Exhibit 54

James P. Kababick

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

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

Deposition of James P. Kababick
Washington, DC
Friday, November 18, 2016
9:32 a.m.

Job No. 114994
Reported by: Laurie Donovan, RPR, CRR

James P. Kababick
Deposition of
JAMES P. KABABICK

Held at the offices of:
U.S. Department of Justice
Consumer Protection Branch
450 Fifth Street, NW
Washington, DC 20530

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

James P. Kababick

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:
U.S. Department of Justice
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By: Claude Scott, Esq.
and
United States Attorney's Office
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By: David O'Neal, Esq.

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James P. Kababick

EXAMINATION INDEX

E X H I B I T S

James P. Kababick

(Exhibits continued)

P R O C E E D I N G S

JAMES PETER PAUL KABABICK,
having been first duly sworn, testified
upon his oath as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT
BY MS. WOOLSON:

Q Good morning.

A Good morning.

Q We met a few minutes ago. We're here today to take your deposition.

Have you ever had your deposition taken before?

A No, I haven't.

Q I'm going to give you some basic instructions about how today is going to proceed.

A Okay.

Q You're going to be answering questions under oath, and even though we're in an informal setting, your answers can be used just as if we were in court, so it's important that you make sure you hear and understand my questions.

If you don't hear it, let me know, and I'll repeat it. If you don't understand it, let me know, and I'll rephrase it. If you answer a

question, I'm going to assume that you heard it, understood it, and are answering it to the best your ability.

It's important that you keep your responses verbal, because the court reporter can't take down gestures or nods of the head, and it's important that I let you finish your answer before I begin my next question, and likewise you let me finish my question before you begin your answer, because the court reporter cannot take down two people talking at the same time. Well, she can, but she prefers not to.

And from time to time Mr. O'Neal may interpose an objection to a question. If he does, just refrain from answering until the attorneys have worked it out. He will instruct you whether or not to answer the question.

Finally, if you need to take a break at any time, let me know. Other than when a question is pending, we can take a break.

Do you understand those instructions?

A Yes.

Q What did you do to prepare for your deposition today?

A I reviewed the scientific papers and data presented to me, the documents, and then I reviewed my expert report again, and yesterday I met with counsel.

Q Okay, and don't tell me anything about your discussions with counsel.

Can you give me the benefit of your educational background.

A Yes. I trained in psychopharmacology in grad school. I didn't complete my graduate degree in that. I went into the workforce.

I studied gas chromatography and separation science with Walter Jennings, who pioneered modern column chromatography, analytical column chromatography.

And I've trained in the private sector extensively in separation science, separating compounds, analytical chemistry, and also trained at FDA in botanical microscopy and forensic microscopy.

Q What is botanical microscopy?

A It's utilizing microscopic examination, a microscope, to determine identity, authenticity of botanical ingredients; in our case, used as

dietary ingredients; and also related to examining components of materials that might be under the ability of the eye to see, so you need a microscope to see.

Q And you said you took graduate courses in psychopharmacology.

What is your undergraduate degree in?

A Undergraduate, I have a bachelor's of science in business administration and a bachelor's of science in psychology.

Q And I take it from your earlier testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?

A I do not have a degree beyond a bachelor's degree.

Q And can you give me the benefit of your work history.

A Yes. I have about 23 years of experience in natural products chemistry, analytical chemistry, and separation science.

Q When you say you have 23 years of experience, can you tell me where you gained that experience?

A Sure. I worked in the private sector

here originally at Chromascentia, which was involved in analysis of essential oils for authenticity, and then formed Flora Research Laboratories in '93, and we started applying the techniques of microscopy and chromatography to testing dietary ingredients of natural products.

And I have not only worked extensively in the field but have taken an extensive number of continuing education training courses. Then also I have participated in a lot of scientific society panels, and I teach at university as well.

Q And you said initially you worked at Chromascentia?

A Yes.

Q And you were examining essential oils?

A Yes.

Q And what techniques were you using to examine the oils?

A Gas chromatography and what we call physiochemical analysis.

Q What do you mean by "physiochemical analysis"?

A That's the analysis of physical properties of the oil -- so density, specific

rotation -- as well as measurements of different classes of compounds through chemical analysis.

Q Okay, and while you were at Chromascentia, did you ever have occasion to review any essential oils from -- we'll start off at Geranium plants. We'll keep it simple.

A Yes.

Q How often did you examine essential oils of Geranium plants while you were at Chromascentia?

A I don't know at what interval, but I was analyzing oils daily, and I analyzed a large number of them.

Q And when you say you "analyzed" them, what did do you with this analysis? What was it used for?

A To characterize the oil for its authenticity as well as to determine the levels of desirable components.

Q And you were doing this analysis for customers or clients of the lab?

A Both for customers and internally for the company for the research of their line.

Q What was their line?

A Essential oils.

Q They had their own line of essential oils?

A Yes.

Q Okay, and when you were doing this analysis, did these -- strike that.

When you were doing this analysis, were you provided with the oils themselves as opposed to having to extract the oil from the plant?

A Are you speaking to Geranium in particular?

Q We can keep it specific to Geranium.

A Yes, the oils were provided.

Q And do you know from what geographic regions these oils came from?

A Yes. They came from Egypt, outside of the Cairo area, as well as China, the Yunnan province. Those are the major ones. There are others, but I don't know all the provinces. It was quite a while back.

Q And did you author or coauthor any studies or papers regarding this analysis of essential oils that you did while you were at Chromascentia?

A Is that related only to Geranium?

Q Yes.

A No, I did not.

Q Now, you mentioned that you created Flora Research Labs.

Who are the members or owners of Flora Research?

A Flora Research Laboratories is owned by myself, and Dana Neal is my partner.

Q Is Dana Neal your wife?

A Yes.

Q It's just the two of you who own the company?

A Yes.

Q Has it always been just the two of you that owned the company?

A Yeah. Originally it was myself, and then both of us.

Q Okay. Are you the sole director at Flora Research, or are there other directors?

A I'm the only director.

Q And who are Flora Research's largest customers currently?

A I'm unable to answer that, because I'm

bound to confidentiality under contract with clients.

MS. WOOLSON: Okay. This came up earlier this week with Dr. Brown, and what Mr. Scott and I discussed was having the United States go back and see whether or not this information can be provided pursuant to the confidentiality order that's in place in this case.

MR. O'NEAL: Okay.

MS. WOOLSON: So I would suggest we proceed similarly and see whether you can get that information. If not, we'll have to take whatever necessary steps we have to take with the court.

MR. O'NEAL: Sure. I would think this would be handled in whatever way you discussed with Mr. Scott previously. We don't represent him in his individual capacity, and so whatever his contractual obligations are, I have to take him at face value, but certainly we will, you know, with everyone, see what can be done and resolve it in the same manner.

MS. WOOLSON: Okay.

BY MS. WOOLSON:

Q Just so you understand, I'm not going to simply allow you to refuse to answer the question. We're going to try and take steps to make sure that you can answer the question and do it in a way that does not violate your contractual obligations.

As you sit here today, can you tell me if Flora Research Labs does work for any United States governmental agency?

A Can you clarify that just a little bit?

Q Sure. Does Flora Research do work for the FDA?

A We don't do compensated work for the FDA directly. We do work for companies that may have samples in detention and need data packages submitted from private labs. They're called "detention without physical examination."

Q And when you say "detention without physical examination," what do you mean?

A When a product comes into the United States, it may be subject to an import alert, and if it's subject to an import alert, it's detained

without testing by FDA sometimes, and it's up to the company to show that it meets specifications and is not adulterated. So we do that work.

Q And does Flora Research Labs currently do work for the National Institutes of Health?

A Not currently.

Q Has it in the past?

A Yes.

Q When is the last time it did work for NIH?

A I believe around 2006 we were given a grant to develop some test methodology.

Q What was the test methodology?

A It was a technique for quantifying benzene in liquid supplements, specifically resulting from the decomposition of the preservative system.

Q So we talked about FDA. We've talked about NIH. I'm going to exhaust my vocabulary of acronyms very quickly.

Any other agency of the United States government for which Flora Research Labs is currently doing work?

A Yes. The US Department of Agriculture's

ag research services.

Q Okay, and what do you do for ag research?

A We were given a grant to develop some techniques for identity of botanicals using spectroscopy.

Q And do you know which botanicals are at issue?

A We're actually working on ginseng.

Q And how long have you been doing that work, "you" meaning Flora Research Labs?

A A few years now.

Q So other than FDA, NIH, and the Department of Agriculture, are there any other agencies of the federal government for which Flora Research Labs is currently doing work?

A Not that I can recall.

Q Are there other agencies of the federal government for which Flora Research Labs has done work in the last ten years?

A Not that I can recall.

Q And when I asked you earlier about the largest customers, were those customers in private industry or were they in government?

A Private industry.
Q Mr. Kababick, would you agree with me that it's important for a scientist to approach research impartially?
A Yes.
Q And would you agree with me that it's important for a scientist to evaluate research impartially?
A Yes.
(Exhibit 1 was marked for identification.)
BY MS. WOOLSON:
Q I'm going to show you what's been marked as Exhibit 1.
Have you seen Exhibit 1 before today?
A Yes, I have.
Q And what is Exhibit 1?
A I'm sorry?
Q What is Exhibit 1?
A It's my expert rebuttal report.
Q And in preparing your expert rebuttal report, did you speak to anyone other than the attorneys for the government?
A You mean as far as preparing this

report?
Q Yes.
A Speak to people regarding the nature of the report or its contents?
Q Yes. Either.
A Not regarding this work, no.
Q Did you tell anyone that you were going to be an expert witness in this case, other than the government?
A I've only told people that are being an expert witness for the DoJ.
Q And who have you told?
A My attorney.
Q And by your attorney, you mean someone other than the attorneys for the United States?
A Yeah, our company's, yeah, and of course, staff people that need to know that I'm out of the office, what's going on.
Q And have you spoken to any colleagues outside of Flora Research about your expert work in this case?
A No, I haven't spoken about the expert work.
Q And in preparing your report, did anyone

assist you?
A No.
Q Did anyone review a draft of the report other than the attorneys for the United States or the attorney for your company?
A No.
Q In paragraph 1 of your report where -- you're discussing your qualifications, and you say you are a "phytoforensic scientist."
What do you mean by "phytoforensic scientist"?
A Phytoforensic science is the application of diverse analytical techniques in the evaluation of natural products and dietary ingredients, specifically focused on global food safety, quality.
Q And if I were to go look up the term "phytoforensic scientist," is that a defined term?
A Yes. Actually, it's a term we developed for this field that I pioneered, but you'll see references to it in LCGC Magazine and other resources.
Q When you say "it's a term we developed," who do you mean by "we"?

A I developed it at the laboratory to describe the specific and unique approach to analysis.
Q So this is a term that you created to describe what you do?
A Yes.
Q You also testified earlier that you were trained as a -- I think I asked you this -- botanical microscopist.
We talked about that. Sorry.
What is the standardized phytoforensic approach and the cross-over analytical technique that you refer to in your report?
A The standardized phytoforensic approach, or SPA, and the crossover analytical technique, or CAT, are two techniques for the systematic review of forensic data relative to this dietary supplement industry, as well as the analysis of data involved in the investigation of issues that stakeholders might be having let's say with a product formulation challenge, qualifying materials, things like that.
The standardized approach is the methodology by which material might be examined,

and crossover analytical technique is the approach to utilize orthogonal methodologies to help form a better picture of what's going on and what approaches might be utilized depending on what data is already at hand.

Q So let me see if I understand what you just said.

The standardized method approach that you're talking about, standardized phytoforensic approach is an attempt to create sort of a operating procedure by which to approach any phytoforensic examination of a substance, like a number of steps that you would walk through to do the analysis?

A It's for specifically -- we're dealing with issues of unknowns or with evaluating a material where routine standard methods aren't out there to answer the question specifically, or where the answer is something that you need to approach in different ways to get a better rounded view of it. It's not really addressing things that are routine and worked out, but more of the emerging and nonroutine things.

Q I guess I'm confused then.

How do you have a standardized approach for something that's not routine?

A This is the reason we developed this, is that a lot of stakeholders were challenged with this problem of how to approach the unknown, and from years of experience doing this, I organized a flow path for doing that and how we would gather information, review information, design experiments, and continue through that process.

Q And what is that flow path?

A The flow path? I'll have to refer to my data on that. I wrote up a paper on that, but I don't remember all the steps off the top of my head right now.

Q And what's the name of that paper?

A It's actually the -- the paper is a -- it was actually a poster, standardized phytoforensic approach scientific poster that I presented at AOAC, and then there's a PowerPoint that was presented at the United States Pharmacopeia Dietary Supplements Workshop.

Q So this standard approach or this flow path -- excuse me -- is a poster in a PowerPoint, correct?

A Well, I've developed a poster PowerPoint to cover it, to provide resources to others.

Q Okay, and this flow path is not incorporated into any study or publication beyond this poster and this PowerPoint, correct?

A I'm sorry. I'm not sure I understand.

Q The flow path, is it the subject of any publication or paper or article beyond just this PowerPoint and this poster?

A I believe it has been addressed in some other articles in the industry educational resources, and I'm actually submitting a paper regarding it to a journal.

Q And when did you prepare this poster and/or PowerPoint?

A I don't remember the exact date, but about two or three years ago. I'd have to check to be sure exactly.

Q And understanding that you don't remember all of the steps of the flow path, what steps do you remember?

A The first thing that I outline is collecting information, so a review of the literature, tapping resources like colleagues that

might have a part of the puzzle or part of the understanding, so reaching out to your peers and colleagues and industry in the scientific fields, looking at the scientific literature that's out there, searching publications, including books, and gathering data.

So the first step is to gather data and review it, and also in defining exactly what the issue is, and taking that data, putting it together into a cohesive understanding of what's known to date, and then designing experimental tests to approach the problem.

Q And is there a particular process that you follow in designing these tests?

A Yeah, it depends on what the test is and what the problem is.

Q And what's after designing the test?

A Conducting the test examinations.

Q And after you conduct the test?

A Reviewing the data to make a determination of what is found and where that points you, and then you would regroup and determine what next steps need to be taken, either further experiments, whether or not you resolve

the issue or got the answers to the questions, make discoveries.

Q So this seems pretty much like the scientific method that most scientists follow when they are doing research, correct?

A Basically, yes. The difference is that a lot of times with these issues, because there are not canned methods or approaches, a lot of my colleagues and peers that have come to me and been stuck or unsure what to do, this provides a framework of a way to think "outside the box," so to speak.

Q Okay, and when you talked about -- well, actually, let me back up.

