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# Exhibit 54

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Page 1 1 James P. Kababick 2 IN THE UNITED STATES DISTRICT COURT 3 FOR THE NORTHERN DISTRICT OF GEORGIA 4 ATLANTA DIVISION 5 - - -+ 6 UNITED STATES OF AMERICA, 7 Plaintiff, Civil Action No. 8 1:13-cv-13675vs. 9 UNDETERMINED QUANTITIES OF WBH-JCF 1,3-DIMETHYLAMYLAMINE 10 HCl (DMAA), 11 Defendant, 12 and 13 HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT, 14 Claimants. 15 16 17 Deposition of James P. Kababick 18 Washington, DC Friday, November 18, 2016 19 20 9:32 a.m. 21 22 23 24 Job No. 114994 25 Reported by: Laurie Donovan, RPR, CRR

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1	James P. Kababick	1	James P. Kababick
2	Deposition of	2	A P P E A R A N C E S
3	JAMES P. KABABICK	3	ON BEHALF OF THE PLAINTIFF:
4	JANUED I. MADI DICK	4	U.S. Department of Justice
5	Held at the offices of:	5	450 Fifth Street, NW
6	U.S. Department of Justice	6	Washington, DC 20530
7	Consumer Protection Branch	7	By: Claude Scott, Esq.
8	450 Fifth Street, NW	8	and
9	Washington, DC 20530	9	United States Attorney's Office
10		10	Northern District of Georgia
11		11	75 Ted Turner Drive
12		12	Atlanta, Georgia 30303
13		13	By: David O'Neal, Esq.
14		14	
15		15 16	
16 17		10	
18	Taken number to notice hefere	18	
19	Taken pursuant to notice, before Laurie Donovan, Registered Professional	19	ON BEHALF OF THE DEFENDANTS:
20	Reporter, Certified Realtime Reporter, and	20	Epstein Becker & Green
21	Notary public in and for the District of	21	One Gateway Center
22	Columbia.	22	Newark, New Jersey 07102
23		23	By: Sheila Woolson, Esq.
24		24	_ J
25		25	
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1	James P. Kababick	1	James P. Kababick
2	PROCEEDINGS	2	question, I'm going to assume that you heard it,
3	JAMES PETER PAUL KABABICK,	3	understood it, and are answering it to the best
4	having been first duly sworn, testified	4	your ability.
5	upon his oath as follows:	5	It's important that you keep your
6	EXAMINATION BY COUNSEL FOR DEFENDANT	6	responses verbal, because the court reporter can't
7	BY MS. WOOLSON:	7	take down gestures or nods of the head, and it's
8	Q Good morning.	8	important that I let you finish your answer before
9	A Good morning.	9	I begin my next question, and likewise you let me
10	Q We met a few minutes ago. We're here	10	finish my question before you begin your answer,
11	today to take your deposition.	11	because the court reporter cannot take down two
12	Have you ever had your deposition taken	12	people talking at the same time. Well, she can,
13	before?	13	but she prefers not to.
14	A No, I haven't.	14	And from time to time Mr. O'Neal may
15	Q I'm going to give you some basic	15	interpose an objection to a question. If he does,
16	instructions about how today is going to proceed.	16	just refrain from answering until the attorneys
17	A Okay.	17	have worked it out. He will instruct you whether
18	Q You're going to be answering questions	18	or not to answer the question.
19	under oath, and even though we're in an informal	19	Finally, if you need to take a break at
20	setting, your answers can be used just as if we	20	any time, let me know. Other than when a question
21	were in court, so it's important that you make	21	is pending, we can take a break.
22	sure you hear and understand my questions.	22	Do you understand those instructions?
23	If you don't hear it, let me know, and	23	A Yes.
24	I'll repeat it. If you don't understand it, let	24	Q What did you do to prepare for your
25	me know, and I'll rephrase it. If you answer a	25	deposition today?
	Page 8		Page 9
1	James P. Kababick	1	James P. Kababick
2	A I reviewed the scientific papers and	2	dietary ingredients; and also related to examining
3	data presented to me, the documents, and then I	3	components of materials that might be under the
4	reviewed my expert report again, and yesterday I	4	ability of the eye to see, so you need a
5	met with counsel.	5	microscope to see.
6	Q Okay, and don't tell me anything about	6	Q And you said you took graduate courses
7	your discussions with counsel.	7	in psychopharmacology.
8	Can you give me the benefit of your	8	What is your undergraduate degree in?
9	educational background.	9	A Undergraduate, I have a bachelor's of
10	A Yes. I trained in psychopharmacology in	10	science in business administration and a
11	grad school. I didn't complete my graduate degree	11	bachelor's of science in psychology.
10	in that. I went into the workforce.	12	() And I take it from your carlier
12	T ( 1° 1 ) 1 ( 1 )	1.2	Q And I take it from your earlier
13	I studied gas chromatography and	13	testimony, you do not have an advanced degree
13 14	separation science with Walter Jennings, who	14	testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?
13 14 15	separation science with Walter Jennings, who pioneered modern column chromatography, analytical	14 15	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
13 14 15 16	separation science with Walter Jennings, who pioneered modern column chromatography, analytical column chromatography.	14 15 16	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.
