Exhibit 52

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Transcript of **Paul Simone, Ph.D.**

November 7, 2016

US v. Hi-Tech Pharmaceuticals, Inc.

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Alderson Reference Number: 67175

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

UNITED STATES OF AMERICA,	)	Civil Action No.
Plaintiff,	)	1:13-cv-3675-WBH
v.	)	
UNDETERMINED QUANTITIES OF...	)	
1,3-DIMETHYLAMLAMINE HCI	)	
(DMAA)...,	)	
Defendants,	)	
and	)	
HI-TECH PHARMACEUTICALS, INC.,	)	
and JARED WHEAT,	)	
Claimants.	)	

DEPOSITION OF PAUL SIMONE, Ph.D.
WASHINGTON, D.C.
MONDAY, NOVEMBER 7, 2016
9:30 A.M.

Job No.: 67175
Reported by: Leslie A. Todd

Deposition of PAUL SIMONE, Ph.D., held at the offices of:

EPSTEIN BECKER & GREEN, PC
1227 25th Street, NW
Suite 700
Washington, DC 20037
(202) 861-0900

Pursuant to notice, before Leslie Anne Todd, Court Reporter and Notary Public in and for the District of Columbia, who officiated in administering the oath to the witness.

A P P E A R A N C E S

ON BEHALF OF PLAINTIFF:
CLAUDE SCOTT, ESQUIRE
JAMES W. HARLOW, ESQUIRE
United States Department of Justice
Consumer Protection Branch/Civil Division
450 Fifth Street, NW
Suite 6400S
Washington, DC 20530

ON BEHALF OF DEFENDANT:
SHEILA A. WOOLSON, ESQUIRE
Epstein Becker & Green, PC
1 Gateway Center #13
Newark, New Jersey 07102
(973) 642-1271

ALSO PRESENT:
DARYL GRIGLAK (Intern)

C O N T E N T S

E X H I B I T S
(Attached to transcript)

E X H I B I T S C O N T I N U E D
(Attached to transcript)

EXHIBITS CONTINUED
(Attached to transcript)

EXHIBITS CONTINUED
(Attached to transcript)

PROCEEDINGS

PAUL SIMONE, Ph.D.,
having first been duly sworn, was
examined and testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFF
BY MR. SCOTT:

Q All right. Could you state your full name for the record, please, sir.

A Dr. Paul Steven Simone, Jr.

Q All right, sir. Now, have you had your deposition taken before?

A I have not.

Q All right. Well, I'm sure you have been over this with your attorney, but a few ground rules to make this a little more easy on all of us, particularly the court reporter.

First of all, you do understand you're under oath?

A Yes.

Q Now, secondly, if during the course of our conversation today I ask a question and you're

not clear on what the question means or what it is I'm seeking by way of information through the information, don't be shy, tell me that, and I will be glad to go back and rephrase the question or explain before you begin your answer.

All right?

A I understand.

Q And if you answer the question, I'm going to assume that you understood it. Okay?

A I understand.

Q Now, in addition, you will have to answer verbally because nods and shakes of the head don't show up very well in the transcript.

Also, as I'm asking questions, there will be a tendency sometimes for you to anticipate where I'm going and try to start answering the question before I finish. Sometimes I will do the same thing in reverse. It's very difficult for the court reporter if we talk over each other. So I will try very hard to give you a chance to finish your answer before I ask another question, and if you could, let me get the question out completely before you begin

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your answer for her sake, if nothing else.
Okay?
A I understand on both counts.
Q Okay. And during the course of the deposition today, if you need to take a break for any reason, just let us know and we will -- at the next appropriate spot in the questioning, we will try to accommodate you. All right?
A All right. Sounds good.
Q All right, sir.
MR. SCOTT: I'm going to note for the record that I have marked as the first exhibit to the deposition a copy of the deposition notice for the deposition.
(Exhibit No. 1 was marked for identification.)
MR. SCOTT: I will also note for the record that this is a deposition of Dr. Simone in two capacities. It is as a fact witness as well as an expert witness, subject to agreement of the parties.
BY MR. SCOTT:
Q Now, Dr. Simone, what, if anything, did

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you do to prepare to testify today?
A I reviewed the expert witness reports of Khan, Brown, and Kompatnick, as well as their rebuttals, and other documents produced in this case.
Q All right, sir. And when did you do that, review those reports and the documents that you just referred to?
A Prior to this deposition.
Q I mean, was it this weekend, last week, three weeks ago?
A All through that time. As best as I can recall.
Q All right, sir. Now, where are you currently employed?
A The University of Memphis.
Q What is your position there?
A Associate professor. I'm tenured.
Q You are tenured?
A Yes.
Q And when did that occur?
A September 1, 2016.
Q All right, sir.

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(Exhibit No. 2 was marked for identification.)
BY MR. SCOTT:
Q All right. So you have in front of you what's been marked as Exhibit 2 to your deposition. It is a three-page document.
The first page says "University of Memphis, Department of Chemistry, Paul Simone, Assistant Professor, Chemistry Department."
Do you see that?
A I do.
Q And do you recognize this document as something that you've seen previously?
A Not that I can recall.
Q All right. So you don't know if this is the information that Memphis puts on its website regarding you?
A It looks like it. I mean, I haven't looked at this in quite a while.
Q Did you look at it before it was posted?
A Probably.
Q Well, in the documents, it says: "About

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Paul Simone: Dr. Paul S. Simone, Jr., is Assistant Professor of Chemistry at the University of Memphis where he earned his BH -- B.S.Ch, M.S. and Ph.D., and started his career as a tenure-track professor at The Citadel in Charleston, South Carolina."
Do you see that?
A Yes.
Q Is all that information accurate?
A Yes.
Q It goes on to say that: "Dr. Simone works at the nexus of research and business, developing new technologies at the University of Memphis to help drinking water utilities comply with ever stricter USEPA regulations of drinking water disinfection byproducts."
Do you see that?
A Yes.
Q Is that accurate?
A Yes.
Q And when you -- the reference there to drinking water disinfection byproducts, what does that mean?

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A Broadly, it is the regulations concerning the concentrations of trihalomethanes and haloacetic acids in drinking water produced during the disinfection of water through chlorination. And the concentrations of trihalomethanes and haloacetic acids range approximately from 1 to 80 parts per billion.

Q All right. Sir, and is that your area of specialization, those types of chemicals and their detection and perhaps treatment in some way?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: Can you repeat the question?

BY MR. SCOTT:

Q Sure. The area of developing technologies to help drinking water utilities comply with ever stricter USEPA regulations of drinking water disinfection byproducts, is that your area of specialty?

MS. WOOLSON: Same objection to form.

You can answer.

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THE WITNESS: I would say my area of specialty is analytical chemistry, and this -- the work that I do in drinking water is a small part of -- well, not small, but a part of what I do as a professor.

BY MR. SCOTT:

Q All right. Sir, your working in drinking water, what percentage does that represent of your independent research and lab work?

MS. WOOLSON: Is there a time frame for that question?

MR. SCOTT: Right now.

MS. WOOLSON: You can answer.

THE WITNESS: Repeat that.

BY MR. SCOTT:

Q Sure. Do you do independent research as part of your job?

MS. WOOLSON: Well, that's a different question.

But you can answer.

MR. SCOTT: I'm aware it's a different question. He asked -- he seemed to not understand

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the other one, so I asked another one. I can do that.

MS. WOOLSON: He asked you to repeat it, but that's okay.

You can answer the question.

THE WITNESS: Yes.

BY MR. SCOTT:

Q Well, as part of your job, do you go into the lab and supervise work that's being done by people?

A Yes.

Q And is most of that work done in the area of drinking water?

MS. WOOLSON: Are you still talking about presently today?

MR. SCOTT: Yes.

MS. WOOLSON: You can answer.

THE WITNESS: Yes.

BY MR. SCOTT:

Q And has that always been the case since you've been at the University of Memphis regarding the lab work that you're involved with that's been

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involved with chemicals in drinking water, that most of it has been?

A Most of it.

Q And when you say "most of it," over the time since you've been with Memphis coming to today, what percentage of your work has been dedicated to issues pertaining to drinking water?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: I can't give you a hard number.

BY MR. SCOTT:

Q Well, give me a loose number then.

A 75 percent.

Q Of the lab work that you've done?

A No. Of the research that I've supervised and directed.

Q Do you yourself directly do lab work?

A Occasionally.

Q And when you say "occasionally," what does that mean?

A When it's necessary.

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Q All right. And when you found it necessary for you yourself to do lab work from the time frame from when you joined the University of Memphis to today, has the majority of that been in the area of drinking water and drinking -- chemicals and contaminants in drinking water?
A Yes.
Q What percentage?
A 75 percent roughly.
Q And the other 25 percent where you've done lab work, what subject matter has that related to?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I guess I don't understand the question.
BY MR. SCOTT:
Q Well, you said 75 percent of your lab work was dedicated to projects related to drinking water. What does the other 25 represent?
MS. WOOLSON: And you are talking about from the day he started at the University of Memphis

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to today?
MR. SCOTT: Yes.
MS. WOOLSON: You can answer.
THE WITNESS: And this is lab work I've specifically done and not directed?
BY MR. SCOTT:
Q Yes, sir.
A I mean, some of it's geranium work; some has been analysis of haloacetic acids in bleach.
Q Anything else?
A Not that I can recall.
Q Now, the 25 percent of the lab work and research that you have supervised that does not relate to drinking water, what does that relate to?
MS. WOOLSON: I'm sorry. You said research he supervised?
MR. SCOTT: Yes.
MS. WOOLSON: Okay. You can answer.
THE WITNESS: The geranium and haloacetic acids in bleach work.
BY MR. SCOTT:
Q How much of that time relating to the

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work that you've directed has been relating to haloacetic acids in bleach versus the geranium work?
A About equal.
Q So about 12-and-a-half percent each?
A Sounds reasonable.
Q And how about the lab work yourself, what percentage -- that you yourself had done, what percent relates to your research pertaining to haloacetic acids in bleach and what relates to geranium work?
A I would say about the same, about 12-and-a-half percent.
Q All right. Are you currently doing any work relating to geraniums?
A What time frame are you referencing?
Q Well, when I said "currently," I meant currently. Are you currently doing any work pertaining to geraniums?
A I guess I don't -- we may have a different definition of "currently."
Q Well, what is your definition of "currently"?

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A I mean, I've -- we have work that is ongoing that is stalled, for lack of a better term, for a variety of reasons, and so we're not putting effort into it right now.
Q Well, let's back up and do it this way: When was the last time that you were actively in your lab doing work pertaining to geraniums and chemicals in geraniums?
MS. WOOLSON: And I assume you mean other than Dr. Simone's appearance here today.
MR. SCOTT: Well, I don't think he is doing this in his lab, so let's --
MS. WOOLSON: I asked you a question. You can clarify.
MR. SCOTT: I don't need to. And if you want to object, you can object. I'm not going to take colloquy from counsel.
MS. WOOLSON: I'm going to defend the deposition as I see fit, and if I think your question is misleading, I'm going to correct it and ask you to rephrase it, which is what I've just done.
MR. SCOTT: And do what you want, and if

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I need to do something regarding your interference with questioning, I will do that too.
MS. WOOLSON: It's not interference with questioning, Counsel.
By MR. SCOTT:
Q Sir, when was the last time you were in your lab doing work pertaining to geraniums?
A Did you -- is that a different question than before?
Q Yes, sir, it is. I get to do that.
A So are you --
MS. WOOLSON: Counsel, no attitude.
MR. SCOTT: I don't have an attitude about this.
MS. WOOLSON: Yes, you do.
MR. SCOTT: No, I don't.
MS. WOOLSON: Yes, you do.
THE WITNESS: So, so I'm clear, just -- are you -- so I think before the question was what lab work I was supervising related to geranium, and now are you asking me what I've done personally on geranium and DMAA?

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BY MR. SCOTT:
Q Yes, sir.
When was the last time you were personally in your lab doing work pertaining to DMAA?
A As best as I can recall, the summer.
Q The summer of what year?
A 2016.
Q And what did that work entail?
A We were trying to develop a method to separate the four stereoisomers of 1,3-DMAA -- I'm sorry -- 1,3-dimethylamylamine and geranium plants using the chiral derivatizing agent and a non-chiral gas chromatography column.
Q All right. And was that work sponsored by anybody in particular?
A No.
Q You were doing that just as a research project?
A The funding for that work had started with USP Labs, I don't remember, back in 2012, 2013, sometime in that time frame. I'll be honest, the -- when the chiral derivatizing agent stuff started, it

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was after the contract work I did for them. But that funding ran out, and I've subsequently pursued it just because I would like to know if it's possible.
Q All right, sir. And when you stopped doing this work pertaining to chiral derivatizing, had you successfully developed a protocol that would allow you to identify or separate the chiral footprint?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Can you repeat the first part of the question?
BY MR. SCOTT:
Q Well, let me withdraw the question and ask it again, perhaps more simply.
A Okay.
Q The work that you were doing on chiral derivatizing, did you consider it to have come to a successful conclusion?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.

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BY MR. SCOTT:
Q And why not?
A We developed a method to extract and -- the 1,3-DMAA, we were able to successfully derivatize it and successfully separate the stereoisomers of 1,3-DMAA and 1,4-DMAA at the same time. I was very excited, and my -- and then basically -- the instrumentation we had is all a decade or more older and it finally gave out, and it hasn't been repaired since.
Q What instrumentation was that?
A The gas chromatograph with mass spectrometer. That was an ion trap system, and unfortunately, our triple quad litho chromatograph tandem MS.
Q All right, sir. And during -- was that also the last time that you had -- were doing work while you were supervising work pertaining to DMAA?
A Yes.
Q Any other projects relating to DMAA ongoing when you shut this particular one down?
A Not that I can recall.

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Q Are you familiar with a group that goes -- I believe I got this right and you can correct me if I'm wrong -- an acronym MAMML?
A Oh, yeah, that's MAMML. Mobile analytical monitoring and modeling laboratory.
Q And what is that?
A It's the research group that I direct with my colleague Gary Emmert.
Q Does all the research you direct go through this group?
A Yes.
Q And what is the -- the mobile lab, is it actually a mobile lab that goes out in like a truck or something like that, or is this something else?
A No, we're actually mobile. We pack up our instruments and we go to various water utilities and set up and conduct week-long monitoring studies or longer at drinking water treatment plants, and these monitoring studies are the longest on record in the field.
Q All right, sir. And the work that's done through MAMML is again work relating to drinking

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water?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: It's related to drinking water. It's related to this DMAA project. It's related to whatever we happen to be doing.
BY MR. SCOTT:
Q All right, sir. Has MAMML taken on any projects pertaining to testing for chemicals in plant medium other than the DMAA project while you've been there?
A No, not that I can recall.
Q Now, have you been involved either personally during research or in a supervisory role in projects pertaining to testing for chemicals from plant medium other than the DMAA project while you've been at Memphis?
A Can you -- I'm sorry. Can you repeat that?
Q Sure. I'll try. The DMAA project that you were involved in looking for chemicals in plant medium, i.e., geraniums -- that's what you were

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involved in both in a supervisory and direct capacity, correct?
A Yes.
Q Is that the only project pertaining to searching for chemicals in a plant medium that you've engaged in since you've been at the University of Memphis?
A As best as I can recall, yes.
Q What about when you were at The Citadel, did you have any projects there that you were involved in either supervising or direct work looking for chemicals in a plant medium?
A Not that I can recall.
Q Now, Exhibit 2 refers to the development of technology pertaining to contaminants, carcinogens and other chemicals in drinking water.
Do you have any patents on any technology that has been developed based on your research?
A Yes.
Q And how many do you have?
A Five or six.
Q Are all of those patents in technologies

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relating to drinking water contaminants?
A Say that again.
Q Sure. Are all of your patents, the five or six that you have, do they relate to technologies associated or related to contaminants in drinking water?
A I would say they are related to technology associated with drinking water disinfection byproducts.
Q Do any of those patents relate in any way, shape, fashion or form to DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Not directly.
BY MR. SCOTT:
Q Indirectly?
A Yeah. Yes.
Q How?
A So as a analytical chemist, my, I guess, specialty really comes down to developing new ways for sample handling and sample preparation, and using those in conjunction with calibrations and

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calibration methods to analyze drinking water disinfection by-products.

But in the end, a good analytical chemistry is still good analytical chemistry, whether it's in drinking water or it's in plants, and it's all the things that I learned in developing those methods for drinking water. I can apply some of those concepts to analysis of 1,3-dimethylamylamine in geranium plants.

Q All right, sir. The patents that you have, did you use any of those techniques in searching for 1,3 or 1,4-DMAA in the context of geraniums?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: Yes.

BY MR. SCOTT:

Q Which ones, which patents?

A There was a patent that used standard addition to analyze for trihalomethanes and haloacetic acids in a single instrument.

Q Standard addition meaning what in that

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answer?

A Standard addition calibration protocol.

Q Which means what?

A Are you asking me to explain standard addition calibration to you?

Q Yeah.

A Okay. So in standard addition, you typically have a sample that you suspect may have interferences or matrix effects. Usually those samples are relatively complex. You may think drinking water is not that complex, but it is a challenging matrix to work in. The haloacetic acids and THMs are at, you know, somewhere between 1 and 80 part per billion depending on the drinking water plant.

At the University of Memphis and in Memphis in general the concentrations of those compounds are very low, 1 to 5 parts per billion. At a place like the city of Houston, they're higher, somewhere around 50 parts per billion for each class.

And so we use standard addition to minimize those effects, and the way we do it is we

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take our sample and we analyze it, and then we take another aliquot of that sample and spike in a standard and analyze it. And then we take a -- and we can take multiple samples, we can do one or multiple, and we spike in successively increasing standards.

And you can do standard addition as either what amounts to single point standard addition where you have a sample and the spike alone, and using an algebraic equation, you can determine the concentration of that sample while minimizing matrix effects. You can also do a graphical standard addition, which is essentially what we did in this 1,3-DMAA project. And, again, that minimizes interferences.

Q Now, the patent that you had that you are referring to here regarding standard additions, you're not saying that you patented the method of standard addition?

A No.

Q You're just saying that in the patent you used standard addition?

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A We patented a way to do online standard addition.

Q Do you do that online standard addition in relation to 1,3 or 1,4-DMAA testing?

A No.

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: No.

BY MR. SCOTT:

Q Now, you said that your particular area of specialty is analytical chemistry, correct?

A Correct.

Q Could you define for me what you mean by analytical chemistry?

A Well, very, very broadly and loosely, the determination of chemical species in various matrices.

Q Well, how do you define "analytical chemistry" in the context of your specialty, your specialization in that?

MS. WOOLSON: Objection to form. Asked and answered.

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You can answer.
THE WITNESS: The determination of chemical species in environmental matrices.
BY MR. SCOTT:
Q What do you mean by "chemical species"?
A Chemical compounds such as, but not limited to, the nine haloacetic acids that are typically present in drinking water, five of which are regulated by the USEPA, the 4-trilomethanes that are regulated by the USEPA, other compounds that may or may not be present and determining whether they're present and whether they're not present. You know, the analysis of bleach solutions, the analysis of -- the analysis of bleach solutions for trihalomethanes and haloacetic acids and hexavalent chromium.
In terms of geranium, the analysis of 1,3-dimethylamylamine and 1,4-dimethylamylamine in geranium plants. It's all different chemical species that we try to develop to analyze the matrices.
Q So do you consider yourself having any specialization or expertise in phytochemistry?
A In what?

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Q Phytochemistry.
A What do you mean by "phytochemistry"?
Q You don't know what the term "phytochemistry" means?
A Yeah, I know what it means, plant chemistry, but --
Q Well, I will ask it that way: Do you have any expertise or training in plant chemistry?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I've got expertise in analyzing 1,3-DMAA and 1,4-DMAA in plants.
BY MR. SCOTT:
Q Well, let me ask you this: Have you had any training in plant chemistry?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: When you say "training," do you mean somebody formally advised me like a Ph.D. advisor or post-doc advisor training, or do you mean using my expertise as an analytical chemist?
BY MR. SCOTT:

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Q Well, generally, when I use the term "training," I'm asking you, have you had any training. Did you take any coursework in plant chemistry in the context of getting any of your degrees?
A No.
MS. WOOLSON: So you're asking the witness if he took a course in plant --
MR. SCOTT: Well, he's already answered the question.
MS. WOOLSON: That's all right. That's fine.
BY MR. SCOTT:
Q Have you had any formal training, class work relating to botany?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I had Biology 101 as a freshman in college.
BY MR. SCOTT:
Q Other than Biology 101 as a freshman in college, have you had any botany training?

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MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I worked as a landscaper in high school and college.
BY MR. SCOTT:
Q Did they give you botany training to work as a landscaper?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: You know, you're -- I guess I'm trying to answer your question as honestly as I can. I mean, I haven't taken any further coursework in botany.
BY MR. SCOTT:
Q Since freshman year Biology 101, you've taken no coursework in botany?
A That's correct.
Q What courses do you teach at the University of Memphis?
A General chemistry --
MS. WOOLSON: Currently?
MR. SCOTT: Yes, currently.

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MS. WOOLSON: You can answer.
THE WITNESS: Right now I teach instrumental analysis.
BY MR. SCOTT:
Q What is that?
A It is a class on using instrumentation to conduct analytical chemistry.
Q Since you have been at the University of Memphis, have you taught other courses other than instrumental analysis?
A Yes.
Q What other courses have you taught?
A I taught General Chemistry I, and two advanced analytical classes at the graduate level, at the doctorate level. And to be clear, instrumental analysis is at the undergrad and graduate level.
Q All right, sir. The advanced analytical chemistry that you've taught, what does that entail?
A I have taught coursework on mass spectroscopy analysis, UV-Vis absorbance analysis, and chromatography.
Q These are techniques or technologies used

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in doing analytical chemistry?
A Correct.
Q Have you taught any coursework where the subject matter was phytochemistry?
A I have taught materials on -- related to 1,3-DMAA and chiral separations, but not specifically phytochemistry.
Q What course did you teach using materials pertaining to 1,3-DMAA?
A It was one of the advanced analytical courses, the graduate level courses where I discussed not specifically 1,3-DMAA but chiral separations and the methods pertaining to those separations.
Q Have you had any training in any courses pertaining to pharmacology?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.
BY MR. SCOTT:
Q Have you had any training in courses relating to plant biological structures?
MS. WOOLSON: Objection to form.