What part of this flow path is outside-the-box thinking, in your mind?

A The things that I see a lot of times are in the designing of experiments that people often forget or get pigeonholed into thinking a certain way about what they're going to analyze, so maybe going directly after some target or analyte, but that may not provide the answer to the question.

And so I talk about looking at other things that might be impurities from process or

other aspects of manufacturing or crop production that might impart knowledge indirectly.

Q And the cross-over analytical techniques that you were discussing, I think you used the word "orthogonal."

Do you simply mean by that, using multiple different techniques in the analysis?

A Yeah, there's different techniques to approach the analysis.

Q So, for example, liquid chromatography, mass spectrometry, gas chromatography, that sort of thing?

A Yes, those could be components.

Q Okay. Looking at your expert report, which we've marked as Exhibit 1, in paragraph 8 you say, "I served on the National Institutes of Health R15 and R21 grant committees."

Do you see that?

A Yes.

Q And what was your role on those committees?

A I was a phytochemistry expert.

Q And what were you reviewing?

A I was reviewing grant applications

involving natural products research for college-level undergraduates and general grant applications.

Q And with whom did you serve on that committee?

A Guido Palli, who is from University of Chicago Urbana-Champaign, and there were several medical doctors and academics, statisticians. I don't remember everybody's name, though.

Q Anybody from NIH?

A I don't recall if there was -- no. Well, yes. I'm sorry. The chair or person heading up the committee was an NIH person.

Q Do you know who that was?

A I don't recall offhand.

Q Were there any other government personnel on the committee that you recall?

A I don't recall if there were.

Q Do you still review grants for NIH?

A Not currently.

Q When did you last review grants for NIH?

A I don't recall the exact time.

Q The last five years, ten years?

A Well, definitely within the last ten

years.

Q And were you compensated for your work in reviewing NIH grants?

A No. It was volunteer. The reimbursement for travel expenses was given, though.

Q And do you currently review grants for any United States government agency?

A No, I don't.

Q Okay. Now back to the question where I'm going to mispronounce something.

What is Synutra Pure?

A Is that here in the --

Q No, it's not in your report.

A Synutra Pure is a company that is involved in the distribution of chondroitin sulphate.

Q And what is your connection to Synutra Pure?

A We did some joint research with Synutra Pure as well as Tampa Bay Analytical Research and United States Pharmacopeia in investigating an adulterant found in chondroitin.

Q Who did you work with at Tampa Bay?

A With Mark Roman, who is deceased at this time.
Q How about U.S. Pharmacopeia?
A Christy -- I don't remember her last name. She's an NMR spectroscopist.
Q And who did you work with at Synutra Pure?
A Weigo, W-E-I-G-O.
Q And other than this work you did on the chondroitin compound, do you have any other interest in Synutra Pure?
A We did conduct some analysis on some chondroitin.
Q And how long ago did you do that work?
A I don't remember the exact date.
Q And how did you come to be involved in that work?
A You mean the work that I published with Synutra Pure and USP?
Q Yes.
A Okay. There was an article regarding the 01. They named the contaminate 01 they were trying to identify, and I had done a lot of work on chondroitin sulphate in the industry and

contacted them to talk about the impurity, and it piqued my interest as a researcher. A lot of our clients use chondroitin, and they had concerns about that contaminant, so I felt it would be good for our company to try to help research and understand it so we could help our clients test. So we got involved with them and USP and Tampa Bay to see if we could help identify it, which we were able to do and write the paper.
Q What work specifically did your company do?
A We did a combination of FTIR, infrared spectroscopy, as well as differential scanning calorimetry, DSC, and then we also did some cellulose acetate membrane electrophoresis to separate the compound.
Q And did you personally do this work, or did people who work at Flora Research do this work?
A Both.
Q What did you personally do?
A I actually collected infrared data and calorimetry data, and I did also the electrophoresis, but I also had staff involved

with me working.
Q And other than that research that you've talked about, that we've just talked about, did you do any other work with Synutra Pure?
A Just the couple of samples that we analyzed for them of chondroitin.
Q And do you or does your wife have any ownership interest in Synutra Pure?
A No.
Q Do you or your wife have any ownership interest in any dietary supplement?
A No.
Q Any company that makes dietary supplements, I should say.
A No.
Q Do you know Paula Brown?
A Yes.
Q Who is she?
A Paula Brown is a scientist in Canada. She's at British Columbia Institute of Technology, and she serves on various AOAC committees that I've been involved with as well, and she's organized symposia that I've spoken at, things like that.

Q Have you authored any papers with her?
A Yes.
Q How many?
A I wrote an article for Nutraingredients or nutrition -- let me see. I'm trying to remember the name of that trade publication. Nutraceuticals World. We wrote a paper together. I believe we authored some publications together, but I would have to look it up to be sure.
Q Do you know who Frank Jaksch is?
A Yes.
Q Who is he?
A Frank Jaksch runs ChromaDex.
Q What is ChromaDex?
A They are a company that provides analytical standards, analytical services and consulting services, as well as some ingredients in the industry.
Q And how do you know Mr. Jaksch?
A When he started ChromaDex, he solicited our business to buy standards, and I knew some scientists that worked there, and so we did business together and know each other from meetings and things like that.

Q When you say "did business together," do you mean anything other than supplying standards?
A Yeah, well, we purchased standards from them, from ChromaDex.
Q When is the last time you spoke to Mr. Jaksch?
A Oh, I would think several years ago, two or three years ago.
Q Does your company still buy standards from ChromaDex?
A I believe we occasionally do, yes.
Q Do you know what standards you buy from ChromaDex?
A I know we purchased creatine ethyl ester. I'm not sure what else, but occasionally we will get phytochemical materials or dietary ingredient materials.
Q Okay. Do you know who Amy Eichner is?
A Yes.
Q Who is she?
A She's a scientist at USADA.
Q That's U-S-A-D-A?
A Yes, I believe it's USADA.
Q How do you know Ms. Eichner?

A She published a paper, and I've heard her speak at some conferences.
Q When you say she published a paper, what paper? I mean obviously it sticks out in your mind, so I want to know why.
A Yes, it was a paper on DMAA in Geranium.
Q Have you ever discussed that paper with her?
A Yeah, I emailed her about that.
Q And what was the subject of your email, the substance of your emails, I should say?
A Just congratulating her on the paper that -- you know, appreciating that it helped shed more light on the issue.
Q And did she publish this paper with anyone else? Did she have coauthors?
A I believe she did, yes.
Q Do you know who they were?
A Not offhand. I would have to check.
Q Do you know Joseph Betz?
A Yes.
Q Who is he?
A Joseph Betz is the director of the NIH Office of Dietary Supplements Methods and

Standards Division.
Q And how do you know him?
A He was my instructor when I was trained at FDA. At that time he was at FDA.
Q And what training specifically did you receive from him?
A Botanical microscopy.
Q And how rigorous -- let me rephrase the question.
How long did the training last?
A It was a 40-hour training course.
Q Over what period of time?
A It was one week intensive.
Q And other than that training class with Mr. Betz, have you worked with him on anything else?
A Yes.
Q What?
A He's been actively involved in AOAC International, which is a scientific society that I'm a fellow in, and he has been involved in the funding of the various official methods that were contracted by the agency for AOAC for development of dietary supplement testing, and my work as the

chair of the methods committee, as well as participating in symposia that were put together. I've interacted with Joe quite a while.
Q You mentioned that the FDA funded, I think you said various official methods that were to be developed by the AOAC.
A The NIH had a funding mechanism. I believe it was an interagency NIH/FDA funded mechanism. They contracted with AOAC, which holds official methods which are recognized as enforcement methods, and to develop priority methods for testing supplements.
Q So let me make sure I understand.
The NIH/FDA interagency funding was provided to the AOAC to develop methods?
A Yes.
Q And you were part of the AOAC committee that received that funding to develop the methods?
A Well, I was a volunteer on the committee that provided the work of review and study. The AOAC funding was to essentially support the infrastructure and mechanism of the organization toward that end.
Q And by "organization," you mean the

AOAC?
A Yes.
Q And who did the actual work, if you will, of developing those methods?
A It was a variety of sources. Sometimes there was funding mechanism for somebody to develop what we call a single lab validated method. Sometimes there were calls for methods where people would submit methods, candidate methods, and sometimes a method would be considered as a potential viable method, and maybe after review it was determined additional work was needed to flesh it out.
So there were a variety of ways those came in.
Q When you say there was funding for a single laboratory validation method, did Flora Research receive any funding for such methods?
A Not through the AOAC mechanism, no.
Q Through some other mechanism?
A Well, the previously disclosed funding I received from NIH for the benzene study was to develop a method, single lab method.
Q Did I ask you when you did that work?

A Yes. I believe it was around 2006. I'd have to verify.
Q Was that the only NIH funding?
A To my knowledge, yes.
Q You mentioned Mark Roman earlier.
Have you published any papers with Mark Roman or done any work beyond the chondroitin studies that we discussed?
A Yes. I worked on the study of a product called Nucleomaxx, which was a subject of a clinical trial, and I did some mass spectrometry as part of that paper -- or poster, I should say.
Q Is that the only other work you've done with Mr. Roman that you recall as you sit here today?
A Mark and I did quite a bit of work over the years together, and I believe there were some other papers published. We worked extensively together on AOAC committees, since we both served on the Committee K.
Q And what is Committee K?
A That's the methods committee on dietary supplements. And then we served on various expert review panels in AOAC.

Q Do you have any patents in your name?
A I do not.
Q Are you a co-author of any patents?
A No.
Q Earlier this morning you mentioned DMAA. What is DMAA?
A DMAA, as I use the term, refers to the compound methylhexaneamine.
Q And just so we're all on the same page for the duration of the deposition, if I refer to this as "DMAA," you will understand that to be methylhexaneamine?
A Yes.
Q I just find it easier for me to say DMAA than all those letters.
A Sure.
Q The other thing is, are you familiar with the term "Pelargonium graveolens"?
A Yes.
Q Are you comfortable if we refer to that as Geranium?
A It is a Geranium.
Q Okay. So we'll just refer to that as Geranium. If during the course of your deposition

for some reason you need to distinguish among types of Geranium, let me know, but otherwise I'm going to assume, if we're talking about Geranium, we're talking about Pelargonium graveolens. Okay?
A Okay.
Q Thank you.
A Before we go further, would it be okay if I used the restroom real quick?
MS. WOOLSON: Sure.
(Whereupon, a short recess was taken.)
(Exhibit 2 was marked for identification.)
BY MS. WOOLSON:
Q When we broke, we talked about some shorthand that we were going to use for the day, at least to try to use for the day to make things a little more straightforward.
How many years, Mr. Kababick, have you been trying to get DMAA banned?
MR. O'NEAL: Object to the form.
THE WITNESS: I haven't been trying to get DMAA banned.

James P. Kababick

BY MS. WOOLSON:

Q No?

A No.

Q Let me show you what's been marked as Exhibit 2.

(Witness peruses document.)

THE WITNESS: Okay.

BY MS. WOOLSON:

Q Have you seen Exhibit 2 before?

A Pardon me?

Q Have you seen Exhibit 2 before?

A Not as this exhibit, no.

Q Okay. Do you recognize Exhibit 2 as, in part, an email that you sent regarding DMAA?

A It appears to be so, yes.

Q And this was in January of 2012, correct?

A Yes, that's the set date on here.

Q And it says "from James Neal Kababick to James Neal Kababick."

Do you see that?

A Yes.

Q To whom did you send this email other than yourself?

James P. Kababick

A I don't recall, actually.

Q If you look at the email at the top of the page, it appears that somehow your communication went to Daniel Fabricant.

Do you see that?

A You mean right here?

Q Yeah, in the middle. Directly above the "James Neal Kababick to James Neal Kababick," there is a to-from that says "from Daniel Fabricant."

Do you see that?

A Where it looks like this is part of something he sent?

Q Yes.

A Yes.

Q Who is Daniel Fabricant?

A He is the CEO of the Natural Products Association.

Q Is he also an FDA employee?

A He was formally [sic].

Q And do you know why --

MR. O'NEAL: Did you mean "formerly"?

THE WITNESS: Yeah, he was at FDA.

James P. Kababick

MS. WOOLSON: As opposed to "formally"?

THE WITNESS: Yes, formerly. Currently he's at --

MR. O'NEAL: I don't think anybody is informally at FDA.

BY MS. WOOLSON:

Q Do you know why you would have been sending to Mr. Fabricant information about DMAA?

MR. O'NEAL: Object as to form. Assumes a fact not in evidence.

THE WITNESS: Could you ask the question again, please.

BY MS. WOOLSON:

Q Sure.

Do you know why you would have been sending to Mr. Fabricant information on DMAA?

A I don't recall the exact nature of this communication and exactly who it went to.

Q In the past have you sent information to Mr. Fabricant regarding DMAA?

A I actually don't recall. I have communicated with him when he was at FDA on various subjects.

James P. Kababick

Q And as you sit here today, you can't recall why you sent this email or to whom you sent this email?

A No. No, I can't.

Q And if we were to look at your email in its native format, would we be able to see if you blind-copied people on this email?

A I'm not sure I understand.

Q Do you know what a blind copy is?

A Yeah, I do, but what's the "native format"?

Q It's a format in which you can look at emails. It preserves all the original data.

Let me rephrase the question.

A Okay.

Q Was it your practice to send emails to colleagues where you BCC'd them instead of CC'ing them?

A Sometimes.

Q Why?

A If I was sending emails to more than one party, and those parties, for one reason or another, were distinct for some reason. For instance, maybe a communication that would be

relevant to two clients, but I wanted to protect the clients' confidentiality, I might BCC them; or if I'm not wanting to disclose an email chain, sharing email addresses with everybody, because I don't know if it's okay to give other email addresses out, I might BCC them.

Q And when you sent this email that we're talking about, was the FDA or Mr. Fabricant a client?

A No, no. He's not a client.

Q And to whom -- to whom else other than Mr. Fabricant may you have sent -- strike that.

Do you recall sending emails regarding DMAA to other people?

A I'm sure I did, yes.

Q And do you know who those people are as you sit here today?

A I may have communicated with Roy Upton at American Herbal Pharmacopeia and Mark Blumenthal at American Botanical Council, and I'm sure I dialogued with probably Ikhlas Khan or others, but exactly who, I don't recall.

Q And what were the circumstances under which you were corresponding with Mr. Upton

regarding DMAA?

A I don't recall the specific details.

Q What about Mr. Blumenthal; what were the circumstances under which you were corresponding with him about DMAA?

A I believe that we were discussing the DMAA in regard to the botanical adulterants program at ABC.