13 14 15 16 17	separation science with Walter Jennings, who pioneered modern column chromatography, analytical column chromatography. And I've trained in the private sector	14 15 16 17	<ul><li>testimony, you do not have an advanced degree</li><li>beyond a bachelor's degree; is that correct?</li><li>A I do not have a degree beyond a</li><li>bachelor's degree.</li><li>Q And can you give me the benefit of your</li></ul>
13 14 15 16 17 18	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	14 15 16 17 18	<ul><li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li><li>A I do not have a degree beyond a bachelor's degree.</li><li>Q And can you give me the benefit of your work history.</li></ul>
13 14 15 16 17 18 19	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	14 15 16 17 18 19	<ul><li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li><li>A I do not have a degree beyond a bachelor's degree.</li><li>Q And can you give me the benefit of your work history.</li><li>A Yes. I have about 23 years of</li></ul>
13 14 15 16 17 18	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	14 15 16 17 18	<ul> <li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li> <li>A I do not have a degree beyond a bachelor's degree.</li> <li>Q And can you give me the benefit of your work history.</li> <li>A Yes. I have about 23 years of experience in natural products chemistry,</li> </ul>
13 14 15 16 17 18 19 20	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.	14 15 16 17 18 19 20	<ul> <li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li> <li>A I do not have a degree beyond a bachelor's degree.</li> <li>Q And can you give me the benefit of your work history.</li> <li>A Yes. I have about 23 years of experience in natural products chemistry, analytical chemistry, and separation science.</li> </ul>
13 14 15 16 17 18 19 20 21	<ul> <li>separation science with Walter Jennings, who pioneered modern column chromatography, analytical column chromatography.</li> <li>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.</li> <li>Q What is botanical microscopy?</li> </ul>	14 15 16 17 18 19 20 21	<ul> <li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li> <li>A I do not have a degree beyond a bachelor's degree.</li> <li>Q And can you give me the benefit of your work history.</li> <li>A Yes. I have about 23 years of experience in natural products chemistry, analytical chemistry, and separation science.</li> <li>Q When you say you have 23 years of</li> </ul>
13 14 15 16 17 18 19 20 21 22	<ul> <li>separation science with Walter Jennings, who pioneered modern column chromatography, analytical column chromatography.</li> <li>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.</li> <li>Q What is botanical microscopy?</li> <li>A It's utilizing microscopic examination,</li> </ul>	14 15 16 17 18 19 20 21 22	<ul> <li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li> <li>A I do not have a degree beyond a bachelor's degree.</li> <li>Q And can you give me the benefit of your work history.</li> <li>A Yes. I have about 23 years of experience in natural products chemistry, analytical chemistry, and separation science.</li> <li>Q When you say you have 23 years of experience, can you tell me where you gained that</li> </ul>
13 14 15 16 17 18 19 20 21 22 23	<ul> <li>separation science with Walter Jennings, who pioneered modern column chromatography, analytical column chromatography.</li> <li>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.</li> <li>Q What is botanical microscopy?</li> </ul>	14 15 16 17 18 19 20 21 22 23	<ul> <li>testimony, you do not have an advanced degree beyond a bachelor's degree; is that correct?</li> <li>A I do not have a degree beyond a bachelor's degree.</li> <li>Q And can you give me the benefit of your work history.</li> <li>A Yes. I have about 23 years of experience in natural products chemistry, analytical chemistry, and separation science.</li> <li>Q When you say you have 23 years of</li> </ul>

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1	James P. Kababick	1	James P. Kababick
2	here originally at Chromascentia, which was	2	rotation as well as measurements of different
3	involved in analysis of essential oils for	3	classes of compounds through chemical analysis.
4	authenticity, and then formed Flora Research	4	Q Okay, and while you were at
5	Laboratories in '93, and we started applying the	5	Chromascentia, did you ever have occasion to
6	techniques of microscopy and chromatography to	6	review any essential oils from we'll start off
7	testing dietary ingredients of natural products.	7	at Geranium plants. We'll keep it simple.
8	And I have not only worked extensively	8	A Yes.
9	in the field but have taken an extensive number of	9	Q How often did you examine essential oils
10	continuing education training courses. Then also	10	of Geranium plants while you were at
11	I have participated in a lot of scientific society	11	Chromascentia?
12	panels, and I teach at university as well.	12	A I don't know at what interval, but I was
13	Q And you said initially you worked at	13	analyzing oils daily, and I analyzed a large
14	Chromascentia?	14	number of them.
15	A Yes.	15	Q And when you say you "analyzed" them,
16	Q And you were examining essential oils?	16	what did do you with this analysis? What was it
17	A Yes.	17	used for?
18	Q And what techniques were you using to	18	A To characterize the oil for its
19	examine the oils?	19	authenticity as well as to determine the levels of
20	A Gas chromatography and what we call	20	desirable components.
21	physiochemical analysis.	21	Q And you were doing this analysis for
22	Q What do you mean by "physiochemical	22	customers or clients of the lab?
23	analysis"?	23	A Both for customers and internally for
24	A That's the analysis of physical	24	the company for the research of their line.
25	properties of the oil so density, specific	25	Q What was their line?
	Page 12		Page 13
1	James P. Kababick	1	James P. Kababick
2	A Essential oils.	2	A Is that related only to Geranium?
3	Q They had their own line of essential	3	Q Yes.
4	oils?	4	A No, I did not.
5 6	A Yes.	5	Q Now, you mentioned that you created
0	Q Okay, and when you were doing this	6 7	Flora Research Labs.
8	analysis, did these strike that.	8	Who are the members or owners of Flora
9	When you were doing this analysis, were	9	Research?
10	you provided with the oils themselves as opposed	10	A Flora Research Laboratories is owned by
11	to having to extract the oil from the plant?	11	myself, and Dana Neal is my partner.