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You can answer.
THE WITNESS: No.
BY MR. SCOTT:
Q And have you had any training in courses that pertain to plant biological functions?
MS. WOOLSON: Object to form.
You can answer.
THE WITNESS: No.
BY MR. SCOTT:
Q Now, other than the work that you did for USP Labs and you published pertaining to that, have you published any articles pertaining to testing for chemicals in plant medium?
A No.
Q Do you currently have any ongoing research projects pertaining to identification of chemicals in plant medium other than anything that you were or are doing pertaining to DMAA?
A No.
(Exhibit No. 3 was marked for identification.)
BY MR. SCOTT:

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Q All right, sir. You have in front of you what's been marked for identification purposes as Exhibit 2 --
MS. WOOLSON: Three.
BY MR. SCOTT:
Q I'm sorry, Exhibit 3, you're right. Let me start again.
You have in front of you a document which has been marked for identification purposes as Exhibit 3 to your deposition. It's a multi-page document.
The first page you see there says "Declaration of Paul S. Simone, Jr., Ph.D.," correct?
A Correct.
Q All right, sir. And if you would turn over in the document to page 49. Let me know when you are there. All right?
A Okay.
Q Is that your signature over the typed line Paul S. Simone, Jr., Ph.D.?
A Yes.
Q And you signed this on or around

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October 4th, 2016?
A Yes.
Q And you understand -- so you signed this document as a declaration, an affidavit swearing to its contents?
A Yes.
Q All right, sir.
Are all of your opinions that you are planning on offering in this case contained in Exhibit 3, your declaration?
A Say that again.
Q Sure.
Do you understand when you prepared the declaration, you were to put in there the opinions you're going to talk about if this goes to trial, right?
A Yes.
Q Are all of your opinions that you plan to talk about at trial within the document?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: As best as I can estimate.

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I mean, I assume so.
BY MR. SCOTT:
Q Well, do you know of any other opinions that you have that you may testify about at trial that you didn't put in the document?
A Not that I'm planning to.
Q I'm not sure what that means, not that you're planning to.
A I don't plan to do that. I mean, I don't -- I don't know what's going to happen at trial. I've never been to trial, so...
Q Well, sitting here today, is it accurate that you are not aware of any opinions that you may offer at trial that aren't in your declaration, Exhibit 3?
A I'm sorry. I missed the first half of the question. Can you state it again?
Q Sitting here today, can you tell me of any opinions that you might offer at trial that aren't in Exhibit 3, your declaration?
A Are you looking for a "yes" or "no" answer?

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Q Yeah.
A I mean, I -- I guess I plan to testify about what's in this document.
Q And right now you don't know of anything else you would testify about?
A Not off the top of my head.
Q Okay. Now, when you were retained to give expert testimony in this case, who contacted you?
A Honestly, I can't remember.
Q Was it a lawyer?
A Probably.
Q All right. Do you recall when it was you were retained?
A No.
Q Do you remember if it was in 2015?
A I -- I honestly don't remember.
Q Do you recall what you were asked to do as an expert?
MS. WOOLSON: Well, I'm going to caution the witness insofar as your question may require him to testify about attorney-client privileged

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communications. Subject to that, you can answer the question.
THE WITNESS: Can you repeat the question?
BY MR. SCOTT:
Q Well, let me ask it this way: At some point you sat down and wrote this report, right?
A (The witness nods.)
Q You have to say "yes" for her.
A Oh. Yes.
Q And when you sat down to write the report, what was it that you had in mind that you were supposed to put in a report? What were you to address?
MS. WOOLSON: Objection. Form.
You can answer the questions, plural.
THE WITNESS: What was in this report, like stuff in this report.
BY MR. SCOTT:
Q Okay. Well, did somebody ask you to cover certain topics in the report, or did you just make it up as you went along without any direction?

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A Oh, oh --
MS. WOOLSON: Objection to form, compound question, calls for the disclosure of attorney-client privileged communication, and misstates facts in evidence.
Subject to all of that, you can answer the question.
MR. SCOTT: So let me just be clear. Are you saying that he is your client?
MS. WOOLSON: He's our expert.
MR. SCOTT: So how are conversations with somebody who is not your client attorney-client communications?
MS. WOOLSON: Counsel, you are perfectly capable of understanding the Rules of Civil Procedure and knowing why I --
MR. SCOTT: Oh, I am, yes, I agree.
MS. WOOLSON: And so am I.
MR. SCOTT: But that's not a well-founded objection.
MS. WOOLSON: So you can understand the objection that I made, and your attitude is duly

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noted and not welcomed.
MR. SCOTT: Well, I have no attitude about this. I'm trying to understand how you can be making the objection that you are making, which I don't think is well-founded. So obviously --
MS. WOOLSON: Well, that's your opinion, but you and I both know the law as it applies to attorneys and clients and experts and what is and isn't proper.
BY MR. SCOTT:
Q Well, let me ask you, you're here to testify, you realize, in your personal capacity as well as an expert, right?
A Yes. But hold on. I'm -- my understanding is I'm here to testify as an expert witness related to my expertise in analytical chemistry as it relates to the presence of 1,3-dimethylamylamine in geranium plants.
Q So you weren't told you're also appearing in your own individual capacity as Paul S. Simone and not as Paul S. Simone, the expert?
A I -- honestly, I'm not a lawyer, and

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like -- I've been told it's a fact and expert, but --
Q So you were told it's a fact and an expert deposition?
A Yes.
MS. WOOLSON: And your question related specifically to his declaration as an expert. So --
MR. SCOTT: Sure. And now I'm asking a different question.
MS. WOOLSON: Well, let's just be clear that that's what you're doing.
MR. SCOTT: Well, I think the record is pretty clear what I asked. And I would ask you to please watch your attitude.
BY MR. SCOTT:
Q Now, the question I had, sir, is, is anybody here representing you in your personal capacity as a fact witness?
A I don't know.
Q Well, did you say to anybody, I'm hiring you to be my lawyer for my fact deposition?
A No.
Q Okay. Now, in relation to the expertise

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that you have shared with us in your report, Exhibit 3, what do you believe that expertise to be?
MS. WOOLSON: Objection to form, asked and answered.
You can answer.
THE WITNESS: The analytical chemistry of 1,3-DMAA in geranium plants.
BY MR. SCOTT:
Q All right. And the basis of your testimony regarding the analytical chemistry of 1,3-DMAA in geraniums plants, is that based on the work that you did for USP Labs?
A Yes. And the work that I've continued since the funding from USP Labs stopped.
Q Which was a continuation of work that you had started for USP Labs.
MS. WOOLSON: Objection to form.
You can answer.
BY MR. SCOTT:
Q Correct?
A I had two contracts from them. One was a simple analysis contract, and the other was the

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contract for NMR and chiral separation.
Q All right. And the work that you said that you were doing through this summer, which was a continuation of work that you had started for USP Labs, that was relating to the NMR and chiral separation contract?
A Yes.
Q All right. So that was work that, although you were doing it through the summer without being paid by USP Labs, it was a continuation of work you had started for USP Labs?
A Yes.
Q Now, the first contract that you had with USP Labs, how did you describe that? It was a simple something -- of a contract?
MS. WOOLSON: Objection to form.
BY MR. SCOTT:
Q Well, let me back up.
The first contract that you had with USP Labs, what was the scope of work that it covered?
A So there is a scope of work document, but to the best of my -- well, actually, do you have the

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scope of work document?
Q Well, I don't know. But I'm asking you a question: Can you tell me what the scope of work was?
A As best as I can recall without the written contractual scope of work in front of me, it was to analyze geranium plants for 1,3-DMAA and 1,4-DMAA.
Q Now, when you say "analyze geranium plants for 1,3-DMAA and 1,4-DMAA," what do you mean by "analyze"?
A I directed and developed a method for analysis of 1,3- and 1,4-DMAA concentrations in geranium plants based off a method developed by Intertek Laboratories.
(Exhibit No. 4 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You've been handed what's been marked for identification purposes as Exhibit 4 to your deposition. It's a multi-page document running from page 59 through 78. And I will

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ask you if that's an article that you were involved in preparing and having published.
A (Perusing document.)
Yes.
Q All right. And does this article describe the work that you did for USP Labs in testing samples of geraniums that you were provided for 1,3- and 1,4-DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Yes.
BY MR. SCOTT:
Q And who is -- the other authors that are listed here, who is Heather L. Fleming?
A She was my first Ph.D. student who has successfully defended her Ph.D., now Dr. Fleming.
Q And then Patricia Ranaivo?
A Ranaivo.
Q Who is she?
A She was the postdoctoral fellow that was funded by the Department of Chemistry at the University of Memphis as part of my startup package.

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She is also a graduate of the Analytical Mobile Monitoring and Miniaturization Laboratory with her Ph.D.
Q All right. So now in relation to the expertise that you bring to the table regarding your expert report and testimony, do you believe you are an expert in FDA regulations?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.
BY MR. SCOTT:
Q All right, sir. In relation to your work as an expert here, have you done any analysis to support any conclusions regarding whether taking DMAA, either in its 1,3 or 1,4 form, causes health problems or risks for humans?
A No.
Q And you have no opinion on that topic?
MS. WOOLSON: You mean as an expert?
MR. SCOTT: Yes.
MS. WOOLSON: You can answer.
THE WITNESS: No. And I don't believe I

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addressed it in my expert report.
BY MR. SCOTT:
Q Well, if you would, look at your article there, Exhibit 4.
A Okay.
Q And over on the introduction portion of the article -- now, let me back up a minute before we get into specific questions about this.
This article was published based on the work that you did for USP Labs?
A Yes.
Q Did USP Labs pay you to prepare the article?
A They funded the work to --
Q Did they -- I'm sorry. Go ahead. I don't want to cut you off.
A I mean they funded the work to do -- to do the analysis.
Q All right. Well, in relation to the preparation of the article, for example, did they pay you an hourly rate to prepare this article?
A No.

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Q Now, in the introduction portion of your article, it says: "There has been significant discussion of 1,3-dimethylamylamine, 1,3-DMAA, and the literature concerning the presence of 1,3-DMAA in geranium plants, pelargonium graveolens."
Do you see that?
A I do.
Q And was your awareness of there being any discussion regarding the presence of 1,3-DMAA in geraniums, did it come to you in the context of doing this work for USP Labs?
A Yes.
Q And then it goes on to say: "1,3-DMAA, also known as 4-methyl-2-hexanone MHA, 1,3-dimethylpentylamine or 2-amino-4-methylhexane can be labeled as geranium extract in dietary supplements."
Do you see that?
A Yes.
Q Where did you get that information?
A Most likely reference number 7.
Q And reference number 7 is what?

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A "United States Food and Drug Administration, FDA, challenges marketing of DMAA products for lack of safety evidence. FDA news release April 27, 2012, accessed" -- well, there is a website from their newsroom press announcements accessed August 10, 2012.
Q And then it goes on to say: "Confirming the presence or absence of 1,3-DMAA as a natural product in geranium plants has important regulatory and commercial consequences for many dietary supplement companies."
Referring back to that same reference, correct?
A Yes.
Q What was your understanding of the potential commercial consequences of not finding DMAA in geranium plants for dietary supplement companies?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: My understanding is that under the -- I think it's the -- well, let's see, I think it's in here. The name always gets me. It's

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the Dietary Health and Supplement Education Act of, I think 1994, something like that, or '96, one of those two. It discusses how dietary supplements can be marketed and -- as it relates to -- and whether they are a naturally occurring product or not. And that's -- like to be clear, that's like off the top of my head. It's been a while since I looked at that regulation.
BY MR. SCOTT:
Q Well, when you were doing the testing of geranium material for USP Labs, did you have an understanding of what the potential impact would be on USP Labs depending on your findings?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Not specifically, no.
BY MR. SCOTT:
Q Did you have a general understanding of USP Labs would not think it was a good result if you didn't find DMAA when you were testing geranium material?
MS. WOOLSON: Objection to form.

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You can answer.
THE WITNESS: Repeat the question.
BY MR. SCOTT:
Q Sure.
When you were doing the testing of the samples that you were provided for USP Labs to see if you could find DMAA, did USP Labs tell you they were hoping you would find it?
A I don't think so. Not that I can recall.
Q Did they tell you why they were looking for it?
A Not that I can recall.
Q Now, in the work that you were doing for USP Labs, who was your contact?
A Erik White.
Q And who is Mr. White?
A As far as I know, he works for USP Labs.
Q Do you know what his position was?
A No.
Q Did you, in doing the work that you did for USP Labs, have any direct contact with any other USP Labs employee?

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A Not that I can recall or know of.
Q All right, sir. Had you ever done any -- had you ever heard of USP Labs prior to doing the testing of the geranium materials that you were provided?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Beyond e-mails with them when we were setting up the contract, no.
BY MR. SCOTT:
Q Well, prior to them -- you being contacted and the contacts leading up to you setting up the contract, had you heard of them?
A No.
Q When you were approached by USP Labs, did you take any steps to investigate the company, find out who they were, the type of business, scope of business, anything like that?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: What was the first half of that?

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BY MR. SCOTT:
Q Sure. Before you entered into a contract with USP Labs, did you investigate the company at all?
A Probably.
Q Do you recall doing that?
A Not specifically.
Q And if you had done that, would any documentation of that be in your file?
A No. I probably looked it up on the internet.
Q But you don't even remember doing that specifically?
A Not specifically.
(Exhibit No. 5 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. Before we get into the document, could you look in your report a minute, Exhibit 3.
And if you would, turn to paragraph 41 on page 73.

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A What page?
Q I'm sorry, it's paragraph 73 on page 41.
Now, if you would read through paragraph 73, the whole thing, and let me know when you are done, and then I will have a few questions for you. All right?
A (Perusing document.)
Okay.
Q All right, sir. Now, paragraph 73 on page 41 of Exhibit 3, that's something that you wrote, correct?
A (The witness nods.)
Q You have to say "yes" or "no" for her.
A Yes.
Q And at the top there, it says: "I can provide insight into our research. I was approached by USP Labs to conduct the analysis of 1,3-DMAA and 1,4-DMAA in some geranium samples as an independent laboratory."
Do you see that?
A I do.
Q And was that the scope of your initial

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assignment with USP Labs?
A As best as I can recall.
Q That's what you put in your report and swore to anyway?
A Yeah, that is. That's correct.
Q And in relation -- and that testing that you -- the reference there in paragraph 73 of your report is the testing that you then described the outcome of in Exhibit 5, your -- I'm sorry, Exhibit 4, the article that you had published, correct?
A Correct.
Q Now, below that it says: "Prior to my contract with USP Labs, I had never heard of them or the controversy surrounding DMAA."
Do you see that?
A Yes.
Q And that's to the best of your recollection?
A Yes.
Q How did they approach you? How did they find you?

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MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I'm sure it's in this e-mail.
BY MR. SCOTT:
Q Well, let's look over the e-mail. You have in front of you what's been marked for identification purposes as Exhibit 5 to your deposition. It's a multi-page exhibit bearing identification numbers UMPS-HT-004885 through 4887, and I will ask you to take a look through that. Look through all of it, and then let me know when you're done, and then we will have some questions. All right?
A (The witness nods.)
(Perusing document.)
Okay.
Q All right, sir. If you would look at the last page of that Exhibit 5 where there is an e-mail from Richard J. Bloomer, dated December 12, 2011, to a Gary Emmert, E-M-M-E-R-T, and yourself.
Do you see that?

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A I do.
Q Who is Gary Emmert?
A He is my Ph.D. advisor and colleague at the University of Memphis, and he's now the chair of the department.
Q Was he the chair of the department at this time back in 2011?
A No.
Q Then it goes on to say that Drs. Emmert and Simone -- well, first of all, let me back up.
Who is Richard Bloomer?
A He is -- at the time he was a professor in another department. I think exercise science, something along those lines.
Q Another department at the University of Mississippi?
A Yes -- no, at the University of Memphis.
Q I'm sorry. University of Memphis.
Okay. Had you dealt with him before receiving this e-mail?
A Not that I can recall.
Q All right, sir. And it goes on to say --

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or the e-mail from Dr. Bloomer: "We do work for a nutraceutical/dietary supplement company which has the need for sample analysis as indicated below. Would either of you have the interest and ability to do such testing? If not, would you know others in your department who may? Any help would be much appreciated. Thank you and regards, Rick Bloomer."
Do you see that?
A Mm-hmm.
Q Yes?
A Yes.
Q Did you have any conversations with Dr. Bloomer regarding this potential assignment?
A Not that I can recall.
Q Now, the description of work down there says that we need either LC/MS/MS or GC/MS analysis for 1,3-dimethylpentylamine (small volatile amine) in a sample matrix of geranium oil."
Do you see that?
A Yes.
Q Is this the first time you had ever heard of that chemical?

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A Yes.
Q And it goes on to say that: "We already have a validated method for the determination and quantitation of 1,3-dimethylpentylamine," parens, "(CAS No. 105-41-9) in geranium oil and geranium plant tissue using LC/MS/MS, so we can supply the method for them which will be a major part of the work."
Do you see that?
A Yes.
Q And then it goes on to say: "I would like to pass along the full method, but we'd have to have an NDA in place first. As far as samples, I would expect 5-10 samples of geranium oil and perhaps 3-5 samples of geranium plant. As far as cost, $100-300 per sample."
Do you see that?
A Yes.
Q Now, above that, it says: "Richard, I am definitely interested in working with you on these sample analyses. However, I need to know some analysis details before I can agree to the work and a

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price per sample. A couple of questions that you can answer without a need of an NDA are: What type of timetable are you looking at for this sample analysis? And do you have the chemicals, glassware, and materials needed to do the analysis?"
Do you see that?
A Yes.
Q Why was it a concern for you regarding the time frame?
A Any time I've worked with a company on doing research and development work and contracts in general, my big question is always how fast do they want it, because their idea of fast and my idea of fast may be different.
Q All right. And it goes on to say: "And two, do you have the chemicals, glassware and materials needed to do the analysis?"
Do you see that?
A Yes.
Q Why were you asking that?
A Did they -- you know, did they have the materials in place already for me to do it or was I

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going to have to budget it in the contract to do it.
Q Well, did you have in place the type of equipment, chemicals, glassware and whatnot to do this type of testing?
A Yes. Let me back up. So without knowing what specifically was required and the method, the description of work was pretty broad. And so it was either they were going to provide it as in Rick Bloomer or the company or they were going to provide me the money to purchase what I needed. I mean chemicals, glassware and materials is pretty broad.
Q All right. In dealing with Mr. White, did he ever use any other name?
A No.
Q Have you ever heard of anyone named Sy Wilson?
A No.
Q Why the grin?
A It was on the subpoena that I received from the -- I think it was the FDA from -- I think it was Mr. Harlow.
Q And do you know who Sy Wilson is?

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A No.
Q Now, if you look at the first page of that exhibit, it says: "As much as I would like to agree to do the analysis work, the time frame of analysis makes it very difficult for us to do. The typical amount of time it takes to learn a new method is longer than 1-2 weeks, and the cost to pay a student and buy the materials would approach the cost of a typical contract analysis lab."
Do you see that?
A I do.
Q What are you referring to there by "typical contract analysis lab"?
A So a contract lab is going to have a lot of things in place, like already kind of like general needs in place already. And we don't typically operate as a contract lab. And so when I do, I have a higher price tag than a typical lab and I need more time.
Q Were you seeing this project as putting you in a position where you would be acting like a contract lab?

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MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean they specified a contract for a price per sample analysis, and that's kind of what I think of when I think of contract lab.
BY MR. SCOTT:
Q All right, sir. And in the response, Erik White says in the e-mail: "Could you suggest what a reasonable time frame and cost would be? We're open on this. Also, would you anticipate publication of these data? It's something we're interested in."
Do you see that?
A Yes.
Q Now, did you have any conversations with him after receiving this e-mail regarding why they wanted you to do it as opposed to a contract lab, which you indicated would already be set up to go ahead and do this type of testing?
A Not that I can recall.
Q Do you recall discussing with anyone why they picked you out to do this as opposed to a

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contract lab or some other university?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Repeat the question.
BY MR. SCOTT:
Q Sure. Did you have any conversation with anyone regarding why you were chosen by USP Labs to do this work as opposed to a contract lab or some other institution?
A Not that I can recall.
Q Did you ever wonder about that?
A No.
Q Now, do you know how much work Mr. Bloomer had been doing for USP labs?
A I don't believe at the time I did. Not specifics.
Q Did you learn how much work Dr. Bloomer had done for USP Labs at some point?
A No.
Q Was the work that Dr. Bloomer was doing for USP Labs, was that paid for directly into Dr. Bloomer or was it paid into the university in

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some form?
A I have no idea. I don't know how he set it up.
Q All right. Do you know how much USP Labs paid Dr. Bloomer for his work?
A No.
Q Now, the work that you did for USP Labs, at least this initial lab where you were testing these samples, was that paid to you directly or to the university?
A To the university. The contract was through the university and administered both by research support services and the accounting office. They handled payments and certification of time and all that.
Q Now, in relation to your initial work in testing these samples, you said here in your report, page 41, exhibit -- paragraph 73: "I can provide insight. I was approached by USP Labs to conduct the analysis of 1,3-DMAA and 1,4-DMAA in geranium samples as an independent laboratory."
What do you mean there by "independent

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laboratory"?
A A laboratory that had no affiliation with them.
Q And when you started the work, though, you knew that they wanted to publish the outcome?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, they stated that in the e-mail.
BY MR. SCOTT:
Q Now, when you say here in your report that they wanted you to conduct the analysis of 1,3-DMAA and 1,4-DMAA, what did you understand that analysis to consist of?
A I'm sorry. Can you repeat the question?
Q Sure. Well, let me ask it a slightly different way.
You said in your report you were approached by USP Labs to conduct the analysis of 1,3-DMAA and 1,4-DMAA in some geranium samples. Do you see that?
A Yes.