Q And did you do any work for ABC regarding the botanical adulterants program?

A I actually am on the board currently, the scientific advisory board, and I, prior to that, have ongoingly provided peer review and input on various botanical-related matters for educational papers that they do.

Q And what about Dr. Khan; what is the context in which you were corresponding with him regarding DMAA?

A I don't remember the specifics of our correspondence. I do remember that I addressed some critiques of a paper that I read on DMAA on Geranium, and I've had ongoing communications with Dr. Khan's group regarding various articles and projects that I've done where I've been seeking

input or papers, reprints, things like that.

Q And the critique of this paper that you referred to, do you know whose paper it was?

A I believe it was the Li paper, the first Li paper.

Q And what other -- you said you had other correspondence with Dr. Khan regarding DMAA. What other projects were you working on that you would have been corresponding with him about DMAA?

A Well, I don't know if I had other correspondence regarding DMAA with Dr. Khan. I remember that communication, but I've had communication with him regarding various botanicals.

Q What botanicals?

A Currently we've been dialoguing regarding ginkgo, and I've also corresponded with him regarding acacia, and I'm trying to think what else.

I know there's other related matters, but I don't recall offhand.

Q Okay, and when you say you're "dialoguing with him" about these botanicals, what do you mean? Are you asking him for help? Is he

asking you for help? What's the nature of the discussions?

A Usually because their group does a lot of publishing and research, I will inquire regarding papers that they published to get reprints or check regarding questions I might have about things to see if they've examined those things.

So I've spoken with his team off and on regarding different things.

Q And when is the last time you had communications with Dr. Khan's group?

A I don't remember exactly, but I would say within the last 60 days.

Q And was this about acacia or ginkgo?

A I believe about ginkgo.

Q Anything else?

A I don't recall offhand.

Q Did you ever review Dr. Khan's expert report in this case?

A Yes, I did.

Q Did you speak to Dr. Khan about his expert report?

A No, I haven't.

Q Did you speak to anybody in Dr. Khan's group about his expert report?
A No.
Q Going back to Exhibit 2 --
A That's this one?
Q That's the email.
A Okay.
Q If I could draw your attention to the second page of the email and the third paragraph down, you say, "I can only hope that FDA is drawing back the bow string on this and not ignoring what I think is a blatant attempt to sell yet another pharmaceutical drug dressed up as a dietary supplement."
Do you see that?
A Yes.
Q What did you mean?
A I believe -- and this was several years ago, but I believe what I was addressing here was the use of large amounts of DMAA in products where it was claimed to be all naturally isolated from Geranium.
Q And what is it you wanted FDA to do?
A I was hoping that they would look into

the matter further and make a determination on whether or not this is a dietary supplement or not a dietary supplement. A lot of clients were on the fence on what to do about this.
Q And when you say "I completely support Health Canada's position on this," what was Health Canada's position?
A I know that their evaluation of the Ping paper was that it was not an acceptable support of naturally occurring DMAA in Geranium. I don't remember the other information from Health Canada.
Q Do you know whether, at the time of this email, Health Canada had ruled that DMAA was not permitted to be sold as a dietary supplement?
A I don't recall.
Q Now, you go on to say, "Despite offers to analyze Geranium stem and leaf for free to see if it really has this compound in it, no takers have shown up yet."
Do you see that?
A Yes.
Q Where did you make these offers?
A I actually put out a call for material to ABC and American Herbal Pharmacopeia, who are

well connected in the industry, to see if we could get material, and I let it be known that I would be interested in looking at that material in its native form.
Q And to whom did ABC or -- the other company whose name I just forgot.
A AHP.
Q AHP. Thank you.
To whom did they send that request?
A I'm not sure.
Q And so is it your testimony that as of the date of this email, no one had responded to your request for material?
A I don't recall at the date of this email anybody offering to provide live plant material or dried whole pieces.
Q Did you ask Dr. Khan or Dr. ElSohly for plant material?
A I don't recall if I did, actually.
Q Did you ask Dr. Li for a sample of plant material?
A I do not think I did, but I don't recall exactly.
Q Did you ask Drs. Fleming or Simone for

plant material?
A No.
Q Was there some reason why you couldn't get your own plant material?
A You mean as far as obtaining my own Geranium?
Q Mm-hmm.
A What I was asking for was material in trade that was being used by manufacturers to extract the DMAA.
Q What do you mean "material in trade"?
A The source material that manufacturers claim that they were extracting the DMAA from, so I wanted to --
Q What was the source material?
A Well, they claimed Geranium stem and some oil, so I wanted to get the material they were using before I did the extraction so I could look at it.
Q Okay, and I go back to my original question, which was: Was there some reason why you couldn't have gotten your own Geranium stem or oil?
A I did not have the information on who

the manufacturers were in China that were making it.

Q Did you ask Dr. Khan, Dr. ElSohly?

A I don't recall.

Q Did you ask Dr. Li?

A I don't think I did, but I don't recall.

Q Did you ask Dr. Simone and Dr. Fleming?

A No.

Q Did you ask anyone?

A Yes, I believe I did.

Q Who?

A I don't recall.

Q As we sit here today, have you run any studies on Geranium plants since the date of this email?

A Could you be more specific?

Q No, I don't think I can be.

A What do you mean by "studies"?

Q Have you analyzed any Geranium plants for DMAA since the date of this email?

A I have analyzed some Geranium plant product, but I don't recall the specifics.

Q What do you mean you "analyzed some Geranium plant product"?

A Well, I've analyzed essential oil obtained from Geranium and I've analyzed some extracts, but I don't recall the details of the specifics who it was from. I know the oil was in regard to authentication. The extract powders, I don't recall the nature of the analysis.

Q And when did you do these analyses?

A I don't recall the exact date.

Q Who were they for?

A These were for clients.

Q And I suppose you won't tell me the name of the clients.

A I'm bound by confidentiality.

Q Speaking of that, we'll take it up.

And when you say you analyzed the Geranium plants, how did you analyze them?

Actually, I take it back.

You said oil and extracts.

A Yes.

Q How did you analyze the oil and extracts?

A Using gas chromatography and mass spectrometry, GC/MS.

Q And have you analyzed any Geranium

plants since the date of this email?

A Not whole plant material. Not that I can recall at least.

Q And how many oils did you analyze?

A Between the time of this?

Q Between the time of Exhibit 2 and today.

A I am not sure.

Q Can you estimate?

A At least a dozen or two.

Q And how many extracts did you analyze?

A That I don't recall at all.

Q And when you did this analysis on the dozen or so, one to two dozen oils, what specifically were you looking for?

A I was looking at the composition for various markers that are used in evaluating the quality of the oil, as well as looking for any compounds that would be considered synthetic.

Q And when you say you were looking at markers, what markers?

A Essential oil constituents, like alcohols, terpenes, oxygenated sesquiterpenoids, aldehydes, esters.

Q Did you look specifically for DMAA?

A In some cases, yes.

Q How many cases?

A I don't recall offhand exactly how many cases.

Q Do you recall the results?

A Yes. As far as I know, I don't recall finding it in any oils that I was able to authenticate as all natural.

Q Where did these oils come from?

A Clients submitted them from their producers or brokers, buyers.

Q Do you know the geographic origin of the oils?

A No.

Q And when you did the GC mass spec analysis, what were the conditions?

A The GC conditions?

Q Both GC and mass spec.

First of all, what did you do to the oil before you analyzed it as GC mass spec?

A It was diluted in a solvent and then injected directly.

Q What solvent?

A We usually use ethanol for Geranium.

James P. Kababick

Q And what were the column conditions?

A I don't recall the exact column conditions, but we replicated the atom's GC/MS essential oil conditions, and then we also ran a second condition which used a lower starting temperature and solvent delay so that we could look at early eluting compounds.

Q And what was the column temperature on the second set of conditions?

A I don't recall exactly.

Q During any of these analyses that you did on the Geranium oils, did you attempt to replicate the conditions in the Li or Fleming studies?

A I don't recall that I did.

Q And same question for the extracts that you analyzed; what steps did you take before you did the GC mass spec analysis?

A Those samples were extracted in an acid base extraction cleanup and then placed into ethyl acetate or chloroform and analyzed as freebase forms.

Q And what were the geographic origins of the extracts?

James P. Kababick

A The extracts were -- the country of origin claim was China.

Q Do you know what province in China?

A No.

Q When you analyzed the extracts, what were you looking for?

A In the extracts I was looking for DMAA.

Q And what were the results?

A There were some samples that had it and some samples that didn't.

Q How many samples had it, if you recall?

A I don't recall, to be honest.

Q And again, the extracts were work that you were doing for a client?

A Yes. They were commercial samples being represented as extracts from Geranium.

Q So getting back to Exhibit 2, you did not attempt to obtain samples yourself of Geranium plants, oils or extracts to study, correct?

MR. O'NEAL: Object to the form.

THE WITNESS: Sorry. Would you repeat the question.

MS. WOOLSON: Can you read it back.

James P. Kababick

(Whereupon, reporter reads requested material.)

THE WITNESS: Well, actually, I did. I tried to get some from industry, so I put out a call for them.

BY MS. WOOLSON:

Q Let me rephrase the question.

You did not make any attempt yourself to go gather samples of Geranium plants, oils or extracts beyond this call you made to industry?

A Actually, I did contact or had my administrator contact some vendors to see if they would send us some material.

Q Which vendors?

A I don't recall offhand, to tell you the truth.

Q Did they send you materials?

A One company at least sent a sample of their DMAA material.

Q When you say DMAA material, are you talking about a standard?

A Well, it's supposed to be a Geranium extract, but it was a white crystalline powder, nearly pure.

James P. Kababick

Q And who was the vendor?

A I don't recall the vendor offhand.

Q And did you test this extract?

A Yes.

Q And beyond that extract, did you receive any other material from any other vendors?

A Not that I recall. I may have, but I just don't remember that far back.

Q And this was about the 2012 time period?

A I don't know exactly when it was, but I know it was during that time I was looking into this matter.

Q The last paragraph on Exhibit 2, you say -- well, you reference "peer-reviewed papers." Do you see that, "peer-reviewed publications"?

A Where is it?

Q The last paragraph.

A 37 years of peer-reviewed publications?

Q Yes. I'm asking you about the terms "peer-reviewed publications" and "peer-reviewed papers."

Do you see where you use those terms?

A Yes.

Q What do you mean by peer-reviewed papers

or publications?
A These were publications that are reviewed by scientific peers that have expertise in the subject matter area and are recognized as reliable scientific publications.
Q What do you mean by "reliable scientific publications"?
A That the journal has a high impact rating, meaning that there's recognition by a larger body of scientists as to the quality of the journal and its editorial scrutiny.
Q And what do you know about the peer-reviewed process for the publication -- I think it's called Analytical Chemistry Insights.
A I would have to check that journal again. I don't remember the exact details on that one.
Q So as you're sitting here today, you don't know whether it's peer-reviewed or not?
A No. I don't recall.
Q All right. In paragraph 15 of your report you talk about the Ping paper.
(Witness peruses document.)
THE WITNESS: Yes.

(Exhibit 3 was marked for identification.)
BY MS. WOOLSON:
Q I'm going to show you what's been marked Exhibit 3. Take a look at that.
(Witness peruses document.)
MR. O'NEAL: For the record, is this a complete version of the document?
MS. WOOLSON: I believe it is.
MR. O'NEAL: Okay.
(Witness peruses document.)
THE WITNESS: Yes.
BY MS. WOOLSON:
Q And do you recognize Exhibit 3?
A It looks like it could be the Ping paper.
Q Okay. What is the molecular formula for DMAA, if you know?
A Offhand? I'd have to look it up to be sure.
Q Okay. If I told you that it was C7H171N, does that make sense?
A That could be the formula.
Q Do you know the molecular weight?

A 115 is the nominal mass.
Q And you would agree with me that in the chart of compounds listed as being detected in the Ping paper, that #30 has a mass of 115, correct?
A Yeah, except on my copy the table names and everything are blacked out.
Q Well, I apologize. That's how it -- that's how we got it. That's how it printed out. It's blacked out on mine, too.
A Okay.
Q The Ping paper was in 1996, correct?
A Yes, I believe so. Yes.
Q And would you agree with me that analytical chemistry has been made advances in the last 20 years since 1996?
A Is there a specific area you're speaking to?
Q In terms of precision, limits of detection, overall ability to separate and detect compounds?
A In some cases, yes, but not really in precision and accuracy.
Q All right. Then you tell me in what ways analytical chemistry has advanced since 1996.

A Computerized data acquisition has changed, so the software has been evolving, and also mass spectrometry has become more mainstream in that there are different types of mass spectrometers, including LCMS, that are now routinely found in analytical labs, things like that.
Q Okay. What is more sensitive, mass spec or NMR?
A It depends on the experiment.
Q Well, in terms of -- let me put it this way.
In terms of detecting a trace quantity or trace concentration of an analyte where you have very low mass recovery.
A When you say "low mass recovery" --
Q So, for example, if I have a sample that is ten grams versus a sample that is ten micrograms, would NMR be better or worse for the 10 microgram sample than mass spec?
A Just to make sure that I understand, do you mean if you were trying to analyze the ten micrograms and it was one compound?
Q Well, all right. That's a fair point.

Let me rephrase the question.

On average, what's the minimum amount of mass that you need for NMR to run the sample?

A It depends on the type of NMR that you're using. If you have an advanced CryoProbe NMR, you could work with microgram samples.

Q And how common are advanced CryoProbe NMRs?

A They're pretty routine at universities now, and several analytical labs have that service as well.

Q And if you didn't have an advanced CryoProbe NMR, how much sample would you need?

A It really depends on the experiment, the pulse rate, relaxation delay, and what you are looking at, C-13 proton, et cetera.

Q Have you reviewed as part of your work in this case the studies that were performed by Dr. Khan and Dr. ElSohly, Dr. Lisi, Dr. Zhang and Dr. Di Lorenzo?

A I reviewed papers published by Li and ElSohly and Khan and others. I believe one of those was the Zhang paper as well.

Q Okay. In paragraph 16 of your report

you say that "Drs. Lisi, Zhang, Di Lorenzo, Austin and ElSohly used validated and adequately sensitive methods."

Do you see that?

A Yes.

Q Are you opining that Drs. Li and Fleming did not use adequate -- did not use validated and adequately sensitive methods?

A No.

Q To your knowledge, based on your review of the publications -- and we'll take just the ElSohly publications first for purposes of this question. How did Drs. ElSohly and Khan get their samples?

A I would have to review the paper. I don't recall exactly offhand.

Q Do you think they went out to China and picked Geranium plants themselves?