12	A Are you speaking to Geranium in	12	Q Is Dana Neal your wife? A Yes.
13	particular? Q We can keep it specific to Geranium.	13	Q It's just the two of you who own the
14	A Yes, the oils were provided.	14	company?
15	Q And do you know from what geographic	15	A Yes.
16	regions these oils came from?	16	Q Has it always been just the two of you
17	A Yes. They came from Egypt, outside of	17	that owned the company?
18	the Cairo area, as well as China, the Yunnan	18	A Yeah. Originally it was myself, and
19	province. Those are the major ones. There are	19	then both of us.
20	others, but I don't know all the provinces. It	20	Q Okay. Are you the sole director at
21	was quite a while back.	21	Flora Research, or are there other directors?
22	Q And did you author or coauthor any	22	A I'm the only director.
23	studies or papers regarding this analysis of	23	Q And who are Flora Research's largest
24	essential oils that you did while you were at	24	customers currently?
25	Chromascentia?	25	A I'm unable to answer that, because I'm
			· · · · · · · · · · · · · · · · · · ·

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1	James P. Kababick	1	James P. Kababick
2	bound to confidentiality under contract with	2	MS. WOOLSON: Okay.
3	clients.	3	BY MS. WOOLSON:
4	MS. WOOLSON: Okay. This came up	4	Q Just so you understand, I'm not going
5	earlier this week with Dr. Brown, and what	5	to simply allow you to refuse to answer the
6	Mr. Scott and I discussed was having the	6	question. We're going to try and take steps to
7	United States go back and see whether or not	7	make sure that you can answer the question and do
8	this information can be provided pursuant to	8	it in a way that does not violate your contractual
9	the confidentiality order that's in place in	9	obligations.
10	this case.	10	As you sit here today, can you tell me
11	MR. O'NEAL: Okay.	11	if Flora Research Labs does work for any United
12	MS. WOOLSON: So I would suggest we	12	States governmental agency?
13	proceed similarly and see whether you can get	13	A Can you clarify that just a little bit?
14	that information. If not, we'll have to take	14	Q Sure. Does Flora Research do work for
15	whatever necessary steps we have to take with	15	the FDA?
16	the court.	16	A We don't do compensated work for the FDA
17	MR. O'NEAL: Sure. I would think	17	directly. We do work for companies that may have
18	this would be handled in whatever way you	18	samples in detention and need data packages
19	discussed with Mr. Scott previously. We	19	submitted from private labs. They're called
20	don't represent him in his individual	20	"detention without physical examination."
21	capacity, and so whatever his contractual	21	Q And when you say "detention without
22	obligations are, I have to take him at face	22	physical examination," what do you mean?
23	value, but certainly we will, you know, with	23	A When a product comes into the United
24 25	everyone, see what can be done and resolve it	24 25	States, it may be subject to an import alert, and
25	in the same manner.	25	if it's subject to an import alert, it's detained
	Page 16		Page 17
1	James P. Kababick	1	James P. Kababick
2	without testing by FDA sometimes, and it's up to	2	ag research services.
3	the company to show that it meets specifications	3	Q Okay, and what do you do for ag
4	and is not adulterated. So we do that work.	4	research?
5	Q And does Flora Research Labs currently	5	A We were given a grant to develop some
б	do work for the National Institutes of Health?		
		6	techniques for identity of botanicals using
7	A Not currently.	7	spectroscopy.
7 8	Q Has it in the past?	7 8	spectroscopy. Q And do you know which botanicals are at
9	<ul><li>Q Has it in the past?</li><li>A Yes.</li></ul>	7 8 9	spectroscopy. Q And do you know which botanicals are at issue?
9 10	<ul><li>Q Has it in the past?</li><li>A Yes.</li><li>Q When is the last time it did work for</li></ul>	7 8 9 10	spectroscopy. Q And do you know which botanicals are at issue? A We're actually working on ginseng.
9 10 11	<ul><li>Q Has it in the past?</li><li>A Yes.</li><li>Q When is the last time it did work for NIH?</li></ul>	7 8 9 10 11	<ul> <li>spectroscopy.</li> <li>Q And do you know which botanicals are at issue?</li> <li>A We're actually working on ginseng.</li> <li>Q And how long have you been doing that</li> </ul>
9 10 11 12	<ul> <li>Q Has it in the past?</li> <li>A Yes.</li> <li>Q When is the last time it did work for</li> <li>NIH?</li> <li>A I believe around 2006 we were given a</li> </ul>	7 8 9 10 11 12	<ul> <li>spectroscopy.</li> <li>Q And do you know which botanicals are at issue?</li> <li>A We're actually working on ginseng.</li> <li>Q And how long have you been doing that work, "you" meaning Flora Research Labs?</li> </ul>
9 10 11 12 13	<ul> <li>Q Has it in the past?</li> <li>A Yes.</li> <li>Q When is the last time it did work for</li> <li>NIH?</li> <li>A I believe around 2006 we were given a grant to develop some test methodology.</li> </ul>	7 8 9 10 11 12 13	<ul> <li>spectroscopy.</li> <li>Q And do you know which botanicals are at issue?</li> <li>A We're actually working on ginseng.</li> <li>Q And how long have you been doing that work, "you" meaning Flora Research Labs?</li> <li>A A few years now.</li> </ul>