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Q What do you mean there by "analysis" in the context of what you were asked to do by USP Labs?
A What was I asked to do?
Q Yeah.
A Take the Intertek lab method and run with it, and analyze 1,3 and 1,4-DMAA in geranium plants.
Q In other words, to test geranium plants and see if you could identify the presence of 1,3 or 1,4-DMAA.
A It was -- I wouldn't characterize it that way. I would say that we were asked to do -- to determine -- to determine -- I guess -- I'm sorry. Your question is worded oddly for me.
So we were asked to do the analysis for 1,3 and 1,4-DMAA and report our results.
Q And the results were primarily whether you found 1,3 or 1,4-DMAA or not in the geranium samples using the Intertek procedure?
A Well, the -- if -- I guess, yes. If the concentrations were there, then we report what they were, you know, if they were above the method detection limit. If they were not there, then we

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would report it as less than method detection limit.
Q What do you mean by the term "method detection limit"?
A That is the lowest concentration that can be distinguished from the noise in the analysis.
Q Now, in relation to the samples that you tested for using the Intertek procedure for USP Labs that are reported in exhibit -- the article itself, were there some of those that you did not detect DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Yes.
BY MR. SCOTT:
Q And with those, did you do any exercise using addition procedures to check and see if there was any evidence that it may be there at below the MDL?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Are you -- well, what was that?

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MS. WOOLSON: I said, Objection to form. You can answer.
THE WITNESS: Are you referring to the standard addition method?
BY MR. SCOTT:
Q Yeah.
A So in the -- what was the question again?
Q Sure. You found -- you tested the samples that you were provided by USP Labs, and some of them you said did not reflect any DMAA. So, therefore, you said it wasn't there at the minimum detection limit.
Does that mean it may be there below the minimum detection limit?
A It's possible.
Q Did you test to see?
A So, if I recall correctly, we had no evidence to suggest that they -- the concentrations might have been there below the detection limit, and we did not pursue it any further.
Q All right, sir. Now, in the course of doing your work for USP Labs and testing for DMAA in

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geranium samples, did you obtain reference samples?
A What do you mean?
Q I mean, did you get a reference from somewhere to use for your testing as a standard for your testing?
MS. WOOLSON: Objection to form.
You can answer.
BY MR. SCOTT:
Q A reference sample, did you get a --
A Are you talking like a -- are you asking about a plant that had a known concentration of 1,3-DMAA in it?
Q Did you go out to a chemical company and buy DMAA?
A Yes.
Q And for what purpose?
A To be a standard that we used for calibration of 1,3-DMAA for the analysis.
Q And where did you get it from?
A Let's see. Pharmakon USA.
Q Was the reference sample that you obtained to use in your testing synthetic DMAA?

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A As far as I'm aware, it is.
Q Did you try to get a naturally produced version of DMAA to use as a reference sample?
A To the best of my knowledge, that's -- I don't know if that's available or not.
Q Did you look for a naturally --
A I don't recall.
Q -- produced version of DMAA to use as a reference?
A I don't recall.
Q Why do you think naturally occurring DMAA is not available as a reference sample?
MS. WOOLSON: Objection to form. Calls for speculation.
You can answer.
THE WITNESS: Well, can you repeat the question?
BY MR. SCOTT:
Q Why do you think that a naturally produced version of DMAA is not available to use as a reference sample?
A I don't know.

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Q But you just don't think it is?
A I -- I don't know.
Q You're not aware of it being -- anywhere that you can get a naturally occurring or naturally produced version of DMAA to use as a reference sample?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No, if it exists, I'm unaware of it.
BY MR. SCOTT:
Q Now, in relation to the work that you did on DMAA, did you do literature research regarding the chemical studies that were relating to the chemical or anything else?
A What do you mean?
Q I mean did you do any literature release search as part of your work for USP Labs?
A More than likely.
Q But you don't recall having done it specifically?
A It was like five years ago. I mean I

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referenced some things in the paper I published, and --
Q Well, you know that Eli Lilly had a patent on DMAA that was issued in the 1940s, correct?
A Yes.
Q Do you recall finding any reference to DMAA in existence as a chemical compound prior to that patent being issued?
A Not that I'm aware of.
Q Now, in the context of the testing that you did for USP Labs that shows up in your Exhibit 4, your article, did USP Labs as part of the exercise that you were hired for ask you to take steps to determine if DMAA was naturally produced by the geranium plant?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I don't understand.
BY MR. SCOTT:
Q Sure. Let me ask it again.
You were approached by USP Labs and USP Labs asked you to test certain samples of geraniums

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to see if you could locate the existence of DMAA in those samples based on the Intertek process and protocol, right?
A Yes.
Q Did they also ask you as part of that exercise to determine if that geranium -- DMAA, if you found it in a geranium plant, if it was something that the geranium plant naturally produced as part of its biological functions?
A No.
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.
BY MR. SCOTT:
Q Did they ever ask you to do that, to -- did USP Labs ever ask you to determine if DMAA was naturally produced as part of the biological functions of geranium plants?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Are you referring to -- not that I can recall.

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BY MR. SCOTT:
Q Okay. Let's turn if we could here -- I will show you another exhibit.
Well, before we do that, let me ask you this: The samples that you worked on that you tested for USP Labs, where did you get them?
A From --
Q Well, we will get to the specifics, but I mean, were they sent to you or did you go out and acquire them?
A Some were sent via shipping services. I think a couple that we got for essentially practice were sourced locally in Memphis.
Q So you got -- you went ahead and bought some geranium samples locally in Memphis so that you could practice using the Intertek procedure; is that right?
A Yes.
Q And then you were sent some by a shipping service from China?
MS. WOOLSON: Objection to form.
You can answer.

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THE WITNESS: Yes.
BY MR. SCOTT:
Q And then did Intertek also send you some samples that it had of geranium plants that it had previously tested?
A Yes.
Q Are you familiar with the name Yi Jin?
A How do you spell that?
Q Well, let me focus you a little bit here since you are looking at Exhibit 4.
If you would, look in Exhibit 4 on page 71 under "Acknowledgments."
A Okay.
Q Under "Acknowledgements," it says: "The authors would like to acknowledge and thank Dr. Yi," Y-I, "Jin," J-I-N, "of Yunnan University for overseeing the geranium sample collection and shipment to the University of Memphis."
Do you see that?
A I do.
Q And does that refresh your recollection about Dr. Yi Jin?

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A Yes.
Q Do you recall now who he was or who he is?
A To an extent.
Q And what is your recollection?
A He's the guy who sent the samples to the University of Memphis from China.
Q Now, had you ever dealt with Dr. Yi Jin before doing this project for USP Labs?
A No.
Q Had you ever heard of him?
A No.
Q Had you ever heard of Yunnan University?
A Not that I can recall.
Q Now, when the samples were sent to you by Dr. Yi Jin, had you contacted him to order those or were they facilitated being delivered to you by a USP Labs person?
A They were facilitated.
Q By a USP Labs person?
A By -- what was the last part?
Q By UPS Labs personnel.

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A Yes.
Q And do you know who for USP Labs was coordinating with Dr. Yi Jin regarding getting these samples?
A To the best of my knowledge, it was Erik White.
Q Okay. Now, the samples that you received from Dr. Yi Jin, did you have any involvement in setting up any protocols for the identification and gathering of those samples?
A No. But I don't think anybody else did either.
Q So what do you mean by you don't think anybody else did either?
A The other researchers.
Q Well, do you know what happened with those and how they got those samples?
A No.
Q Well, in the context of yours, your samples that you got, Dr. Yi Jin didn't get any instruction from you on how to select or prepare the samples to be shipped to you?

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A No.
Q Did all the information that you had regarding the selection, preparation of the samples that you were sent by Dr. Yi Jin come to you through USP Labs?
A Say that again.
Q Sure. Did the information that you had, whatever it was, regarding the selection and preparation of your samples of geraniums from Dr. Yi Jin, did that information come to you through USP Labs, Erik White?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I don't know. I mean I clearly have written that they were authenticated by -- I will try to pronounce the name -- Xu Youkai, but I don't recall how I got that information. It could have been from Dr. Yi Jin.
BY MR. SCOTT:
Q Okay. Did you -- the gentleman that you just said authenticated these, did you deal with him directly?

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A No.
Q And you don't -- and the information that you got about him authenticating the plants came either through Dr. Yi Jin or USP Labs?
A To the best of my knowledge.
Q And what information were you given regarding what that means, that he authenticated the samples that you eventually tested?
A That they were in fact pelargonium graveolens samples and the regions they were collected from.
Q Were you given any information regarding the growing conditions of the plants that were sampled and provided to you to test for USP Labs?
A Just what's in my published paper.
Q All right. And does your published paper include anything regarding growing conditions, climatological conditions, geographic conditions, soil conditions, anything like that regarding your samples?
MS. WOOLSON: Objection to form.
You can answer.

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THE WITNESS: It says -- do you want me to read it to you?
BY MR. SCOTT:
Q Sure.
A It says: "Samples were collected from three regions in China, Changzhou, Guiyang, Kunming, during three different harvest seasons. The Chinese Academy received the geranium herbs as potted plants originally grown in the field. Multiple plants," parentheses, "ranging from two to ten in number," closed parentheses, "were collected from each location. The plants from each location were combined prior to shipment to the University of Memphis. Therefore, concentrations of 1,3-DMAA and 1,4-DMAA of individual plants and variations thereof are not reported here."
And the samples were sent by Express Mail, stored at minus 20 Celsius, and then I have the dates that each one was collected.
Q Is that the sum total of the information you have regarding the selection and preparation of the samples that you tested?

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A Very likely.
Q So if that is the sum total, you did not have any information regarding soil conditions, correct?
A No.
Q Or growing conditions, correct?
A What do you mean by growing conditions?
Q The climate it was grown in, the circumstances where it was grown, anything like that.
A I have the seasons they were grown in.
Q Beyond the seasons, do you have any information regarding the growing conditions associated with the plants that you tested?
A No.
Q Do you have any information regarding the water, soil or fertilizers that may have been used to grow these plants?
MS. WOOLSON: Objection to form.
THE WITNESS: No.
MR. SCOTT: All right. We've been going at this a while. Why don't we take a short break.
MS. WOOLSON: Okay.

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(Recess.)
(Exhibit No. 6 was marked for identification.)
BY MR. SCOTT:
Q All right. We're back on the record after a short break.
Dr. Simone, I will remind you, you are still under oath. All right?
A I understand.
Q And, again, if my questions are unclear, let me know. Okay?
A Okay.
Q And if you need to take a break at any point, please let us know.
A Okay.
Q All right, sir. Let me hand you a document. You've been given a document which has been marked for identification purposes as Exhibit 6 to the deposition. It is a multi-page document bearing -- running from pages 1 through 45. The first page is "Analysis of dimethylamylamine DMAA in Geranium Plants Using HPLC-MS/MS," Heather L.

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Fleming, Department of Chemistry University of Memphis.
Have you seen this document before?
A I probably helped Heather put it together.
MS. WOOLSON: Just let me note for the record that this doesn't seem to have Bates-stamped numbers on it, so I don't know that it was part of the government's production or any production in this case.
MR. SCOTT: Well, actually it was part of the production from the University of Memphis. Unfortunately, because of the form in which it was produced, because it is a slide, the Bates numbers did not convey with it. But it was produced by the University of Memphis, and I understand you folks also have a copy of this from that production.
MS. WOOLSON: I'm not sure that is correct, but I will accept that representation for purposes of today.
MR. SCOTT: Well, if you don't have it from the University of Memphis, you should take it up

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with them, but I understood that their production had been turned over to everybody.
BY MR. SCOTT:
Q All right, sir. Exhibit 6 there, you said that you've seen this before?
A If I produced it, then, yes, I've probably seen it before.
Q And Heather Fleming you said was one of your grad students?
A Yes.
Q And do you recall helping her prepare this particular slide show?
A I mean, not specifically. I'm pretty sure I did.
Q All right. And why do you think you helped her to prepare the Exhibit 6?
A Because she at one point gave a seminar in the Department of Chemistry related to this work.
Q Relating to the DMAA work.
A Well, this -- yeah, and this -- this particular slide show.
Q Okay. So you think that she used this

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slide show in a seminar that she gave regarding your work on DMAA in the U of M chemistry department?
A Yes.
Q And so, therefore, you would have helped her put it together?
A Yes.
Q All right, sir. And do you recall when that slide show -- when that seminar was, when she gave that?
A After April 2013.
Q Were you there when she gave the presentation based on the slide show?
A As best as I can recall.
Q All right, sir. You can set that aside for the moment.
Let me send you back to Exhibit 3, your report, page 41.
A Okay.
Q And still in paragraph 73, about five lines down there, there's a sentence that says: "The work at MAMML proceeded and the initial results determined two outcomes: One, there were matrix

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effects present in the analysis; and, two, 1,3-DMAA was present and detected in the Changzhou samples where the concentrations were below the detection limit for the Guiyang and Kunming samples."

Do you see that?

A I do.

Q And that's information that you included in this report yourself. You wrote that.

A Yes.

Q Now, what do you mean by there were matrix effects presented -- present in the analysis?

A There were -- so based on the percent recovery that we got from our preliminary extraction protocol that we outlined in the paper, Exhibit 4, we found that the -- let me look at the sample analysis.

So the percent recoveries for those samples, the Changzhou, Kunming, and Guiyang, were relatively low. Here they range from 19 to 44 percent. And what we believed occurred was signal suppression in the electrospray ionization source of the tandem mass spectrometer. And basically due to that, it lowered the signal from our 1,3- and

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1,4-DMAA analytes and basically the matrix effects.

Q When you say "matrix," what are you talking about in the context of plant material?

A The -- so the matrix is everything in the sample you are analyzing that is not your analyte. So if you've got your analyte, in our case it is 1,3-DMAA and 1,4-DMAA, the matrix is like literally everything else in the sample itself.

Q Now, further down in exhibit -- in paragraph 73 of 41, it said: "Based on my review of the literature time, I knew that this would be considered an outlier analysis."

Do you see that?

A Yes.

Q What do you mean there by "outlier analysis"?

A Well, in the context of this gestalt of 1,3-DMAA work published by myself and others, there have been four reports of 1,3-DMAA present in sample. The Fleming paper, the Li paper from Intertek, the Ping paper, and Professor Khan and ElSohly's work as produced in the documentation for this deposition in

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discovery and all that.

Q All right. So it's your position that Dr. Khan and ElSohly found DMAA?

A Based on the documentation that they provided after I submitted the report.

Q All right, sir. And that's not in your report?

A That is not in my report.

Q So this is an opinion that's not in your report?

A I mean, I wrote my opinion based on the documentation that I had at the time, and then new documentation became available that was different than what had been presented to me before, and so...

Q Now, did the documentation that you saw pertaining to Dr. ElSohly and Dr. Khan's work, did they write that up? Was that published?

A It was not published.

Q So they did a study that they didn't publish anything about?

MS. WOOLSON: Objection to form.

You can answer.

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THE WITNESS: No, it was part of their 2015 multi-center study, and one of their centers reportedly found 1,3-DMAA concentrations at a pretty low level. And I think they further determined that their analysis through their methods of confirmation was less than their stated detection limits. So they had a -- what's the word for it? -- a -- some preliminary evidence that it may in fact have been in the sample. I reviewed the chromatograms, and it looks like it could have been there. And to the best of my knowledge, they did no further work to try to resolve whether that peak was there or not.

BY MR. SCOTT:

Q Now, is it your understanding that there is a chromatogram in some work associated with the multi-lab work done by Drs. ElSohly and Khan that shows a peak that you think might be DMAA?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: It matches the retention time and the multiple reaction monitoring signal from 1,3-DMAA based on their admittedly poorly reproduced

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chromatograms.
BY MR. SCOTT:
Q And did they do any work associated with that poorly reproduced chromatogram to determine -- to determine whether or not what was shown there was DMAA?
A I don't know.
Q Did they do any work to try and verify any of the outcomes that were shown by the labs where this work was done, including this one?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: To the best of my knowledge, they look to be discussed in their e-mails.
BY MR. SCOTT:
Q Did they do any work to test whether or not that particular outcome was accurate to the extent it showed there was DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: They -- based on my

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recollection of the e-mail, somebody had analyzed the sample at approximately 2 nanograms per mil of 1,3-DMAA, and which was less than their stated detection limit. And the signal-to-noise ratio on that sample was approximately 38, which is generally well above the typical standard we use for method detection limits of 3, assuming a signal-to-noise ratio of 3 for the method detection limit, and the limit of quantitation of signal-to-noise ratio of 10.
BY MR. SCOTT:
Q And when did you do this analysis?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: When I was presented with the e-mails.
BY MR. SCOTT:
Q And when was that?
A After my expert report was turned in.
Q How long after?
A I think I saw it like last week maybe. Maybe -- yeah, last week, sometime last week.
Q All right, sir. Has there been any

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effort to generate a supplemental report adding this analysis or any conclusions you reached from it to your report or give us notice of what you were relying on in doing the analysis?
MS. WOOLSON: Objection to form. He's relying on documents that you produced.
MR. SCOTT: I understand that. And the federal rules say if you are relying on documents, wherever you got them from, you are supposed to give the other side notice that there is an opinion and they are being -- documents are being relied on to support it, which you haven't done.
MS. WOOLSON: Well, I think you can rest assured it's coming.
MR. SCOTT: And we will depose him again.
MS. WOOLSON: And we raised the issue at Dr. Khan's deposition.
MR. SCOTT: And we will depose him again once we get something.
MS. WOOLSON: And we will depose Dr. Khan again.
BY MR. SCOTT:

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Q So did anybody -- have you put any of this in writing?
A No. No.
Q Are there any other opinions that are not in your report that you would like to share with me?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I don't believe so.
BY MR. SCOTT:
Q Have you done any work to answer the question of whether a geranium plant produces DMAA as a natural function of its biology?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: What do you mean?
BY MR. SCOTT:
Q I mean, have you done any scientific work to answer the question of whether or not a geranium plant actually, through its natural biological processes, produces DMAA in any form, 1,3 or 1,4?
MS. WOOLSON: Objection to form.
You can answer.

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THE WITNESS: No.
BY MR. SCOTT:
Q Now, the DMAA that you report in your -- the document that you published, Exhibit 4 to your deposition, that DMAA was identified for you at what level of concentration? What was the measure of concentration that you found?
A Can you restate the question?
Q Sure. Let me ask it a little more specifically, maybe it will help. The DMAA that you report in your article, Exhibit 4, was found at parts per billion levels?
A In the plant?
Q Yeah.
A Yes.
Q Would you consider that to be a trace concentration of the chemical?
A Yes.
MS. WOOLSON: Objection to form.
BY MR. SCOTT:
Q And you are using the term "trace," so the record is clear here, what do you mean?

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A Well, there is a variety of definitions for "trace." If I recall correctly, I think "trace" refers to kind of the textbook definition as 1 to 100 -- 1 part per billion to, I think, 10 to 100 part per million. But as somebody who does work at the part per billion level routinely, working at a single part per billion or 10 part per billion is very different than working at 10 part per million, which is -- you know, 10 part per million is a thousand times higher in concentration. And so the way you go about measuring concentrations at 10 part per million can be very different than those at 10 part per billion.
Q Different in what general sense?
A They have to be more sensitive and more selective.
Q Is there also, because they have to be more sensitive and selective looking at 10 parts per billion, more possibility of there being some type of error in the quantification and identification of chemicals?
A What kind of error?

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Q Any type of error, in what you've identified, whether it's what you say it is, the concentration levels, anything.
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: There is always error in any analytical protocol that you undertake. The errors at 1 to 10 parts per billion are traditionally much higher simply because the concentrations are lower. And you could see errors on a range as high as 100 percent from one lab to another. And I would say that is not uncommon in this line of work.
BY MR. SCOTT:
Q Okay. And when you say you can see errors from one lab to another as much as 100 percent, are you talking about errors in the identification of chemicals or the quantification for chemicals or both?
A We're talking about the reported concentration as determined by the lab. Multiple labs.
Q Now, in relation to your article,

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Exhibit 4, did you include any information regarding potential error rates in the work that you had done?
A I don't understand your question as phrased.
Q Sure. Well let's do it this way: If you would, turn in the document to Table 2. It's on page 65.
A All right.
Q Now, you have there Table 2 which has some headings across the top with numbers flowing below there.
Do you see that?
A I do.
Q Analysis Set 1, Analysis Set 2 and Analysis Set 3, what were they?
A Those were the sets of analysis we did for each batch of samples that we reported.
Q These were the samples that USP Labs supplied you from China or you got from Intertek?
A These are the labs that I received directly from China and from Intertek.
Q Did you pay anybody in China for

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gathering and shipping the samples of geraniums to you for testing?
A No.
Q Who did that, who paid?
A I don't know.
Q Do you know of anyone other than USP Labs who might have been willing to pay them for this work?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I have no data regarding who paid for the shipment of those samples.
BY MR. SCOTT:
Q So you have no data that would indicate someone other than USP Labs paid, correct?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Ask that question again.
BY MR. SCOTT:
Q Sure. So you have no data to suggest that someone other than USP Labs paid the folks in China to gather and send you the geranium samples

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that you tested, correct?
MS. WOOLSON: Objection to form, misstates testimony.
You can answer.
THE WITNESS: What I know is the samples were shipped from China to the University of Memphis and from Intertek to the University of Memphis. I don't know if USP Labs paid for it. I don't know if they were paid for by the people who shipped it.
BY MR. SCOTT:
Q So you think the people who gathered the geranium samples may have paid themselves to gather them and ship them to you?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I don't know. I mean, we've collected samples and shipped them out ourselves, so whether we paid ourselves or not is internal accounting.
BY MR. SCOTT:
Q All right. So now in relation to Table 2, what does the information under the heading

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"Check Standard UG/L" mean?
A That's the check standard concentration as -- and for 1,4-DMAA at concentrations of 3 micrograms per liter and 8 micrograms per liter, and going down, and micrograms per liter is equivalent to a part per billion.
Q And then "USEPA MDL UG/L," what does that information represent?
A That is the method detection limit using the USEPA, United States Environmental Protection Agency protocol for determination of the method detection limit.
Q All right. So the method detection limit, is that the minimum level at which you can detect the particular concentration?
A That is the lowest concentration distinguishable from noise.
Q All right. And so it appears that it varies from analysis set to analysis set and in some cases from sample to sample, correct, the MDL?
A It changes from -- it changes based on any number of factors. The method detection limit

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that you report for a given analysis should be done prior to that analysis, and we're talking about best analytical practices. And if we talk about what amounts to broadly the philosophy of analytical chemistry, the method detection limit in any report is simply an estimate. It's kind of hard to tell what the true method detection limit is other than when you run the instrument at that given time and that given conditions, you determine the method detection limit prior to the analysis of samples so that you can provide a reporting of those concentrations.
And so in Table 2, for 1,4-DMAA we see that our method detection limit ranges from approximately 0.8 on what was likely a very good day to 2.4 micrograms per liter at the high end. And the fact that it ranges is not uncommon.
Q Well, what are the factors that go into the range being different over time?
A The environmental conditions the analysis was performed under, so like temperature of the lab, the response of the instrument itself, the -- well,

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that's a big chunk of it.
Q What does "mean percent recovery" mean?
A That is the -- that's our estimate of accuracy of the method. And when you are within a factor of 2 to 5 of your method detection limit, that mean percent recovery can range from approximately 50 to 150 percent and be considered normal.
Q And percentage RSD, what does that relate to?
A That is our estimate of precision, and it's the percent relative to standard deviation as determined by the standard deviation of your seven measured check standards, the standard deviation of their concentration divided by the average concentration times 100 percent, and when you are within a factor of 2 to 5 of that method detection limit, the percent relative to standard deviation can be as high as 30 to 40 percent.
Q So does that mean that you have a -- the RSD, does that mean that there is an error rate potential in there or not?
A Yeah, when --

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MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Restate the question, please.
BY MR. SCOTT:
Q Sure. RSD, does that relate in any way to potential error rates in your analysis?
A Yes.
Q And how does it relate to potential errors?
A It provides you an estimate of the error on that day for the analysis itself.
Q So the analysis on the day -- for example, Analysis Set 2, the first sample there, that would be a 30 percent error rate?
A Yes. So when you are at concentrations of approximately 3 micrograms per liter as measured by the instrument, the error rate can range from -- as its written here, from 10 to 30 percent. If you are at a higher concentration, such as 8 micrograms per liter as what's right below it, the error rate is going to likely be lower. And as you get closer to your method detection limit for the analysis, the error rates -- not the error rates, but the percent relative to standard deviation on that check standard is going to increase.
Q All right. And the MDL factor, what is that?
A That is how close you are to the method detection limit. So you see we are -- so a good example of this is -- the thing we were just talking about, Analysis Set 2, line number 1 at 3 part per billion, our MDL factor is 1.5, which means that our method detection limit was within a factor of 1.5 of our check standard. And when your -- when your detection limit is that close to your check standard, the error rates are going to be very high.
But then as we look, let's call the line at the bottom of that, where Analysis Set 2, line 4, for 8 part per billion, you will see our MDL factor is 3.9, so about 4. So our method detection limit was 2.1, when we determined it on a check standard of 8.0, and you see that the percent RSD is substantially lower.

