here as an expert -- for the sponsor of a study, be it a government entity or a commercial entity, to comment on the research as it's being conducted by the researchers to provide them feedback?

A Not necessarily.

Q Is it inappropriate for the sponsor of a study, be it a government entity or a commercial entity, to provide any editing or comments to a draft of the manuscript that's submitted for publication? Is that inappropriate?

MR. DAVENPORT: Objection to the form of the question.

You can answer.

THE WITNESS: Not necessarily.

BY MR. WENIK:

Q Is it inappropriate for the sponsor of a scientific study to ask the researchers to change their conclusions?

MR. DAVENPORT: Objection to the form of the question.

You can answer.

THE WITNESS: It would be inappropriate for the sponsor of a study to ask the researchers to change their conclusions.

BY MR. WENIK:

Q When a scientist or researcher conducts a peer-reviewed piece of research, is it the generally accepted norm in the scientific world that they report all of the data that they found, including data that goes against their hypothesis?

A A well-founded study, the results of a study would provide all of the information that went into that conclusion, both positive and negative.

Q Would you consider it inappropriate, as a matter of science, for a researcher to exclude from the published manuscript only that data that contradicted their hypothesis?

MR. DAVENPORT: Objection to the form of the question.

You can answer.

THE WITNESS: It would be inappropriate to exclude information that went against the hypothesis, yes.

BY MR. WENIK:

Q Would you consider it an act of scientific dishonesty for a researcher to falsify the results that are published in a peer-reviewed paper?

A Yes.

Q Okay. Turning back to your CV, I'm looking at page 1, and in the second block, under the January 2015 to February 2016 block, I'm looking at the third bullet point, and you talked about "directed enforcement initiatives with CFSAN's Office of Compliance for three violative dietary ingredients, resulting in more than 20 Warning Letters."

Do you see that?

A Yes.

Q All right. So my first question to you is: What were the three violative dietary ingredients that you're referring to there?

A I believe it would be an ingredient called -- an ingredient FDA refers to as "DMBA." I can spell that out if you would like.

Q I'm familiar with DMBA.

A Okay. An ingredient we refer to as

"BMPEA."

Q I'm also familiar with that one. Thank you.

A And possibly -- I'm looking at the dates. I would guess the ingredient picamilon.

Q All right. So let me -- so I guess I first ask you, for the clarity of the record, what is CFSAN stand for?

A The Center for Food Safety and Applied Nutrition.

Q All right.

So looking at your CV -- and let's stick with the FDA positions for a moment -- I'm looking at page 2, and it says that from September 2014 to February 2016, you were the Dietary Supplement Regulations Implementation team leader.

Do you see that?

A Yes.

Q So that position overlapped some of these other positions; is that right?

A Yes. That was the permanent position I was in.

Q Okay.

A I had some acting positions during that

time period.

Q All right. So what were your duties then as the Dietary Supplement Regulations Implementation team leader? What were you responsible for in that role?

A I was officially a team leader of I believe eight FDA employees. Our work, the work of these eight employees reviewed CGMP cases, reviewed labeling cases, claims cases. They review applications for certificates of free sale. They review notifications for structure function claims.

Q All right. In that role did you have an enforcement responsibility as far as issuing warning letters and seizure actions and the like?

A The actions, the compliance and enforcement actions from CFSAN, Center for Food Safety and Applied Nutrition, are worked -- are spearheaded from the Office of Compliance. We are the experts, the subject matter experts, so the actions often require a support memorandum from our office, from that team in particular, for GMPs, for labeling and for claims.

Q So when you assumed the role of -- I

guess I should go through these, not each one. You also talk about "Regulatory Special Assistant." What was that? You did it from January to September of 2014.

A That was the initial position I had at FDA. I was -- I, I worked on the Regulations Implementation Team. I was one of the team members.

Q You were one of the subordinates, if you will?

A Yes.

Q Okay, and then you became the acting deputy division director and eventually acting division director of the Division of Dietary Supplement Programs; is that right?

A The dates are actually opposite. So first I was an acting division director from January 2015 --

Q Oh, interesting. Okay.

A -- to May 2016, and then I was acting deputy director from May 2015 to February 2016.

Q All right. So what were your duties when you were the acting division director?

A I led the division. I supervised all

22, 23 employees. I was, I was the director for both of the principal teams in the division, both the Regulations Implementation Team and the New Dietary Ingredient Review Team. I was in charge of the medical officer, reviewing adverse event reports. I -- all of that. I led the division.

Q Just so I understand, so when you say you directed the enforcement initiatives, so in that capacity you're recommending that this other entity, the Office of Compliance, take action, or is it some other description?

A It is a process worked out between the two groups. We are one "vote" in the matter, so to speak. They are the other. They have to carry out the actions, so they need to have resources in order to carry out the actions. We are the subject matter experts, so we need to have -- we need to be able to support the science or the regulatory position.

Q So would it be fair to say that your division as the, quote-unquote, "subject matter expert" would identify the areas for the enforcement action?

MR. DAVENPORT: Objection to the

form of the question.

You can answer.

THE WITNESS: Yes.

BY MR. WENIK:

Q Okay, and now your current position is senior advisor, so how have your duties changed, if at all, as senior advisor?

A I am no longer an official supervisor of any employees. I am in a leadership position, supporting our office director with the areas that he needs. So it's a lot of policy review. I often take point on drafting regulatory documents or guidance documents. I still review the CGMP reports that leave our office, that sort of thing.

(Exhibit 4 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a document that I marked for identification as Welch Exhibit 4, and as you can see, it was used at a prior deposition as well.

Have you seen this organizational chart before?

A Yes.

Q All right. So I just want to get an understanding.

So when you came on board in January of 2014 to the FDA, does this reflect, this document, Welch Exhibit 4, the structure of the Food & Drug Administration that existed when you came on board in January 2014?

A It's specific to the Center for Food Safety and Applied Nutrition, but yes, as I understand it.

Q All right. So would you have been part of -- I'm looking at the bottom right, the Office of Nutrition, Labeling and Dietary Supplements. Would that have been where you were a part of when you came on board?

A Yes. That's the office that housed the Division of Dietary Supplement Programs.

Q Okay, and my understanding is that has changed very recently in 2016; is that right? The Division of Dietary Supplements is now an office in its own right; is that correct?

A That happened in December of 2015, but yes, the Office of Nutrition, Labeling and Dietary Supplements was split into two offices, the Office

of Nutrition and Food Labeling, which we are no longer a part of, and then separately the Office of Dietary Supplement Programs.

Q All right, and these positions that you have -- so when you're a senior advisor, are you still in the Office of Dietary Supplement Programs, or are you in some other sub-part of the FDA?

A I'm in the Office of Dietary Supplement Programs.

Q All right. So as an office, does the Office of Dietary Supplement Programs now have increased staff and resources as compared to when it was just a lowly division of the Office of Nutrition and Labeling?

MR. DAVENPORT: I'm going to object to the form of the question.

You can answer.

THE WITNESS: I don't believe we have any additional resources or employees. We are the same size as the Division of Dietary Supplement Programs. We're just a separate office now.