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9 10 11 12 13 14 15 16 17 18 19 20	<ul> <li>Q Has it in the past?</li> <li>A Yes.</li> <li>Q When is the last time it did work for</li> <li>NIH?</li> <li>A I believe around 2006 we were given a grant to develop some test methodology.</li> <li>Q What was the test methodology?</li> <li>A It was a technique for quantifying benzene in liquid supplements, specifically resulting from the decomposition of the preservative system.</li> <li>Q So we talked about FDA. We've talked about NIH. I'm going to exhaust my vocabulary of acronyms very quickly.</li> </ul>	7 8 9 10 11 12 13 14 15 16 17 18 19 20	<ul> <li>spectroscopy.</li> <li>Q And do you know which botanicals are at issue?</li> <li>A We're actually working on ginseng.</li> <li>Q And how long have you been doing that work, "you" meaning Flora Research Labs?</li> <li>A A few years now.</li> <li>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?</li> <li>A Not that I can recall.</li> <li>Q Are there other agencies of the federal government for which Flora Research Labs has done work in the last ten years?</li> </ul>
9 10 11 12 13 14 15 16 17 18 19 20 21	<ul> <li>Q Has it in the past?</li> <li>A Yes.</li> <li>Q When is the last time it did work for</li> <li>NIH?</li> <li>A I believe around 2006 we were given a grant to develop some test methodology.</li> <li>Q What was the test methodology?</li> <li>A It was a technique for quantifying benzene in liquid supplements, specifically resulting from the decomposition of the preservative system.</li> <li>Q So we talked about FDA. We've talked about NIH. I'm going to exhaust my vocabulary of acronyms very quickly.</li> <li>Any other agency of the United States</li> </ul>	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	<ul> <li>spectroscopy.</li> <li>Q And do you know which botanicals are at issue?</li> <li>A We're actually working on ginseng.</li> <li>Q And how long have you been doing that work, "you" meaning Flora Research Labs?</li> <li>A A few years now.</li> <li>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?</li> <li>A Not that I can recall.</li> <li>Q Are there other agencies of the federal government for which Flora Research Labs has done work in the last ten years?</li> <li>A Not that I can recall.</li> </ul>
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	Page 18	Page 19
1	James P. Kababick	<sup>1</sup> James P. Kababick
2	A Private industry.	<sup>2</sup> report?
3	Q Mr. Kababick, would you agree with me	$^{3}$ Q Yes.
4	that it's important for a scientist to approach	<sup>4</sup> A Speak to people regarding the nature of
5	research importially?	<sup>5</sup> the report or its contents?
6	A Yes.	<sup>6</sup> Q Yes. Either.
7	Q And would you agree with me that it's	$^{7}$ A Not regarding this work, no.
8	important for a scientist to evaluate research	<sup>8</sup> Q Did you tell anyone that you were going
9	impartially?	<sup>9</sup> to be an expert witness in this case, other than
10	A Yes.	<sup>10</sup> the government?
11	(Exhibit 1 was marked for	<sup>11</sup> A I've only told people that are being an
12	identification.)	<sup>12</sup> expert witness for the DoJ.
13	BY MS. WOOLSON:	<sup>13</sup> Q And who have you told?
14	Q I'm going to show you what's been marked	<sup>14</sup> A My attorney.
15	as Exhibit 1.	<sup>15</sup> Q And by your attorney, you mean someone
16	Have you seen Exhibit 1 before today?	<sup>16</sup> other than the attorneys for the United States?
17	A Yes, I have.	<sup>17</sup> A Yeah, our company's, yeah, and of
18	Q And what is Exhibit 1?	<sup>18</sup> course, staff people that need to know that I'm <sup>19</sup> out of the office, what's going on
19 20	A I'm sorry?	out of the office, what's going on.
20	Q What is Exhibit 1?	Q And have you spoken to any concagues
22	<ul><li>A It's my expert rebuttal report.</li><li>Q And in preparing your expert rebuttal</li></ul>	<ul> <li>outside of Flora Research about your expert work</li> <li>in this case?</li> </ul>
23	report, did you speak to anyone other than the	<sup>23</sup> A No, I haven't spoken about the expert
24	attorneys for the government?	$^{24}$ work.
25	A You mean as far as preparing this	$^{25}$ Q And in preparing your report, did anyone
	······································	
	Page 20	Page 21
1	Page 20 James P. Kababick	Page 21 <sup>1</sup> James P. Kababick
1 2		<ol> <li>James P. Kababick</li> <li>A I developed it at the laboratory to</li> </ol>
2 3	James P. Kababick assist you? A No.	<ol> <li>James P. Kababick</li> <li>A I developed it at the laboratory to describe the specific and unique approach to</li> </ol>
2 3 4	James P. Kababick assist you? A No. Q Did anyone review a draft of the report	<ol> <li>James P. Kababick</li> <li>A I developed it at the laboratory to</li> <li>describe the specific and unique approach to</li> <li>analysis.</li> </ol>
2 3 4 5	James P. Kababick assist you? A No. Q Did anyone review a draft of the report other than the attorneys for the United States or	<ol> <li>James P. Kababick</li> <li>A I developed it at the laboratory to</li> <li>describe the specific and unique approach to</li> <li>analysis.</li> <li>Q So this is a term that you created to</li> </ol>
2 3 4 5 6	James P. Kababick 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?	<ul> <li>James P. Kababick</li> <li>A I developed it at the laboratory to</li> <li>describe the specific and unique approach to</li> <li>analysis.</li> <li>Q So this is a term that you created to</li> <li>describe what you do?</li> </ul>
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1	James P. Kababick	1	James P. Kababick
2	and crossover analytical technique is the approach	2	How do you have a standardized approach
3	to utilize orthogonal methodologies to help form a	3	for something that's not routine?