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Q All right. And the equation of linear regression, what does that represent?
A That is the equation of the line for the calibration curve determined by linear regression that we use to -- that relates the analytical signal of the response of our tandem mass spectrometer, our HPLC tandem MS, to the concentration of the analyte standard. So on the x-axis we plot -- not plot. On the X-axis is concentration, on the Y-axis is signal, and we generate a line from a series of standards that we run.
Q All right, sir. And R2, R squared?
A That is -- let me see. I want to be sure I use the right term. I believe the term "coefficient of variance," I think. Anyway, it's a measure of how well your line fits to the data that you have used to generate that line. So, ideally, if everything is perfect, that line is going to be 1, a 1.00 on a range of zero to 1. In this case, our R squareds were greater than 0.995 or higher, which is excellent.
Q All right, sir.

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THE WITNESS: Can we take a break so I can use the restroom?
MR. SCOTT: Oh, certainly.
(Recess.)
BY MR. SCOTT:
Q All right. We're back on the record after a short break.
Dr. Simone, I will remind you that you are still under oath.
A Understood.
Q And again, if my questions are unclear, let me know. And again, if you need to take a break, we will try to accommodate you.
A Okay.
Q In relation to your work as an expert in this matter, are you offering an opinion that you have a scientific basis to conclude that the geranium plant as a natural function of its biology produces 1,3- or 1,4-DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I'm offering my expert

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witness report and I guess testimony that I was -- I had sets of plants, I analyzed them at a sufficient degree of analytical rigor. Those plants were determined to have 1,3- and 1,4-DMAA in them as outlined in the paper that I published. And that's my statement, that 1,3-DMAA is naturally occurring in those plants.
BY MR. SCOTT:
Q All right. And what part of your study directed itself as determining how those particular samples obtained or got in the DMAA that you found in them?
Strike that. Let me ask it a different way.
So the basis for your saying that DMAA naturally occurs as a geranium plant is the testing you did of the samples for USP Labs that is reported in Exhibit 4?
A Yes.
Q And in Exhibit 4, do you offer that opinion, that it's naturally occurring?
And let me direct you to page 71, the

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first column there. The first paragraph, last sentence -- or, actually, next to the last sentence which says: "Finally, the diastereomers in ratios of 1,3-DMAA in geranium plants from Changzhou are similar to those in the synthetic standards. This indicates that 1,3-DMAA could be a natural product extract fulfilling the requirement of the Dietary Supplement Health and Education Act."
Do you see that?
A I do.
Q Was that your opinion at the time?
A Yes.
Q Has your opinion changed?
A No.
Q Are you in a position where you can say to a reasonable degree of scientific certainty today that in fact geraniums produce 1,3- and 1,4-DMAA naturally?
A Yes.
Q And that's based on finding it in the samples you tested for USP Labs?
A Yes.

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Q Anything else that you are basing that statement on?
A Does that include materials that I've provided in the discovery process?
Q I have no idea what you're talking about. Do you have any basis, other than the work that you did for USP Labs as reported in Exhibit 4, for your opinion that you just articulated that DMAA is a naturally occurring product of geranium plants?
A Based on the work that I did for USP Labs and the published paper, that's my basis.
Q Any work that you are relying on, other than what's described in the published paper that you did for USP Labs, for your position that the geranium plant naturally produces DMAA?
MS. WOOLSON: I assume you are including in that his expert report?
MR. SCOTT: I don't think he did that for USP Labs.
MS. WOOLSON: Well, you're asking him the basis for his opinion.
MR. SCOTT: Yeah.

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MS. WOOLSON: And you're asking if it's limited to just Exhibit 4, his article; is that correct?
MR. SCOTT: No, I'm not. And if you have an objection, make it. I'm not going to debate the questions with you.
MS. WOOLSON: I'm not asking you to debate the question.
MR. SCOTT: Actually you are.
MS. WOOLSON: I'm asking you to verify the question.
MR. SCOTT: You are.
MS. WOOLSON: No. I think you are trying to mislead the witness.
MR. SCOTT: No, actually, I'm not, but you're obviously trying to coach the witness.
MS. WOOLSON: No.
MR. SCOTT: Oh, really.
BY MR. SCOTT:
Q Doctor, for your opinion that the geranium plants naturally produce 1,3- and 1,4-DMAA, are you relying upon any scientific evidence other

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than the testing that you did for USP Labs that's described in your article, Exhibit 4?
A Can you repeat the question one back time?
MR. SCOTT: Read it back, please.
THE WITNESS: What?
MR. SCOTT: She will read it back.
MS. WOOLSON: He's asking the court reporter.
(Whereupon, the requested record was read.)
THE WITNESS: I am relying on the testing that I did for USP Labs.
BY MR. SCOTT:
Q Anything else?
A Not that I can recall.
Q Are you relying on any testing you did for USP Labs other than what is described -- the testing that was done and described in Exhibit 4?
A We had a paper we submitted that was for peer review in addition for chiral separation that has yet to be published that showed there was

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1,3-DMAA in a Home Depot geranium plant.
Q Was that the graveolens geranium plant?
A I believe so, yeah.
Q And does that paper that is yet to be published regarding that Home Depot geranium, does that article explain why you think that is a naturally occurring portion of the geranium?
A I don't believe it does, other than its presence in the geranium plant.
Q All right. Have you done any work to determine whether or not there is a biological pathway by which a geranium plant can make DMAA?
MS. WOOLSON: Objection to form. Asked and answered four times.
THE WITNESS: No.
(Exhibit No. 7 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You have in front of you what has been marked for identification purposes as Exhibit 7 to your deposition. It's a one-page document bearing identification numbers

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UMPS-HT-002361. It appears to be a letter dated August 8, 2012, to a Professor Thevis, T-H-E-V-I-S, from you.
Do you see that?
A I see it.
Q Is this a letter that you prepared and signed?
A Say that again.
Q Is this a letter that you prepared and signed?
A Yes.
Q Now, who is Professor Thevis?
A Based on the letter, I assume he is an editor at Drug Testing and Analysis.
Q Is that one of the periodicals that you submitted your article to for potential publication?
A I ultimately did not submit this paper to Drug Testing and Analysis.
Q And why was that?
A I believe there was a conversation where Erik White and I were discussing where to submit the journal, and we agreed upon Analytical Chemistry and

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Science.
Q Did you submit it to any periodicals that did not accept it?
A No.
Q Now, the letter dated August 8, 2012, in the third paragraph there, it says, talking about your article: "To the best of our knowledge, this is the first report providing confirmation of 1,3-DMAA in geranium plants using standard addition analysis and in a laboratory sample analysis between labs, which both quantify 1,3-DMAA in an identical geranium plant sample."
Do you see that?
A Yes.
Q You are referring to testing that Intertek did?
A For the -- for what?
Q For the other lab.
A Yes.
Q And it says: "However, we believe there's a regional effect on the presence of the 1,3-DMAA species in geranium and is detailed in the

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manuscript."
And you see that?
A Yes.
Q "Additionally, this manuscript contains the first report of a comparison of the diastereomer ratios of the 1,3 species confirmed to be present in the geranium plant to synthetic standards. The diastereomer ratio of the 1,3-DMAA in the plant and synthetic standards were of similar magnitude."
Do you see that?
A I do.
Q And what does that mean?
A It means that -- so 1,3-DMAA exists as four stereoisomers, and within those four stereoisomers there are two pairs of enantiomers, and then those two pairs of enantiomers are diastereomers. And because they are diastereomers, they have different physical and chemical properties compared to the enantiomers. So you get two peaks when you separate 1,3-DMAA on a standard non-chiral chromatography column.
And Zhang in his paper, as detailed in my

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paper as I summarized, measured the diastereomer ratios of two standards, Sigma-Aldrich and ChromaDex, along with the dietary supplements, and what he found was that the supplements had identical ratios to those standards.
And then based on Zhang's work, we took it upon ourselves to measure the diastereomer ratios of our plants and our standards as well, which we did. And what we found was that the ratios ranged. They were similar to the synthetic standards presented here, as well as to the standards and supplements analyzed by Zhang.
Q Okay. So the standard -- the ratios of the diastereomers that you found within the samples that you tested were identical to the ratios that you saw in the standards that you got which were synthetic, correct?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Say that again.
BY MR. SCOTT:
Q Sure. The ratios of the diastereomers

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that you saw were equivalent to the ratios that you saw in the standard which was synthetic?
MS. WOOLSON: Same objection. Form.
You can answer.
BY MR. SCOTT:
Q Right?
A Are you -- you're referring to the plants in the standards that we --
Q Yeah.
A Okay. You didn't mention plant, so I'm just trying to be precise.
So, yes, we measured the diastereomer ratios of the plants, we found that they varied. And we measured them in the standards, and they were similar.
Q Okay.
A Some overlapped and some did not.
Q I mean normally in plants, would you expect there to be a difference in the diastereomers?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Yeah, probably.

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BY MR. SCOTT:
Q How often have you in looking at plants found the ratio to have different -- a ratio of diastereomers to have something other than a constant ratio?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Well, in the plants we measured here, they're not all the same.
BY MR. SCOTT:
Q Have you found that in any other plant that you ever measured?
A Not that I have directly measured.
Q Are you aware of any other plants where the ratio differs in the plant material?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I'm going to say no, but I find your question to be oddly worded.
BY MR. SCOTT:
Q Well, I mean from the standpoint of if you've got a chiral profile of the four peaks, is the

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plant generally going to have a standard looking profile where the ratio -- they're all pretty much the same, the chiral peaks.
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: To the best of my knowledge, nobody else has measured four peaks of 1,3-DMAA in the plant.
BY MR. SCOTT:
Q I'm not talking about DMAA. I'm talking generally now.
In plants, are you going to expect normally to see the chiral profile to be of a standard as opposed to having different ratios of the chiral peaks that you see?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I don't know.
BY MR. SCOTT:
Q All right, sir. Back to the exhibit.
It goes on to say here: "This result indicates that 1,3-DMAA could potentially be a

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natural extract of geranium plants, and thus, has important ramifications for commercial interest with respect to the regulations and the Food and Drug Administration."
Do you see that?
A What exhibit are we on?
Q We are on Exhibit 7, the last sentence.
A Okay. Okay. (Perusing document.)
Okay.
Q Was that your position and opinion at the time?
A I wrote it, yes.
Q All right, sir. So based on the work that you did for USP Labs as reported in Exhibit 4, your position was because you found DMAA in some samples of geraniums, it could possibly be that they were producing it naturally, the geranium plants?
A Yes.
Q Did you ever get past the point where your opinion was, based on finding DMAA in some samples, it was possible that it could be naturally occurring, part of the geranium plant, the DMAA?

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A I don't understand your question.
Q Well, did your opinion ever get beyond the possibility to a point where you could say that based on your evidence, to a reasonable degree of scientific evidence, you believe that the geranium plants were producing DMAA as a natural part of their biological function?
A Yes.
Q And what did you base that on?
A Some -- I guess our further work and analysis that we did as part of the USP Labs contracts.
Q What further work and analysis did you do for USP Labs that caused you to go from DMAA could possibly be a natural product from geranium plants to saying it actually -- yes, you believe to a reasonable degree of scientific certainty that it is?
A Our work with the chiral derivatization and detection of 1,3-DMAA in additional plants.
Q And did that tell you how the plant got that DMAA?
A No.

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Q Whether it was by natural or some type of contamination or something along that line?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Can you repeat the question?
BY MR. SCOTT:
Q Sure.
Did the additional work that you did regarding the chiral platform where you identified some DMAA in another geranium, did that tell you whether it got there naturally or by some other means?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: It was there.
BY MR. SCOTT:
Q But it didn't tell you how it got there?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.
BY MR. SCOTT:

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Q And it didn't identify any biological mechanism by which the -- that work didn't identify a biological mechanism by which the geranium plant could make DMAA, did it?
MS. WOOLSON: Objection to form. Asked and answered six times.
You can answer.
THE WITNESS: No.
MR. SCOTT: All right. Why don't we break for lunch. Let's shoot for coming back around 1:00, a little after maybe, depending on how long it takes to get there.
(Lunch recess.)
(Exhibit No. 8 was marked for identification.)
BY MR. SCOTT:
Q All right. We're back on the record after a lunch break.
Dr. Simone, I will remind you, you are still under oath. All right?
A Understood.
Q And, again, if you don't understand my questions, let me know. All right?
A Will do.
Q And if you need to take a break, let us know.
A Okay.
Q So let me hand you a document which has been marked for identification purposes as Exhibit 8 to your deposition.
It's a multi-page document bearing identification numbers UMPS-HT-005617 through 5619. And the first page is an e-mail from Erik, USP Labs, to Paul Simone, dated July 1st, 2012.
And just look through it and familiarize yourself that you're -- you know, that this is a series of e-mails between you and Erik at USP Labs, and then after you've done that, let me know, and I will have a couple of questions.
A (Perusing document.)
Okay.
Q Do you recognize that as an e-mail going back and forth between you and Erik at USP Labs?
A I don't remember writing the e-mail, but

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I'm -- it looks to be something I wrote, yes.
Q All right, sir. If you would, turn to the last page of Exhibit 8.
A Okay.
Q And the e-mail that's on that page again is directed to Erik at USP Labs. It starts over on the prior page. Would that be Erik White?
A Yes.
Q All right. Now, if you would, look on the last page of the exhibit, Exhibit 8, the third paragraph down, about halfway down there is a sentence that says: "Independent interlaboratory analysis should be undertaken with samples from the regions of China shown to contain 1,3-DMAA and other parts of the world where geraniums may grow and those geranium plants grown at the University of Mississippi used by ElSohly to determine whether the effects seen are regional or artifact of a laboratory bias for all involved in the analysis."
Do you see that?
A I see that.
Q What does that mean?

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A It means that you've essentially got -- you've got multiple laboratories that are in disagreement as whether or not 1,3-DMAA is occurring in geranium plants. And in order to essentially hash out what is actually happening, he should have multiple people look at these geranium plants and see if it's there.

Q You say here "to determine whether the effects seen." I take it whether geranium -- DMAA is in geraniums or not is the effect you're talking about?

A Yes.

Q And it goes on to say that "... are a regional or artifact of a laboratory bias for all involved in the analysis." What do you mean there by "artifact of a laboratory bias"?

A I mean it's -- as I previously mentioned, there are errors in all analytical methods, and both random and systematic, and determining if there is a random or systematic error can be difficult. So it's a -- that's one way to take a look at it.

And the bias could be bias for not

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finding it and the bias could be for finding it. And, you know, if this is a factfinding mission essentially for the truth of whether 1,3-DMAA is present in geranium plants, as I've stated it is, then the goal should be that you get laboratories that find it and laboratories that don't find it together analyzing the same set of samples.

Q All right, sir. And did you ever reach out to any of the laboratories who tested geraniums and did not find 1,3-DMAA regarding doing such a study?

A No.

Q Now, it goes on to say in the next paragraph on the last page of Exhibit 8: "The interlaboratory analysis is certainly a gamble, but I believe that it would be something to buy you time to do more detailed studies and to let cooler heads prevail."

Do you see that?

A I do.

Q What do you mean there by "the interlaboratory analysis is certainly a gamble"?

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A I mean it's possible that the -- even if we did the interlaboratory study, there would still be disagreement.

Q Would it also be possible if you did the interlaboratory study that it may be determined that in fact DMAA is not in geranium plants?

MS. WOOLSON: Objection to form.

BY MR. SCOTT:

Q Would that be part of the gamble?

A I mean, that would be possible. I mean, I could -- you know, I -- to be frank, I have analyzed plants that show it's there and show it's not, and if -- and it's pretty clear that it's a -- it's a thing where it's hard to determine which plants are going to have 1,3-DMAA and which are not.

And further in there I speak of it being a shotgun approach to determining whether 1,3-DMAA is present, and -- and beyond the Changzhou samples consistently showing 1,3-DMAA in it, those are the -- those are the only ones that I have found that contain 1,3-DMAA.

Q The Changzhou samples that you are

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referring to there, how many shipments of samples did you receive that showed DMAA?

Well, let me ask the question, it may be simpler: The Changzhou samples that you say had DMAA in them, that you found DMAA in, were those the ones that are referenced by your article, Exhibit 4?

A Yes.

Q Did you receive any additional samples after that testing from Changzhou that showed DMAA?

A I can't speak with certainty.

Q Do you recall receiving any more samples from China after you did the testing there that is outlined in your Exhibit 4?

A Yes.

Q You received additional shipments from China?

A Yes.

Q And did you receive shipments from Changzhou, geraniums from Changzhou?

A I think it was.

Q Do you recall whether or not you tested that material and whether it showed to have DMAA in

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it?
A I believe I did, and it had 1,3-DMAA in it.
Q All right, sir. And when did that testing occur?
A After this analysis. The timing is -- I believe it was in 2013 or so.
Q Okay. And when did you get those shipments, the additional shipments of Changzhou geranium plants?
A Well, to be clear, I can't recall if they were Changzhou or not. When did I get them or where did I get them?
Q Yes, where did you get them from?
A They were shipped directly from China.
Q From Dr. Yi Jim?
A I don't remember. Probably.
Q Were they shipped based on any efforts by -- on your part, or did you order them, give instructions to whoever shipped them to you?
MS. WOOLSON: Objection to form.
You can answer.

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THE WITNESS: No, these were shipped as part of a shipment for the second USP Labs contract.
BY MR. SCOTT:
Q And were they handled the same way as the shipment of geranium material for the first USP Labs contract?
A Yes.
MS. WOOLSON: Objection to form.
You can answer.
BY MR. SCOTT:
Q Now, in your view, would the -- an interlab study, as you describe there in the document that we were just talking about, Exhibit 8, having such a thing, would that be a gamble for USP Labs?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, if -- I -- I mean, I clearly wrote that.
BY MR. SCOTT:
Q What did you understand the gamble to be as it relates to USP Labs?
MS. WOOLSON: Objection to form, asked

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and answered.
You can answer.
THE WITNESS: I -- I mean, I -- you know, whether everybody came up with the same answer or not.
BY MR. SCOTT:
Q Or the answer came out in a way that they didn't -- wasn't in line with their commercial interest of wanting to sell DMAA products, right?
MS. WOOLSON: Objection to form, asked and answered.
You can answer.
THE WITNESS: No, the -- I guess maybe that would be the case.
BY MR. SCOTT:
Q When you say to let cooler heads prevail, what are you talking about?
A Honestly, I don't remember.
Q Okay. You can set that one aside.
(Exhibit No. 9 was marked for identification.)
BY MR. SCOTT:

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Q All right, sir. You have in front of you a document which has been marked for identification purposes as Exhibit 9 to your deposition. It is a two-page document bearing no identification numbers. It's headed "Fertilizer Analysis."
And I will ask you if you recognize this document as something you've seen previously.
A (Perusing document.)
When you say "seen previously," what do you mean?
Q Well, do you recognize the document, Exhibit 9?
A Yeah. Yes.
Q What is Exhibit 9? How do you recognize it?
A It looks like a document related to an analysis of fertilizers for 1,3-DMAA and 1,4-DMAA using what is likely equipment at the University of Memphis.
Q Do you know who prepared this document?
A I mean -- I'm not really sure how to answer that.

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Q Well --
A I mean --
Q Did you write this document?
A It's probably a group effort between me and the graduate student.
Q So this document, Exhibit 9, would have been prepared by you in concert with Ms. Fleming?
A Probably. Did this come out of the University of Memphis --
Q Yes.
A -- discovery? All right. Yeah.
Q And do you recall when this document was prepared?
A Late 2013 probably.
Q All right, sir. And what prompted you folks to develop this fertilizer analysis protocol?
A I was trying to rule in or rule out a plausible reason for 1,3-DMAA in geranium plants.
Q All right. And did somebody outside of the university ask you to do this or was this done at your volition?
A It was done at my volition.