BY MR. WENIK:

Q Has that been an issue within the FDA for a while, that the resources devoted to dietary supplements have been static or limited?

MR. DAVENPORT: Objection to the form of the question.

You can answer.

THE WITNESS: I'm not sure it's my place to say that it is a problem. The number of employees has stayed fairly similar for the last several years.

BY MR. WENIK:

Q And has the industry grown in that period of time?

A The dietary supplement industry is certainly touted to be a constantly growing industry, so I would assume yes, it has grown, while the office or division has retained the same number of employees.

Q All right. So when you came on board, where would Dr. Fabricant have fit in on this organizational chart that I have here as Welch Exhibit 4? Would he have been replacing Mr. Spiller that's listed here or been above

Mr. Spiller?

A Dr. Fabricant was the division director in the Office of Nutrition, Labeling and Dietary Supplements, so he would not have shown up on this organizational chart.

Q Okay, all right, and are you familiar with Dr. Keefe?

A Yes.

Q And how are you familiar with him?

A He is a colleague at the Center for Food Safety and Applied Nutrition.

Q All right, and I see him listed on this diagram, Exhibit 4, to the far left in the Office of Food Additive Safety; is that right?

A Yes.

Q Does he still work in that entity of the Food & Drug Administration?

A As far as I'm aware, yes.

Q All right. Does Dr. Keefe have any role in any of these enforcement initiatives regarding dietary supplements since you have been at FDA?

A Dr. Keefe? Not necessarily. We do work with his office from time to time on establishing whether an ingredient is an approved food additive

or is "GRAS," referring to "generally recognized as safe."

Q Okay. Let me jump ahead for a minute then, being you're talking about that.

(Exhibit 5 was marked for identification.)

BY MR. WENIK:

Q Dr. Welch, I've placed before you a document marked for identification as Welch Exhibit 5, which is the expert declaration of Dr. Keefe.

Have you seen this document before?

A I have not.

Q Okay. If you will bear with me for a moment, you don't mind to turn to page 4 and look at paragraph 9 of this document, and Dr. Keefe wrote in his report that "The purpose of this Report is to provide my expert opinion that DMAA meets the definition of a 'food additive.'"

Do you see that?

A I do see that.

Q All right. Are you making any expert opinions in this litigation as to whether or not DMAA is a food additive?

A I am not.
Q Okay. So let me just ask, looking back at your CV, so when you were the Dietary Supplement Regulations Implementation Team leader, who was your direct report? Who did you report directly to within the FDA in that role?
A I -- when I was the regulations and implementation team leader, I reported to a number of acting division directors. We didn't have a permanent division director at that time, so I reported to -- do you want me to list the names?
Q Please.
A I reported to Charlotte Christin. I then reported to -- I believe in October of 2014 until January 2015, I reported to Dr. Dan Levy.
Q And now as a senior advisor, who do you report to?
A I report to our office director, Steven Tave.
Q And when you first came on board to the FDA, did you report to Dr. Fabricant?
A Yes.
Q All right. Were you familiar with someone at the FDA known as Dr. Robert Moore?

A I am familiar with him, though I've never worked with him.
Q Okay. How are you familiar with him?
A When I was at NPA, I had some communications with Dr. Moore. I believe he attended some meetings that we attended at FDA and had some email communication with him on labeling topics, I believe. I'm not sure.
Q What was your understanding of his area of expertise?
A I believe his expertise is dietary supplement regulations, claims, labeling. I'm not sure on his expertise with GMPs, but I believe it's more on claims and labeling and ingredient identity.
Q Was he someone that had a good reputation in the industry when you were at the NPA?
A I don't know that we ever -- I don't know.
Q Okay. All right.
So going back to your declaration, and I'm looking at paragraph 5 on page 3.
A Yes.

Q Okay. So you wrote that that you have "reviewed FDA enforcement actions involving dietary supplements to ensure the actions were supported by sound scientific principles and consistent with FDA policy."
Do you see that?
A Yes.
Q So just so I understand what you're saying there, do you look at these enforcement actions before the fact, do you weigh in on them, or only after the fact, because in reading your CV, I got the sense that it was before the fact.
MR. DAVENPORT: Objection to the form of the question.
You may answer.
THE WITNESS: Largely probably before the Act. I can foresee situations where it may be after the fact.
BY MR. WENIK:
Q Okay. So you would be part of the group of officials recommending proceeding in one fashion or another against somebody that, in your view, was violating some portion of the FDA Food, Drug & Cosmetic Act?

A In my current role, yes, I would be part of that conversation.
Q Okay, and you said that you have "served as the project officer for CFSAN's Cooperative Agreement with the National Center for Natural Products Research at the University of Mississippi, directing botanical dietary supplement research priority since May of 2014.
Do you see that?
A Yes, I do.
Q All right. So when you wrote in your CV, Exhibit 3, I'm looking at the first block and the second bullet point, you talk again about the National Center for Natural Products Research, and you wrote that you "managed the $2.5M budget."
Do you see that?
A I do see that.
Q Does "$2.5M" stand for two and a half million?
A Yes.
Q And looking at the second page of Exhibit 3, in your block experience of January 2014 to February 2016, in that block of block of experience in your second to the last

bullet point, you talk about the National Center for Natural Products Research at the University of Mississippi "directing botanical dietary supplement research priorities and managed the $2.5M budget."

Do you see that?

A Yes.

Q Does the 2.5M there stand for two and a half million?

A Yes, it does.

Q All right. So when you say both in your expert declaration and in your CV that you're directing the research priorities, does that mean that you are telling the Center what areas of research the FDA would like them to look into?

A What do you mean by "center"?

Q The National Center for Natural Products Research at the University of Mississippi.

A To an extent, yes.

Q Was one of the items, when you came on board in January 2014, that the natural products research center was looking at DMAA?

A I believe so. I believe the research was largely finished. They were working on one

final manuscript when I started in May of 2014.

Q And as part of your role in approving the $2.5 million budget, do you have communications with Dr. ElSohly of the University of Mississippi?

MR. DAVENPORT: Objection to the form of the question regarding approving budget.

You can answer if you're able.

THE WITNESS: I don't have much conversation with Dr. ElSohly. My conversations are largely with Dr. Khan and Dr. Chittiboyina, Amar Chittiboyina.

BY MR. WENIK:

Q All right, and do you have conversations with Dr. Khan as to renewing the funding for the Center at the University of Mississippi?

A Yes.

Q And is it your understanding that the FDA, through this cooperative agreement, provides the lion's share of the funding for the National Center for Natural Products Research at the University of Mississippi?

A I am not aware what percent of their

total funding we provide. We have provided as much as $2.5 million per year. In recent years it has been less than that.

Q All right. Was it $2.5 million in 2014?

A I believe it was, yes.

Q Now, you mentioned that at that time there was a final manuscript being prepared regarding DMAA by the University of Mississippi researchers; is that right?

A I believe so, yes.

Q Did you comment on that draft manuscript before it was finalized?

A I don't recall at this time.

Q Would that have been something that in your role as the project officer, that they would submit to you the research product that the Center was producing?

A Dr. Khan will often send me manuscripts, not necessarily for my approval but for my review.