4	better picture of what's going on and what	4	A This is the reason we developed this, is
5	approaches might be utilized depending on what	5	that a lot of stakeholders were challenged with
6	data is already at hand.	6	this problem of how to approach the unknown, and
7	Q So let me see if I understand what you	7	from years of experience doing this, I organized a
8 9	just said.	8	flow path for doing that and how we would gather
10	The standardized method approach that	10	information, review information, design
11	you're talking about, standardized phytoforensic	11	experiments, and continue through that process. $Q_{1}$
12	approach is an attempt to create sort of a	12	Q And what is that flow path?
13	operating procedure by which to approach any phytoforensic examination of a substance, like a	13	A The flow path? I'll have to refer to my
14	number of steps that you would walk through to do	14	data on that. I wrote up a paper on that, but I don't remember all the steps off the top of my
15	the analysis?	15	head right now.
16	A It's for specifically we're dealing	16	Q And what's the name of that paper?
17	with issues of unknowns or with evaluating a	17	A It's actually the the paper is a
18	material where routine standard methods aren't out	18	it was actually a poster, standardized
19	there to answer the question specifically, or	19	phytoforensic approach scientific poster that I
20	where the answer is something that you need to	20	presented at AOAC, and then there's a PowerPoint
21	approach in different ways to get a better rounded	21	that was presented at the United States
22	view of it. It's not really addressing things	22	Pharmacopeia Dietary Supplements Workshop.
23	that are routine and worked out, but more of the	23	Q So this standard approach or this flow
24	emerging and nonroutine things.	24	path excuse me is a poster in a PowerPoint,
25	Q I guess I'm confused then.	25	correct?
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1	James P. Kababick	1	James P. Kababick
2	A Well, I've developed a poster PowerPoint	2	might have a part of the puzzle or part of the
3	to cover it, to provide resources to others.	3	understanding, so reaching out to your peers and
4	Q Okay, and this flow path is not	4	colleagues and industry in the scientific fields,
5	incorporated into any study or publication beyond	5	looking at the scientific literature that's out
6	this poster and this PowerPoint, correct?	6	there, searching publications, including books,
7	A I'm sorry. I'm not sure I understand.	7	and gathering data.
8	Q The flow path, is it the subject of any	8	So the first step is to gather data and
9	publication or paper or article beyond just this	9	review it, and also in defining exactly what the
10	PowerPoint and this poster?	10	issue is, and taking that data, putting it
11	A I believe it has been addressed in some	11	together into a cohesive understanding of what's
12	other articles in the industry educational	12	known to date, and then designing experimental
13	resources, and I'm actually submitting a paper	13	tests to approach the problem.
14	regarding it to a journal.	14	Q And is there a particular process that
16			
15 16	Q And when did you prepare this poster	15	you follow in designing these tests?
16	and/or PowerPoint?	16	A Yeah, it depends on what the test is and
16 17	and/or PowerPoint? A I don't remember the exact date, but	16 17	A Yeah, it depends on what the test is and what the problem is.
16 17 18	and/or PowerPoint? A I don't remember the exact date, but about two or three years ago. I'd have to check	16 17 18	<ul><li>A Yeah, it depends on what the test is and what the problem is.</li><li>Q And what's after designing the test?</li></ul>
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16 17 18 19 20 21 22 23	<ul> <li>and/or PowerPoint?</li> <li>A I don't remember the exact date, but</li> <li>about two or three years ago. I'd have to check</li> <li>to be sure exactly.</li> <li>Q And understanding that you don't</li> <li>remember all of the steps of the flow path, what</li> <li>steps do you remember?</li> </ul>	16 17 18 19 20 21 22 23	<ul> <li>A Yeah, it depends on what the test is and what the problem is.</li> <li>Q And what's after designing the test?</li> <li>A Conducting the test examinations.</li> <li>Q And after you conduct the test?</li> <li>A Reviewing the data to make a</li> <li>determination of what is found and where that</li> </ul>

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1	James P. Kababick	1	James P. Kababick
2	the issue or got the answers to the questions,	2	other aspects of manufacturing or crop production
3	make discoveries.	3	that might impart knowledge indirectly.
4	Q So this seems pretty much like the	4	Q And the cross-over analytical techniques
5	scientific method that most scientists follow when	5	that you were discussing, I think you used the
6	they are doing research, correct?	6	word "orthogonal."
7	A Basically, yes. The difference is that	7	Do you simply mean by that, using
8	a lot of times with these issues, because there	8	multiple different techniques in the analysis?
9	are not canned methods or approaches, a lot of my	9	A Yeah, there's different techniques to
10	colleagues and peers that have come to me and been	10	approach the analysis.
11	stuck or unsure what to do, this provides a	11	Q So, for example, liquid chromatography,
12	framework of a way to think "outside the box," so	12	mass spectrometry, gas chromatography, that sort
13	to speak.	13	of thing?
14	Q Okay, and when you talked about well,	14	A Yes, those could be components.
15	actually, let me back up.	15	Q Okay. Looking at your expert report,
16	What part of this flow path is	16	which we've marked as Exhibit 1, in paragraph 8
17	outside-the-box thinking, in your mind?	17	you say, "I served on the National Institutes of
18	A The things that I see a lot of times are	18	Health R15 and R21 grant committees."
19	in the designing of experiments that people often	19	Do you see that?
20	forget or get pigeonholed into thinking a certain	20	A Yes.
21	way about what they're going to analyze, so maybe	21	Q And what was your role on those
22	going directly after some target or analyte, but	22	committees?