A I don't know that they did that.

Q Do you think that they had somebody from China send them plants?

A I don't know.

Q And if I asked you the same questions regarding Dr. Lisi, Dr. Zhang and Dr. Di Lorenzo,

would your answer be the same?

A Yeah, I don't know the exact details of how they obtained their samples, the specifics.

Q And do you know the exact details of the samples' growing conditions, soil, anything about how the plant is grown?

A For --

Q Let's say Dr. ElSohly and Dr. Khan studies.

A I believe in one of their papers they discussed some of the production of material grown at the University of Mississippi.

Q And did they give details about the soil conditions in that paper?

A They provided some information, but I don't recall the specifics.

(Exhibit 4 was marked for identification.)

(Exhibit 5 was marked for identification.)

BY MS. WOOLSON:

Q So I've marked as Exhibit 4 the ElSohly/Khan et al. study of 2012 and Exhibit 5 as the ElSohly/Khan et al. study of 2014.

(Witness peruses documents.)

THE WITNESS: Okay.

BY MS. WOOLSON:

Q Okay. Now that you've had a chance to look at Exhibits 4 and 5, do you recognize them as the 2012 and 2014 ElSohly studies?

A Yes.

Q Looking at Exhibit 4, which is the 2012 study, what does the study say about how the samples were obtained, the plant samples were obtained?

A They were obtained from various sources, Institute of Integrative Medicine and then also the Medicinal Plant Garden at the university, and -- let's see here. In both cases they were authenticated by experts.

Q And when you say "they were authenticated by experts," why do you say they're experts?

A The research scientist at NCNPR, National Center for Natural Products Research, and the other scientist is the head of the Plant Biotechnology Division.

Q So you mean they have Ph.Ds and they

authenticated the plants, basically?
A No, I'm not saying it's because they have Ph.Ds. It's because they are in plant authentication as part of their work, from my understanding.
Q Okay, and is your understanding from anything other than the paper?
A Well, generally botanists are -- botany is a science, and it includes plant identification through features.
Q Okay. I'm just asking.
So you're basing your statement that these gentlemen were experts -- and I'm assuming they're gentlemen; that may not be correct -- but based on the information in the paper as opposed to external sources. That's all I'm asking you.
A To the best of my knowledge, yes.
Q Okay. Now, does anything in Exhibit 4 tell you anything about the growing conditions, the soil, the water, the air, the nutrients, anything?
A No, I don't believe it does.
Q And so these samples in Exhibit 4 of the plants were obtained by third parties for

Drs. ElSohly and Khan, correct?
A It appears so.
Q Exhibit 5. What information in Exhibit 5 is there about the source of the plant samples that were studied?
A The accession numbers, and for those in the NCNPR collection, they're referenced under those.
Q And does anything in Exhibit 5 tell you anything about the growing conditions, soil, water, nutrients of those plants?
A Not that I see offhand.
Q If I could just have you flip back to Exhibit 4 for a second, where did Drs. Khan and ElSohly get their reference sample of DMAA?
A They indicate that they obtained the standard from Sigma-Aldrich.
Q And again, I'm sorry to make you flip back and forth, but with respect to Exhibit 5, the samples were obtained by third parties and provided to Drs. Khan and ElSohly, correct?
A It indicates that they were obtained by NCNPR, but that's the group which Dr. Khan leads, so I'm not sure what his involvement was in the

collection.
Q Well, not all the plants came from NCNPR, correct?
A Right.
Q Okay. So we can at least agree that the plants that did not come from the NCNPR were obtained by a third party, correct?
A I actually don't know, because I don't see where it says -- it says there were materials from sources, but I don't know how those materials were collected.
Q Okay. So that information is not in this paper, to the best of your ability to tell?
A Yeah. Currently looking at it, I don't see that.
Q Now, it's not unusual for samples to be obtained by a third party and sent to a lab for research, is it?
A You mean like in general?
Q Like in general, yes, like for plants to be obtained by a third party and sent to a lab to be researched.
A Yeah, that happens.
Q Have you yourself ever studied plants

that were gathered by a third party and sent to you for research?
A Yes.
Q Now, what, if anything, did Drs. ElSohly and Khan do in Exhibit 4 and Exhibit 5 to determine if their plant material was contaminated in any way?
A I'm not sure that they did any testing for contamination.
(Exhibit 6 was marked for identification.)
(Witness peruses document.)
THE WITNESS: Is this 2012 paper part of this document at the back?
BY MS. WOOLSON:
Q No. Sorry. Just a copying error. That's the next exhibit you're going to get, the Di Lorenzo paper. You should never let attorneys make photocopies.
(Witness peruses document.)
THE WITNESS: Yes.
BY MS. WOOLSON:
Q So you have in front of you Exhibit 6. Do you recognize Exhibit 6?

A It appears to be a paper from the Drug Testing and Analysis Journal.
Q And it's by Dr. Lisi et al., correct?
A Yes.
Q Have you read this paper before?
A I think I recall reading this paper.
Q Okay, and this paper involved Geranium oil and Geranium -- Geranium oil and supplements, correct?
A It did involve Geranium oil, and let me see here. Yes, and supplements.
Q And where did the Geranium oils come from? What was their origin?
A They list their origins as France, Egypt, and then a -- yeah, just France and Egypt right here in the table.
Q And do you see on -- I just lost my place. Oh, under "Experimental" on page 2 of the report, these Geranium oils were purchased over the internet, correct?
A Yes.
Q Okay, and what steps, if any, did Dr. Lisi et al. take to determine if the Geranium oil samples were contaminated?

A I don't know that they took any steps. They don't discuss that here.
(Exhibit 7 was marked for identification.)
BY MS. WOOLSON:
Q Let me show you what's been marked as Exhibit 7. Take a look at that.
(Witness peruses document.)
THE WITNESS: Okay.
BY MS. WOOLSON:
Q So showing you Exhibit 7, have you seen that before?
A I think I did see this before.
Q Okay. If it's helpful --
A There's actually another paper attached to it, by the way.
Q Oh, okay. There you go. Not anymore.
A So it's just this particular paper, right?
Q It's the Di Lorenzo paper, correct?
A Yes.
Q If it's helpful, if you look at paragraph 16 of your report, you refer to the Di Lorenzo study.

A Yes.
Q Where do the plant samples in the Di Lorenzo study come from?
A They were obtained, it says, at a plant nursery.
Q And what information does the paper have about the growing conditions, soil, nutrients, water that were used on the plants?
A They don't indicate that in the paper.
Q And what steps did Di Lorenzo et al. take to see if their plant samples were contaminated in any way?
A I don't know.
Q Have you ever had conversations with Dr. Khan -- well, strike that.
Several times during the course of this morning, I mentioned Dr. ElSohly.
Do you know Dr. ElSohly?
A Yes, I've met him before.
Q Okay, and when is the last time you spoke to Dr. ElSohly?
A Last year I was at a conference at ASP, and that was held at the University of Mississippi campus, and we talked about cannabinoid chemistry

and analysis of cannabinoids.
Q And when is the last time you spoke to Dr. Khan or Dr. ElSohly about DMAA?
A I don't recall. I don't know if I've ever spoken to Dr. ElSohly about it, and for Dr. Khan it would have been a while back.
Q Okay, and would your answer be the same regarding email communication as opposed to just verbal communication?
A Yeah, I don't recall any emails recently about that.
Q Have you ever spoken to Dr. ElSohly or Dr. Khan about what we've marked as Exhibit 5, the 2014 multi-centre study?
A I may have spoken with Dr. Khan about this. I don't recall speaking with Dr. ElSohly about this.
Q And when did you -- assuming that your recollection is correct, when do you think you had that conversation or conversations with Dr. Khan?
A Probably around the time of the paper or maybe, maybe at the ASP conference 2015.
Q And do you remember the substance of your conversation?

A Not offhand, no.
Q If you look at Exhibit 5, can you tell me where -- well, first of all, how many centers were involved in this multi-centre study?
A It indicates here that there were four laboratories participating.
Q Which were? Who were they?
A Based on the information up front, it would have the NCNPR University in Mississippi, Shanghai Institute Materia Medica School of Pharmacy in Shanghai, and I'm not sure which of the other ones is the participating laboratory.
Q If you look at the paper, do you see any published results regarding the Shanghai Institute?
A The one named in the paper here?
Q Yes.
A I don't see anything that says it's exclusively from their institute offhand.

(Exhibit 8 was marked for identification.)

BY MS. WOOLSON:
Q Before we get to questions about Exhibit 8, are you aware that the Shanghai Institute

actually found DMAA in Geranium plants when participating in this multi-centre study?

MR. O'NEAL: Object to the form.

THE WITNESS: I don't know that they did.

BY MS. WOOLSON:
Q Look at Exhibit 8 for me, and let me know, first of all, if you've ever seen this before.

(Witness peruses document.)

THE WITNESS: Okay. I don't know that I recall this email chain, but I've read through it here.

BY MS. WOOLSON:
Q Okay, and you would agree with me that in this email chain -- or would you agree with me that in this email chain, the Shanghai Institute is reporting that it detected DMAA in some of its plant samples?
A It would appear that somebody from the institute believes they saw DMAA in plant samples.
Q Before today, were you aware of that?
A I'm not sure, to tell you the truth. I may have heard something about it, but I don't

recall offhand the specifics.
Q When you say you "may have heard," it seems like you have a recollection.
What is it you're recalling?
A There were a lot of discussions about DMAA with various folks over the years, and I don't remember if this was part of a discussion or not, but I remember discussing mass spectrometry data and chromatography data, but I don't remember if this was the subject or not.

(Exhibit 9 was marked for identification.)

BY MS. WOOLSON:
Q I'm going to show you what we've marked as Exhibit 9.

(Witness peruses document.)

THE WITNESS: Yes.

BY MS. WOOLSON:
Q I've shown you what's been marked as Exhibit 9.
A Yes.
Q Have you seen that before?
A Yes.
Q What is Exhibit 9?

A It's the Fleming paper regarding DMAA analysis in Geranium plants.
Q Okay. Now, do you agree that the Fleming study was a validated study?
A As far as the analytical approach for the measurement, it appears to be a valid scientific paper.
Q And what protocol did Fleming et al. follow?
A They used an LCMS procedure.
Q I'm sorry. Let me revise that.
Did they follow a particular organization's method for performing the analysis?
A You mean for performing the actual tests on the samples for the reported values?
Q Let me rephrase the question.
So with regard to reporting detection limits, accuracy, precision, linearity, things like that.
A Okay. For the validation?
Q Mm-hmm.
A Yeah, they reference utilizing the Environmental Protection Agency's methodology for contaminant testing.

Q Have you ever followed that methodology for any of the analyses that you've done in your lab?

A No. We use other methodologies.

Q And how do your methodologies vary from EPA's method, if at all?

A I would have to review the EPA methods again to look at the specific aspects of how they would differ.

Q Are you opining that use of the EPA method was incorrect?

A No, I'm not saying that.

Q In your report in paragraphs 18 and 19, you discuss contamination.

Do you see that?

(Witness peruses document.)

THE WITNESS: Yes.

BY MS. WOOLSON:

Q What facts do you have to -- strike that.

What facts are you relying upon for your opinion that the -- well, first of all, let me ask it a different way.

Is it your -- are you opining that the

DMAA that was detected in the Fleming study is the result of contamination?

A Yes.

Q And what is your factual basis for saying that?

A The larger body of scientific evidence does not report this compound in any of the DMAA -- or any of the Geranium samples tested overall, and in this case they were detected. DMAA was detected at extremely low levels within a range of what we would expect pesticide residues and solvents to be detected in samples, or metal contaminants, and those low levels were not evaluated further and stand as outliers in the larger data.

Subsequent to my report reviewing Dr. Brown's report, she also discusses the metabolic pathways and opines that it's not possible for the plant to make this compound, which supports my understanding of the larger data showing that it's not being detected.

Q So beyond the fact that there are other studies that did not detect DMAA in Geranium plants, and that the concentrations were low, and

Dr. Brown's opinion that there is no metabolic pathway or biosynthetic pathway for DMAA to exist in Geranium plants, any other facts?

A Yes. Dr. Simone reported finding DMAA in plant fertilizers, and suggested that further studies be done by using the fertilizer to grow Geranium plants to see what kind of uptake is involved so that could be ruled out or confirmed.

Q Okay. Anything beyond those four things?

A Not that I recall at this time.

Q Okay. Now, with regard to the metabolic or biosynthetic pathways that were the subject of Dr. Brown's opinion, are you an expert in biosynthetic pathways in plants?

A No, I'm not.

Q And to your knowledge -- I understand you're not an expert in biosynthetic pathways -- has the biosynthetic pathway for every single plant on this planet been identified?

A No.

Q And in fact, there's a lot of biosynthetic pathways for plants that haven't been identified yet, correct?

MR. O'NEAL: Object to form.

THE WITNESS: I'm not sure.

BY MS. WOOLSON:

Q And you yourself have not spent any time looking at the biosynthetic pathways for Geranium plants, have you?

A No, I have not.

Q And with regard to the other studies that you have cited as support for your position that the DMAA in Geranium plants is a contaminant, did those plant samples come from the same region as those studied by Fleming et al.?

A I don't see where they specifically say they were. There are samples included, but they don't indicate the province of where they were located.

Q And which studies have those samples --

A The Khan paper, the Khan/ElSohly paper.

Q Okay. So as you sit here today, you don't know whether those plants came from the same region of China as those plants that Fleming tested and found DMAA, correct?

A Yes.

Q Okay, and we looked at an email

regarding the multi-centre study where Shanghai Institute did detect DMAA in Geranium plants, correct?

MR. O'NEAL: Object to the form.

THE WITNESS: In that email, they said that they thought they found DMAA.

BY MS. WOOLSON:

Q Okay, and low levels of DMAA, that was your third basis.

Do you agree with me that plant species like the Geranium plant -- strike that.

When you did your analysis on Geranium oils, how many components did you find?

A I don't know the exact number.

Q Can you give me an estimate?

A Well over a hundred.

Q Well over a hundred, and what was largest component of the oils that you found?

A The largest components were oxygenated compounds, alcohols, esters, formaldehydes.

Q And roughly, percentage-wise, what percentage of those did they take up of the oil?

A I'd have to look to see exactly, but they were a major percentage.

Q 90 percent?

A I would say over 40, 50.

Q And so you have still 100 components or more in the oil, at least 40 to 50 percent of which are compounds other than amines, correct?

A I'm sorry. What was the question again?

Q You have over 100 components in Geranium oil, correct?

A Yes.

Q And you said at least 40 to 50 percent of those components are chemicals other than amines, correct?