Q Does Dr. Khan periodically provide you updates as to the progress of the research that the FDA is funding pursuant to this cooperative agreement?

A Yes. We have quarterly, if not more

than quarterly, meetings.

Q Are you aware of a 2012 article published by the University of Mississippi by Drs. Khan and ElSohly regarding DMAA?

And just for ease of reference, if you can look at reference 15.

A Yes. I'm aware of the 2012 article.

Q All right, and that article was the result of research conducted at the National Center for Natural Products Research at the University of Mississippi; isn't that correct?

A I believe so, yes.

Q All right. Do you know who at the FDA was the project manager for this relationship prior to your assuming that role in January of 2014?

A The project officer prior to me was Dr. Dan Fabricant. I am not sure when he became the project officer.

Q Okay. So Dr. Fabricant would have been the one then receiving these quarterly updates from the Center?

A I would assume, yes.

Q Did you ever have any discussions with

Dr. Fabricant about the 2012 article that is cited as reference 15 in your expert report?

A I don't believe I've ever discussed this article with Dr. Fabricant.

Q Did you ever ask anyone at the FDA why the conclusion section of the article was changed after it was published?

MR. DAVENPORT: Objection to the form of the question. Assumes facts.

You may answer if you are able.

THE WITNESS: I am actually not able to answer this question.

BY MR. WENIK:

Q Were you aware that the conclusion section of the research that resulted in the article that you cite was changed to read "finding trace amounts of DMAA" to "finding no DMAA"? Were you aware of that change?

MR. DAVENPORT: Objection to the form of the question.

You may answer if able.

THE WITNESS: I was not aware.

(Whereupon, a short recess was taken.)

BY MR. WENIK:

Q Are you familiar with an entity known as ElSohly Laboratories, Inc.?

A Yes, I am.

Q How are you familiar with that entity?

A I believe that is a firm of sorts, a laboratory run by Dr. ElSohly at NCNPR. I believe it's a separate entity.

Q Does some of the two and a half million dollar annual funding block go toward work done by ElSohly Laboratories, Inc.?

MR. DAVENPORT: Objection to the form of the question.

You may answer.

THE WITNESS: I don't believe so.

BY MR. WENIK:

Q How about an entity known as Phytochemical Services, Inc. or PSI? Are you familiar with that entity?

A Not -- no, I am not familiar with it. I don't believe I'm familiar with them.

Q Okay. How about ChromaDex; are you familiar with that entity?

A I am familiar, yes.

Q How are you familiar with ChromaDex?

A ChromaDex is -- they may still be. When I was at NPA, ChromaDex was a member, and their principals sat on some committees that I oversaw.

Q Was Dr. Khan one of those principals of ChromaDex?

A Not that I'm aware of. I don't believe Dr. Khan is an employee of ChromaDex.

Q Do you know whether Dr. Khan is a significant shareholder of ChromaDex?

A I have no knowledge of this.

Q Does ChromaDex perform any work that is funded by this FDA block of funding to the National Center for Natural Products Research or NCNPR?

A No. ChromaDex isn't part of that cooperative agreement.

Q Okay.

Have you had any discussions or contact with any of the -- and I'm not asking you for the substance of the question. I just want to know if you've had contact with any of the lawyers for the Federal Trade Commission that are litigating currently against Hi-Tech Pharmaceuticals.

A I'm not aware that I've had contact with these particular lawyers you're speaking of.

Q Okay. Amanda Basta; is that a name that you are familiar with?

A No.

Q Edward Mendelson?

A No.

Q Have you reviewed any of the expert reports that have been prepared in the FTC litigation involving Hi-Tech Pharmaceuticals?

A No, I have not.

Q Okay.

So I want to talk a little bit about the scope of your expert opinions that you're rendering here. I want to make sure I have a very clear understanding of the limits.

So the first question to you is: Are you offering any expert opinion as to whether or not DMAA is contained in geraniums?

A I am not offering an expert opinion on that.

Q Are you offering any expert opinion as to the composition or chemical nature of any of the items that have been seized in this

litigation?
A No.
Q Are you offering any opinions as to the safety of DMAA?
A No.
Q Are you offering any opinions as to the efficacy of DMAA, be it for weight loss or workouts or anything?
A No.
Q Okay.
So turning back to your expert report or declaration, in paragraphs 3 and 11 you state that the purpose of your report is to "provide my expert opinion about the methods and processes available to and used by FDA to regulate dietary supplements," and you say the same exact thing at paragraph 11.
Do you see that?
A I do.
Q So is one of the methods and processes available to the FDA to regulate dietary supplements a ban of a dietary ingredient or supplement?
A I wouldn't use the word "ban," but yes,

we can remove dietary ingredients or dietary supplements from the market.
Q Is that what happened with ephedra?
A We did a rulemaking for ephedrine alkaloids, stating they adulterate dietary supplements because they present a significant or unreasonable risk of illness or injury.
Q So would rulemaking be one of the -- to use your phrase -- "methods and processes available to the FDA to regulate a dietary supplement"?
A Yes.
Q And with regard to ephedra, what exactly did that rulemaking entail? What did the FDA do?
A I was not an employee of FDA at that time, but we did a rulemaking to state that ephedrine alkaloids, not all ephedra, just the ephedrine alkaloids, present a significant or unreasonable risk of illness or injury. Therefore, a dietary supplement containing ephedrine alkaloids is considered adulterated.
Q Was the rulemaking published in the Federal Register?
A Yes, it was.

Q Was public comment solicited?
A Yes, it was.
Q Could the same process that was used with ephedrine alkaloids be employed with regard to DMAA?
A No, it could not.
Q Why not?
A The FDA's opinion is that DMAA is not a dietary ingredient. Therefore, that provision would not apply to an ingredient that is not a dietary ingredient.
Q Okay. So if it were a dietary ingredient, could it be subject to the same rulemaking that has been applied to ephedrine alkaloids?
A Ephedrine alkaloids are dietary ingredients, so that method is available. Other dietary ingredients could go through that same process.
Q So just to be clear, if DMAA were a dietary ingredient, then it could be subject to the same rulemaking process that was used with regard to ephedrine alkaloids; is that right?
A FDA's opinion is that DMAA is not a

dietary ingredient. If it were a dietary ingredient, rulemaking is one of many methods that could be used to regulate products containing it.
Q Okay. So when we're talking about something that's not a dietary ingredient, what, in your expert opinion, are the different methods and processes available to the FDA to regulate that? What are the alternatives that you can employ?
A There are -- I'm sure there are a number of methods to employ. Products that list an ingredient that is not a dietary ingredient on their label stating it is a dietary ingredient, those products would be misbranded. If this ingredient that is not a dietary ingredient is considered to be an unsafe food additive, then products containing it would be adulterated.
There are other provisions of the adulteration provision that could apply, I'm certain. If a product is misbranded or adulterated, we can send warning letters. Those are public advisory actions, clarifying for the firms that it is misbranded or adulterated, whichever provision applies.

We could move to administrative actions. We can administratively detain adulterated or misbranded food. Or we can move to judicial actions, including injunction or seizure, injunction of the firm to produce the product, or seizure of the actual products.