23	that may not provide the answer to the question.	23	A I was a phytochemistry expert.
24	And so I talk about looking at other	24	Q And what were you reviewing?
25	things that might be impurities from process or	25	A I was reviewing grant applications
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1	Page 28	1	Page 29
1	James P. Kababick	1	James P. Kababick
2	James P. Kababick involving natural products research for	2	James P. Kababick years.
2 3	James P. Kababick involving natural products research for college-level undergraduates and general grant	2 3	James P. Kababick years. Q And were you compensated for your work
2 3 4	James P. Kababick involving natural products research for college-level undergraduates and general grant applications.	2 3 4	James P. Kababick years. Q And were you compensated for your work in reviewing NIH grants?
2 3 4 5	James P. Kababick involving natural products research for college-level undergraduates and general grant applications. Q And with whom did you serve on that	2 3 4 5	James P. Kababick years. Q And were you compensated for your work in reviewing NIH grants? A No. It was volunteer. The
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		Demo 21
	Page 30	Page 31
1	James P. Kababick	<sup>1</sup> James P. Kababick
2	A With Mark Roman, who is deceased at this	<sup>2</sup> contacted them to talk about the impurity, and it
3	time.	<sup>3</sup> piqued my interest as a researcher. A lot of our
4	Q How about U.S. Pharmacopeia?	<sup>4</sup> clients use chondroitin, and they had concerns
5	A Christy I don't remember her last	<sup>5</sup> about that contaminant, so I felt it would be good
6	name. She's an NMR spectroscopist.	<sup>6</sup> for our company to try to help research and
7	Q And who did you work with at Synutra	<ul> <li><sup>7</sup> understand it so we could help our clients test.</li> <li><sup>8</sup> So we got involved with them and USP and Tampa Bay</li> </ul>
8 9	Pure?	so we got involved with them and ost and rampa bay
10	A Weigo, W-E-I-G-O.	to see if we could help identify it, which we were
11	Q And other than this work you did on the	<ul> <li>able to do and write the paper.</li> <li>Q What work specifically did your company</li> </ul>
12	chondroitin compound, do you have any other interest in Synutra Pure?	<sup>12</sup> do?
13	A We did conduct some analysis on some	<sup>13</sup> A We did a combination of FTIR, infrared
14	chondroitin.	<ul> <li><sup>14</sup> spectroscopy, as well as differential scanning</li> </ul>
15	Q And how long ago did you do that work?	<sup>15</sup> calorimetry, DSC, and then we also did some
16	A I don't remember the exact date.	<sup>16</sup> cellulose acetate membrane electrophoresis to
17	Q And how did you come to be involved in	<ul> <li>separate the compound.</li> </ul>
18	that work?	<sup>18</sup> Q And did you personally do this work, or
19	A You mean the work that I published with	<sup>19</sup> did people who work at Flora Research do this
20	Synutra Pure and USP?	<sup>20</sup> work?
21	Q Yes.	<sup>21</sup> A Both.
22	A Okay. There was an article regarding	<sup>22</sup> Q What did you personally do?
23	the 01. They named the contaminate 01 they were	A I actually collected infrared data and
24	trying to identify, and I had done a lot of work	<sup>24</sup> calorimetry data, and I did also the
25	on chondroitin sulphate in the industry and	<sup>25</sup> electrophoresis, but I also had staff involved
	Page 32	Page 33
1		
1 2	James P. Kababick	<sup>1</sup> James P. Kababick
		<sup>1</sup> James P. Kababick
2	James P. Kababick with me working.	<ol> <li>James P. Kababick</li> <li>Q Have you authored any papers with her?</li> </ol>
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1	James P. Kababick	1	James P. Kababick
2	Q When you say "did business together," do	2	A She published a paper, and I've heard
3	you mean anything other than supplying standards?	3	her speak at some conferences.
4	A Yeah, well, we purchased standards from	4	Q When you say she published a paper, what
5	them, from ChromaDex.	5	paper? I mean obviously it sticks out in your
6	Q When is the last time you spoke to	6	mind, so I want to know why.
7	Mr. Jaksch?	7	A Yes, it was a paper on DMAA in Geranium.
8	A Oh, I would think several years ago, two	8	Q Have you ever discussed that paper with
9	or three years ago.	9	her?
10	Q Does your company still buy standards	10	A Yeah, I emailed her about that.
11	from ChromaDex?	11	Q And what was the subject of your email,
12	A I believe we occasionally do, yes.	12	the substance of your emails, I should say?
13	Q Do you know what standards you buy from	13	A Just congratulating her on the paper
14	ChromaDex?	14	that you know, appreciating that it helped shed
15	A I know we purchased creatine ethyl	15	more light on the issue.
16	ester. I'm not sure what else, but occasionally	16	Q And did she publish this paper with
17	we will get phytochemical materials or dietary	17	anyone else? Did she have coauthors?
18	ingredient materials.	18	A I believe she did, yes.
19	Q Okay. Do you know who Amy Eichner is?	19	Q Do you know who they were?
20	A Yes.	20	A Not offhand. I would have to check.
21	Q Who is she?	21	Q Do you know Joseph Betz?
22	A She's a scientist at USADA.	22	A Yes.
23	Q That's U-S-A-D-A?	23	Q Who is he?
24	A Yes, I believe it's USADA.	24	A Joseph Betz is the director of the NIH
25	Q How do you know Ms. Eichner?	25	Office of Dietary Supplements Methods and
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1 2	James P. Kababick	1 2	James P. Kababick
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1	James P. Kababick	1	James P. Kababick
2	AOAC?	2	A Yes. I believe it was around 2006. I'd
3	A Yes.	3	have to verify.
4	Q And who did the actual work, if you	4	Q Was that the only NIH funding?
5	will, of developing those methods?	5	A To my knowledge, yes.