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Q And to what degree did Ms. Fleming assist you in developing this protocol?
A I -- I'm trying to give a good percentage. Probably 50/50.
Q And did in fact you folks, you and Ms. Fleming, put this fertilizer analysis protocol into action? Did you actually analyze fertilizers to determine if they had 1,3- and 1,4-DMAA as part of their constituents?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: We tried.
BY MR. SCOTT:
Q And what fertilizers did you analyze?
A So let me be clear. In terms of specific memory, I honestly don't remember. But I read the expert reports and they mention -- I think Osmocote is one of them, so I went back and reviewed the record, and Osmocote was in fact one of them.
Q Did you find DMAA in Osmocote?
A So the -- so looking at our records and looking at some of the expert reports and the

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proposal that I wrote to USP Labs, the preliminary estimates I believe said there was 1,3-DMAA in the fertilizer.
Can we --
Q In Osmocote or more than one?
A In Osmocote.
THE WITNESS: Can I take a break and use the restroom?
MR. SCOTT: Sure.
(Recess.)
BY MR. SCOTT:
Q All right, sir. And do you recall if you found DMAA in fertilizers in addition to Osmocote?
A There might have been one other, but let me be clear about the level of rigor that was involved in that. And so the preliminary estimates came up positive. And -- but we were really never able to publish that work. And it's -- that's because the -- I could not -- we could not get the method reproducible enough. There were significant matrix effects. And the analysis was actually pretty hard on the instrument, and so it was a very

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difficult analysis.
And if I compare that to the -- what ended up being an unpublished report using the chiral stuff, we actually submitted that to a journal and got reviews back, and did our best to address the reviews. But then we were unable to finish that work due to instrumentation problems.
Q Okay. But you did some work on fertilizers, and the preliminary results showed DMAA, correct?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Very preliminary, correct.
BY MR. SCOTT:
Q And did you ever do any work that reversed those results, that showed that in fact these fertilizers that you preliminarily identified as having DMAA actually didn't have it?
MS. WOOLSON: Objection to form, misstates testimony.
You can answer.
THE WITNESS: No. I believe -- and like

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I said, I have not looked very closely at some of that work since then. We essentially abandoned that work. And, you know, the -- I believe we -- and -- I'm actually kind of nervous about talking about this because I don't have the data in front of me to talk about it.

But, you know, the only report I made to the presence of 1,3-DMAA in the fertilizer was that proposal to USP Labs that I can recall. And the reason in that proposal we actually wanted to continue doing that work was to actually solidify the research we had done up to that point, which was is it in there or is it not. And so we found it in kind of like a screening preliminary analysis but were never able to confirm it to an acceptable standard for publication.

BY MR. SCOTT:

Q Well, based on the work that you described that you did and looking at fertilizers to see if it had DMAA, were you able to eliminate fertilizer contamination as a possible source of DMAA in geraniums that you had tested?

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A I had no reason to believe the geraniums that we tested were contaminated.

Q Do you know what fertilizers were used with the geraniums that you --

MS. WOOLSON: Objection to form.

You can answer.

BY MR. SCOTT:

Q -- that you tested?

A Repeat the question.

Q Sure. You got geraniums from -- samples from China. What fertilizers were used to grow them?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: I have no data indicating whether fertilizer was or was not used in those geraniums, and based on my reading of other -- of other people's papers, they also don't have -- they don't know whether fertilizer was used in growing their plants.

BY MR. SCOTT:

Q Were you able to eliminate fertilizer with DMAA in it as a source of potential contamination for geranium plants?

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MS. WOOLSON: Objection to form.

You can answer.

BY MR. SCOTT:

Q Based on the work you did?

A I was never able to confirm nor deny it. The level of rigor in that work is preliminary for a reason. It was never published for a reason, because we couldn't get the method to work reproducibly.

(Exhibit No. 10 was marked for identification.)

BY MR. SCOTT:

Q All right, sir. You have in front of you what's been marked for identification purposes as Exhibit 10 to your deposition. It's a multi-page document bearing identification numbers UMPS-HT-001088 through 1093. And I will ask you -- the heading on the first page is "Confidential: Do not distribute. Analysis Survey for 1,3-DMAA and 1,4-DMAA in Food and Geranium Plants." It says -- it has listed here Paul Simone and Randall Bayer.

Is this the proposal you put together to

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give to USP Labs for additional work?

A Yes.

Q And who is Mr. Bayer?

A He is the chair of the biology department at the University of Memphis, and his role was going to be simply authentication of the plants.

Q All right, sir. If you would, turn to page 4 of the document. The third paragraph down --

A Let me -- I want to amend that previous answer. So it was authentication and help growing the plants.

Q Okay. And was this proposal given to USP Labs?

A I think so, yes.

Q Did they adopt it? Did they tell you to go ahead with this work?

A No.

Q Now, if you would turn to page 4, the third paragraph down there starts: "Prior to planting of the geranium plants, all soils and fertilizers will be analyzed for 1,3-DMAA and 1,4-DMAA. This is an important step as a

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commercially purchased time-release fertilizer Osmocote was found to contain 12 ng/g of 1,3-DMAA, which could potentially contaminate plants if blindly used."

Do you see that?

A I do.

Q Is that 12 ng/g, is that parts per billion?

A Yes, nanograms per gram.

Q Is that the same unit of measure that you used in the tests that you did for geranium samples, parts per billion?

A Yes.

Q And it goes on to say: "A screening of fertilizers will be conducted to identify commercially available sources with high nitrogen, phosphorous and potassium content to provide growth to all aspects of the plants."

Do you see that?

A I do.

Q And then it goes on to say: "Fertilizers containing DMAA could potentially act as a source of

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DMAA into the human food diet. If all fertilizers analyzed contain 1,3-DMAA, then a custom mix of fertilizer will be reproduced from a reagent grade fertilizer equivalence, all scheduled for both DMAA species."

Do you see that?

MS. WOOLSON: Objection to form.

THE WITNESS: I do.

BY MR. SCOTT:

Q By "DMAA species," you're talking about 1,3- and 1,4-DMAA?

A Correct.

Q Now -- and this was presented to USP Labs?

MS. WOOLSON: Objection to form, asked and answered.

You may answer.

BY MR. SCOTT:

Q This document?

A I e-mailed it to them. I e-mailed it to Erik White. I'm sure there is an e-mail in there somewhere that shows it.

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Q Why were you concerned, at least in the context of this document, of fertilizers containing DMAA potentially acting as a source of DMAA into the human food diet?

A If the fertilizer contained DMAA, then the -- based on my conversations with Randy Bayer, he said that it could be taken up into the plant.

Q Absorbed into the plant through the root system, DMAA?

A I assume so, yes.

Q And why would that matter to you in the context of what you were proposing to do here whether or not the plants were absorbing DMAA through the root system based on fertilizer contamination?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: We were looking for 1,3-DMAA in these other plants.

BY MR. SCOTT:

Q To determine if it was there naturally as opposed to through some contamination?

MS. WOOLSON: Objection to form.

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THE WITNESS: Yes.

BY MR. SCOTT:

Q And USP Labs did not authorize this work?

A What do you mean?

Q I mean, you made a proposal. Did they say, Go do it? The proposal that is set out here in Exhibit 10.

A Are you -- so -- can -- can you -- I'm sorry. Can you restate the question?

Q You called Exhibit 10 a proposal that was sent to USP Labs. Correct?

A Correct.

Q Did they tell you to do the work set forth in the proposal, Exhibit 10?

A They did not fund the work.

Q Did you do any work to screen fertilizers for DMAA after you sent this proposal to USP Labs?

A Not that I can recall.

Q Did the preliminary work you had done in fertilizers to identify whether DMAA may be there based on the protocol you developed with this one, was that done before this proposal was sent?

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MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Yes.
BY MR. SCOTT:
Q Now, based on the work that you did looking at the fertilizers, were you able to eliminate fertilizer contamination from DMAA as a source of DMAA potentially being in geranium samples?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Based on the work that I did, I had no reason to suspect that the geraniums that I analyzed were contaminated by fertilizer.
BY MR. SCOTT:
Q Well, my question is a little broader than that. My question is, were you able to eliminate as a general matter DMAA in fertilizer as a potential source of contaminate of geraniums?
MS. WOOLSON: Objection to form, asked and answered twice.
You can answer.
THE WITNESS: I was neither able to

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confirm nor deny that DMAA was in fact in the fertilizer to begin with. The -- as I said, the results, you know, stated here concerning the presence of 1,3- and 1,4-DMAA in the fertilizer were preliminary. If I had had concrete results, I would have attempted to publish them. But we couldn't get concrete results, and part of the work presented in this proposal would have been developing a method that was able to actually do that analysis.
BY MR. SCOTT:
Q Now, in the proposal that you made to your client, USP Labs, you state there that: "This is an important step. As a commercially purchased time-release fertilizer Osmocote was found to contain 12 ng/g of 1,3-DMAA." And I'm on page 4.
A Okay.
Q Do you see that sentence?
A I do.
Q Is there anywhere in there you say that your results on this are preliminary, unreliable or anything of that ilk?
MS. WOOLSON: Objection to form.

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You can answer.
THE WITNESS: It's not written there, no. But the -- as I said, if this was a preliminary thing, and I don't know any other way to describe it, that if we had been able to essentially nail down whether or not it was there, we would have done so and we would have published it, whether or not -- regardless of how it actually affected all this other stuff.
(Exhibit No. 11 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You have in front of you what has been marked for identification purposes as Exhibit 11 to your deposition. It's a multi-page exhibit of spreadsheets and graphs. The first page is headed FHLF111 dated August 17, 2013. And I will ask you if you can identify this as work product that was generated by your lab?
A Yes, it very likely is.
Q Now, at the bottom there, it says: "Fertilizer sample: Osmocote, Scott." Do you see

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that?
A Yes.
Q And the numbers that go through -- beyond that are -- say "Concentration." Do you see that?
A Yes. CONC, period?
Q CONC, period. Does that reflect that there was a concentration of DMAA, 1,3 and 1,4, found in the Scott and Osmocote fertilizers?
A What it reflects is the fact that the analysis came up with a concentration of -- let's see. Oh, the units are on here. Presumably -- let's see, I have to see what -- let's see. So presumably concentration of micrograms per liter as measured by the instrument.
Now, if you look at those numbers, those concentration numbers, they are all less than the method detection limit of the fertilizer -- of the analysis. And so as we previously discussed, if it's less than the method detection limit, and as many of my other colleagues, for lack of a better term, who publish in this area, if it's less than the method detection limit, then you don't report it.

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Now, if I recall correctly, we very likely, as what I would have done, actually tried to analyze a higher mass of fertilizer to see if that concentration was in fact real. And then that's where we get into the -- I couldn't make it reproducible enough to actually get a number out of it, because as we increased the mass, the extraction became significantly more complex.

Q But you were able to get a number sufficient to tell your client that you found it in Osmocote at 12 parts per billion in your proposal, correct?

A It appears so, yes.

Q Okay. You can set the graph aside for a moment.

Are you familiar with a fertilizer called Lesco?

A Yes.

Q Did you test that for DMAA?

A Possibly. Is it on that sheet of paper?

(Exhibit No. 12 was marked for identification.)

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BY MR. SCOTT:

Q You have in front of you what's been marked for identification purposes as Exhibit 12 to your deposition. The first page of the spreadsheet is headed "FHLFF135, 9/18/2013, Lesco."

Do you see that?

A Where do you see Lesco?

Q At the top next to the date.

A Oh, I see it. Okay.

Q Have you seen this document before?

A Not specifically. I mean it's a document produced in our lab, but I don't think I've --

Q Does this reflect a test showing the presence of either 1,3 or 1,4-DMAA in the test sample?

A (Perusing document.) Can you repeat the question?

Q Sure. Does that reflect a test that shows the presence in the sample, the Lesco sample, of 1,3- or 1,4-DMAA?

A Apparently it does, at a concentration of 0.05 nanograms per gram. A factor of 100 to 1000

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below what we typically found in the plants.

Q All right, sir. Before testifying here today, did you go back and look at any of the testing that you had done relating to the presence of DMAA in fertilizer?

A Not in this detail.

Q Well, what level of detail did you do it?

A Scanned our lab notebooks that said we had done it.

Q And did you look at what the concentration levels were found to be?

A Not in detail.

Q At all?

A I simply looked at the lab notebooks that had mentioned it.

Q Okay. And you didn't look at the -- what sample concentrations were?

A No. I did not specifically look at these spreadsheets.

Q Well, I'm not talking about just these spreadsheets. Any evidence in your own records regarding what samples you found when you were

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testing fertilizers for DMAA.

A No, I did not.

MS. WOOLSON: Objection to form. It's been asked and answered.

You can answer.

THE WITNESS: And I didn't -- I did not rely on this for my expert report, just as I did not rely on the work we had attempted to publish relating to the chiral derivatization of 1,3-DMAA.

BY MR. SCOTT:

Q All right, sir. Would you agree that there is a probability that plants have been and can be contaminated with DMAA through soil and fertilizer contamination?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: Well, if we are talking about work that I did not include in my expert report, further work we did related to this, we almost killed the plants when we tried to spike in 1,3-DMAA into the geranium plants.

BY MR. SCOTT:

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Q Spiking it at levels higher than you found in the fertilizers?
A I don't believe so.
Q And when was that work done?
A Sometime around some of this.
Q Was any of that documented?
A I believe it was. But it was -- this is essentially a qualitative assessment of we put 1,3-DMAA in water that we poured over the plants, and they about died doing it.
Q And what concentration levels were the DMAA in the water?
A Sufficient to be approximately equal to that of what we found in the plants.
Q All at one time you put the -- what you found in the plants, that concentration level in the water and poured it on the plant?
A (The witness nods.)
Q Would you expect if the plant was absorbing DMAA through its root system that it would take up the entire concentration in one event?
A I have no idea.

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MS. WOOLSON: Objection to form.
BY MR. SCOTT:
Q Was Ms. Fleming involved in this study, this work?
A Yes. And I directed her doing it.
Q And so do you remember when that was?
MS. WOOLSON: Objection to form, asked and answered.
You can answer.
THE WITNESS: Sometime around when this was going on. I mean, honestly, I don't remember.
BY MR. SCOTT:
Q Was it before this document and this presentation was done?
MS. WOOLSON: What presentation?
MR. SCOTT: The presentation that's marked as Exhibit 6. He gave us a date on that, I believe of April of 2013.
THE WITNESS: No, I gave you an after date. I said it was after April 2013.
BY MR. SCOTT:
Q Okay. Well, was the work that you were

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talking about pouring spiked water on geranium plants done before or after this presentation?
A (Perusing document.) I don't know.
Q Well, if you would turn to page 39 in Exhibit 6. That's the one in your hand.
A Okay.
Q Up on the top there is a heading "Planned Research." It's kind of hard to read.
A Yes.
Q But down at the bottom it says: "Investigate probability that plants are being exposed to DMAA and absorbing the compound," with a bullet point under that, "Soil, fertilizer analysis."
Do you see that?
A I see it.
Q Did you write that language?
A Probably.
Q And certainly if Ms. Fleming wrote it, you saw it before she gave the presentation?
A Yes.
Q Do you know what is meant there by "Investigate probability that plants are being

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exposed to DMAA and absorbing the compound"?
A It's probably poor word choice on our part, and as I say, looking to see if DMAA could be exposed to -- I mean DMAA could be -- the plants could be exposed to DMAA through the soil and fertilizer.
Q Well, now, let me back up to something you talked about a while ago. As I understand it, you said you did an exercise where you got geranium plants, live geranium plants, correct?
A Yes.
Q And then you put DMAA in water in concentration levels equivalent of what you had found when you did your DMAA testing of geranium plants for USP Labs, correct?
A Approximately the same concentrations.
Q Well, the concentrations in those -- your samples, you know, had some ranges there. So do you recall what range you picked? Was it the high end or the low end?
A No.
Q Or something in between?

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A No.
Q But it was something that approximated what you found -- the concentration levels in the water that you poured over the plants, it approximated the levels that you found when you did your testing of USP Labs samples, correct?
A Correct.
Q And then you said that once you poured the water over them, the -- did you do it all at one time?
A We repeatedly watered the plants.
Q With the concentration levels that were in what -- equivalent to what you found when you did your testing?
A Correct.
Q Each water sample had the same concentration level in it?
A To the best of my knowledge.
Q Now, if you are watering geranium plants with water that's been spiked with DMAA equivalent of what you found in your test causes them to die, how do you juxtapose that with your view that the

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geranium plants naturally produce the product at those concentration levels?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: You know, I can't really give you a good answer. It -- we -- well, for the same reason I didn't include it in my report. We -- about that time period, I moved at the time Ms. Fleming, now Dr. Fleming, to another project because it had more pressing needs, and that was related to haloacetic acids in drinking water and bleach. And the work here was no longer being funded by USP Labs, and so I moved on.
BY MR. SCOTT:
Q Well, that all may be, but my question was a little more specific than that.
My question is, do you have an explanation of why -- if geranium plants naturally produce DMAA at the concentration levels that you found it in your test for USP Labs, why pouring that concentration level over them in water would kill them?

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MS. WOOLSON: Objection to form, asked and answered.
You can answer.
THE WITNESS: I don't know.
(Exhibit No. 13 was marked for identification.)
BY MR. SCOTT:
Q You have in front of you what's been marked for identification purposes as Exhibit 13 to your deposition. It's a two-page document bearing identification -- well, no identification numbers. This was produced by the University of Memphis. It's headed "FHLFF131, Fertilizer, 09/11/13."
And I will ask you, first of all, to take a look at it and see if you've seen this before.
A I have not seen it before, but it looks like something that came out of our lab.
Q All right, sir. And there are several products or names here starting with Lesco. Do you see that?
A I do.
Q Is that a fertilizer?

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A Presumably.
Q Spring Valley, is that a fertilizer?
A I believe it is.
Q Scott Extract, is that a fertilizer?
A I believe it is.
Q And Earthmate, is that a fertilizer?
A I believe it is.
Q Now, do these appear to be chromatographs that were done of samples of each of the fertilizers I just named?
A Yes.
Q Do any of these show the presence of DMAA, either 1,3 or 1,4-DMAA, in those fertilizers?
A I don't know.
Q What would you have to do to determine that?
A I would have to look at a standard run approximately at the same time, look at the retention times, and do a much more detailed analysis than -- I might look at some chromatograms on a sheet of paper that aren't labeled.
Q All right, sir.

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(Exhibit No. 14 was marked for identification.)

BY MR. SCOTT:

Q All right, sir. You have in front of you what's been marked for identification purposes as Exhibit 14 to your deposition. It is a multi-page document, pages 1 through 23. The first page is "Analysis of 1,3-DMAA and 1,4-DMAA in geranium plants using high performance liquid chromatography with tandem mass spectrometry and nuclear magnetic resonance, Heather L. Fleming, September 2013."

Do you see that?

A I do.

Q And do you know what this document is?

A Probably her prospectus document.

Q And what's that?

A That's the document that she writes as part of her cumulative examinations to qualify as a Ph.D. candidate at the University of Memphis.

Q All right, sir. Did you have any involvement in the preparation of this?

A I probably edited it, more than likely.

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I mean -- yes.

Q And so you would have looked it over and told her go/no go with the document before she submitted it?

A Yes.

Q All right, sir. You can set that aside.

MR. SCOTT: Let's take a short break here while I shift materials.

(Recess.)

BY MR. SCOTT:

Q Back on the record after a short break.

Doctor, I will remind you you're still under oath, all right?

A Understood.

Q And please let me know if my questions are unclear.

A Understood.

Q And if you need a break, again let me know.

If you would, grab Exhibit 4, your published study.

A Okay.

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Q Now, in your published study you talk about a number of other studies that were performed pertaining to trying to identify DMAA in geranium plants. Right?

A Right.

Q Now, are you familiar with something that is generally referred to as the Ping study?

A Yes.

Q And do you refer to or cite the Ping study in your published study there, Exhibit 4?

A No.

Q Why is that?

A I had not read that study.

Q All right. So when you did your work for USP Labs, you had not seen the Ping study?

A That's correct.

Q Were you aware of it?

A I don't recall.

Q But certainly when you put forward your findings in Exhibit 4, you had not reviewed the Ping study and were not relying on it for any purpose?

A I had not reviewed it and I did not

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reference it.

Q Did you rely on it for anything?

A No. I had not read it, had not seen it.

Q All right, sir. When do you recall first seeing the Ping study?

A Sometime after it was provided to me during this -- the generation of my expert report as related to this particular case.

Q Okay. So you first saw Ping after you were retained as an expert in this case?

A That's correct.

Q And I will assume a lawyer gave it to you?

MS. WOOLSON: Objection to form. You can answer.

THE WITNESS: Yeah, it was provided as part of the documents that were given to me.

BY MR. SCOTT:

Q Okay. Now, I probably should have asked this earlier, but in the course of preparing as an expert here, have you had any conversations with anyone at Hi-Tech?

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A I don't understand.
Q You've been working as an expert for Hi-Tech in this matter. Have you talked to anybody who works directly for Hi-Tech as opposed to lawyers working for Hi-Tech?
A I've only spoken to the lawyers, that I'm aware of.
Q When you were doing your work that resulted in Exhibit 4 being prepared, your -- the published article about your study, did you have any direct communications, conversations with anyone employed by Intertek?
MS. WOOLSON: Did you say Intertek?
MR. SCOTT: Yes.
THE WITNESS: Not that I can recall.
BY MR. SCOTT:
Q Have you had any conversations with anyone employed by Intertek since you've been employed as an expert in this case?
A No.
Q If you would, flip over to your report in this case, Exhibit 4.

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MS. WOOLSON: Report?
MR. SCOTT: Report.
MS. WOOLSON: That's not Exhibit 4.
MR. SCOTT: I'm sorry. Exhibit 3. You're correct.
BY MR. SCOTT:
Q Flip over to Exhibit 3, the report you prepared, the declaration that you prepared as an expert in this matter, and turn to page 23.
A Okay.
Q Paragraph 39 there starts off: "The publication as the stem of many discussions and analysis in the peer-reviewed literature is Ping 1996."
You see that?
A I do.
Q And it goes on to say: "Here Ping reports using gas chromatography, GC, with mass spectrometry, MS, to identify components, including 1,3-DMAA in geranium oil extract."
Do you see that?
A I do.