Q And what factors play into the decision-making process as to which of these alternatives to employ, the warning letter versus the administrative procedure versus the judicial action?

A There are a number of factors that play in. FDA is a public health agency, so the safety factor of the ingredient and the products of commerce would certainly weigh in. We would evaluate what is publicly known about a product or an ingredient. If we have stated in the past that it is not a dietary ingredient and, therefore, products listing it as a dietary ingredient are misbranded and the firms continue to disregard our notice, then we may move on to either administratively detaining or seizing the products.

The safety of the product weighs into

how quickly we take action, so there are a number of factors that come into play.

Q Okay. So as an expert, and you claim to be an expert in the methods and processes to regulate dietary supplements, is it an appropriate factor to consider whether you like or dislike the owner of the company that produces the product in question?

A I would not say one person's opinion of another person weighs into what action FDA as an agency is taking.

Q Is it your expert opinion that the factors are limited to the safety of the product? Is that what drives the decision?

MR. DAVENPORT: Objection to the form of the question. Mischaracterizes her prior testimony.

BY MR. WENIK:

Q Do you want me to rephrase, or do you feel able to answer the question?

A Can you rephrase?

Q Sure.

The factors that you described, are they solely focused on the nature of the product at

issue?

MR. DAVENPORT: Objection to the form of the question.

You can answer if you're able.

THE WITNESS: I wouldn't say it is solely on the nature of the product. It is largely on the nature of the product.

BY MR. WENIK:

Q Does the ownership of the company that produces the product factor into your decision-making?

A I would not say the ownership of the product factors in, because that implies a particular person. The firm and firm history may weigh in, but not necessarily.

Q Should the ethnic composition of the workforce of the product -- let me rephrase that.

Should the ethnic composition of the workforce of the company that produces the product be a factor in your decision as to whether to take action against that product?

A FDA does not have statistics on the ethnic composition of firms producing a particular product, so that does not weigh into account.

Q Would you agree with me that it would be inappropriate to take action against a product based on the fact that the majority of the management of the entity is African-American?

A To repeat my answer before, FDA doesn't keep information on the ethnic composition, for lack of a better word, of firms producing a product, so it wouldn't weigh into our factor, because we don't know this information.

Q Did you have any conversations with the inspectors that conducted the seizures at the Georgia facilities of Hi-Tech Pharmaceuticals?

A I don't believe I had any conversations with the investigators.

Q Are you aware of any comments by the investigators as to the ethnic makeup of the workforce at Hi-Tech Pharmaceuticals?

A I am not aware of any comments by the investigators or any position they have on the ethnic makeup of the firm you speak of.

Q Would it be appropriate, in your mind, to have it weigh in in any way, shape or form on the enforcement action, the ethnic makeup of the workforce that produces a product subject to FDA

regulation?

MR. DAVENPORT: Objection to the form of the question. It's been asked and answered.

You may answer again.

THE WITNESS: I would repeat my answer that FDA does not have statistics or information on the ethnic makeup of any particular firm, so it does not weigh into our decision.

BY MR. WENIK:

Q Okay. So I'm looking at paragraph 15 of your expert report, which is Welch Exhibit 2, and you talk about "the regular work of ODSP to regulate diet supplements includes."

So I guess first, for the record, I should ask you: What does "ODSP" stand for?

A It stands for the Office of Dietary Supplement Programs.

Q And that was an entity that you've held positions with at the FDA; is that correct?

A That is the office that I am currently a member of.

Q All right, and you wrote that "the

regular work of ODSP to regulate dietary supplements includes, but is not limited to," and you list various items here, including "investigating potentially problematic dietary supplement ingredients."

So what do you mean by "potentially problematic dietary supplement ingredients"?

A I'm using that phrase to cover many potential regulatory issues FDA may have with an ingredient. Our office evaluates ingredients based on whether they fit the statutory definition of a dietary ingredient, whether they are properly tested, properly manufactured, if the products -- whether they are safe, whether the product, including that ingredient, the product of commerce, is safe.

Q Now, in paragraph 13 of your declaration, you quote the statutory definition of what a dietary ingredient is; is that right?

A Yes.

Q Okay. So looking at that paragraph and compared to what we just looked at in paragraph 15, is it fair to say that you can have a substance that meets the definition of a dietary

ingredient, but for one reason or another it is still problematic in some fashion?

A Yes. Dietary ingredients can be problematic in one fashion or another.

Q And so a dietary ingredient that is problematic, you would take some sort of regulatory action against that ingredient; is that right?

A It depends what level of problem is at issue.

Q All right. So for something that meets the definition of a dietary ingredient yet presents a problem, in your expert opinion of the methods and processes available to take action, what are the different tools available to you to take action against a dietary ingredient that presents an issue as opposed to what you've described before as to something that may not be a dietary ingredient?

A Dietary ingredients have -- a dietary ingredient, if it is a new dietary ingredient, would have to go through the -- would likely have to go through the new dietary ingredient notification process prior to being marketed in a

dietary supplement. That is one method the industry is responsible for doing.

If we find a dietary ingredient is a new dietary ingredient, and a notification should have been submitted but was not, that product is adulterated according to section 402(f) of the Act. I'm referring specifically to section 413(a)(2) of the Act.

That's the result of the dietary ingredient. The methods or processes which would bring it to the attention of the firm would be similar to products that contain ingredients that aren't dietary ingredients. So if the product is adulterated, if it's adulterated because it's a new dietary ingredient or if it's adulterated because it presents a significant or unreasonable risk of illness or injury, or if it is -- there's also sections 402(f)(1), (f)(1)(C) and (f)(1)(D) of the Act, referring specifically to dietary supplements containing dietary ingredients.

So those adulteration provisions are at our disposal. If we decide that a product containing a dietary ingredient is adulterated, we would go through the same decision processes as

before, bringing it to the attention of the firms in question, either through -- likely through a warning letter, an advisory action. Depending on the result, how the firm takes that position, we could administratively detain the products or seize the products or enjoin the firm.

Q All right. So let me just show you something here.

(Exhibit 6 was marked for identification.)

BY MR. WENIK:

Q Dr. Welch, I've placed before you a document I've marked for identification as Welch Exhibit 6, which, for the record, is an FDA warning letter that I printed off of the FDA website, and it pertains to caffeine.

Have you seen this document before?

A I have seen the warning letter before. I have not seen this exact document before.

Q All right. So were you involved with the decision-making process to sending out the warning letters regarding caffeine?

A I was.

Q And is caffeine a dietary ingredient as

defined under the statute?

A It is.

Q All right. So in this instance, what was the thought process as to why caffeine, which is already a dietary ingredient, needs a warning letter?

MR. DAVENPORT: Objection to the -- correction. I'll object. You're calling for deliberative process.

MR. WENIK: You're correct. Let me rephrase that.

BY MR. WENIK:

Q So is this warning letter an example of an instance where there is a dietary ingredient that meets the definition, yet, nevertheless, the FDA takes some action against it?

A Yes.

Q And in this instance, looking at the warning letter, is this a safety concern that prompted the warning letter?

A This warning letter is stating that the product in question, Caffeine Anhydrous 400 Grams product, presents a significant or unreasonable risk of illness or injury under the conditions of

use recommended or suggested in the labeling. So yes, it is a safety concern.