6	A It was a variety of sources. Sometimes	6	Q You mentioned Mark Roman earlier.
7	there was funding mechanism for somebody to	7	Have you published any papers with Mark
8	develop what we call a single lab validated	8	Roman or done any work beyond the chondroitin
9	method. Sometimes there were calls for methods	9	studies that we discussed?
10	where people would submit methods, candidate	10	A Yes. I worked on the study of a product
11	methods, and sometimes a method would be	11	called Nucleomaxx, which was a subject of a
12	considered as a potential viable method, and maybe	12	clinical trial, and I did some mass spectrometry
13	after review it was determined additional work was	13	as part of that paper or poster, I should say.
14	needed to flesh it out.	14	Q Is that the only other work you've done
15	So there were a variety of ways those	15	with Mr. Roman that you recall as you sit here
16	came in.	16	today?
17	Q When you say there was funding for a	17	A Mark and I did quite a bit of work over
18	single laboratory validation method, did Flora	18	the years together, and I believe there were some
19	Research receive any funding for such methods?	19	other papers published. We worked extensively
20	A Not through the AOAC mechanism, no.	20	together on AOAC committees, since we both served
21	Q Through some other mechanism?	21	on the Committee K.
22	A Well, the previously disclosed funding I	22	Q And what is Committee K?
23	received from NIH for the benzene study was to	23	A That's the methods committee on dietary
24	develop a method, single lab method.	24	supplements. And then we served on various expert
25	Q Did I ask you when you did that work?	25	review panels in AOAC.
			-
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1	James P. Kababick	1	James P. Kababick
2	Q Do you have any patents in your name?	2	for some reason you need to distinguish among
3	A I do not.	3	types of Geranium, let me know, but otherwise I'm
4	Q Are you a co-author of any patents?	4	going to assume, if we're talking about Geranium,
5	A No.	5	we're talking about Pelargonium graveolens. Okay?
6	Q Earlier this morning you mentioned DMAA.	6	A Okay.
7	What is DMAA?	7	Q Thank you.
8	A DMAA, as I use the term, refers to the	8	A Before we go further, would it be okay
9	compound methylhexaneamine.	9 10	if I used the restroom real quick?
1.0			MG WOOD CON C
10	Q And just so we're all on the same page		MS. WOOLSON: Sure.
11	for the duration of the deposition, if I refer to	11	(Whereupon, a short recess was
11 12	for the duration of the deposition, if I refer to this as "DMAA," you will understand that to be	11 12	(Whereupon, a short recess was taken.)
11 12 13	for the duration of the deposition, if I refer to this as "DMAA," you will understand that to be methylhexaneamine?	11 12 13	(Whereupon, a short recess was taken.) (Exhibit 2 was marked for
11 12 13 14	for the duration of the deposition, if I refer to this as "DMAA," you will understand that to be methylhexaneamine? A Yes.	11 12 13 14	(Whereupon, a short recess was taken.) (Exhibit 2 was marked for identification.)
11 12 13 14 15	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	11 12 13 14 15	(Whereupon, a short recess was taken.) (Exhibit 2 was marked for identification.) BY MS. WOOLSON:
11 12 13 14 15 16	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.	11 12 13 14 15 16	<ul> <li>(Whereupon, a short recess was taken.)</li> <li>(Exhibit 2 was marked for identification.)</li> <li>BY MS. WOOLSON:</li> <li>Q When we broke, we talked about some</li> </ul>
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11 12 13 14 15 16 17 18 19 20 21 22	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?	11 12 13 14 15 16 17 18 19 20 21 22	<ul> <li>(Whereupon, a short recess was taken.)</li> <li>(Exhibit 2 was marked for identification.)</li> <li>BY MS. WOOLSON:</li> <li>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.</li> <li>How many years, Mr. Kababick, have you been trying to get DMAA banned?</li> <li>MR. O'NEAL: Object to the form.</li> </ul>
11 12 13 14 15 16 17 18 19 20 21	<ul> <li>for the duration of the deposition, if I refer to this as "DMAA," you will understand that to be methylhexaneamine?</li> <li>A Yes.</li> <li>Q I just find it easier for me to say DMAA than all those letters.</li> <li>A Sure.</li> <li>Q The other thing is, are you familiar with the term "Pelargonium graveolens"?</li> <li>A Yes.</li> <li>Q Are you comfortable if we refer to that as Geranium?</li> <li>A It is a Geranium.</li> </ul>	11 12 13 14 15 16 17 18 19 20 21	<ul> <li>(Whereupon, a short recess was taken.)</li> <li>(Exhibit 2 was marked for identification.)</li> <li>BY MS. WOOLSON:</li> <li>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.</li> <li>How many years, Mr. Kababick, have you been trying to get DMAA banned?</li> <li>MR. O'NEAL: Object to the form. THE WITNESS: I haven't been trying</li> </ul>
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	Page 42		Page 43
1	James P. Kababick	1	James P. Kababick
2	BY MS. WOOLSON:	2	A I don't recall, actually.
3	Q No?	3	Q If you look at the email at the top of
4	A No.	4	the page, it appears that somehow your
5	Q Let me show you what's been marked as	5	communication went to Daniel Fabricant.
6	Exhibit 2.	6	Do you see that?
7	(Witness peruses document.)	7	A You mean right here?