A Yeah, at least.

Q What would be the second largest category of compounds in the Geranium oil?

A It would be other volatile oil constituents, sesquiterpenoids, monoterpenes, things like that.

Q What percentage approximately of the Geranium oil would those comprise?

A I would have to look at that. It can vary widely, depending on the distillation technique and other things. The particular chemotype.

Q And why would the concentration of those compounds vary depending on the distillation procedure?

A The distillation procedure, whether or not it was done as a steam distillation, a hybrid distillation, or with or without vacuum in the altitude could all impact the rate of hydrolysis and composition.

Q Okay. So the technique that you use can affect the composition that you find?

A If you're talking to the way that it's distilled commercially, yes. It can change the ratios.

Q And when you're talking about "chemotype," what do you mean?

A There are a variety of Pelargoniums that are out there produced for different scents, like a rose or citrus or what-have-you, and so there are varieties that have been bred commercially for different types of scent.

Q And so the composition of those different varieties of Geraniums may also be different?

A Yeah, the hybridization.

Q And do you know the chemotypes of the Geraniums that were studied by ElSohly and Khan?

A I believe they were all just rose Geranium.

Q That's the Pelargonium graveolens that we talked about earlier?

A Yeah, there were some other items in there, but I have to refer back to it to see. They may have had a citriodora.

Q And what were the chemotypes of the Geranium plants studied by Fleming et al.?

A I'd have to refer back to the paper, but I believe they were the rose Geranium types.

Q When you say "rose Geranium types," are there more than one type of rose Geranium?

A It's a species that covers the main common essential oil producing, what we call Geraniums Pelargonium. It's all the same species, as far as I know.

Q And that's the graveolens?

A Yes.

Q Just want to make sure we're all on the same page.

So we talked about chemotype. We talked

about distillation.

Anything else that can affect the composition?

A After production and before production, how the material was handled can impact it.

Q In what way?

A There's a potential for oxidative degradation, decomposition that could result in polymerization or the formation of aldehydes or amines. If it's not properly stored and it's exposed to light, you can get photooxidative breakdown products.

Q And would the same be true for plants versus oils?

A For the storing of plants, do you mean?

Q Yes, for Geranium plant.

A Yes, to a degree it would be.

Q Okay. So we were talking about the composition of I guess the sesquiterpenoids and monoterpenes or terpenes of the Geranium oils that you had studied. You said that the percentage of those could vary depending on these things we were just talking about, in terms of the handling and processing of the oils.

Allowing for that variation, can you estimate for me the percentages of those compounds in Geranium oil?

A No, I couldn't.

Q Okay. What's the third largest category of components in Geranium oil?

A I don't know that they would be broken down into further categories. I'd have to look.

Q So there are a number of components in the Geranium oil or Geranium plant, correct?

A Yes.

Q And the largest percentage of those have nothing to do -- strike that.

The largest percentage of those are not amines, correct?

A For the oil, yes.

Q Not true for the plant?

A The plant, I have not seen amines indicated as a major constituent.

Q Now, you said that the concentrations of DMAA that were detected were in the range of -- I think you said they were pesticides or solvents or trace metals?

A Yeah, trace metals.

Q But DMAA is clearly not a trace metal, is it?

A No.

Q And it's not a pesticide, is it?

A No.

Q And it's not a solvent, is it?

A It can be a solvent.

Q Okay. In what circumstances could it be a solvent?

A I would have to look, but it could be involved in an organic synthesis.

Q In what way?

A It could be a -- as a freebase it's a liquid, mobile liquid, and it could be involved in the furtherance of compounds or manufacture.

Q Okay. I think the fourth thing you talked about was fertilizer, correct?

A What's that?

Q I think the fourth factor, the fourth basis for your opinion that the DMAA that was detected by Fleming et al. was a contaminant was fertilizer, correct?

A What I was saying that, that Simone discussed that there were fertilizer studies found

DMAA in, and that it's possible that it could have come from that and should be studied further, yes.

Q And what were the concentrations of the DMAA found in the fertilizer by Dr. Simone?

A I'd have to refer back to the data to see the levels.

Q Why don't you look in your report, because I think you have something in your report.

A I believe I do.

Yeah, these two reported at 8.4 and 8.1 nanograms per gram.

Q And how does that compare with the levels of DMAA that Dr. Simone and Dr. Fleming reported in the Geranium plants?

A I'd have to look back and see what their reported levels were.

Q You can look at Exhibit 5 if that helps.

A They would fall above their detection limit, and according to this table, they would be below the Changzhou S11-1 and the Changzhou 1 samples.

Q You mean the concentrations of fertilizer?

A The DMAA they reported in those two is

higher than the DMAA he reported in fertilizer.
Q And have you done any analysis of fertilizer to determine if it has DMAA in it and, if so, the concentrations?
A No.
Q Are you aware of any efforts by the United States government to analyze fertilizer to determine if there is DMAA in it and how much the concentrations would be?
A No.
Q Are you aware of any work by Drs. ElSohly or Khan to analyze fertilizer to determine if there is DMAA in there and how much concentration there would be?
A No.
Q Are you aware of work by anybody other than Dr. Simone to determine if there's DMAA in fertilizer?
A No.
Q And as you sit here today, you don't have any knowledge of what type of fertilizer, if any, was used on the plants that Dr. Simone and Dr. Fleming analyzed and detected DMAA, correct?
A No.

Q And as you sit here today, you don't have any facts about the growing conditions of the plants in which Dr. Simone and Dr. Fleming detected DMAA, correct?
A Only that they were transferred, according to the paper, from the soil to potted plants and transferred to the institute.
Q Institute?
A In China where they were authenticated.
Q Okay, but you don't know anything about the composition of the soil or the water that was used or the pot that was used, anything?
A No.
Q Okay. Are you aware that Dr. Simone also detected 1,3-DMAA in a Geranium plant that was purchased in the United States?
A I don't recall that.
Q In paragraph 22 of your report, you say that Dr. Simone did not consider his 2012 study -- "did not consider in his 2012 study or his current declaration that the DMAA identified in the limited number of Geranium samples could be a contaminant."
Do you see that?

A And what was the question again?
Q Well, first I just referred you to the paragraph and asked you if you saw that sentence that you wrote.
A What was the sentence again?
Q That Dr. Simone "did not consider in his 2012 study or current declaration that the DMAA identified in the limited number of Geranium samples could be a contaminant."
Do you see that?
A Oh, yeah, the second half of the sentence, yeah.
Q What's your basis for saying that he did not consider whether the DMAA could be a contaminant?
A He did not discuss the potential for it being a contaminant in the paper or in his declaration.
Q So in your mind, the fact that he didn't discuss it means he didn't consider it as opposed to he considered it and didn't think it was worth mentioning?
A What I'm saying is that he didn't address it in his paper or declaration.

Q You also say in your report in paragraph 21 the fact that there was 1,4-DMAA identified in fertilizer also suggests to you a source of contamination.
Do you see that?
A I'm sorry. What was the question on this paragraph?
Q Paragraph 21. I just wanted you to orient yourself, to look at that paragraph.
My question to you is: What were the levels of 1,4-DMAA detected in the fertilizer?
A I would have to go back and look at the data.
Q Do you know if they were higher or lower than the concentrations found in the Geranium plants?
A I don't recall.
Q If you'll now go to paragraph 23 of your report, you say, "In the studies by Li and Fleming, the specimens were not directly obtained by the researchers. Their chain of custody is dependent on third parties in China."
Do you see that?
A Yes.

James P. Kababick

Q As we discussed when we were reviewing the various studies that we marked as Exhibits 4, 5, 6, 7, the vast majority of these researchers obtained their specimens from third parties, correct?

A In the case of the paper by Khan and ElSohly where they obtained them at NCNPR, I don't know that the link of the relationship of those are their past experience of the samples, but there were materials obtained by third parties.

MS. WOOLSON: It's 12:25. Do you want to break now?

MR. O'NEAL: That's fine.

(Whereupon, the lunch recess was taken.)

(Exhibit 10 was marked for identification.)

(Exhibit 11 was marked for identification.)

BY MS. WOOLSON:

Q Are you ready to resume, Mr. Kababick?

A Yes.

Q And you're still under oath.

A Yes.

James P. Kababick

Q I put in front of you what's been marked as Exhibit 10. Take a look at that and tell me if you've seen it before.

(Witness peruses document.)

THE WITNESS: Okay.

BY MS. WOOLSON:

Q So I'm showing you what's been marked as Exhibit 10.

Have you seen that before?

A Yes.

Q And what is Exhibit 10?

A This is the Li paper.

Q And did you read the Li paper at or about the time it was published?

A I believe so, yes.

Q And what, if anything, did you do after you read the Li paper?

A If I'm remembering correctly, I did review this paper and evaluated the data and the validation metrics.

Q And for what purpose did you do that?

A Well, it was reporting the detection of these compounds which was contrary to the larger body of data, and that was a very significant

James P. Kababick

finding, so I wanted to evaluate further the validity of the paper as well as the steps that were taken throughout.

Q And what did you do with that analysis of the paper?

A I did, I believe, discuss that with some colleagues in email communications.

Q And why did you do that?

A There was a lot of interest among many stakeholders in industry about DMAA in Geranium, and we were looking at the various papers that were out and discussing what the findings are and what might be going on.

Q Did you seek to have a consensus statement issued by a particular group?

A Yeah, I believe I talked to -- I'm drawing a blank now. I'm sorry. Mark Blumenthal at American Botanical Council about putting out a statement regarding the findings to date, because so many stakeholders in the industry were then confused about what's going on, because there's all these papers saying it's not there and other papers saying it's present, and what's the consensus of experts that are working in the

James P. Kababick

industry.

Q And was there a consensus statement issued?

A I don't know that there actually was a consensus statement issued, but the botanical adulterants program may have put out a guidance on Geranium. I don't recall.

(Exhibit 11 is handed to the witness.)

(Witness peruses document.)

THE WITNESS: Okay.

BY MS. WOOLSON:

Q Okay. Have you seen Exhibit 11 before?

A Yes.

Q What is Exhibit 11?

A It's an email chain discussing the Li paper.

Q And to whom -- well, let me strike that.

Who is on this email chain?

A It looks like we have Mark Roman, Mark Blumenthal, Joe Betz, John Cardellina, Ikhlas Khan, ElSohly, Anthony Armada, myself, Armstrong, Frank Jaksch and Daniel W. I'm not sure who that is.

Q I think that may be Daniel W. Armstrong.
A Probably.
Q And what is the relationship between all these people on this email?
A All scientists that have an interest in the DMAA issue.
Q How is it that all of you came together in this email?
A Well, many of us have co-served on committees and panels or members of scientific societies that worked on a lot of the methodology in industry today and worked on a lot of the educational outreach, and often communicate with each other about various matters, and I believe this one was related to seeking some input for the American Botanical Council.
Q If you look down on the bottom of the first page, it says, "Jim Kababick has given me permission to send you his detailed comments on the Li paper. He previously sent these to Ikhlas Khan and to Frank Jaksch."
Do you see that?
A Yes.
Q What was the purpose in disseminating

your comments to this wider audience?
A You mean to allow Mark to distribute it to the larger audience?
Q Yes.
A He wanted to get input from various other people on it and to see what they thought of my thoughts, so I said he could share that information and get feedback on it.
Q And did you get responses to your email?
A I don't recall if I got responses to the email specifically.
Q Okay. So let's take a look at what you have to say.
You say you have "some serious issues with the paper."
Do you see that?
A Yes.
Q And the first issue is that you're not familiar with the journal that published the article?
A Yes.
Q And why was that of concern to you?
A I'm pretty familiar with the major journals recognized in our industry and the

journals that typically carry the information related to discoveries of natural products and such. This journal, I had never seen any natural products research published related to the work in our industry before.
Q And so is it your position that the article is somehow less worthy because it wasn't published in a journal of which you are familiar?
A I don't know that I would say that. I would say that journals accept or decline articles on a number of reasons, and a journal like Journal of Agricultural and Food Chemistry, which has a very high impact rating, will pick the best of the best science to publish, and often the submission to journals who will accept the paper and publish it doesn't necessarily have to do with the accuracy of the data, but it has to do with the overall caliber of the data among peer reviewers.
Q And as you sit here today, do you have any information about the peer review process for the journal that published the Li paper?
A What I understand is that you can refer peer reviewers for your paper and that they guarantee rapid publication upon acceptance, and

following these papers, there was a large exposé on pay-to-publish journals, and many, many papers of credible or thought to be credible scientists have been discredited, and so pay-to-publish journals are under a lot of scrutiny by scientists and academics right now.
Q As you sit here today, do you know who peer-reviewed the Li article?
A I do not.
Q And as you sit here today, you say a lot of the pay-to-publish journals have been discredited.
To your knowledge, is Analytical Chemistry Insights one of those?
A I'm not sure.
Q What would you need to do to be sure?
A I would have to check some of the academic watchdog groups that monitor the journals and see if anything has come up on those lists.
Q If that were the case, would you have included that in your report?
A Pardon me?
Q If it were the case that Analytical Chemistry Insights has come up on this list of

questionable publications, would you have included that information in your expert report?

A Yeah, if I had that knowledge, I would have included it.

Q The second comment that you have about the report is that you don't understand -- and I'm paraphrasing -- you don't understand why the Li authors made the statement that they are not aware of any publication that identifies 100 percent of the oil content.

Do you see that?

A Yes.

Q And it seems to me you agree that no one has identified 100 percent of the oils content, so I'm not sure I understand why this comment bothered you.

A I would have to look at what this was speaking to specifically in the paper to see what this was regarding, because I don't recall specifically.

Q Well, in the paragraph you say, "I know of no credible scientist that would report the values of zero percent or 100 percent in analytical chemistry."

Do you see that?

A Yes.

Q And why is that?

A Because those are hypothetical states, essentially, in analytical chemistry.

Q And why is that?

A Because you can't be absolutely sure that there's not at least one molecule present or one molecule absent of something.

Q Okay. In comment number 3 you talk about the chromatography column that was used, and you say that you would "expect resolution issues and possibly other chromatography problems from an overload."

Do you see that?

A Yes.

Q Did you make any attempt to replicate the conditions in the Li study to see if there were chromatography problems or resolution issues?

A No, I did not.

Q In paragraph 4 you say you would have expected some "decomposition and formation of aroma chemical compounds that are amine-like in nature after a long travel from China."

Do you see that?

A Yes.

Q Why were you asking if it was unusual?

A Where I say "do you see this as unusual"?

Q Yes.