Q Is there, in your expert opinion, a premarket approval requirement by the FDA for dietary supplements that include dietary ingredients that meet the statutory definition?

A I'm sorry. Can you repeat the question?

Q Sure.

For a product that contains a dietary ingredient that meets the statutory definition that you set out in paragraph 13 of your report, does that product need premarket approval by the FDA before it can be marketed?

A No.

Q If a product contains dietary ingredients that meet the definition of dietary ingredient as you define in paragraph 13 of your report, is the burden on the FDA to show that the product presents an unreasonable risk of harm or is unsafe in some manner?

A If a dietary supplement containing dietary ingredients is marketed, the burden is on FDA to demonstrate the product is adulterated.

Q And does demonstrating it's adulterated

involve the safety or create any unreasonable risk?

A Not always.

Q So under DSHEA, it's not your opinion that the burden is on the FDA to demonstrate a product is unsafe before moving it from the marketplace if it contains only dietary ingredients that meet the statutory definition?

A The definition of "dietary supplement" involves more than just containing dietary ingredients. However, if FDA is removing a product, stating a product is adulterated according to safety concerns, again, the burden is on FDA to demonstrate a product is adulterated.

Q All right. So in paragraph 3 and 11, you state that it's your expert opinion that DMAA does not qualify as a dietary ingredient as defined in 21 U.S. Code 321(ff) or basically as defined in paragraph 13 of your report, and you say that again in paragraph 11.

Is that opinion a scientific opinion or a regulatory opinion?

MR. DAVENPORT: Objection to the form of the question. Counsel, when she

cites to 321(ff), that's 321(ff(1)(A),(B, (C, (D, (E).

MR. WENIK: Fair enough.

MR. DAVENPORT: And we agreed that's not the entire section of 321(ff), and I want to make sure that's clear.

MR. WENIK: Okay.

THE WITNESS: My expert report is based on a scientific evaluation of the evidence available to my review, stating or concluding that DMAA does not qualify as one of the dietary ingredients enumerated in, as Josh just stated, Section 21 U.S. Code 321(ff)(1)(A) through (E). I did not weigh an opinion on (F).

BY MR. WENIK:

Q Okay. Do you make that opinion as a matter of science or as a matter of law, or is it a combination?

A I would say largely as a matter of science, I looked at the structure of DMAA and whether it fits into vitamin, mineral, herbal or botanical amino acid or dietary substance.

Q So just so we're all clear, looking at

paragraph 13 of your report, and you actually list word for word in Section 321 -- 21 U.S. Code 321(ff), all right, and your opinion only goes through subsection (A) through (E) and not (F); is that correct? Your expert opinion?

A That is correct. My expert report covers 21 U.S.C. 321(ff)(1)(A) through (E).

Q Okay. All right. So let me turn your attention to paragraph 17 of your report.

By the way, let me ask you another couple preparatory questions.

Do you have any legal training? Did you attend any law school classes of any sort or anything like that?

A I have not.

Q Okay. You have no degrees in law, I assume; is that right?

A I have no degrees in law.

Q Look at paragraph 17 of Exhibit 2, which is your report.

MR. DAVENPORT: Hold on. Are we done with --

MR. WENIK: Yeah, we're done with them.

(Discussion was held off the record.)

BY MR. WENIK:

Q By the way, at the end we'll give all the originals to her so she can have the spellings, and you'll have an opportunity to read and sign the transcript if there's any typos or improperly transcribed.

A Okay.

Q In paragraph 17 you talk about DMAA not being a vitamin, and in the last line on page 8, paragraph 17, you say "DMAA is an organic substance."

What do you mean by an "organic substance"?

A It is composed of carbon compounds, carbon hydrogen, and oxygen and nitrogen for DMAA's purposes.

Q In paragraph 18 in the middle of the paragraph, you refer to DMAA as an "organic compound."

Is there a distinction between what you mean when you call something an "organic substance" versus an "organic compound," or are

the two phrases interchangeable?

A I use them interchangeably. I refer to the same thing.

Q Okay, so when you say -- you're saying it's organic. Does organic compounds include plants?

A A plant is not a single compound, so no.

Q Does a plant include multiple organic compounds?

A Yes.

Q Can a constituent of a plant be a dietary ingredient?

A Yes.

Q Can a constituent of a botanical be a dietary ingredient?

A Yes.

Q Can an extract of a botanical be a dietary ingredient?

A Yes, according to section 201(ff)(1)(F).

Q Can an extract of a plant be a dietary ingredient?

A Yes, according to that same section, (F).

Q Are geraniums dietary ingredients?

A Geranium would be considered an herb or other botanical, so yes, it would be a dietary ingredient under Section 201(ff)(1)(C) of the Act.

Q And would a constituent of a geranium be a dietary ingredient?

A Yes, the constituent -- a constituent of a geranium would be considered a dietary ingredient according to Section 201(ff)(1)(F) of the Act.

Q Would an extract of a geranium be a dietary ingredient?

A Yes, an extract of a geranium would be a dietary ingredient according to Section 201(ff)(1)(F) of the Act.

Q All right. In your expert report you have a "Materials Reviewed" section on page 14, and you talk about that one of the things you have reviewed was the amended complaint, which I want to show you and ask you a couple of quick questions about.

(Exhibit 7 was marked for identification.)

BY MR. WENIK:

Q So, Dr. Welch, I have placed before you

a document I've marked for identification as Welch Exhibit 7, which is the government's amended complaint in this action.

Is this what you were referring to, I take it, in your materials reviewed, the amended complaint?

A Yes.

Q So I'd just like to direct your attention to paragraphs 22, 23 and 24, and if you could take a moment just to read those to yourself, then I'm going to ask you a couple of quick questions.

(Witness peruses document.)

THE WITNESS: I've read 22, 23, and 24.

BY MR. WENIK:

Q So would you agree with me that paragraphs 22, 23 and 24 discuss alleged instances where the defendant, Hi-Tech, purportedly mislabeled the product as containing DMAA when it did not?

A Yes, it seems to be.

Q Okay. My only question to you is: Are you offering any expert opinions in this case on

this subject matter, as to whether or not products that are labeled as having DMAA in them are misbranded because they do not, or adulterated because they do not have DMAA? Are you offering any expert opinions on this topic?

A I am not offering any expert opinion on that.

Q Thank you. Okay.

So turning back to your expert report, I'm looking at paragraph 22, which is on page 11.

You wrote that "To determine whether there is any history of DMAA's use in food which could qualify DMAA as a dietary substance for use by man to supplement the diet by increasing the total dietary intake, ODSP staff, acting under my direction, conducted a search in September 2016 of food databases and published scientific literature."

Do you see that?

A I do.

Q Okay. So my understanding in reading that is that you did not personally conduct any database searches in this matter; is that right?

A Correct.

Q Okay. So what did you do to determine the accuracy of the database searches that were conducted to buttress your expert opinion?

A I reviewed the memorandum they put together for me, ODSP staff. It included some screenshots of the databases, the database search result.

Q And the staff that conducted these database searches, what were their qualifications? Were they scientists, student interns, clerks? Who were they?