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Q Then it goes on to say there: "This manuscript should be viewed for what it is, a typical chemical survey using GC/MS to separate, provide relative quantity and initial identification of the compounds present in the geranium oil extract."
Do you see that?
A I do.
Q What do you mean by "a typical chemical survey"?
A Well, based on my review of additional literature as part of this report, there were multiple surveys referenced for geranium that used similar methods to identify the components.
Q Okay. And do you rely on those for any purpose, those other surveys in your report?
A (Perusing document.) Yes.
Q And what purpose do you rely on those other general surveys for?
A The composition of geranium plants as referenced by multiple authors, and the composition of those geranium plants and oil extracts vary widely, based on the metal ion variation of the soil,

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the growing region and growing climate. In addition, the method of preparation can affect the apparent composition of the geranium plant oil extracts. And what I said was -- yeah.
Q You are reading from part of your report?
A I am.
Q What page?
A 42, paragraph 74.
Q All right, sir. Now, in any of -- do any of the other general surveys of components of the geranium plants and oil extracts identify DMAA as a component, anybody beyond Ping?
A Can you repeat the question?
Q Sure. You said that you looked at and relied on for some purpose general surveys of geranium oil and components, right?
A Correct.
Q Do any of the -- do any general surveys of geranium oil components other than Ping identify DMAA as a component?
A Not that I'm aware of, at the concentrations that they reported their components

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at.
Q What concentrations did Ping report his at?
A I don't remember off the top of my head. I would have to actually look at it.
Q Do you consider the Ping report to conclusively demonstrate that it found DMAA?
MS. WOOLSON: I'm sorry. Could you repeat that question?
MR. SCOTT: Read it back.
(Whereupon, the requested record was read.)
MS. WOOLSON: You can answer.
THE WITNESS: They reported that they did, and -- and I assume, like I do with others, that the results were reported in good faith.
BY MR. SCOTT:
Q Well, people make mistakes. Correct?
A Correct.
Q Well, let me ask you this: Have you seen the Ping report in its original Chinese?
A Maybe. I don't remember.

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Q Were you given an English translation of it?
A Yes.
Q Did you attempt to duplicate the results of Ping?
A No.
Q Now, based on the information that's provided in the Ping study, would it be possible to actually follow what they did and try to duplicate its results?
A Do you have a copy of the Ping paper?
Q Sure.
Well, let me ask you this: Do you know -- while I pull it out, in relation to the Ping paper, did Ping compare a chromatograph to a reference library to identify what he says was DMAA?
A I would have to read the paper to tell you.
Q Well, let me ask you this: When you were given the paper, did you do anything to determine whether or not his results were in fact subject to duplication?

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A I don't understand.
(Exhibit No. 15 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You've got in front of you what's been marked for identification purposes as Exhibit 15. It's a multi-page document bearing identification numbers HT 06200 through 6207. The first page is "A Study on the Chemical Constituents of Geranium Oil."
Is that the translation of the Ping study that you were provided?
A Yes.
Q Now, did Ping take a chromatograph and compare it to a reference library to identify substances that it said were DMAA?
A (Perusing document.)
So what was the question?
Q I'm not even sure at this point.
MR. SCOTT: What was the last question?
(Whereupon, the requested record was read.)

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THE WITNESS: Potentially.
BY MR. SCOTT:
Q You can't tell whether he did that or not?
A There's a sentence that says: "Furthermore, complex quantitative operations such as a spectrum temperature control, collection of spectrum data, data storage and mass spectrum image examination will be performed by a computer."
Q Was any of the results of that reported in his study, in his report, that exhibit?
A I mean, he reported the conditions of the GC/MS, and that's his analysis conditions. The -- the specifics of data storage were not described, but basically nobody describes the specifics of how you store the things on the computer. And the mass spectrum image examination is what I assume to be the -- a scan against the reference library.
Q Okay. Did he tell you what reference library he used?
A No.
Q Did he tell you how close the match was,

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either quantitatively or qualitatively?
A No.
Q Would it be possible for you to go back then and take what he gave you in the chromatograph and determine if his analysis was done correctly?
A I mean, can -- can you repeat the question?
Q Sure. How would you duplicate the results that he has without knowing the reference library used or the closeness of the match?
A I would start with the equipment provided and -- and the scan speed, the column conditions, the temperature of the oven, the injector port and the detector conditions. Start with all of those, as well as the column that he provided, and the 5 percent benzyl polysiloxane fused silica capillary column. He's got the scan speeds here. The electron -- the electric potential for the ionization is there, which is the standard 70 electron volts that has been used for as long as I've been an analytic chemist. And provided -- I think he provided somewhere how they did the oil extraction.

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Let's see. That's where I would start.
Q All right, sir. If you would look at your report again, paragraph 38.
A Okay.
Q Page 22.
A What page?
Q Page 22, paragraph 38.
A Okay.
Q It states there: "In either case, the most credible publications of 1,3-DMAA analysis report parameters such as detection limits, accuracy, precision, and percentage recoveries."
Do you see that?
A Yeah.
Q Does Ping supply you with that information in his report?
A No. And neither do -- there's a few other papers that I reviewed that also did not.
Q But you are relying on Ping but not the others, correct?
MS. WOOLSON: Objection to form.
You can answer.

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THE WITNESS: I was -- I don't know if I would --
BY MR. SCOTT:
Q I'm sorry, I didn't hear you.
A Hold on one moment. I'm looking for my statement.
So in my Summary of Opinions, page 87, I state that: "It is my opinion that the geranium plants analyzed by Li, 2012, and Fleming, 2012, contain concentrations of 1,3-DMAA in the stated range for both, and that these studies were done to the same level of rigor as ElSohly, 2012 and 2015; Austin, 2013; Zhang, 2011; and DiLorenzo, 2012, both in terms of the analytical chemistry and level of authentication of the geranium plants."
Q Well, I'm confused because earlier in your testimony I thought you said that you were relying on four studies that you said found DMAA, including Ping. So are you not relying on Ping?
A I guess I misstated it. That should be three.
Q So you are not relying on Ping for any

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purpose in your report?
A Other than I reviewed it as a report that purported to contain DMAA, and then I would say that my analysis of Ping is -- it is what it is.
Let me put it this way: It is not the -- I guess the same level of rigor that the other more quantitative papers used. It's a qualitative identification.
Q Did Ping use a reference sample to identify the DMAA he claims to have found?
A I don't know. It's not stated.
Q If he did, he didn't say so?
A Correct.
Q Do you know if in the Ping paper what he identifies as DMAA elutes at the level and time frame that you would expect to --
A Can you repeat that or restate it?
Q Sure, are you familiar with the term "elutes"?
A Yes.
Q And what is that?
A It's the -- well, that's the -- it's

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referring to a chemical compound exiting a chromatography column.
Q And they generally exit at a given time frame based on the size and configuration of the molecule, correct?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Based on the -- it's a little more complicated than that. It's based on the stationary phase, the -- and the interaction between it and the molecule.
BY MR. SCOTT:
Q Is the time frame in the analysis in which Ping reports DMAA to have eluted consistent with what you understand the time frame that DMAA will elute in doing this type of analysis?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: (Perusing document.) Can you restate the question just so I'm clear?
BY MR. SCOTT:
Q Sure. Have you looked at the Ping study

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sufficiently to determine if he is reporting what he considers to be DMAA to be eluting the process at the time frame that you think DMAA should be shown to be eluting the process?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I have not reviewed it in that detail, no.
BY MR. SCOTT:
Q Based on the information that you have and based on your review of Ping, to the extent that you have had a chance to review it, can you confirm within a reasonable degree of scientific certainty that what he claims to have found as DMAA in fact was DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: (Perusing document.)
Can you -- just so it's clear, can you restate what -- the question that you asked?
BY MR. SCOTT:
Q Let me withdraw the question and ask you

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this: You don't know when Ping says DMAA eluted in the process, do you?
MS. WOOLSON: Objection to form.
THE WITNESS: Yeah, I don't see the -- I don't see 1,3-DMAA or 4-methylhexane on there.
BY MR. SCOTT:
Q Do you see in the Ping paper 1,3-DMAA or 1,4-DMAA listed at all?
A No. Not as stated.
Q All right, sir. If you go back to your report, Exhibit 3.
In Exhibit 3, if you would, turn to page 27, paragraph 46.
A Okay.
Q Now, I take it certainly you've reviewed the Li protocol used in testing geranium plants for 1,3-DMAA and 1,4-DMAA?
A Correct.
Q And, in fact, you implemented those protocols in doing the testing for USP Labs that is reported in your article, Exhibit 4, correct?
A Correct.

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To be clear, I got what amounts to a -- I reviewed their standard analysis method. I didn't review the paper before.
Q All right. So you reviewed their standard analysis method when you did your testing. You hadn't actually seen their final paper since then?
A That's correct.
Q Do you have any understanding of what the conclusions were reached in the final paper?
And we'll get to that. I'm asking if you -- is that something you looked at in the course of doing your expert work?
A Yes.
Q Is that something you did before looking -- doing your expert work, looked at the Li paper to see what his conclusions were?
A I may have.
Q You don't have a specific recollection of that?
A No. I mean, other than what I probably mentioned in my publication.

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(Exhibit Nos. 16 and 17 were marked for identification.)
BY MR. SCOTT:
Q All right, sir. You have in front of you a document which has been marked for identification purposes as Exhibit 16 to your deposition. It's a multi-page document bearing identification numbers UMPS-HT-00682 through 686.
And I will ask you to take a look at this, and tell me if this is a copy of the standard analytical method that you were provided pertaining to the work done by Intertek.
A Yeah, as best as I can recall.
Q All right, sir. And there's also Exhibit 17, which bears identification numbers UMPS-HT-687 through 691. The first page is headed "Standard Analytical Methods, Intertek ACC Labs."
Is this an additional standard analytical methods sheet that you were provided by Intertek while you were doing your work for USP Labs?
A I don't believe I ever received these from Intertek.

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Q Where did you get them?
A Through USP Labs.
Q All right. But these were both given to you by USP Labs while you were doing your work on the samples that they provided?
A As best as I can recall, that's correct.
Q Now, do you rely on the Intertek work to support your view that geranium plants naturally produce DMAA?
A What do you mean?
Q I mean you've offered the opinion, I thought, correct me if I'm wrong, that DMAA is naturally produced by geranium plants, and you based that in part, I thought, on the studies that you did and the testing of the geranium samples provided by USP Labs. Am I right so far?
A You're -- hold on. The question was really long, so I'm sorry.
Q Is it your opinion that geranium plants naturally produce DMAA?
A Well, yeah, as I wrote in my report, yes.
Q And is it your -- did you rely on any of

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Intertek's work or do you rely on Intertek's work to support that opinion?
A I based it on the paper that they published.
Q Okay. And did you -- what -- and what in the paper did they publish are you basing -- are you using for support?
A Do you have the paper on you?
Q Sure.
(Exhibit No. 18 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You have in front of you what's been marked as 19 to your deposition -- 18, I'm sorry.
You have in front of you what's been marked as Exhibit 18 to your deposition. It is a multi-page document bearing identification numbers HT-06140 through 06151. The first page is headed "Identification and Quantification of Dimethylamylamine in Geranium By Liquid Chromatography Tandem Mass Spectrometry," J. S. Li,

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M. Chan, and Z. C. Li are the authors.
Do you see that?
A I see that.
Q This is the write-up of the Li work, the Intertek work, correct?
A As far as I know, yes.
Q Have you seen this before?
A Yes.
Q And is there anything in the Intertek work that you're relying upon to support your position that geranium plants naturally produce DMAA?
A They have plants and oils, what looks to be three plants and three oils from various regions of China that they analyzed and report to contain concentrations of 1,3-DMAA and 1,4-DMAA.
Q Now, does anything in their study in your view support a conclusion that their work shows that geranium plants actually naturally produce DMAA as opposed to, Well, we tested some samples and we found it?
MS. WOOLSON: Objection to form.
You can answer.

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THE WITNESS: Can you restate the question?
BY MR. SCOTT:
Q Sure. Do you know what they were asked to do by USP Labs in doing this work?
MS. WOOLSON: That's a different question completely.
MR. SCOTT: Yes, I know it. I'm asking a different question because he didn't understand the other one.
MS. WOOLSON: No, he asked you to restate it. Now you're asking him a completely different question. And that's fine, but that's what you're doing.
Go ahead, you can answer.
MR. SCOTT: So what's the objection if it's fine for me to ask a different question?
MS. WOOLSON: The witness asked you to restate the question that you asked him, and instead, you chose to ask him a completely different question in response.
MR. SCOTT: Yes, and do you have an

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objection or is it just you want to get involved --
MS. WOOLSON: Yes, my objection is the witness asked you to restate the question, and you didn't do that. You chose to ask him a different question from what he asked you to do.
MR. SCOTT: Okay. I still haven't heard an objection.
MS. WOOLSON: I'm just making sure we're clear for the record that you did not respond to the witness's request.
BY MR. SCOTT:
Q Sir, you read the Intertek paper as part of you being an expert in this case, right?
A Correct.
Q Did you rely on that for your conclusion in any form or fashion that DMAA is naturally produced by geranium plants?
MS. WOOLSON: Objection to form. Asked and answered three times.
You can answer.
THE WITNESS: Yes.
BY MR. SCOTT:

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Q And what was that?
MS. WOOLSON: Objection to form. Asked and answered three times.
You can answer.
THE WITNESS: That they measured -- that they analyzed plants from three different regions in China, and the oils that they analyzed, although I'm not sure if I specifically mentioned the oils themselves because I did not analyze them, but they did the three different plants from China, three different regions and found DMAA in all of them above their detection limits.
BY MR. SCOTT:
Q Okay. What did Intertek do, if anything, to ensure that the plants they tested had not been contaminated before they reached Intertek's lab by water, air or fertilizer or soil?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I have no evidence in any way, shape or form of -- that their plants could have been contaminated, and the -- there was no evidence

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based on my dealings with -- where I got my samples from that they were adulterated or contaminated.
BY MR. SCOTT:
Q Were fertilizers used on the plants that you tested in growing them?
MS. WOOLSON: Objection to form, asked and answered.
You can answer.
THE WITNESS: Can you repeat that?
BY MR. SCOTT:
Q Sure. The plants that you received for testing, had fertilizer been used to grow them?
MS. WOOLSON: Same objection.
You can answer.
THE WITNESS: I don't know.
BY MR. SCOTT:
Q Were fertilizers used on the plants that were grown and supplied to Intertek?
A I don't know.
Q All right, sir. Is there anything that Intertek did that you rely upon to support your conclusion that geranium plants actually produce DMAA

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other than they tested samples provided by USP Labs and found what they believed to be DMAA in those samples?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Can you repeat the question?
BY MR. SCOTT:
Q Sure. Is there anything other than Intertek -- in the Intertek report that you are relying on for your opinion that geranium plants naturally produce DMAA other than the fact that they tested samples that USP Labs had sent to them and found trace elements of DMAA in some of those samples?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I'm -- I'm not really sure what -- I don't understand your question.
BY MR. SCOTT:
Q Okay. Well, let me make it very, very simple.

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A Great.
Q You say you read the Intertek report.
A Correct.
Q And it says in there that USP Labs gave us samples of geraniums, we tested them and found some DMAA, right?
A Let me see. (Perusing document.)
It says they received their plants and geranium -- their plants from Mr. Yi Jin of Yunnan University and authenticated by Professor Xu Youkai of the Xishuangbanna Tropical Botanical Garden, Chinese Academy of Sciences.
Q Just like you did.
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Yes.
BY MR. SCOTT:
Q Okay. They got those samples, and they tested them and found some DMAA. They say that in their report, right?
A Correct.
Q Do you rely on anything other than that

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in the report to support your conclusion regarding DMAA being naturally produced by geraniums?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, I've looked at their report, and it said they found it in there. I've used my report, we found it, and that's what I in my report based my conclusions on.
BY MR. SCOTT:
Q All right, sir. Turn to page 57 of Exhibit 18, the Li study.
A Okay.
Q Up at the top of that page, it says that: "Further study is needed to elucidate the biosynthetic pathway of DMAAs in the geranium plant."
Do you see that?
A I see that.
Q I know you said you haven't talked to anybody from Intertek regarding their study, right?
A Correct.
Q And do you know what they meant by that?
A Based on what knowledge?

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Q Based on any you have.
A I mean, I read Dr. Brown's report and she discussed needing to come up with a biosynthetic pathway, but I'm presuming that means the plant takes something in and makes DMAA.
Q Okay. Well, I mean -- well, moving away from Dr. Brown, do you have any idea of what Intertek meant here by "elucidate a biosynthetic pathway of DMAAs"?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, that's not -- that sounds like to me somebody needs to go do some biochemistry research to figure out what it is.
BY MR. SCOTT:
Q To figure out what what is?
A What the biosynthetic pathway is.
Q And do you -- based on reading Dr. Brown's report or any other source, do you have an understanding of what a biosynthetic pathway is as it relates to a chemical like DMAA?
MS. WOOLSON: Objection to form, asked

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and answered.
You can answer.
THE WITNESS: I mean, I --
BY MR. SCOTT:
Q I mean as a general idea what a biosynthetic pathway is. I'm not asking you if you know of one particular chemical.
A No, I think I understand. I think -- I'm not sure if that's a question -- like I'm not sure that's a question that my background covers, let me put it that way.
Q The question of what a biosynthetic pathway is, is not something that is typically to be dealt with by an analytical chemist. Is that what you're saying?
A Yeah.
Q Now, when you looked at Dr. Brown's report and she talked about biosynthetic pathways in determining whether the geranium plant could make DMAA or not, you saw that?
A I saw that.
Q And did you agree with her view that that

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was important in determining whether the DMAA that you found was either synthetic or naturally produced by geranium plants?
MS. WOOLSON: Objection. Form.
You can answer.
THE WITNESS: You're going to have to show me where she wrote it, so I can read what she stated.
BY MR. SCOTT:
Q Okay. But you've done -- strike that.
Now, in doing your work on your study, did you do ion detection analysis?
A What are you talking about?
Q Did you use ions or identifying ions to try to determine whether or not what you were seeing was DMAA in your study, your analysis?
A I understand you're saying did I use ions, but I'm not -- I don't understand -- it's an oddly worded question. I mean, like ions is pretty broad.
Q All right. Well, we will hold that one and get back to it.

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A Okay.
Q Now, do you know if the levels of DMAA that Li reports that he found in samples of DMAA were lower or higher than were reported by Ping?
A (Perusing document.)
So I previously stated that I didn't see 1,3-DMAA on the --
Q On the Ping study?
A -- on the Ping study.
Q Okay. I'm sorry. I had forgotten that.
Okay. Well, look at the Li study, if you would, Exhibit 18 to your deposition. If you would, turn to page 55.
A Okay.
Q Under the heading there, "Application of the Method to Investigating Geranium Plants and Geranium Oils," do you see that?
A I do.
Q And under that it says: "The current method was applied to analyze geranium plants and geranium oils from different sources. The results are shown in Table 5."

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Do you see that?
A I see that.
Q And feel free to take a look at Table 5 if you'd like.
A (Perusing document.) Okay.
Q Now, on Table 5, we have there various concentrations of DMAA that they purport to have found in samples from China.
Do you see that?
A I see that.
Q And do you know which of these samples you also tested?
A Yes.
Q Which ones?
A I believe it is the -- I believe it's the Changzhou sample, but I would have to like basically look at Google Maps to figure out -- make sure the regions were right. We -- we did the work to tie them all together when we published the paper, but -- the specifics are hazy.
Q All right, sir. Now, if you would, look down at the bottom of the page, at Table 6 there on

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that same page. It has "The relative intensity of transitions for qualifying DMAAs in geranium pelargonium graveolens."

Do you see that?

A I see that.

Q And it says: "Detection ion MZ precursor production ion." And then it's got some numbers in the column going off to the right, 116, 43, 57 and 99. Do you see that?

A I see that.

Q Do you have any understanding what that information represents?

A Yes.

Q What is that?

A That is the transitions that we used and multiple reaction monitoring analysis using tandem mass spectroscopy.

Q All right, sir. And when it says "detection ion," what is a detection ion?

A That is the mass-to-charge ratio of the ions used in the mass spectrometer for the analysis.

Q All right, sir. And how many ion

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transitions, if I'm using that term correctly, did Li use in doing his analysis?

A He used two transitions.

Q And how many ions is he using?

A Either two or three, depending on how you look at it.

Q And when you say "two or three, depending on how you look at it," what would we be looking at to make that differential?

A So if you -- in a tandem MS you've got three quadrupoles in series, for a triple quad at least, and the analysis that is being done here, what Li has stated is that MS1 is set to 116, a mass-to-charge ratio, and then he measures the products of -- at 57, I think, the product of the collision cell at 57 and 99, where 57 was used for quantification for the measurement and 99 was used as his qualifying ion.

Q Did you do a similar analysis in part of your work?

A Yes.

Q How many ions did you use?

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A The same.

Q The same ones?

A Mm-hmm.

Q How many transitions did you do?

A Let me double-check.

(Perusing document.)

So I used the 116 to 99.7 and 116 to 57.

Q So you did two transitions?

A Yes.

Q Using how many ions?

A Two measurement ions.

Q All right, sir. Turn to page 28 in your report.

A Okay.

Q If you would, read through paragraph 47 there on page 28 in your report, and let me know when you are done.

A (Perusing document.)

Okay.

Q Now, the last sentence of that paragraph says: "Importantly, Fleming, et al., reported concentrations of 1,3-DMAA present in samples arising

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from the Changzhou region of China, but not the Kunming or the Guiyang regions."

Do you see that?

A I do.

Q What do you mean there, "importantly," in reference to those findings?

A I think it's highlighting the fact that I -- that we determined that they were present in -- 1,3-DMAA was present in geranium samples in the Changzhou region, but we didn't find anything above the detection limit in Kunming or Guiyang.

Q And in fact, with the Kunming and Guiyang samples, you did addition -- standard addition work with them, correct?

And if you look up in paragraph 47, I can save you some time. It says: "Fleming, et al., used standard addition, which works by analyzing a sample, a sample with known concentrations of 1,3-DMAA added in to determine concentrations."

A I -- yeah, we used standard addition.

Q And so does that mean you spike a sample with DMAA to see if then you can measure -- get a

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measure, a detection indication that would be over the spiked amount?