A Having worked with lots of fresh material shipped from other countries, it is very hard to get fresh material into the US without delays such that usually, when it comes in, it is compromised. Even an extra day delay can cause issues unless it's shipped on dry ice or kept cold another way.

Q Okay, and the decomposition that you're referring to, is that a natural process or phenomenon?

A It can be.

Q Okay. In the fifth paragraph you say that the standard for DMAA was purchased from Sigma.

Do you see that?

A Yes.

Q Isn't that where Drs. Khan and ElSohly purchased their sample -- their standards as well?

A Yes. I don't know if it's the same catalog number, though. I have to go back and check.

Q Okay. In paragraph number 6 you say, "I find the chromatographic separation, even for a fused core column, to be remarkable, considering I can't fully baseline resolve these diastereomers on a GC column with full baseline resolution (unless derivatized)."

As of the date that you had sent this email, which looks like August 9, 2012, when was the last time that you had attempted to resolve the DMAA diastereomers?

A Resolved on a GC column?

Q Yes.

A I don't recall.

Q Have you, in fact, tried to resolve the DMAA diastereomers on a GC column?

A Yes, I did work on that, and I got the diastereomers almost baseline resolved.

Q What were you using as the source of the DMAA when you were doing this work?

A I had isolated some from trade material, commercial DMAA being proffered to industry that I

obtained, and also standard from ChromaDex, and I also obtained the CPR standard from Sigma, the uncertified one.

Q And were you doing this work for a client?

A Actually, it was for a method development for client services, yes.

Q When you say it was "method development for client services," do you mean it was work that you were doing to develop a method for a specific client?

A No. It was for developing methodologies to offer to clients.

Q And has Flora offered -- strike that. Have you developed such a method and now offer it to clients?

A We currently offer the analysis of compounds or mixtures to detect the presence of DMAA. We're not right now quantifying DMAA.

Q Is there a reason why you're not quantifying DMAA?

A There's not enough demand right now for that.

Q So you haven't developed a method to do

that?

A No. I have a method developed to do that.

Q You just don't offer it commercially?

A Right.

Q Okay, and when I asked you about resolving the diastereomers on a GC column -- well, I asked you about resolving the diastereomers on a column, and you said GC.

Have you done other work with regard to the DMAA diastereomers in attempting to resolve them?

A Yes. I've run it on liquid chromatography, too.

Q And was the source of the material the same, trade material?

A Yes, the three materials that I mentioned.

Q In paragraph 9 you talk about "the addition of .1 percent formic acid."

Do you see that?

A Yes.

Q Did you do any work to determine if there was any shift in the retention times caused

by the acid?

A No, I did not.

Q In paragraph 11 you talk about working in the "pesticide residue chemistry area."

What work have you done in pesticide residues?

A We developed special methods for the analysis of trace residues in ginseng and botanicals, and I have collaborated, through the AOAC, on methodology with the Food and Drug Administration's -- what's the acronym? Not CDER. CFSAN, Center for Food Safety and Applied Nutrition with Dr. John Wong and Alex Krynitsky.

Q In the same paragraph you go on to say, "They may be the luckiest chemists ever. The data is extremely tight, and this data is not consistent with the work by Horwitz, which shows that accuracy and precision are empirical function of the level of analyte in the matrix."

What did you mean?

A Dr. Horwitz was a statistician and editor for the official methods of AOAC International. He was awarded the Priestley medal for his work in developing what's called the

HorRat equation. He had hypothesized that as technology advanced, that he would see precision and accuracy improve over time. So if we looked at older methods to measure something and newer methods, the newer methods would have tighter precision and accuracy.

What he found out was that never changed. Precision and accuracy were always a function of the analyte concentration and matrix, and so much so that he developed a formula that will give you the approximate window for performance.

In this case, these precision and accuracy data points are extremely tight compared to what one would expect for the working concentrations being measured, and so it is unusual, because, according to 130, 140 years of research data, statistical studies, you shouldn't be able to get that.

Q Have you seen other studies where the values are better than what would be predicted by Horwitz and his equation?

A I have. Some of those, I should say, were fabricated.

Q And how do you know they were fabricated?

A Further work and investigation yielded that information.

Q Okay, and as you sit here today, do you have any facts to suggest that the Li results were fabricated?

A I do not.

Q Okay. I just want to go back to the question I was asking you about quantification of DMAA. You said that that is not a service that you offer for clients.

Have you, in fact, attempted to quantify any DMAA in any substance?

A We did do some of that work in the past, but it rapidly dropped off with the, you know, removal of DMAA from products. We didn't pursue it.

Q Do you agree with me that it is possible for racemic mixtures to be created naturally?

A Some.

Q Now, at the end of your analysis -- it's on the page marked ElSohly 2630.

A Yes.

Q You say, "Considering that one of the authors declares in the paper that he provided expert witness services for the company funding the study, I feel it is even more critical to emphasize why they are the only group that was able to obtain samples of oils and botanical materials that had DMAA when all other researchers were unable to do so."

Do you see that?

A Yes.

Q And in your mind, what relevance is it that one of the authors provided expert services to a company funding the study?

A Your question was why -- I'm sorry.

Q Of what significance is it to you that one of the authors of the study was providing expert witnesses for the company who funded the study?

A Well, there is a claim by USPlabs, if I'm correct, that Geranium is a natural source of the compound. The only scientist who really come out and show that in the plant were Li at this point, and he also was helping them as an expert witness in that aspect. And therefore, the fact

that his data goes against the larger body of scientific evidence, and he's working with a group arguing this naturalness, that I think it's really important to establish, you know, exactly why he feels nobody else could see that material and what's going on there.

Q Okay. This is Exhibit 4, the ElSohly 2012 study.

A Yes.

Q Is that study funded by the FDA and the NIH?

A It says it was supported by the U.S. Anti-Doping Agency.

Q Okay, and who are the co-authors on the paper with Drs. Khan and ElSohly?

A There's Waseem Gul, Kareem ElSohly, Timothy Murphy. I'm going to maybe have trouble with this name. Aroona Weerasooriya. Then Amar Chittiboyina, Bharathi Avula, Ikhlas Khan, Amy Eichner and Larry Bowers.

Q Who is Amy Eichner?

A Amy Eichner is a scientist at USADA.

Q And who is Larry Bowers?

A I believe he is also a scientist at

USADA.

Q And to your knowledge, has Dr. ElSohly acted as an expert witness for USADA?

A I'm not sure.

Q To your knowledge, has Dr. Khan acted as an expert witness for the United States government?

A I believe he has, yes. He did an expert report for this case.

Q If you'd turn now back to Exhibit 11 and specifically to page ElSohly 2633, there's an email that starts on the bottom of that page, and it carries over to 2634.

A I'm sorry. Which page?

Q 2633.

A Oh, the one for Mark Blumenthal?

Q Yes.

You see where it says "Jim K. has suggested a possible consensus statement on this matter, possibly coming from ABC"?

A Yes.

Q And that was the consensus statement we talked about earlier this afternoon?

A Yeah, the one about the various papers

and the synthesis of all the data, yes.
Q And you see right above that email, Joseph Betz says that he "doesn't think a consensus statement would be useful just yet"?
A Yes.
Q Did you have any conversations with him about why he didn't think that would be useful?
A I don't recall any.
Q Okay. Let's go back to your report, Exhibit 1. In paragraph 19, you're discussing the possibility of foreign DNA in plant samples.
Do you see that?
A Yes.
Q And you cite to a paper by Newmaster, Ragupathy and Hanner, right?
A Yes.
(Exhibit 12 was marked for identification.)
BY MS. WOOLSON:
Q So this is Exhibit 12. Take a look at that and let me know when you're ready to proceed.
(Witness peruses document.)
THE WITNESS: Okay.

BY MS. WOOLSON:
Q So this paper discusses next-generation sequencing, correct?
A Yes, of botanicals.
Q And it discusses the problem of incidental DNA in next-generation sequencing, correct?
A Yeah, the problem with incidental DNA, meaning DNA that shows up, or fragment DNA that shows up that is linked to a certain botanical species.
Q And the studies that were run by Dr. Fleming and Dr. Li had nothing to do with next-generation sequencing, did they?
A No.
Q And they weren't detecting DNA, were they?
A Not in those studies, no.
(Whereupon, a short recess was taken.)
BY MS. WOOLSON:
Q Back to your report.
A Yes.
Q In paragraph 25 you say -- well, are you

there? You say, "Dr. Simone also failed to utilize other available analytical techniques to gain additional evidence about the naturalness of DMAA in the Geranium samples studied, such as isotope ratio mass spectrometry."
Do you see that?
A Yes.
Q First of all, what information would you expect to get from running isotope ratio mass spectrometry?
A Isotope ratio mass spectrometry would give you the ratios of different carbons, carbon 12 and 13, 14. It could also give you isotope data on other elements such as hydrogen and oxygen. The goal is to determine if a compound has an isotope ratio consistent with a plant source or a Petra chemical source. It's used extensively in authenticating natural products that are also available synthetically.
Q What is the difference in the ratios between plant and synthetic?
A I'd have to look it up. It's calculated against Pee Dee Belemnite and expressed in a percent-percent basis, so the data is compared to

these, and then you run a formula to compare those.
Q And I take it, as you sit here today, you did not run isotope ratio mess spectrometry on any Geranium plant samples, did you?
A No.
Q And would you run the isotope ratio mass spectrometry on the sample itself or like on a, just a ground-up sample of Geranium plant, or would you process the sample somehow?
A You would prepare the sample, and depending on what analysis you were going to do by isotope ratio, I would either prepare it by isolating and purifying the compound or setting it up in a volatile state where it could be separated by gas chromatography.
Q When you say "isolating the compound," what compound are you talking about? DMAA?
A Yeah, whatever compound I would want to study. The most recent one I did was on caffeine.
Q To your knowledge, has anyone run isotope ratio mass spectrometry on Geranium plants?
A Yes. I believe that there have been

analyses conducted on constituents of the oil.
Q And by whom?
A I'd have to review the literature again.
Q And were any of those constituents DMAA?
A Not to my knowledge.
Q In the next paragraph you say, "They failed to conduct the necessary additional studies needed to show that the compound is plant-derived and to rule out likely contamination sources."
Do you see that?
A Yes.
Q Leaving aside the isotope ratio mass spectrometry that we just discussed, what necessary additional studies are you referring to?
A What I would do in this case, in addition to IRMS on the compound, is to get a larger population of samples to see what percentage in a larger population the material appears, and multiple replicates of samples, so from each region, additional samples. And if the material seemed to be only in certain samples, I would further evaluate what might be the source of the contamination.
Q Okay, and is there a particular

guideline or methodology that prescribes these additional studies, or is that simply your opinion of what should be done?
A It's considered basic good scientific practice, if you're identifying a compound that is generally considered not to be occurring naturally in a product, to explore that further and make sure that that compound actually is coming from the plant and not a byproduct of degradation, contamination or anything like that.
Q My question was: Is it set forth in a particular methodology or procedure or guideline that those are the steps that need to be taken?
A Not that I can recall offhand.
Q And those steps that you've just identified for us, you didn't do any of those steps, did you?
A No.
Q And Dr. Brown didn't do any of those steps, did she?
A I'm not sure if she did.
Q You read her expert report?
A I did.
Q Did you see anything like that in her

expert report?
A I don't recall that I did.
Q Did Dr. Khan do any of those studies?
A I'm not sure that he did.
Q Now, you talked about replicates. How many replicates did Drs. Fleming and Simone do?
A I'd have to refer back to the paper.
Q Okay. You can. It's Exhibit 9.
A It looks like in some cases from a given region, they collected or tested two samples. In other cases, one. The samples were made up by mixing a variety of plants together, which they say is two to ten mixed up together. They weren't individual plant specimens.
Q Okay. As part of your -- as part of the preparation of your expert report, did you review Dr. Simone's studies on the derivatization of 1,3-DMAA and 1,4-DMAA?
A You mean the GC or LC derivatization for analysis?
Q Yes, using I think it's called FLEC.
A Yes, I believe so.
Q What factors can affect the concentrations of analytes in plants?

A Is there a specific analyte class that you're looking at, or levels?
Q Just generally.
A Generally, broadly speaking, this would, of course, vary tremendously with what the analytes are, their concentrations and other variables, but how they are collected, how they are grown and collected, how they're stored, how they're processed, those would all be factors.
Q What about the environment in which they're grown?
A Yes.
Q What about the season in which they're harvested?
A That could.
Q What about the soil in which they grow?
A Yes.
Q What about the weather? I guess that would be environment, so --
A Right.
Q Okay, and as you sit here today, do you have knowledge about any of those factors for any of the Geranium plants that have been studied, whether by Dr. ElSohly, Dr. Khan, Dr. Lisi,

Dr. Fleming, Dr. Li?

A Only the mention that there were summer and winter harvests in the one paper.

Q Beyond that, nothing?

A Not that I recall.

MR. O'NEAL: Which paper?

THE WITNESS: The Li and Fleming paper.

BY MS. WOOLSON:

Q We've talked a lot about --

A Yeah, the -- am I getting my papers mixed up? The Fleming and Simone paper. Let me see if I got my wires crossed here.

I believe one of the papers refers to seasonal harvest, but I need to check that, see which one it was here.

Yeah, "during three harvest seasons," yeah, so it's the Fleming/Simone paper here.

Q Okay. We've talked at various points today about something called the AOAC.

What is that?

A The AOAC is a professional scientific society that is a group of scientists and interested parties that collaborate, cooperate to

develop analytical methods and put those methods or promulgate those methods out to industry.

Originally, a long time ago, AOAC was part of the FDA. It was a society within the FDA many years ago. It was privatized and is now an independent entity, and it includes scientists from all over the world.

The organization manages the official methods of analysis which are recognized under the C.F.R. as official test methods and are used all over the world, and when methods are needed and there's a call for methods, the call goes out, experts are assembled, and methods are evaluated and taken to different action statuses.

The process has changed over time because of the rapid response needed to changing global conditions, but they have what are called "official methods, first action methods," and then there are methods that meet what they call "standard performance requirements" or "SPM methods," and these cover all kinds of things from fertilizers to infant formula, vitamins, to, you know, water testing and food and supplements and pharma. That's pretty extensive.

Q And when you say "when a call goes out for a method," who is making -- who is sending out the call?

A The call could be stakeholders. For instance, recently, Mead Johnson, makers of infant formula, they wanted to get a unified method for analyzing the level of nutrient vitamins in infant formula, and that was using a more modern technique, and they sponsored the development of a method along with some other infant formula companies.

Q So stakeholders who have an interest in developing the method can send out the call and then sponsor the work?