A The September 2016 search was conducted by a botanist and a chemist, both FDA employees.

Q All right, and you list in paragraph 22 the search terms that were used; is that right?

A Yes.

Q Who selected those search terms?

A They are the same search terms that were the subject of the previous versions of these database searches in December of 2015 and sometime in 2011.

Q Was any consideration given to expanding the universe of search terms for purposes of your expert report?

A There was no need to expand the search terms. That's a pretty sufficient list, complete list of the nomenclature for DMAA the compound.

Q Geraniums or any synonym for the term geraniums were not part of these database searches, were they?

A No.

Q Why not? Why didn't you search for geraniums or any name that's a synonym for the geranium plant?

A We were looking to determine whether DMAA, a chemical compound, was a substance of the diet, not whether geranium was the substance of the diet.

Q Did anyone conduct a database search for geraniums or any synonym for that term presented to you, but you did not include it in your report?

A There were no database searches for geranium presented to me for this report.

Q Okay. Then you talk about the databases that were searched in the balance of paragraph 22. Do you see that?

A I do.

Q Who selected those databases?

A I don't know who. They are -- the databases -- the NDI review team, the New Dietary Ingredient review team typically search to determine whether an ingredient is a substance of a diet.

Q In paragraph 23 you describe scientific database search of PubMed; is that right?

A Yes.

Q Okay, and like the database search that you describe in paragraph 22, you did not personally conduct that database search that you describe in paragraph 23; is that correct?

A Correct. I did not.

Q What did you do to ensure that that database search was accurate?

A I reviewed the memo that ODSP staff prepared for me. It included a listing of the results, the 51, 3 and 15 publications that were a result of the PubMed search. It was a listing of the article names.

Q My reading of this paragraph is that these search results, the 51, 3 and 15 publications that were identified as a result of the search, that you did not actually review those

publications; is that right? That's how I read this. Is that correct?

A Correct. I did not review all 51, 3 and 15 publications. I didn't read through all the publications.

Q Did you read through any of them?

A I read through some of them.

Q Who selected which ones you would actually read? Did your staff say to you read these four or these five, or did you select them?

A I selected them.

Q All right, and how many of the 70 some odd publications did you actually read?

A The publications that I reviewed for my expert report are listed in Exhibit 1.

Q So all the ones that you list here, these 24 are the things you actually read through in Exhibit 1?

A Those 24 references in Exhibit 1, some of them are publications which I read through. Some of them are other types of --

Q I see. So this list of Exhibit 1 would include some of the things that were a result of the database search you describe in paragraph 23?

A Correct.

Q Okay, and similar to the database search you did and describe in paragraph 22, I don't see geraniums or any synonym for geranium listed for the scientific literature database search; is that right?

A Correct.

Q And why was that? Why didn't you search for geraniums in the scientific literature?

A Our search was to determine whether DMAA, the chemical compound, was a substance of the diet, not whether geranium was a substance of the diet.

MR. WENIK: Okay, and let's take a brief break. I think I'm going to be done before lunch time.

MR. DAVENPORT: Okay.

THE WITNESS: Good.

(Whereupon, a short recess was taken.)

BY MR. WENIK:

Q Back on the record. I'm moving very, very efficiently.

(Exhibit 8 was marked for identification.)

BY MR. WENIK:

Q Okay. So, Dr. Welch, I have placed before you a document I marked for identification as Welch Exhibit 8, which, for the record, is a November 1, 2011 memorandum by Louis Carlacci to Dan Fabricant, amongst others, and you had mentioned earlier when we were talking about the database searches that there was some memorandum, and I think you referred to one from 2011, one from 2015, and one from 2016.

A Yes.

Q Is this the 2011 memorandum that you were referring to?

A Yes, this is.

Q Let me ask you a couple of questions about this.

So what is your understanding of what the purpose of this document was that was prepared in November of 2011?

A The purpose of this memo was a review of DMAA and whether it fits as a dietary ingredient.

Q Okay, and if we look at the first page,

it lists the search terms that were used for some database searches; is that right?

A Yes.

Q All right, and are these the same -- let me actually cross-check it. I'll take the opportunity now.

Are these terms basically the same that you describe in paragraph 22 of your expert declaration?

A My expert report searches more terms than are listed here. It also includes DMAA, 1,3-dimethylamylamine, and dimethylamylamine.

Q So for purposes of your report, you had the search terms expanded somewhat from what was done back in 2011?

A Seems to be, yes.

Q Okay, but again, looking back at 2011, we don't see anything here for geraniums or any synonym for geraniums, do we?

A It doesn't seem to be, no.

Q Okay. Let's turn to the second page.

So my understanding of reading this, if you look at the very bottom of the first page, it says "databases," and that was searched, and then

we have these listed here on page 2.

A Yes.

Q All right. So the first item that's listed is Herbs of Commerce.

Is this a publication you're familiar with?

A Yes, it is.

Q What is Herbs of Commerce?

A Herbs of Commerce is a book published by the American Herbal Products Association, listing out herbs or botanicals used in commerce, for lack of a better term.

Q Okay. It talks about a second edition that was looked at.

Do you know whether that book has been revised since 2000?

A I don't believe they've published a third edition, but I do think they are working on it.

Q "They" meaning the American Herbal Products Association?

A Yes, the American Herbal Products Association.

Q Okay. Then if we go to the next

database, it says "NNFA," and it says, "NNFA List of Dietary Supplement Ingredients."

Is the NNFA part of the Natural Products Association?

A NPA was formerly known as the NNFA or the National Nutritional Foods Association.

Q I see. All right.

Then we have "CRN." What is your understanding of what "CRN" is or what it stands for?

A CRN is the Council for Responsible Nutrition.

Q And what is the Council for Responsible Nutrition?

A CRN is a dietary supplement trade association.

Q Is it, for lack of a better word, a competitor to the NPA of some sort or --

A Yes, for lack of a better term.

Q All right. So the first three databases here, Herbs of Commerce, NFA and CRN, look to be dietary supplement databases, correct?

A Yes.

Q And these other databases that follow,

AGRICOLA USDA, GRAS, PAFA, OFAS, EAFUS, these are government databases?

A Yes, they are.

Q Okay.

(Exhibit 9 was marked for identification.)

BY MR. WENIK:

Q Doctor, I have placed before you a document that I've marked for identification as Welch Exhibit 9, which, for the record, is a memorandum dated December 31, 2015 from Rebecca Allen to you.

My first question is: Do you recognize this document?

A I do.

Q And is this the memorandum that you referred to earlier when you said that there were three iterations, if you will, one from 2011, one from 2015, and one from 2016 of these database searches? Is this the 2015 one you were talking about?

A It is.

Q Okay, and so if we look at this document, it lists on the first page the key words

that were used.

Are these all the same as what you list in paragraph 22 of your declaration?

A Yes, it appears to be the same.

Q Okay. What is your understanding of what the purpose -- let me back up for a minute.

Did you direct that this database search take place in December of 2015?

A I did.

Q And what was the purpose of your having this database search done in 2015?

A In preparation of my expert report, I wanted to have an updated search of the food databases, particularly to ascertain if DMAA is a component of the diet, so I asked two staff members, Rebecca Allen and Steven Casper, to do an updated search.