Well, let me withdraw the question and ask it in a different way.

Did you use standard addition analysis with the Kunming sample, for example?

A Yes.

Q And what did you do?

A I -- we had -- in this case -- let me see if I can kind of walk you through it.

All right. So we would have taken the individual plant sample -- if we're doing standard addition and we did this for all the samples -- we would take the sample, we'd analyze it. We would spike in a known concentration of 1,3- and 1,4-DMAA into that plant, you know, level 1. And then we would spike in into another sample, another aliquot of that sample, level 2.

So we have the unknown, level 1 spike and level 2 spike. We analyzed all three of those samples for 1,3- and 1,4-DMAA. And then we generate a plot, and from that plot of signal versus spiked-in

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concentration, the negative X intercept is the concentration in that aliquot that we spiked in, and then we back calculate based on the dilution factor an extraction protocol that we use to determine the concentration present in those samples.

Q So by doing this, you're trying to determine if the original sample where you didn't see signs of DMAA may have it at concentrations below your ability to detect?

A Can you repeat that?

Q Sure.

So you got a sample, you're not showing DMAA; you use standard addition and you spike it. Is this exercise to determine -- to double-check to determine whether or not DMAA is present in the sample below your MDLs?

A We used -- I guess the best way to describe it is that we used an external calibration procedure to determine concentrations, and we also used the standard addition procedure to determine concentrations, and both should agree approximately with each other.

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Q And both agreed that you found no signs of DMAA in the Kunming and Changzhou samples?

MS. WOOLSON: Objection to form.

THE WITNESS: That's correct.

BY MR. SCOTT:

Q Did Intertek find DMAA in samples from those regions?

A That is correct.

Q And were you using the same samples that they used?

A For one of them.

Q Which one?

A The Changzhou sample. Changzhou, it's got a specific number. Changzhou S11.

Q And he found -- and that was the same sample that you tested, a split from it?

A Yes, that was -- it was a split sample.

Q And at what concentration levels did they find it?

A Approximately 165 nanograms per gram.

Q And you didn't find it at all?

A No. I found it at 254 nanograms per

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gram, roughly.

Q All right. And was there a sample where they found it and you didn't?

A Yes. The Kunming and Guiyang samples.

Q Were they splits?

A No. No. The Changzhou was the only one that was an actual split sample.

Q Okay. And the difference again was 156 versus 254 in concentration?

A Li had 165, and Fleming reported 254, plus or minus 17 nanograms per gram.

Q All right, sir. And how do you account for the difference in concentration levels across the two tests?

MS. WOOLSON: Are you talking about the S11 sample?

MR. SCOTT: Yeah.

THE WITNESS: So as I previously discussed earlier, you know, we were operating at concentrations that are considered trace levels on the parts-per-billion scale, and at those levels the differences between laboratories can be as high as

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100 percent, you know, basically using textbook definitions.
BY MR. SCOTT:
Q How do you account for Li finding DMAA in the Kunming and Changzhou -- not Changzhou -- the Kunming and the Guiyang samples and you not finding it?
A So, one, they were different samples. Let me be clear about that. Two, so they -- so they have one, their Yunnan China one, they're reporting 13.6 micrograms per gram -- I'm sorry, nanograms per gram of 1,3-DMAA in their plant.
Now, assuming that we were to get that same plant sample, based on the analysis and analysis at two, that was less than our method detection limit, and in that case we actually would agree on the report. I report as less than the method detection limit of 20, plus or minus 4; and Li reported basically 14. And so I wouldn't detect that.
As far as the one at 365 nanometers, again, I did not get that sample -- I'm sorry,

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not nanometers -- 365 nanograms per gram, I did not get that sample, so I can't really provide a reason why I wouldn't have detected it.
Q What region are you talking about for that sample?
A That's Guizhou (phonetic).
Q So Guizhou, they came in -- Li came in at 165 nanograms?
A No, 365 nanograms.
Q 365 nanograms per gram?
A Correct.
Q And you didn't find it at all.
A I didn't find it at all. And so, now, obviously that is above my method detection limits. So if I had that sample, I should have been able to detect it. And based on past performance, they detected -- you know, in their Changzhou sample where they detected at 165 and I detected at 265 nanometers, it's very likely I would have detected it. And if the trends hold, I probably would have detected it somewhere around 400 or 450 nanograms per gram, but I didn't have that sample, so I didn't

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detect it.
Now, you know, why did they detect it and I didn't? I mean, if it's a different harvest season, which, you know, I think I mentioned in my report that is a factor in variability as referenced by other people.
Q Now, did you do any scientific analysis to determine why they were finding DMAA in samples that you weren't, whether it was impacted by harvest season or any other things specific to the regions in China where these samples came from?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: What do you mean? You mean like --
BY MR. SCOTT:
Q Well, let's turn to your report.
A Okay.
MS. WOOLSON: His report or his study?
MR. SCOTT: His study. I'm sorry.
BY MR. SCOTT:
Q Now, your original retention by USP Labs

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did not include you doing any work to display any discrepancies between results that you had and results that Li had, correct?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: What do you mean?
BY MR. SCOTT:
Q Well, when you were hired by USP Labs to test samples, did they also ask you to review Li's work for any purpose?
A Like -- I mean, I looked at -- as far as I know, as far as I remember, I looked at these, and ran with the sample, I ran with the analysis, and I think at some point along the way, they, either through publication from Li or via e-mail, I found out what their results were, but I don't remember now.
Q Well, did USP Labs make any suggestions to you regarding positions, arguments, information that they would like to see in the report when it was published?
A I don't recall off the top of my head.

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Q What was the limit of detection on your -- the studies, the testing that you did of the samples you were given?
A What are you asking again?
Q You tested samples from USP Labs.
A Okay.
Q Did your analysis, the protocol you followed, have an LOD that was applicable to your work?
A Yes.
Q And what was that?
A For Kunming, it was 20. For Analysis Set 2, it was 20. For Analysis Set 3, it was 10 parts per billion. 10 nanograms per gram on Analysis 3. And then Analysis Set 1, looks like it's 0.5 nanograms per gram for 1,3-DMAA.
THE WITNESS: Do you mind if I use the restroom real quick?
MR. SCOTT: Sure.
(Recess.
BY MR. SCOTT:
Q Back on the record after a short break.

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Dr. Simone, I will remind you you're still under oath. All right?
A Understood.
Q And you understand that if you don't understand my questions, you should tell me that.
A Absolutely.
Q And if you need to take another break, that's in the cards too, all right?
A Great.
Q If you would, look at Exhibit 4, your article.
A Okay.
Q Flip over to page 71.
A All right.
Q If you would, on the left-hand column, second paragraph down, read through that, and let me know when you have, and I will have a couple of questions.
A The one that starts "The results"?
Q Yes, sir. On page 71.
A (Perusing document.)
Okay.

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Q All right, sir. Now, in that paragraph, it says that: "The results reported here provide evidence that 1,3-DMAA naturally occurs in geranium plants in agreement with Li, but clearly in disagreement with other previously reported articles by well-respected chemists and organizations."
Do you see that?
A I see that.
Q Now, it goes on to say: "However, this may not be a question of right and wrong. In analytical chemistry, the critical review of data is important for explaining the differences on reported results. These data -- the differences can also provide insight into why analysis of seemingly identical plant species can result in very different outcomes."
Do you see that?
A I do.
Q Now, it goes on to say here that: "Khan has published an extensive review showing that it is not uncommon for plants in different locations to exhibit variations in their chemical compositions."

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Do you see that?
A Yes.
Q Now, is it your understanding, based on the research that you've done, that plants can demonstrate different chemical profiles from location to location based on the type of chemical that's in their profile?
Let me back up. You look confused, so let me try it again.
Now, you say here that fluctuating -- that: "Khan has published an extensive review showing it's not uncommon for plants in differing locations to exhibit variations in their chemical compositions."
Do you see that?
A I see that.
Q What do you understand that to mean, that they can show differences in their chemical compositions from different locations?
A I mean -- it means exactly what it says it means.
Q Well, does that mean that they might

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make -- that a plant in one location might make different chemicals than a plant in another location?
A I guess it's possible. But I'm not necessarily an expert on that.
Q So that's something that you really don't know one way or the other?
A I mean --
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I read the paper and he talked about how plants at different locations exhibit variations in chemical compositions. I relied on his expertise for that statement in his paper that he published, and -- I mean, that seems to be the -- I mean, I figured if he wrote it, it must be true.
BY MR. SCOTT:
Q Well, when you read it, did you understand he was saying that plants -- the same plant in different locations might make different chemicals as opposed to making different concentrations of a common set of chemicals across

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the plants?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, I'm not sure if that statement suggests that one way or the other.
BY MR. SCOTT:
Q You don't know the answer to that one way or the other?
A I would have to go like read the paper and see what he says.
Q Well, your next statement here is: "For example, studies show that fluctuating geographical dynamics, such as water stress and nutrient availability in the soil, are associated with variations and cyanide concentration in the cassava plant."
Do you see that?
A I see it.
Q And did that come from Dr. Khan's paper?
A No. It came from another paper we found.
Q Reference 19?
A Yeah. By a guy named Burns.

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Q All right, sir.
A And others.
Q And did you see any paper that indicated that a plant, depending on its location, depending on things like water intake and that type of thing, might make a different type of chemical from other versions of it in another location, other versions of the same plant?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Not that I can recall.
BY MR. SCOTT:
Q Now, if you would look at the next paragraph down, it says there: "Regional environmental variations could explain the presence of 1,3-DMAA in the Changzhou S11, Changzhou March 2012 and Changzhou May 2012 samples, and the absence of 1,3-DMAA concentrations in Kunming and Guiyang geranium samples reported here."
A Mm-hmm.
Q I will stop there for the moment.
Now, what were the differences in the

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three Changzhou samples?
A (Perusing document.)
Just can you just restate the question?
MR. SCOTT: Would you read it back, please.
(Whereupon, the requested record was read.)
THE WITNESS: They were collected at different times of the year.
BY MR. SCOTT:
Q All right, sir. And did you find -- were your results in testing for DMAA of those three samples different?
A Yes.
Q And how -- to what degree were they different?
A If we look at Analysis Set 2 and 3, we've got Changzhou S11-2, a concentration of 254 nanograms per gram. So probably spring 2011 is my guess is when it was harvested.
Well, let me not guess and tell you.
June 9th, 2011, and then Changzhou 3 was

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collected on May 18, 2012.
Q What was the concentration of that?
A Roughly 69 nanograms per gram.
Q And the third?
A Well, the Changzhou 1, which was collected on March 10th, 2012, came up as 213 nanograms per gram, although the -- yeah.
Q Were you about to say something?
A No.
Q What was the error rate on that particular sample?
A We only were able to analyze one sample is what it looks like. Let me see if I can find it in the --
Q Well, I've seen a reference to you losing one sample. Is this that circumstance?
A Let me see. Yeah, I think it is. Let me see if I can find where I specifically said that.
Q Yeah. "There is no reported spike analysis for Changzhou 1 due to a sample loss during analysis."
And we had no additional sample of it.

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So we reported it but were truthful about what happened to the spike.
(Exhibit No. 19 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You have in front of you what's been marked for identification purposes as Exhibit 19 to your deposition. It's a two-page document bearing identification numbers UMPS-HT-005487 through 5488.
Now, first, let me ask you, did you do any scientific research yourself to determine if there was any regional variation in either whether or not a geranium plant can produce DMAA or an effect on the concentration levels that you might find in there, in a geranium plant?
A Is that question related to this document?
Q No, it's not. It's outside of that document. We will get to the document in a minute.
A Okay. So can you repeat the question?
Q Sure.

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Did you do any scientific work to determine whether or not there were any regional effects on a geranium plant's ability to produce DMAA naturally?
A We measured plants from three different regions and found variations in those results.
Q All right, sir. And does that in and of itself establish to a reasonable degree of scientific certainty that there is a regional impact on a geranium plant's ability to produce DMAA?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I believe it is.
BY MR. SCOTT:
Q Okay. If you would, look at the exhibit. Is this a series of e-mails between you and Erik White at USP Labs?
A That's what it looks to be.
Q All right, sir. At the bottom e-mail there, there's a reference from Paul Simone, an e-mail sent August 9, 2012, to Erik at USP Labs, "Subject: A couple of quick questions."

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Do you see that?
A Oh, yeah.
Q Now, was this the time frame when you were writing your article, Exhibit 4?
A Probably, but I would actually have to look at the timestamps and all of that to give you a definitive answer.
Q Well, the e-mail there says on the first line: "The draft of the paper is coming together quite nicely, but I need to know the source of the summer 2011 Intertek sample that ended up at the University of Memphis."
Do you see that?
A Then, yes, this is while I was writing the paper.
Q It goes on to say in the next paragraph: "Did it also come from the Changzhou region in China or was it grown at Intertek? I need to know because the Intertek and Changzhou samples were the only two that I analyzed that clearly showed 1,3-DMAA and 1,4-DMAA concentrations as opposed to literally everybody else who has published but Li at Intertek."

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Do you see that?
A I see that.
Q And then it goes on to say: "So I'm crafting a regional differences argument. This is why I need to know the origin."
Do you see that?
A I see that.
Q And what do you mean there by "regional differences argument"?
A I mean what I stated in the paper, the -- these results can be explained by regional differences of the plants' origins.
Q But do you have scientific support that that actually is the explanation as to why you found differences in the plants?
MS. WOOLSON: Objection to form.
BY MR. SCOTT:
Q That regional differences had an impact?
A I had Khan's paper, which seemed pretty credible.
Q Did that deal with geraniums?
A I don't recall if it did or not.

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Q How about DMAA, did Khan's paper that you were relying on deal with DMAA?
A I don't recall that it did, off the top of my head.
Q All right, sir. You can put that one aside for the moment.
Did anyone from USP Labs provide you any suggestion that you might want to make a regional differences argument regarding your findings relating to DMAA?
A Not that I can recall.
(Exhibit No. 20 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You've been handed what's been marked for identification purposes as Exhibit 20 to your deposition. It's a multi-page document bearing identification numbers UMPS-HT-002154 through 2168.
And I will ask you if you can identify this as a draft of what was eventually your published article, Exhibit 4?

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A (Perusing document.)
It looks to be a draft, yes.
Q Did you prepare the draft or was basically the pen handled by Ms. Fleming with you editing it?
A The what?
Q Is Ms. Fleming the one that did most of the drafting with you editing her work?
A I don't think that's -- I think it's -- she wrote sections, I wrote sections, I edited it.
Q All right. If you would, turn to the page in Exhibit 20 that is marked with the identification number 2156.
A Okay.
Q And there is a comment box there. Do you see that?
A I see it.
Q Do you know who wrote that?
A It looks like it was me.
Q And it says there: "Redo the section in terms of variation in region rather than right/wrong. More likely to get through reviewers this way."

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Do you see that?
A I see it.
Q What did you mean by that?
A Which part?
Q Well, "Redo the section in terms of variations in region rather than right/wrong," what did you mean by that?
A Well, let me read this, and then I can tell you.
(Perusing document.)
I have no idea why that comment is there. Nothing in that comment relates to regional variations.
Q Nothing in the comment or --
A Nothing highlighted by that comment refers to regional variations.
Q Well, does that indicate perhaps you wanted something in there about regional variations?
A No. I mean, this was a -- this was a draft, and, I mean, things come in and out of drafts.
Q Do you believe that talking in the context of possible regional variations would have an

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impact on your ability to get this published?
A Say that again.
Q Sure. Well, there is a suggestion there, "Redo this section in terms of variation in region rather than right/wrong. More likely to get through reviewers this way." What reviewers are you referring to?
A Probably the peer reviewers of the paper.
Q So did you believe that if you talked about your results in the context of possibly there being some regional variations in the geranium plants' ability to produce DMAA that that would help you get it past reviewers for publication?
A Let me step back and put it to you this way. Have you -- well, so in the peer review process, all right, you are trying to get your peers in the field to -- they are reviewing your work as well as criticizing it, right. And so then you are going to get those reviews back and you are going to try to address them.
So there's two ways to go about this. One, you go all willy-nilly and you put everything

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you ever wanted to say in a paper, whether they are founded by -- they are backed up or not. Or you take a critical eye at your own work and you review that work as if you were a reviewer yourself.
And I looked at what had been written as if I was a reviewer, and I made some comment. I don't know why it's -- I don't know why it's highlighted in that section, because this was done in roughly the time frame of August 2012, so four years ago. So like why I highlighted a particular section, I couldn't tell you.
But I mean that highlight -- I mean that comment does get to what ultimately ended up in this paper that this isn't necessarily a case of right and wrong, this is a case of regional availability. We went and looked for a reference due to that. So that when we put it in the paper, we actually had something to reference. Instead of just me saying it, who was an analytical chemist with, you know, limited background in regional variability of plants, I got a reference that somebody who has a very extensive background in regional variability in

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plants, namely Khan, I. A. Khan, I believe -- yeah, I. A. Khan, who is an expert in that, and thus, give my statement more credibility, rather than just coming from some analytical chemist.
Q Okay. Are you offering an opinion in this case regarding the regional variability of geranium plants as it relates to the production of DMAA?
A Based on -- (perusing document.)
Based on the review of literature by -- that I referenced, the composition of geranium plants and extracts varies widely based on metal ion variation in the soil, growing region and growing climate. The method of preparation can affect the apparent composition of the geranium oil extracts, three additional references. That's on paragraph 74. And thus, unless the samples and methods of preparation were comparable, the results of the various studies could differ.
Q Okay. We'll get to that one and we will talk about it.
If you would turn in your report, which

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is Exhibit 3, to page 35.
A Okay.
Q Now, before we get into page 35, I want to ask you a question that doesn't have anything to do with it, so I don't want you to get confused here. Okay?
A All right.
Q Did you consider for your work using GC with flame ion detector, the work that you did testing for DMAA for USP Labs?
A I don't recall specifically considering it.
Q Would you consider that to be a useful technology to use in looking for DMAA?
A Yeah.
MS. WOOLSON: Objection to form.
THE WITNESS: Yes.
BY MR. SCOTT:
Q In paragraph 23, page 15 of your report.
MS. WOOLSON: We're not going to page 35?
MR. SCOTT: Nope. We're going to go to 15 now.

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THE WITNESS: What page?
BY MR. SCOTT:
Q Page 15?
MS. WOOLSON: 15. Paragraph 23.
BY MR. SCOTT:
Q Paragraph 23.
A Okay.
Q It says there that: "The trend in detection over the last 30 years has been to replace chemically and specific detectors; e.g., flame ionization detection for GC, or ultraviolet visible absorption and fluorescent detectors for HP/LC with mass spectrometry MS techniques."
Do you see that?
A Mm-hmm. Yes.
Q And it goes on to say: "For example, the flame ionization detector is selective for reduced carbon in a chemical compound. This means that it detects chemicals like methane, propane, butane, gasoline, benzene, 1,3-DMAA, et cetera."
Do you see that?
A I do.

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Q And it goes on and says: "Because it responds to all forms of reduced carbon, it is merely a universal detector and, thus, prone to interferences."
Do you see that?
A I see that.
Q What does that mean?
A So if we -- you are asking what it means. So your original question was, is it useful? Yeah, it's useful. But, I mean, it means exactly what it say it means. The flame ionization detector responds to reduced carbon, which means typically carbon with hydrogen bonded to it, so in the case of propane, it's three carbons, I think eight hydrogens, and so it's going to produce a signal that is proportional to the number of those reduced carbons.
But for organic compounds, it's essentially universal, and so if you have a lot of chemical species present in whatever you're sampling that are also reduced carbon, the flame ionization detector will produce a signal for those as well.
Now, the reason I kind of put that all in

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there is because while FID, flame ionization detection, is nearly universal, it's not what you would call the most selective of detectors. It's going to give a peak whenever you have reduced carbon.
MS techniques, mass spectroscopy, is nice because it's universal and similar in universality to the FID, if not more so, and it's also more selective. So you can specify what you're looking for rather than -- so if you look at GC/MS and you're using retention time and the mass-to-charge ratio that is detected with flame ionization detection, you're using solely the retention time as your identifier, and so you end up with basically two chemistries for identification when you use GC/MS or separation with an MS detector.
Q Okay. When you say that the flame ionization detector is prone to interferences, what does that mean?
A It means that when you do your separation on your gas chromatography column, if there is -- if two compounds coelute, then that means they elute at

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the same time, emerge from the column at the same time, then you're going to get essentially one peak. You're not going to be able to necessarily tell the difference between those two if you simply use external calibration, and one way you get around that is actually use standard addition to provide -- to minimize interferences due to coelution.
Q Now, did you use frame ionization in your work?
A No.
Q Is that because of the interference problem?
A No.
Q Why then?
A Because the -- well, two reasons. One, at the time I don't believe I had the GC/FID to do the analysis. That I could devote to the project. And, two, the HPLC with tandem MS provides more selectivity and better detection limits than the gas chromatography with flame ionization detection.
Q All right. So it's more accurate?
A No, it's -- it has better detection

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limits and better selectivity.
Q Okay. All right. So now back to page 35.
There is a heading there on page 35 of your report, Exhibit 3, that says: "There are three reports of 1,3-DMAA being present in geranium oils or plants: Ping 1996; Li, et al., 2012; and Fleming, et al., 2012. There are six reports of 1,3-DMAA not being detected in geranium oils or plants: Lisi 2011; DiLorenzo, et al., 2012; ElSohly, et al., 2012; Zhang, et al., 2012; Austin, et al., 2013; and ElSohly, et al., 2015."
Do you see that?
A I do.
Q And you do not include in this any of the surveys of geranium oil, the general surveys that were done that did not show there was DMAA in them, correct?
A I did not.
Q And why is that?
A Because if we look at only those reports that provide detection, that provide limits of

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detection at or near the 1 to 300 ppb range where 1,3-DMAA has been mostly commonly reported. Then we have two reports demonstrating presence of 1,3-DMAA, Li, 2012; Fleming, 2012; and four demonstrating the absence, ElSohly, 2012 and 2015; Zhang, 2012; and Austin, 2013.
Q Now, is it your view that the Ping study is of equal scientific validity of the other studies that are referenced in this paragraph?
MS. WOOLSON: Objection to form, asked and answered.
You can answer.
THE WITNESS: Which paragraph?
BY MR. SCOTT:
Q Paragraph 63.
A I mean paragraph 64 says no. In terms of my -- I guess my viewpoint of if you are going to claim detection or absence, then you need to provide the analytical figures of merit, and those parameters that I discussed, such as limit of detection, to provide a boundary condition on whether it is or is not there.