A Yes, or sometimes it will come from regulatory, there's a need, or maybe part of a clinical research project, there might be a need to develop a method.

Q Okay. So, for example, FDA could send out a call saying we need to develop a method to do X, or NIH could send out a request and say we need a method for Y?

A Yeah, and then normally these are based on the input of what's called the IRS, the

Ingredient Ranking Subcommittee. So for the dietary supplements, this committee has been charged with determining what the priority order is for methods that might need to be developed, and that can be rearranged over time. That depends on what's going on in the market and things like that.

Q Okay. I just wanted to clarify something. You said "IRS." You didn't mean the Internal Revenue Service?

A No, no.

Q Because it didn't make any sense.

MR. O'NEAL: He said what the letters were.

THE WITNESS: Ingredient Ranking Subcommittee.

MS. WOOLSON: I heard "IRS," and I was like, what?

MR. O'NEAL: We'll stipulate that the Internal Revenue Service should not be involved.

THE WITNESS: Yes. I think that was not the best choice for an acronym.

(Exhibit 13 was marked for identification.)

BY MS. WOOLSON:

Q You don't have to read the whole thing. You can, but you don't have to. The questions will be targeted.

MR. O'NEAL: We'll be adjusting our travel schedule.

THE WITNESS: Yes.

BY MS. WOOLSON:

Q Have you seen Exhibit 13 before?

A Yes.

Q And what is it?

A This is Appendix K, which are guidelines for dietary supplement and botanical methods.

Q And these are guidelines issued by whom?

A They are issued by the AOAC.

Q Okay, and if you could turn for me to page GOV-031203.

A Yes.

Q At the bottom of that page, there's a paragraph right above the table that says "Data Acquisition."

Do you see that?

A Oh, on the right side.

Q "Data acquisition follows the sample preparation step and requires advanced analytical techniques, as the ultra-complexity of samples for metabolomic analysis makes it impossible to technologically separate, quantify and identify every metabolite within a biological sample."

Do you see that?

A Yes.

Q Do you agree with that statement?

A I would say in the context of top-down metabolomic pathway studies, yes, as this is talking.

Q When you say "top-down metabolomic studies," what do you mean?

A That's the studying of metabolic plant pathways by looking at a variety of compounds and data-mining those compounds using chemometric modeling.

Q And to what end I guess is the question.

A Tracing the pathways by which metabolites are produced in the plant.

Q And if you turn to the next page, there's Table 2, and it's got listed some standard

techniques that are used in metabolomic analysis.

It's Table 2, not Figure 2.

A Oh, sorry. You have a question regarding the --

Q I do.

So on Table 2 there are various techniques that are listed for analyzing compounds, and this morning I was trying to ask you, in a very inarticulate fashion, questions about NMR versus mass spec, so hopefully this table will help me ask a more articulate question of you.

So looking at the table, it says for the technique of NMR, nuclear magnetic resonance, it's "low sensitivity."

Do you see that?

A Yes.

Q And then for gas chromatography mass spec, it says "high sensitivity."

A Yes.

Q And for LC mass spec, it says "medium sensitivity."

A Yes.

Q What is your understanding of what this

table means regarding sensitivity and why NMR is low sensitivity versus mass spec methods?

A In this, related to metabolomic analysis, the NMR, the way it's being referenced here, to my understanding, is looking at an extracted sample. You have in that sample multiple components as a -- we call Gestalt. They're all together at once. You're getting all the signal from everything that responds to NMR, where GC/MS and LC/MS involve some degree of chromatographic separation of the compound, so you're now getting compounds separated from other compounds.

Q And when you're talking about separation of compounds, does that mean that you are somehow performing an action on the initial product or substrate in order to effect that separation?

A I'm not sure I understand.

Q Sure.

You're talking about separating compounds in LC and mass spec.

A Yes.

Q And so my question was: Does that mean that you're operating in some way upon the

original substrate in order to effect that separation?

A You're operating on whatever you prepared for analysis, which could be a simple extraction from something like into a solvent, but even then, one must keep in mind that that's somewhat selective. You don't put -- if you're working directly with plant material, not everything is going to go into solution, so you're always getting some kind of bias in what you're seeing, but once you get onto the instrument, whatever you have put on the instrument, the goal there is to get separation.

You don't always get separation of everything. It depends on what the detector can detect, what separates on the column and their concentrations.

Q So it depends on the conditions that you're employing?

A Right, partly, yes.

Q Okay. Do you agree that the guidance that the AOAC and similar organizations publish are simply that, they're guidance?

A In general, they're guidelines, yes.

Q So that other approaches may be used if they're deemed to be appropriate?

A Yes, that is the case.

Q Do you agree that some compounds that are characterized as drugs can still be naturally occurring compounds?

A When you say "categorized as drugs," do you mean that they are compounds that are recognized as pharmaceutical drugs by FDA?

Q I don't know.

(Exhibit 14 was marked for identification.)

BY MS. WOOLSON:

Q I'm showing you Exhibit 14, which I think you will recognize is an article that you authored.

A Yes.

Q Okay. So this was an article that you wrote about yohimbine?

A Yes.

Q I think I said that right.

A You did.

Q And my understanding is that it has been categorized as a scheduled prescription drug in

several parts of the country, but yet it is also something that is a natural product; is that --

A Yohimbine hydrochloride is a monograph drug in the United States Pharmacopeia, and it is recognized as a drug by FDA, as far as I know. The yohimbine in yohimbine bark is in the freebase form. It's a freebase form, the difference being the salt moiety and the source of the material.

Q And can you take the freebase yohimbine in the bark and then make it rather easily into the prescription drug that we're talking about?

A You could turn it into a hydrochloride salt, which would have the same structure as the pharmaceutical form.

Q Okay. So when I asked the question earlier about can something that is a prescription drug also be naturally occurring, it was in the context of this article that I was asking that question.

So with that in mind, what is your answer?

A It could be the same molecular compound as far as structure goes, yes.

Q Let's go back to Exhibit 2 for a minute.

It's the email that we talked about this morning.

A Yes.

Q In your email that is Exhibit 2, you start the email by saying, "Dear colleagues and remaining friends who don't yet hate me for pointing out dangerous supplement issues."

Do you see that?

A Yes.

Q What dangerous supplement issue were you trying to point out in this email?

MR. O'NEAL: Object to the form.

THE WITNESS: I think in this particular thing what I was speaking to is in general, when I brought up concerns about supplement issues, which most of them have been related to phosphodiesterase 5 inhibitors, Sibutramine and analogues of Sibutramine and contaminants such as getting the wrong species mixed up, it's toxic, that kind of thing.

And then in this case we were looking into the reports on the Forthane DMAA safety issues, and so I was pointing that out in the larger general sense.

BY MS. WOOLSON:

Q Okay. In the next paragraph you say, "In my continuing argument that DMAA (a/k/a Geranium, a/k/a methylhexaneamine) is a drug with dangers," and then you continue on.

How long have you been making that argument?

A As far as that there could be potential dangers with methylhexaneamine?

Q Yes.

A I don't know the specific amount of time. When the issue started coming up, I started looking into it, but I don't have a time window, to tell you the truth.

Q Can you estimate? Was it five years, ten years?

A Oh, no, I don't think anything like that.

Q Okay, and what --

A This was all rapidly happening at the time.

Q Okay. So the use of the term "continued argument" suggests that there had been preceding argument.

Do you recall what, if any, steps you had taken before this email?

A I don't actually recall specifically what I did. I don't have a good recollection of all the timing of how this played out, because it was so long ago.

Q Okay. You're not a physician, correct?

A No, I'm not a physician.

Q And as you sit here today, are you opining about the safety of DMAA?

A No, I'm not opining on the safety.

Q Now, at the end of your email you say, "Finally, if I turn out to be wrong about this, and methylhexaneamine is actually found in Geranium oil as per the Ping paper and confirmed using mass spec and IRMS to be natural and authentic, I will be happy to be the first person to publish a correction to my position."

Do you see that?

A Yes.

Q Did you publish anything to change your position after the Li and Fleming papers were issued?

A No, I did not. They did not meet the

requirement here.

Q And in what way did they fail to meet the requirement?

A They didn't use isotope ratio mass spec, and the papers, while they identify the presence of DMAA, they don't confirm that it's a naturally occurring material.

Q And again as you sit here today, you don't have any information about the conditions of the plant, the treatment of the plant, the handling of the plant samples, nothing, correct, beyond what's in the papers?

A Beyond what's in the papers, no.

Q And as you sit here today, you don't have any facts to demonstrate that the plants were contaminated with DMAA beyond the fact that there are studies that don't find DMAA, and there are studies that do find DMAA?

A Well, actually, no. After reading Dr. Brown's report that states -- her expert report that DMAA can't be made by the metabolic pathways in Geranium, it supports my position that it must be a contaminant, because there's no other explanation.

Q Again, you're not an expert in biosynthetic pathways, correct?

A No. I'm relying on her expertise, which I have no reason to question.

Q And you've already testified that there are many biosynthethic pathways for plants that have not yet been identified, correct?

A I would imagine there are.

Q And do you know what steps, if any, Dr. Brown took to identify potential biosynthethic pathways?

A I'm not familiar with that. I'm solely relying on her expertise in the field.

Q And when you had issued this report that you've been looking at as Exhibit 1, had you read Dr. Brown's report by that time?

A No, I didn't read her report until after I did my report.

Q What, if any, reports had you read when you drafted your report, other than Dr. Simone's?

A Dr. Simone's and Dr. Heuer's, I believe. Yeah, Heuer. I read these two reports, and I think I may have read something from Dr. ElSohly, too. I'm not sure, or am I thinking of the paper?

I'm not sure.

MR. O'NEAL: Are you talking about expert reports?

THE WITNESS: There was -- I think I may be thinking about his paper. There were these two expert reports I read, and then after I did my report, I was provided with Dr. Brown's and Ikhlas Khan's report and read those following it, but I read Dr. Simone's and Dr. Heuer's, and I reviewed the other documents related to the case, the papers and articles and things.

(Exhibit 15 was marked for identification.)

(Witness peruses document.)

THE WITNESS: Yes.

BY MS. WOOLSON:

Q You've seen Exhibit 15 before?

A Yeah, it looks like an email communication that I sent, and this article is -- looks like it's from Wall Street Journal, possibly.

Q Okay. This email that you sent, you sent to William Martin at FDA. It looks like a

group called "ORAHQ, ORS Management at FDA."

What group is that?

A That would be the Office of Regulatory Affairs Headquarters Management.

Q And why were you communicating with them?

A I don't recall why we were communicating regarding this.

Q Okay, and you also sent it to the ORA lab directors?

A Yes.

Q And you CC'd Daniel Fabricant, correct?

A Yes, it appears so here.

Q When you look at the email, it says, "I've had a chance to review the embargoed paper and saw those two erroneous hits, and the MS data did not support it, in my opinion."

What embargoed paper are you talking about?

A That I'm not sure. I remember looking at embargoed paper, but I do not recall whose paper it was. I've looked at some articles that were embargoed, given an opportunity to review and comment before it went to press, and also was

asked to peer-review additionally a paper because of my familiarity with DMAA, but I don't know if this was Armstrong's paper or the joint collaborative one with ElSohly and Khan.

Q Did you peer-review either one of those papers?

A I reviewed them at the request of the authors prior to their release, but not actually through the journal process as a primary reviewer, as a final reviewer.

Q And the ElSohly study that you reviewed; was that the multi-centre study?

A Yes.

Q And when you reviewed the multi-centre study, did you have benefit of the information that we discussed today about the Shanghai Institute and its detection of DMAA?

MR. O'NEAL: Object to the form.

THE WITNESS: I'm not sure exactly what data was provided, but I remember there being some raw data to look at and evaluate.

BY MS. WOOLSON:

Q Okay, and as you sit here today, you don't know what embargoed paper this email is

discussing, correct?

A Not exactly, but I think it would be one of those -- let me see here. I'm not sure if this article is linked to this communication or not.

Q You see further down in the email it says, "Regardless, I was very pleased the final paper did not have that data."

Do you see that?

A Yes.

Q Why were you pleased that the final paper did not have data in it?

A In particular, I believe this is addressing some data that suggested DMAA was present, but in looking at the spectral data, the mass spec data was not matching, and in one case the data that I looked at, the signals were below detection limits of the method, so in those cases you can't make a scientifically valid call that that's DMAA.

Q And so you think that omitting the data altogether from the paper is appropriate?

A I think that not saying that it's a compound when you're below the level at which you say you can detect the compound is appropriate.

Q Well, that's not what my question was. My question was: Do you think omitting the data from the paper is appropriate?

A It depends on how it would be presented. The way it was, yes, because it was making an inaccurate, unscientifically supported claim.

Q How is presenting data making an inaccurate and unscientifically supported claim? The data is the data, is it not?

A Well, when you present it saying that it identifies a compound that you're unable to actually empirically confirm that, then that's misrepresenting the data.

Q But I think you're taking my question further than my question went.

My question was simply: Do you think omitting the data, not making any conclusion, but omitting the data entirely from a paper just because it doesn't fit, is inappropriate?

A I'm not sure if you're speaking specifically to this mass spec data or in general as a practice.

Q Well, let's say in general as a practice.

A And when you say the data "doesn't fit," is that that you determine it's not valid data?

Q No, that it doesn't fit your conclusion.

A Well, how would it not fit the conclusion?

Q Well, if you're concluding that there's no DMAA in a plant, for example, and you find data that suggests there is DMAA in a plant, that would not be consistent with the conclusion, right?

A In this hypothetical situation, just so I understand, are you saying that the findings are empirically supported by the methodology or that -- because in the cases that I recall looking at, it was like taking noise from a radio and saying, oh, I hear the same frequencies that I hear in this Michael Jackson song, so that must be the Michael Jackson song. You can't say that, because you're in the noise.

My concern with this was that signal was in the noise, which is the level at which, as scientists we say, as analytical chemists we can't actually say what this is scientifically, and therefore we don't name this compound, because it's not able to be named. And in the one case,

it was missing critical ions, so it didn't even look like the compound.

So, yeah, I would say definitely in that case.

Q In that case, okay, but if you detect something or you may detect something within the noise level, shouldn't you go back and do more studies to confirm whether it's there?

A It depends on what you detect and what's going on and what your scope of the application is. So if you're looking to say whether or not you're seeing something at or above a certain level and you're seeing it at that level, that's one thing. If you're seeing it below that level and you'd like to change your method and redevelop it to go lower, you could opt to go back and study it further.

Q Wouldn't you want to do that if you wanted to know for sure whether something was there or not?

A It depends on what the goal of the method is. It depends on what the scope is and what levels you're trying to achieve.