Q So if I compare Welch Exhibit 9 to the 2011 document which I labeled as Welch Exhibit 8, and Welch Exhibit 9 lists the databases that were searched on page 1, continuing on to page 2, and notably it does not list any of the dietary supplement databases that were searched back in 2011, specifically to Herbs of Commerce or the

predecessor to the NPA or to CRN, why was that? Why were the dietary supplement databases not searched in 2015 when you directed this update to be prepared?

A The point of the December 2015 memo is to ascertain if DMAA is a component of the diet. The Herbs of Commerce, NFA list and CRN list are pieces of evidence to determine whether an ingredient is a dietary supplement ingredient, particularly prior to 1994.

So it's not reasonable to search dietary supplement databases to determine if an ingredient is a component of the diet. We are looking for components of the conventional food diet.

Q Did you direct that they search any cookbooks or cooking websites or anything of that nature?

A I did not direct that they look at cookbooks or cooking websites. FDA needs to have a standard list of databases and lists and sources to determine whether an ingredient is a component of the conventional food diet. Cookbooks and cooking websites are not part of that --

Q I see.

A -- typical search.

Q I see.

Is there any reason why in 2015 you didn't search any non-governmental databases, any commercial websites of any sort?

A No, there's no particular reason why we didn't.

Q And would you agree with me that in 2015, geraniums or any synonym for geraniums were not looked at either?

A Correct. Geranium or synonyms of geranium were not searched in the 2015 memo.

(Exhibit 10 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you what's been marked for identification as Welch Exhibit 10, which, for the record, is a September 21, 2016 memorandum from Steven Casper and Rebecca Allen to you.

My first question is: Have you seen this document before?

A Yes.

Q All right. What is your understanding

of what this document is?
A This memo is an update to the December 2015 memo. As I was finalizing my expert report, I wanted to ensure we had done a more recent review, since nine, ten months had gone by.
Q And the search terms remained the same as they were in December 2015?
A Yes, they appear to be.
Q And were the databases the same as well?
A According to the memo, the September 26 memo searches the dietary supplement label database by NIH, whereas the December 2015 memo searches the dietary supplement ingredient database, which is actually separate, because they are two different databases.
Q And were any hits derived from that label database?
A The September 2016 memo, there are results from the dietary supplement label database search.
Q And where would those appear in the body of the memo here?
A They don't appear to be in the body of the memo.

Q Okay, but I take it DMAA did not come up. Is that what the people that looked at this concluded?
A It looks like they had some hits for labels containing some of the search terms. Those would have been dietary supplement labels, which does not weigh into whether an ingredient is a component of the conventional food diet.
Q I see.
So what would you have been looking for in these database searches to establish that something was a component of the conventional food diet? If you're not looking for a recipe, if you're not looking at a cooking website, if you're not looking at natural products or commercial websites, what is it that you expect to find?
A Some of the databases, GRAS substances, the PAFA, EAFUS, are databases or lists of ingredients that are known to be in foods. Some of them -- the AGRICOLA is looking for foods that list certain ingredients. A plant database would be looking to see if a plant is known to be used in the food diet. The USP or the food chemicals Codex is a list of chemicals found in foods.

So we're looking for information that DMAA, the particular chemical compound, is used in foods.
Q I see.
So I just want to make sure I understand the scope of your opinion.
Are you offering an expert opinion based on what we see here, that DMAA was not in the food supply prior to October 15, 1994?
A I am offering an opinion that DMAA is not a substance of the diet, referring to the conventional food diet, not limited to a date of October 15, 1994.
Q So never part of the --
A DMAA, according to my research, the evidence for my review, DMAA has never been a component of the conventional food diet.
Q All right, and I'm looking back at your expert report, and on page 12, the very last sentence, I want to make sure I understand exactly what you mean in this sentence.
You say, "The food database searches revealed no results for the compound DMAA, which provides the basis for our conclusion that DMAA is

not a food ingredient."
Do you see that sentence?
A I do.
Q All right. So what do you mean by "food ingredient"? Is that something different than a dietary ingredient?
A Yes. A conventional food ingredient is one provision of a dietary ingredient. Paragraph 13, I think it was, listed out what can be a dietary ingredient. "Generally a dietary substance for use by man to supplement the diet by increasing the total dietary intake. If an ingredient is a food ingredient, it will likely fit under category E of the dietary ingredient."
Q All right, and so basically, if I understand what you're saying, it's your expert opinion that DMAA does not meet subsection 321(ff)(1)(E)?
A Correct. That's my opinion.
Q All right, and the basis for that opinion, if I understand what you're saying here, are these database searches that are reflected in Welch Exhibits 10, 9 and 8?
A Yes.

(Exhibit 11 was marked for identification.)

BY MR. WENIK:

Q Okay. So let me for a moment focus your attention back on Exhibit 9.

A Yes.

Q And in Exhibit 9, the memo, one of the articles that was found, if you look at the next to the last page of the document --

A Oh, sorry. Next to the last.

Q Yeah.

A Yes.

Q All right. If you look at reference number 7 here, "methylhexaneamine is not detectable in Pelargonium or geranium species and their essential oils, a multi-center investigation," and it lists a 2015 cite, and it also notes that it was e-published in 2014.

Do you see that?

A I do.

Q And if I look at your declaration, you cited in reference -- in your Exhibit 1 to your expert declaration, reference 24, the 2015 version of the ElSohly article.

A Yes.

Q All right. I placed before you what I've marked for identification as Welch Exhibit 11, which is the e-published version of this article that came out in 2014.

My question to you is: Did you review the e-published version of the article in conjunction with preparing your expert report in this matter as opposed to the version that came out in 2015?

A I don't recall at this time.

Q Okay. So you came on board at the FDA in January of 2014; is that right?

A Yes.

Q All right, and is it fair to say that one of your responsibilities in that first year that you were with the FDA, one of your responsibilities was to be the project manager for the University of Mississippi Natural Products Research Center?

A Yes. I was project officer in May of 2014.

Q Okay. So the e-version of this came out in August of 2014, Welch Exhibit 11.

Do you see that up at the top?

A I do.

Q So my question to you is: From May 2014 to when this was published, do you recall any conversations you had with any of the authors as to what conclusions they were going to publish in the article?

A No, I don't recall any conversations.

Q Okay. So if we look at the abstract to the article, it says in the very last line, "None of the laboratories detected MHA in any of the samples at or around the ten parts per billion detection level of the procedure used."

Do you see that?

A I do.

Q What is your understanding what "MHA" stands for?

A Methylhexaneamine.

Q Is that a synonym for DMAA, if you will?

A It is.

Q All right. Did the authors of the study ever reveal to you in 2014, before it was published, that some of the study centers had, in fact, found DMAA in some of the plant samples that

were reviewed?

MR. DAVENPORT: Objection to the form of the question.

You can answer if able.

THE WITNESS: I am not aware of any conversation discussing what you proposed.

(Exhibit 12 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a document I've marked as Welch Exhibit 12, and I suspect you've probably not seen this before, so please take a minute or two to just thumb through it, and I want to ask you a couple of questions.