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Q All right, sir. So we have here, you've got -- in paragraph 64, it says: "If we consider only those reports that provide limits of detection at or near the 1 -300 ppb range" --
That's parts per billion?
A Yes, parts per billion.
Q -- "which is the levels of 1,3-DMAA most commonly reported, then it is two reports demonstrating presence of 1,3-DMAA," Li and Fleming, right?
A Yes.
Q -- "and four demonstrating absence," ElSohly, 2012 and 2015; Zhang, 2012; Austin, 2013.
Do you see that?
A I see that.
Q Now, referring back to the six articles that you talked about there, it says: "While these studies are approximately equal in terms of rigor," what do you mean by that?
A They have provided the method detection limits or limits of detection and other analytical figures of merit to make a judgment on their report

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of presence or absence. And that that judgment is applied equally. You know, it's two reports for and four reports against.
Q So it goes on to say: "That While these studies are approximately equal in rigor, the importance of interlaboratory confirmations of the presence of 1,3-DMAA in plants cannot be understated."
Do you see that?
A I do.
Q And what do you mean by that?
A It means that when we look at analysis, it's having essentially two independent labs analyze a sample and come up with a similar number is a good thing. That's an additional level of rigor for the presence or absence of that compound.
Q Okay. Well, in this case you had two labs taking the same sample and applying the same protocol to test it, the one that was developed by Intertek, correct?
A Correct. Roughly.
Q Would you really expect to find -- get

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any different results than what you got from the standpoint of you finding DMAA in the sample that you tested?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, the -- yeah, the personnel were different. The specifics of the analysis, like the instrumentation used, as far as I know, were different. And not only did we -- yes, we built upon Li's method, but then we added our own additional standard addition on top of that really to make the paper as bulletproof as we could.
(Exhibit No. 21 was marked for identification.)
BY MR. SCOTT:
Q All right, sir. You've got in front of you what is marked for identification purposes as Exhibit 21 to your deposition. It is a multi-page document bearing identification numbers UMPS-HT-005965 through 5969.
If you would look at that, and it appears to be some e-mail traffic between you and Erik of USP

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Labs on or around April 19, 2013.
A Do you want me to read the --
Q Just familiarize yourself with that that's what it is, and then I will point you to some specifics and then with questions.
A Okay. (Perusing document.)
Q All right, sir. If you would, look on the first page, the e-mail that was written by you, where it says from Paul Simone, dated April 19th at 7:13 p.m.
Do you see that?
A I see that.
Q In that e-mail, third paragraph down, it says: "So my thoughts were that the Li paper and the Fleming paper ended up being a very small interlaboratory study using a split sample of geranium, Changzhou sample, based on the Li, et al., method that was published first."
Do you see that?
A I do.
Q What do you mean there by "a very small interlaboratory study"?

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A I mean it was a two-lab interlaboratory study. That's about as small as you can get.
Q Particularly when you're dealing with one sample.
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Just in terms of laboratories. I mean, two laboratories is as small as you can get. One laboratory is not an interlaboratory study.
BY MR. SCOTT:
Q Have you done interlaboratory studies before where you were dealing with a test of one split sample as part of that study?
A Before this?
Q Yeah.
A No.
Q Since then?
A We have participated in an interlaboratory study with three samples.
Q How many labs?
A I believe it's three.

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Q And had one of the labs already tested the sample to see what was in it before you did this interlaboratory study?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.
But I will say that apparently the Changzhou region is difficult to get samples from.
BY MR. SCOTT:
Q Pardon?
A Apparently the Changzhou region is difficult to get samples from. I don't know why.
Q Have you tried to get them and couldn't?
A No. But Professor ElSohly's group, his multi-center study, did not.
Q Turning to page 37 of the report.
A My expert report?
Q Yes, sir.
A Okay.
Q It says there in paragraph 67 that: "The FDA falsely states that detection of 1,3-DMAA requires derivatization for analysis at the low

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concentrations reported." And then it goes on to say: "The FDA clearly does not understand the purpose of derivatization in analysis."

Did in fact you conduct a derivatization analysis as part of your study of the samples provided to you by USP Labs?

A I did both. I did both with and without derivatization. In the first study in the published geranium paper in the 2012 Analytical Chemistry Insights paper, we did direct detection of 1,3- and 1,4-DMAA.

In the second set of analyses that we did for the chiral analysis of the 1,3-DMAA, we used derivatization to convert the two pairs of enantiomers to four diastereomers to more effectively separate our stereoisomers.

And so in terms of detection of the 1,3-DMAA at the parts per billion level, you don't have to derivatize it. In terms of separating the stereoisomers, you have to do it one of two ways. You have to have either a chiral column, which we tried, and that chiral column was actually developed

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by Armstrong's group, Daniel Armstrong, who published with Zhang. It turns out it didn't work. I don't really know why it didn't work. The chiral column separation didn't work. And so then we turned to the chiral derivatizing agents of Fleck and Mosher's acid chloride.

Q Was any of this work used as a basis for any of the opinions you are offering in this case?

A No, I did not refer to the -- to the Fleck or Mosher's acid chloride work.

Q All right. Have you done NMR analysis of geranium plants for DMAA analysis?

A We tried, yeah.

Q And does that mean you have not been able to successfully do that?

A Well, we -- we were able to develop an extraction method for NMR analysis of 1,3-DMAA in geranium, but the detection limits were not low enough to successfully detect it. The detection limits were somewhere between 100 and 1000 times too high for NMR.

And that's not uncommon for NMR. NMR is

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not as sensitive as tandem MS or really any other methods, such as like flame ionization detection. So like the fact that it didn't work didn't necessarily surprise me. It was a high risk/high reward proposal.

Q All right, sir. If you would, turn to page 38 of your report. And I will direct you to paragraph 69.

About halfway down that paragraph, it says that: "The FDA makes a point to note that the four studies not funded by USP Labs did not find 1,3-DMAA in geranium, but ignores the fact that those studies were funded by agencies such as the U.S. Army Medical Research and Materiel Command, the Australian government through the anti-doping research program of the Department of Prime Minister and Cabinet, and U.S. doping agencies."

Do you see that?

A Mm-hmm. Yes.

Q What is the point you are trying to make there?

A Well, if I recall that FDA letter

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correctly, and others, they've previously noted that the studies funded by USP Labs were -- what is the word for it? -- I guess influenced because of their funding agency.

And what I'm pointing out there is that this is basically how academic research works. Most people don't do work and they don't start work unless it's -- and they -- they don't go through major efforts unless it's funded by somebody. You've got to pay for your time. I've got to pay for my time. I've got to pay for graduate student time. I've got to pay for supplies, materials, reagents. And the same is true of those other reports that did not fund.

And that's -- you know, that's the -- that's the landscape of academic research today. Not everybody gets funding from the alphabet agencies of the United States government. That's getting harder and harder to get. And so we turn to alternative sources for funding and to do research.

Q Was your ability to attract funding for research one of the factors that went into whether or

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not you receive tenure?
A Repeat the question.
Q Sure. Was your ability to attract funding to support research one of the factors that was looked at in making a tenure decision regarding you?
A Yes. In fact, it's stated in all our job ads for the University of Memphis, that you are expected to develop an externally funded research program, and part of that is getting funding from any source. A dollar is a dollar, it all spends the same. And on top of that you're expected to publish and graduate students, and that's -- that's the life as a professor.
Q In relation to your published study pertaining to the DMAA work, was a payment made to the publisher to publish that particular study?
A Yes. Which is pretty normal for open access articles. Somebody's got to pay those publication costs.
Q When you say "open access" publishers, what are you talking about there?

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A So Analytical Chemistry Insights is an open access publisher, which means that instead of articles being behind a pay wall that requires a subscription or a per-article payment to gain access to that article, it's freely available to the public.
There are some journals that are solely open access, and there are some journals that are a hybrid. And I -- I believe -- so a good example is one that I published in the past is -- Analytica Chimica Acta is a highly respected international applied analytical journal, and when you submit the paper, you've got a choice between submit as a closed source, closed access, where you have to have a subscription, or you can choose to pay the open access publication fee to make it available.
Another good example, as best as I can tell, is that Drug Testing and Analysis operates on that hybrid model where some are open access and some are not.
Q Now, USP Labs paid to have your article, Exhibit 4 to your deposition, published?
A Yes.

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Q Have you published any other articles in open access periodicals where someone had to pay for that to be published?
A Yes.
Q And how many others have you published that way?
A I published an article in a journal called Beverages, and the publisher themselves paid for the fee by waiving the fee.
Q Have you had anybody else who, for example, you were doing the research, they funded it, and then they paid for your publication, other than USP Labs?
A No, but it's not particularly uncommon to have funded proposals have publication fees in them to pay for publication.
Q Okay. And have you -- other than the one in the Beverages magazine where the publisher waived the fee, have you paid to publish any other articles?
A Not that I can recall.
Q Now, in the next page, page 40 of your report --

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A Expert report?
Q Yes, sir.
-- it says that: "The analytical chemists conducting the research are there to review published work, report the findings of the research, and try to determine why the differences arise. The presence of 1,3-DMAA in geranium is not right and wrong. There is credible evidence supporting the presence of DMAA in geraniums. Other researchers came up with contradictory results. The real question for FDA is should be why are they contradictory."
Do you see that?
A I do.
Q Now, did you do any additional work to determine why the results that you got are contradictory from everyone else who has published except for Li and Ping?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: No.
BY MR. SCOTT:

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Q Turn, if you would, in your expert report to page 42.
A Okay.
Q And on page 42, in the second paragraph, it says: "This explanation does not answer the why, why do the Li and Fleming, et al., reports differ from the rest of the published research regarding the presence of 1,3-DMAA in geranium."
Do you see that?
A I see that.
Q And then it goes through and based on the review of the literature, and there are several articles there or authors there that are referenced, beginning with Jain, J-A-I-N, in 2001, going down to Khan in 2006.
And then the text picks up and says: "The composition of geranium plants and oil extracts varies widely depending on metal ion variation in the soil, growing region and growing climate."
Do you see that?
A I see that.
Q What work did you do to study the soil,

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growing region and growing climate of the samples of geranium that you tested for USP Labs where you found DMAA?
A Like us personally in the research lab, did we test those things?
Q Yes.
A I did not.
Q Were you able to identify any method of preparation regarding the geranium plants that you were testing that might affect the chemical profile that you were able to find once you did the testing?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I mean, when you are doing the extraction and the analysis, there's a point where you do the same cleanup step. And so you've got -- you're partitioning matrix elements. I don't really know what they are other than matrix elements. Things that are not analyte. You're partitioning that between hexane and the acidified extraction solution of -- of hydrochloric acid.

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And so at that point you've actually got -- as long as your acid solution is sufficiently acidic, you are unlikely to have significant portions of your 1,3-DMAA partition into hexane. That's reducing your detection limits.
Another good example is there is a point where we neutralize our acid extraction solution so that the pH is roughly 12 while the -- and when we talk about DMAA, it's an amine, and the pKa for that amine is approximately nine and a half to 10. It's -- I don't know if it's actually been measured, but that's roughly what it is. And so if the pH of your extraction solution is nine and a half, then you're going to get about 50 percent, maybe a little bit more, of your DMAA out of that solution, because half of it is ionized and half of it is neutral.
So in that case if you make sure you raise your pH to 12, then you essentially ensure that all of your DMAA is sufficiently neutral to extract most of that out.
BY MR. SCOTT:
Q Did any of the studies that looked at

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DMAA in geranium plants and did not find it or reported not to find it handle the samples in a way that impacted the presence of DMAA in the samples when they were tested?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: Well, possibly. I -- if I -- if I recall correctly, I believe the ElSohly work -- let me see if I can find the exact discussion of it. I don't want to say something wrong here.
Based on the evidence in front of me that was given to me by the -- and given to me as exhibits -- well, what was the question again? I'm sorry.
MR. SCOTT: Please read it back.
(Whereupon, the requested record was read.)
THE WITNESS: Based on the exhibits given to me and that I can recall reading and in my expert report, I don't recall if there are or are not.
BY MR. SCOTT:
Q What do you mean by the term "metal ion

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variation in the soil"? And it's on page 42, paragraph 74.
A Well, based on my review of the literature, one of those discussed metal ion variations in the soil and how it impacted composition of the geranium plant.
Q How does ion -- metal ion variation in the soil impact production of DMAA by geranium plants?
A I have no hard data to discuss that.
Q You don't know?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: I don't know.
BY MR. SCOTT:
Q All right, sir. If you would, still on page 42, look down at paragraph 75.
A Okay.
Q And it says there that: The stereoisomer chemistry of 1,3-DMAA, as discussed above in paragraphs 27 through 36, is at the core of the arguments concerning whether 1,3-DMAA in supplements

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is naturally occurring."
Do you see that?
A I do.
Q What do you mean by that?
A So -- let me look at 27 to 36 just so I can be sure what I'm talking about there.
(Perusing document.)
I am discussing how the -- can you repeat the question?
Q Sure.
Beginning on page 42, paragraph 75, you say that: "The stereoisomer chemistry of 1,3-DMAA, as discussed above in paragraphs 27 through 36, is at the core of the arguments concerning whether 1,3-DMAA in the supplements is naturally occurring."
Do you see that?
A I see that.
Q And what did you mean by that?
A It's how the -- the ratios of the stereoisomers and diastereomers are at the core of the arguments on people arguing for and against the naturally occurring presence of 1,3-DMAA in geranium.

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Q And that relates to what is actually being sold in this sentence, DMAA in supplements?
A I thought it was the DMAA in the plants.
Q Well, your sentence says "DMAA in the supplements."
A Oh, oh, oh, oh. Okay.
So based on -- so let me put it this way: I guess the argument is that -- let's see. I think I addressed it. Okay.
So if the DMAA in the supplements is naturally occurring, then the composition of the stereoisomers in the plants and the supplements should be similar. What -- that's -- yeah, it should be similar.
Q Do you know of any supplement seller who is selling products with DMAA in them that is using a naturally occurring DMAA as opposed to a synthetic one in its products?
MS. WOOLSON: Objection to form.
You can answer.
THE WITNESS: My understanding is that commercial DMAA is all synthetic, to the best of my

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knowledge. I mean, it's -- and based on my review of -- you know, it seems USP Labs have been synthetically produced.
But the -- so when you get to the plant, the argument is, well, it's not there from ElSohly and others. And I argue differently, that it is in fact there. I detected it in the plants that I analyzed. And so now it becomes, well, okay, if the -- if the stuff, the DMAA in the plant should be -- should have an enantiomeric excess -- this is based on ElSohly's arguments -- that because it's a -- because it's biosynthetically produced within the plant itself, that it should have an enantiomeric excess of one or -- an enantiomeric excess of at least one chiral center. So 1,3-DMAA has two chiral centers. Those are four stereoisomers.
Now, what we have shown in the plant is that we've got two diastereomer peaks which are -- if you are looking at the supplement, those diastereomer peaks are each composed of two additional stereoisomer peaks, right. Because we can't separate those pairs -- we can't separate the enantiomers

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within that peak, the diastereomer peak without using some kind of chiral derivatization technique.

Now, in the plant there has been no published work that shows whether -- that shows the composition, the stereoisomer ratios of those four stereoisomers.

BY MR. SCOTT:

Q All right. Well, let me ask you to flip over to page 47 of your report, paragraph 86.

A Okay.

Q It says there: "Given the state of knowledge regarding the presence of 1,3-DMAA in geranium plants and the diastereomer ratios measured therein, the 1,3-DMAA found in the plant is equivalent to the 1,3-DMAA found in the supplement."

So that means that what you're seeing in the artificial -- from the standpoint of the stereoisomer and the diastereomer ratios in the plant, that based on your work that you're seeing are the same as those ratios for the -- understand -- what you understand to be artificial or synthetically produced DMAA in the supplements?

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MS. WOOLSON: Objection to form.

You can answer.

MR. SCOTT: Let me withdraw that one and try it again.

BY MR. SCOTT:

Q There is a ratio, a diastereomer --

A Diastereomer.

Q -- diastereomer ratio that you see in the supplements which you know to be synthetic DMAA.

A As reported by Zhang and others, I think.

Q And you don't have any reason to dispute that?

A No.

Q And you're seeing the same ratio in the DMAA that you see in the plant?

A Correct. Roughly.

Q Now, have you been able to find any reference sample of what is purported to be a naturally occurring extract of DMAA?

A As in?

MS. WOOLSON: That's the full question?

MR. SCOTT: Yes.

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MS. WOOLSON: So, beyond what we've talked about all day long and all the sentences we have talked about all day long?

MR. SCOTT: Wow, so we've got an extract of natural DMAA somewhere, we talked about that at some point?

MS. WOOLSON: I'm asking you --

MR. SCOTT: I'm asking a question.

MS. WOOLSON: -- to clarify your question. We've been here for seven-and-a-half hours now.

MR. SCOTT: I'm happy with it. Let's go.

THE WITNESS: Am I answering the question?

MS. WOOLSON: If you understand the question, you can answer it.

THE WITNESS: What is the question again?

BY MR. SCOTT:

Q Sure.

Have you found a standard of natural extract of DMAA anywhere?

A A -- so I understand, somebody has taken

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geranium that has been proven to contain DMAA or known to grow 1,3-DMAA and extracted it and provided a reference sample?

Q Yes.

A To the best of my knowledge, no.

Q All right, sir. Now, in paragraph 86 on page 47, you go on to say: "If at some point in the future the measurement of the ratios of the four 1,3-DMAA stereoisomers can be successfully done in the plant material that shows the plant has a distinctly different stereoisomer ratio than the supplements, then we may be able to say that the two are not equivalent."

What did you mean by that?

A So -- it kind of goes back to the -- so we have -- for 1,3-DMAA we have four stereoisomers. Now, the state of knowledge thus far, as published, has only measured the two peaks that contain those four stereoisomers. And so within those two peaks, it -- what we don't know is are the pair of enantiomers equal or are they different.

So -- if we -- so our four stereoisomers

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are RR, SS, SR, RS, two sets. So RR and SS are a pair. But what we don't know is, is the ratios of RR to SS equal or are they different? And there is no published study that shows whether they are equal or they are different in the plant. What Zhang has shown is that they -- they are apparently equal in the supplements.

Q Okay. So the stereoisomer ratio, no one knows whether they're equal or not in the plants based on the research that's been done to date?

A Correct.

Q But in the synthetic, we know that they are equal, the stereoisomer ratios in the supplements, the synthetic version that is used in the supplements?

A So to be clear, Zhang, as far as I know, only measured one supplement that was reported. And I don't -- and I think there was that one CE paper that I think reported the supplements. I don't remember if they were equal or not.

Q Okay. But then -- so we don't know what is in the plants based on any scientific evidence?

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A We know the diastereomer ratios are equal.

Q Based on your work?

A Roughly equal. My work and -- did Li measure it?

(Perusing document.)

It looks like Li could have measured it, the 2012 Li paper, but it does not look -- I cannot tell if he reported it or not. So it looks like I'm the only one who has explicitly reported that diastereomer ratio in the plants.

Q All right, sir. Now, under the heading on page 48, "Summary of Opinions," your first opinion is, in summary, it's your opinion that geranium plants analyzed by both Li and Fleming contain concentrations of DMAA in the amounts that are reported in your -- in your respective studies, correct?

A Correct.

Q And then it goes on to say that these studies were done to the same level of rigor in your view as the ElSohly 2012, 2015; the Austin 2013;

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Zhang 2012; and De Lorenzo 2012 studies, both in terms of analytical chemistry and the level of authentication of geranium plant samples.

Do you see that?

A I see that.

Q And so it goes on to say that: "The differences between the sets of reports have yet to be adequately explained. The best explanation is the geranium plants composition varies based on a variety of factors that were not addressed by the studies."

That's your opinion?

A That's what I wrote.

Q Okay. And that -- and you've testified that you have no opinion regarding whether or not there is a biological pathway by which geranium plants can actually produce DMAA, correct?

A I don't really know much about biological pathways, so yes.

Q Okay. And it goes on to say that on 90, that no one has been able to demonstrate that the 1,3-DMAA in the plants is composed of only two of the four stereoisomers rather than all four stereoisomers

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present in the supplements, correct?

A Correct.

Q And at the moment, the only information or support for finding that the stereoisomers in the plant are equivalent to those in the supplements is your study.

MS. WOOLSON: Objection to form.

You can answer.

BY MR. SCOTT:

Q Correct?

A Say that again.

Q Sure. Has anybody but you measured the stereoisomers in the plant, the DMAA where -- in a plant?

MS. WOOLSON: Objection to form.

You can answer.

THE WITNESS: Not explicitly.

MR. SCOTT: Let me take a few minutes and confer, and see if we can't get you out of here, sir.

THE WITNESS: I will use the restroom.

MR. SCOTT: Sure, go ahead.

(Recess.)

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MR. SCOTT: All right. We're back on the record after what I believe to be our final break.

Dr. Simone, we're done for the day.

I will note for the record that on the chance that we get additional opinions from you or supplemental opinions from you, we reserve the right to reopen and continue the deposition.

THE WITNESS: I understand.

MS. WOOLSON: All right. Duly noted.

MR. SCOTT: All right. Thank you.

THE REPORTER: Sheila, would you like a copy of the transcript?

MS. WOOLSON: Yes, I would. I would like a draft e-mailed as soon as possible, and we will take the transcript regular time turnaround.

(Whereupon, at 5:27 p.m. the deposition of PAUL SIMONE, Ph.D. was concluded.)

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Notice Date: November 17, 2016
Deposition Date: November 7, 2016
Deponent: Paul Simone, Ph.D.
Case Name: US v. Hi-Tech Pharmaceuticals, Inc.

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CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me. Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

_____
Signature of Deponent

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this _____ day of _____, 2016, and executed the above certificate in my presence.

_____
NOTARY PUBLIC IN AND FOR

_____
County Name

MY COMMISSION EXPIRES:

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CERTIFICATE OF NOTARY PUBLIC

I, LESLIE ANNE TODD, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me in stenotype and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by and the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

LESLIE ANNE TODD
Notary Public in and for the
District of Columbia

My commission expires:
November 14, 2017