Q And again as you sit here, and having

looked at this Exhibit 15, it doesn't refresh your recollection about what article you were reviewing?

A I don't recall with absolute certainty.

Q And what would you need to look at to recall with absolute certainty?

A If I had the article, that would be great, or the data.

Q The end of the sentence, you say, "The lack of authentication means they could have been testing adulterated oils, and I see more adulterated Geranium EO than clean EO in today's market."

Do you see that?

A Yes.

Q Is your comment based solely on the fact that you think that the oils were not properly authenticated as opposed to what the results of the study were?

A Yeah, the -- my concern is, in my research on essential oils I have seen over the years multiple papers discussing the chemistry of oils, and in some cases they were naming compounds which are known to be absolutely synthetic, and

they were making decisions based on the assumption that what they had was natural when they didn't have it.

And the NIH established expert panels, which I was involved in, to help researchers make sure that they are doing clinical research on natural products that are actually the natural products they think.

So it's very important to have a good chain of custody and authentication on materials, because if you're going to make a conclusion about something present and you don't know if the material has been tampered with, that could be a concern.

Q Well, authentication of samples is different than tampering with samples, is it not?

A Authentication would be the process of determining if the material appears to be an authentic material. Tampering would be the process of modifying that material.

Q Right. So they're two different things?

A Yes.

Q Okay, and as you sit here today, do you have any facts to suggest that the Geranium plants

that were examined by Drs. Li and Fleming were tampered with?

A Tampered with in regard to deliberately adulterated, no.

(Whereupon, a short recess was taken.)

BY MS. WOOLSON:

Q Mr. Kababick, I may have asked you this, and if I did, I apologize for asking it again.

This morning you testified that you had done some DMAA testing on extracts of Geranium plants.

Do you remember that testimony?

A Yeah, there were materials sent to me that were reported to be Geranium plant extracts, but I didn't know for sure if they were Geranium plant extracts.

Q With regard to these, the extracts in which you did detect DMAA, did you do that isotope mass spec ratio that you discussed earlier?

A No, I didn't, because my goal in that was just to see if it was DMAA and in one case what levels were there, so it wasn't necessary.

Q And I take it then you didn't do any

carbon 14 dating analysis that you discussed this afternoon either?

A Yeah, that's isotope ratio. Same thing.

Q Sorry. My chemistry days are long gone.

When you determined the DMAA in those extracts, did you attempt to determine the diastereomer ratio?

A No, I didn't.

(Exhibit 16 was marked for identification.)

BY MS. WOOLSON:

Q Showing you what was marked as Exhibit 16.

(Witness peruses document.)

THE WITNESS: Okay.

BY MS. WOOLSON:

Q Have you seen Exhibit 16 before today?

A I don't recall if I have.

Q This is a publication from the New Zealand government, correct?

A It appears to be so, yes.

Q You see on page 3 of 8, the last paragraph, it says, "Evidence suggests it is likely that DMAA does occur naturally in Geranium

plants"?

A Yes.

Q Have you been asked to comment on the New Zealand government's publication saying that DMAA -- the evidence suggests that DMAA naturally occurs in Geranium plants?

A I don't recall that I have, actually.

Q And you haven't discussed that with any of your colleagues at AOAC?

A I don't recall specifically discussing this.

Q If you could turn back to Exhibit 1, which is your report, please, and I'm on page 17.

You see under "Expert Report" you list Dr. Brown's report?

A Yes.

Q So does that refresh your recollection about whether you had looked at Dr. Brown's report before you prepared your report?

A I definitely did not.

Q You definitely did not look at Dr. Brown's report?

A No. I drafted my report, and I -- before I finalized my report, I reviewed

Dr. Brown's report and Ikhlas Khan's report. I had not reviewed them prior to drafting my report.

Q But you did review it prior to finalizing your report?

A Yes, and I made no changes.

Q So you didn't include anything about Dr. Brown's biosynthetic argument, did you?

A No, I did not.

Q And if you could go back to page 3 of your report, paragraph 4, you say, "As one of the leading experts in my field."

What is the basis for that statement?

A I'm recognized as an expert by the Food and Drug Administration, National Institute of Health, AOAC International, and the United States Pharmacopeia have appointed me to the Council of Experts.

Q When you say you're recognized as an expert by FDA, what do you mean?

A It means that I satisfied the vetting requirements to serve as an expert on FDA-funded committees in AOAC.

Q FDA-funded committees in AOAC?

A And also that they recognize my work in

clandestine and drug adulteration analysis for detention samples.

Q And when you say you were vetted by the FDA, what does that involve?

A The AOAC has to review candidates for the appointments, and they compare that to what FDA expects of an expert to serve in those funded committees.

Q What does FDA expect of an expert in those funded committees?

A They have to have knowledge of the chemistry of the compound's analytical techniques, validation techniques, and experience in the analysis of various components.

Q And is the vetting the same for NIH?

A It's similar.

Q In what way is it different?

A Depending upon the position at NIH, you may or may not need certain types of grant review experience.

Q And do you have to meet with or interview with anyone from FDA or NIH in order to be considered an expert?

A No. I just had to fill out an

application and submit my CV, and then that process was handled by others.

Q Do you know who it was handled by?

A In the case of AOAC, it would have been handled by the executive staff, the paid staff. There's an employed staff that administers the organization in Gaithersburg, but I don't recall the exact person that was handling it. It would have been whoever was in charge of the development of the dietary supplement community for the organization.

Q Did someone nominate you to become an expert for FDA and NIH?

A I was actually asked by one of the scientists at AOAC, based on their experience with my work and my presentations over the years at conferences.

Q And what scientist was that?

A I'm trying to recall her name. She's moved on. I don't recall her name. I'm sorry.

Q Okay. Paragraph 8, we were talking about the grant committees, and I don't think I asked you what R15 and R21 were.

A Yeah, R15 grant committees -- R15 grants

are grants specifically designed to expand and advance the science at the undergraduate level, so it's funding that is designed specifically to help students gain a more in-depth research skill set.

In relation to this, it was related to things involving natural products, studies of crops, chemistry of crops and such, and the funding mechanism is designed such that the actual undergraduate students get a chance to do the research, more like what they might do in grad school, to kind of spur and advance the level of science they might get.

The R21 grants come in for research of natural products from academics, private sector, a variety of parties, and those grants are based on a variety of things, either applying for early studies on pharmacological efficacy, chemical composition, characterization of materials and such.

Q Okay. Did you ever attempt to replicate the conditions that were in the Ping study?

A No, because you can't replicate them.

Q Have you tried to replicate the conditions in the Ping study?

A No. It would be like trying to put a gallon of water in this cup. It just cannot be done. It's against the laws of physics.

Q I take it you have not even attempted to do that.

A No.

Q Have you done any work regarding 1,4-DMAA?

A No.

Q In paragraph 24 of your report, you're talking about "clandestine and economic adulteration."

Do you see that?

A Yes.

Q And you say you've identified ingredients in products from China that were "spiked with stimulants, laxatives, erectile dysfunction drugs, diabetes drugs, antibiotics, sedatives, psychiatric drugs, bath salts, cannabinoids" and others, correct?

A That were adulterated, yes.

Q But that doesn't -- strike that.

You're not -- let me start that over again.

You're not saying in your report that you have identified products that were spiked with DMAA from China, have you?

A In this particular report? You mean relative to this?

Q In your report, Exhibit 1.

A No, I did not say that in this.

Q Have you been asked -- strike that.

Do you have plans to undertake in the future any analysis of Geranium plants for DMAA?

A I don't have any plans per se, but I'm not saying that I wouldn't do that. It would depend on the situation.

Q But as you sit here today, you've not been asked to undertake any studies in the future?

A Not at this time, no.

Q And beyond the things that we discussed this morning, which were the low levels of detection of DMAA, Dr. Brown's opinion that there's no pathway, the possibility that DMAA is in fertilizer, and the studies that did not detect DMAA, do you have any additional facts upon which you are relying for your opinion that the DMAA detected by Li and Fleming was not natural to the

Geranium plant?

A The fact that the larger body of scientific evidence does not report finding it, and that other potential contamination sources, water, environment, shipping and handling, degradation, were not evaluated.

Q And when you use the word "potential," that means you don't know one way or the other, right?

A It means that they are possible routes that should be explored.

Q But as you sit here today, you don't know one way or the other, do you?

A One way or the other --

Q Whether those are sources of contamination.

A For the presence of DMAA?

Q Yes.

A No, I don't have specific evidence showing that those are contamination sources in this case.

MS. WOOLSON: Okay. I think I'm done. Just let me do one final review.

MR. O'NEAL: Okay.

(Whereupon, a short recess was taken.)

MS. WOOLSON: I have no further questions.

MR. O'NEAL: I just have one.

EXAMINATION BY COUNSEL FOR PLAINTIFF

BY MR. O'NEAL:

Q Mr. Kababick, you were just previously talking about paragraph 24 with counsel, is that correct, of your expert report?

A Yes.

Q Have you, in the course of operating your laboratory, ever identified any products that were adulterated with DMAA?

A Yes.

MS. WOOLSON: Objection to form.

BY MR. O'NEAL:

Q And what products were those?

A I tested a raw material that was supposed to be a Geranium extract, and it was nearly pure DMAA, and I tested a product that said it had Geranium extract in it that contained DMAA, but the DMAA was very high, in excess of 100 milligrams per gram, which would not be

feasible for a natural source.
Q So then was your previous response to counsel merely that DMAA was not listed in paragraph 24?
MS. WOOLSON: Objection to form.
THE WITNESS: Yeah, that's what I thought was being asked.
MR. O'NEAL: Okay. I have no further questions.
FURTHER EXAMINATION BY COUNSEL FOR DEFENDANT
BY MS. WOOLSON:
Q Mr. Kababick, why would you not include that information in your expert report if you believed those samples were spiked?
A Because I was opining on the Li and Fleming papers and the discussion of the naturalness of DMAA.
Q So you would put in your report a statement that you have investigated or identified several botanical materials that were spiked with various substances, but you would leave out DMAA?
A Well, the body of my report was discussing DMAA. These were additional components that I identified in a larger picture of my work.

Q And you omitted DMAA from that exhibit?
A Well, I discuss DMAA in the rest of the whole report. This was an addition, number 24. These other things that I have also found showing that there is a history of adulteration issues and in so many of these cases, their argument was made these were naturally occurring, and in many or all cases, they were ruled not to be.
Q And yet so you left out the two examples that you claim are evidence of spiking of DMAA from an expert report about the presence of DMAA?
MR. O'NEAL: Object to the form. Mischaracterizes his testimony.
THE WITNESS: No, I wouldn't say that.
BY MS. WOOLSON:
Q And where did these two extracts come from?
A One was submitted by a client for testing, and the other one was provided by an importer.
Q And from where in the world did these extracts purport to come?
A China.

Q And the client that submitted the extract to you, was this the one that you said was pure DMAA or the one that was 100 milligrams per gram?
A 100 milligrams per gram or greater.
Q And the client -- did the client indicate to you where the sample had come from, i.e., who the manufacturer was?
A No. Just that it was from China.
Q And that's all you know about the sample was that it came from China?
A Yes.
Q And the extract that was 100 milligrams per gram, where did that come from?
A That was reported to come from China.
Q And that was sent to you by an importer?
A No. The extract was sent to me by the client. A pure compound or near pure compound was sent to me by an importer.
Q So let me start over.
The pure -- the product that was purported to be an extract but you tested and believed to be pure DMAA, was that sent to you by an importer?

A Yes.
Q And you were told that that sample came from China?
A Right. Yes. That's correct.
Q And the 100 milligrams per gram sample, that came from a client?
A Yes.
Q And you were told that came from China?
A Yes.
Q And was this client an entity that was interested in manufacturing or selling or using this extract?
A Yes. They were interested in utilizing it in their product.
Q And what was their product?
A I don't know exactly what it was. They said they had a formulation they were working on.
Q You don't even know what kind of category the product was in?
A No, I don't. I don't remember if it was a sports or a weight loss or what.
Q And other than these two extracts, you have not identified any other product, natural products that were purportedly spiked with DMAA?

James P. Kababick

MR. O'NEAL: Object to the form.

THE WITNESS: I'm not sure I understand the question.

BY MS. WOOLSON:

Q What don't you understand about the question?

A Are you saying have I identified products that were claimed to be spiked with DMAA? Is that what you asked?

Q No. I asked you: Other than these two extracts that you just now remembered, did you test any other natural products that you're claiming were spiked with DMAA?

A I believe I did.

Q And what natural products were those?

A One of those was a weight loss product, but the goal of the analysis was not to test for DMAA. It was related to other compounds, but it had a DMAA claim on the label. I don't know if it actually had DMAA in it, because that was outside the scope of what I was working on.

Q So you didn't actually test for DMAA?

A Not in that one, no. It wasn't requested.

James P. Kababick

Q What was the weight loss product?

A I don't recall the exact name of the weight loss product.

Q Other than the two extracts and now this weight loss product that you didn't test for DMAA, any other products, natural products you believe that you've tested were spiked with DMAA?

A I'm not recalling any offhand. There may have been others, but due to the time that's passed and the tens of thousands of samples I've analyzed, I don't recall specifically.

Q And I believe we talked -- it might have been this morning, it might have been this afternoon -- about your lab developing methods for detection for DMAA. These three examples that you've just given me, were they detected -- well, the two examples where you actually tested for DMAA, were they tested using this method that your lab developed?

A Yes, they were.

Q And I believe you told me that you no longer -- are you no longer offering the DMAA detection, or is it the quantification?

A The quantification.

James P. Kababick

Q So when is the last time you ran a DMAA detection test for a sample?

A It's been several years, to my knowledge.

Q So these two examples of extracts that you identified, how many years ago were they?

A I believe they were around the time of this paper, 2012, right in there. I'd have to check to be sure, though.

MS. WOOLSON: Subject to the request for information about the identities of major customers of Flora Labs and the identities of the customers for whom these extracts tests were run, I have no further questions.

MR. O'NEAL: Okay. We'll read and sign.

(Signature having not been waived, the deposition of JAMES P. KABABICK was concluded at 3:27 p.m.)

James P. Kababick

ACKNOWLEDGEMENT OF WITNESS

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

_____ _____

(DATE) (SIGNATURE)

ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

Pg.	No.	Now Reads	Should Read	Reason
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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME
THIS ____ DAY OF _____, 2016.

_____
(Notary Public) MY COMMISSION EXPIRES:_____

James P. Kababick

CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

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

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 23rd day of November, 2016.

My commission expires: March 14th, 2021

_____
LAURIE DONOVAN
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA

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