(Witness peruses document.)

THE WITNESS: Okay.

BY MR. WENIK:

Q All right. So my first question to you is: Having had an opportunity to look at what I've marked for identification as Welch Exhibit 12, which, for the record, is an email chain accompanied by a series of chromatograms, have you seen this document before?

A I have not.

Q Okay. In the first page, the scientists in the email chain refer to having found "DMAA could be detected by MRM method." I know you have some experience in chemistry.

What is your understanding of what the MRM method is, if you have an understanding?

A I don't recall at this time.

Q Okay.

So I'm looking at the fourth page in, which is page 5894.

A Okay.

Q All right, and there is some series of chromatograms there, and it says Figure 5, and it says that the "isomer of 1,3-dimethylamylamine," I'll just say DMAA, "was detected in samples 13040, 13041, 13047, 13048 and 13049."

And if I turn your attention to what I marked as Welch Exhibit 11, to page 3, there's a table, Table 1, that lists all the samples with their identifying numbers, and if we look at the list here, it lists 13040, 13041, 13047, 13048 and 13049 as having no DMAA detected in those samples.

My question to you is: Were you aware of the discrepancy between chromatograms submitted

to the researchers that published this article and the data that they actually published?

MR. DAVENPORT: Objection to the form of the question, one. Two, Counsel, she's not here to render an opinion on DMAA as a constituent of the geranium plant, which is the subject of Exhibits 11 and 12.

MR. WENIK: And that's fair, but I think, candidly, she's a fact witness to the extent she was the project manager for these people, and she was on board in 2014 and in theory would have reviewed this. So I agree with you. I'm not asking her as an expert.

BY MR. WENIK:

Q But I'm asking you, as a matter of fact, you were the project manager and gave these people two and a half million dollars in 2014. Did they share this with you?

MR. DAVENPORT: I'm going to object again to the form of that question, and object to your characterization.

With that understanding, you can answer, Dr. Welch, if able.

THE WITNESS: I'm not familiar with

these chromatograms at all, and I don't have all of the information at hand, so I don't -- I can't answer whether there is a discrepancy.

BY MR. WENIK:

Q Okay. As the project manager, did you choose the centers that the research was conducted at that is reflected in this article, or was that delegated to these researchers?

A The project officer -- my role as the project officer, I had nothing do with the design of this study.

Q Is there a written contract that governs that grant, that two-and-a-half-million-dollar grant between the University of Mississippi Natural Products Research Center and the FDA?

MR. DAVENPORT: Objection to the form of the question.

THE WITNESS: It's not a contract. It's a cooperative agreement, which is much more similar to a grant. There is a -- I don't know the appropriate term. There is a grant agreement of sorts.

BY MR. WENIK:

Q Okay, and would they submit that to you as project manager for your review every year?

A Part of being a project officer is I receive quarterly -- I have quarterly meetings with NCNPR. I explain to them FDA's research priorities pertaining to botanical dietary ingredients and dietary supplements. We discuss the research that they are working on. We don't get to the level of reviewing results in any particular fashion.

Q Is there a provision in the grant application to rescind payment if they falsify research results?

A I have no idea.

Q In preparing your expert opinions, did you rely on any analyses or memoranda from any international regulatory bodies from other countries?

A I'm sorry. Can you repeat the question?

Q Yeah.

Coming to your opinions that are reflected in your research, I didn't see in your reference list any citations which I've seen in

other depositions to any of the DMAA analyses that have been conducted by other countries such as Denmark and Canada, Australia, what-have-you.

Did you not consider any of that in coming to your opinions?

A I don't believe so. The references that I did consult and draft in my expert report are listed in Exhibit 1.

Q All right. Are you familiar with a conference that is held annually called the Oxford International Conference on the Science of Botanicals that is held in Oxford, Mississippi?

A Yes, I'm aware of it.

Q What is your understanding of what this conference is?

A It's an international conference, largely focused on botanical dietary supplements, botanical dietary ingredients. It is put on by NCNPR at U Miss. It is part of the cooperative agreement that NCNPR has with FDA.

Q Did you attend this conference in your capacity as an employee of the Natural Products Association before you came on board with the FDA?

A Yes, I believe so.

Q Would you make it a point of going every year?

A I did not attend every year.

Q Do you know whether you attended in 2013, the year before you joined FDA?

A I believe I did.

Q As part of the cooperative agreement between the FDA and the University of Mississippi Natural Products Research Center, do they submit for your review, for the project officer to review, PowerPoint presentations that they're going to make at this conference?

A No.

Q Do you recall attending any PowerPoint presentation by Dr. ElSohly at the 2013 conference?

A I don't remember. I don't recall.

Q Have you seen the PowerPoints from that 2013 conference regarding his purported research on DMAA?

A I don't recall at this time. If I attended that presentation in 2013, I would have seen it. I don't recall particularly having viewed his or other presentations from 2013.

Q If he had prepared PowerPoints which contained false information, would that have been something of interest to you as the project officer for this cooperative agreement?

A FDA has this cooperative agreement with U Miss, the Natural Center for Natural Products Research, because they are experts in the field of botanical dietary supplements and botanical dietary ingredients. They are considered experts, not just by FDA, but by other external parties as well.

So it's certainly important to the program's success if they are very clear in the scientific results that they publish, important to FDA, important to other parties, and, of course, important to the University of Mississippi.

Q Let me ask you this.

So I'm looking back at your report, your expert report, Welch Exhibit 2, and you cite as references -- in reference 15 you cite the 2012 ElSohly research regarding DMAA that was published as a result of the University of Mississippi research, in reference 15, and you cite in reference 24 the research they did on DMAA at the

University of Mississippi that was published in 2015, as I've shown you e-published in 2014.

Would it change your opinions, your expert opinions in this matter if you determined that one or both of those articles had been manipulated to publish false results?

MR. DAVENPORT: Objection to the form of the question.

You can answer if able.

THE WITNESS: I have no indication that they falsified their published reports. If evidence came to us that they had presented false information with no explanation as to why, it would be important to me as project officer.

BY MR. WENIK:

Q And how would it affect your expert opinion in this matter?

A The results published in those articles don't weigh into -- don't largely weigh into whether DMAA is a vitamin, a mineral, an herb or botanical, an amino acid or dietary substance for use by man to supplement the diet. So largely it wouldn't affect my expert report.

Cara R. Welch, Ph.D.

MR. WENIK: Okay. I think that is as good a place as any for me to conclude my questioning.

MR. DAVENPORT: I have no questions. We'll read.

(Signature having not been waived, the deposition of CARA R. WELCH, Ph.D. was concluded at 12:20 p.m.)

ACKNOWLEDGEMENT OF WITNESS

I, Cara R. Welch, Ph.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached Errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

NAME OF CASE:
DATE OF DEPOSITION:
NAME OF WITNESS:
Reason Codes:
1. To clarify the record.
2. To conform to the facts.
3. To correct transcription errors.

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CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

I, Laurie Donovan, Registered Professional Reporter, Certified Realtime Reporter, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 2nd day of December, 2016.

My commission expires: March 14th, 2021

_____

LAURIE DONOVAN
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA

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