8	THE WITNESS: Okay.	8	Q Yeah, in the middle. Directly above the
9	BY MS. WOOLSON:	9	"James Neal Kababick to James Neal Kababick,"
10	Q Have you seen Exhibit 2 before?	10	there is a to-from that says "from Daniel
11	A Pardon me?	11	Fabricant."
12	Q Have you seen Exhibit 2 before?	12	Do you see that?
13	A Not as this exhibit, no.	13	A Where it looks like this is part of
14	Q Okay. Do you recognize Exhibit 2 as, in	14	something he sent?
15	part, an email that you sent regarding DMAA?	15	Q Yes.
16	A It appears to be so, yes.	16	A Yes.
17	Q And this was in January of 2012,	17	O Who is Daniel Fabricant?
18	correct?	18	A He is the CEO of the Natural Products
19	A Yes, that's the set date on here.	19	Association.
20	Q And it says "from James Neal Kababick to	20	Q Is he also an FDA employee?
21	James Neal Kababick."	21	A He was formally [sic].
22	Do you see that?	22	Q And do you know why
23	A Yes.	23	MR. O'NEAL: Did you mean
24	Q To whom did you send this email other	24	"formerly"?
25	than yourself?	25	THE WITNESS: Yeah, he was at FDA.
	Page 44		Page 45
1	James P. Kababick	1	James P. Kababick
2	MS. WOOLSON: As opposed to	2	Q And as you sit here today, you can't
3	"formally"?	3	recall why you sent this email or to whom you sent
4	THE WITNESS: Yes, formerly.	4	this email?
5	Currently he's at	5	A No. No, I can't.
6	MR. O'NEAL: I don't think anybody	6	Q And if we were to look at your email in
7	is informally at FDA.	7	its native format, would we be able to see if you
8	BY MS. WOOLSON:	8	blind-copied people on this email?
9	Q Do you know why you would have been	9	A I'm not sure I understand.
10	sending to Mr. Fabricant information about DMAA?	10	Q Do you know what a blind copy is?
11	MR. O'NEAL: Object as to form.	11	A Yeah, I do, but what's the "native
12	Assumes a fact not in evidence.	12	format"?
13	THE WITNESS: Could you ask the	13 14	Q It's a format in which you can look at
14	question again, please.	14	emails. It preserves all the original data.
15 16	BY MS. WOOLSON:	15	Let me rephrase the question.
17	Q Sure.	17	A Okay.
18	Do you know why you would have been	18	Q Was it your practice to send emails to
19	sending to Mr. Fabricant information on DMAA?	18	colleagues where you BCC'd them instead of CC'ing
20	A I don't recall the exact nature of this	20	them?
20	communication and exactly who it went to.	20	A Sometimes.
21	Q In the past have you sent information to	21	Q Why?
23	Mr. Fabricant regarding DMAA?	23	A If I was sending emails to more than one
24	A I actually don't recall. I have communicated with him when he was at FDA on	23	party, and those parties, for one reason or another, were distinct for some reason. For
25	various subjects.	25	instance, maybe a communication that would be
-	various subjects.		instance, maybe a communication that would be

	Page 46		Page 47
1	James P. Kababick	<sup>1</sup> James P. Kababick	
2	relevant to two clients, but I wanted to protect	<ul> <li><sup>2</sup> regarding DMAA?</li> </ul>	
3	the clients' confidentiality, I might BCC them; or	<sup>3</sup> A I don't recall the specific details.	
4	if I'm not wanting to disclose an email chain,	<sup>4</sup> Q What about Mr. Blumenthal; what	were the
5	sharing email addresses with everybody, because I	<sup>5</sup> circumstances under which you were corr	
6	don't know if it's okay to give other email	<sup>6</sup> with him about DMAA?	oponoing
7	addresses out, I might BCC them.	<ul> <li>A I believe that we were discussing t</li> </ul>	he
8	Q And when you sent this email that we're	<sup>8</sup> DMAA in regard to the botanical adultera	
9	talking about, was the FDA or Mr. Fabricant a	<ul> <li><sup>9</sup> program at ABC.</li> </ul>	
10	client?	<sup>10</sup> Q And did you do any work for ABC	1
11	A No, no. He's not a client.	regarding the botanical adulterants progra	
12	Q And to whom to whom else other than	<sup>12</sup> A I actually am on the board currentl	
13	Mr. Fabricant may you have sent strike that.	<sup>13</sup> the scientific advisory board, and I, prior t	
14	Do you recall sending emails regarding	that, have ongoingly provided peer review	
15	DMAA to other people?	<sup>15</sup> input on various botanical-related matters	
16	A I'm sure I did, yes.	<ul> <li><sup>16</sup> educational papers that they do.</li> </ul>	
17	Q And do you know who those people are as	<sup>17</sup> Q And what about Dr. Khan; what is	the
18	you sit here today?	<sup>18</sup> context in which you were corresponding	
19	A I may have communicated with Roy Upton	regarding DMAA?	
20	at American Herbal Pharmacopeia and Mark	<sup>20</sup> A I don't remember the specifics of o	ur
21	Blumenthal at American Botanical Council, and I'm	<sup>21</sup> correspondence. I do remember that I add	
22	sure I dialogued with probably Ikhlas Khan or	<sup>22</sup> some critiques of a paper that I read on DI	
23	others, but exactly who, I don't recall.	<ul> <li>Geranium, and I've had ongoing communi</li> </ul>	
24	Q And what were the circumstances under	<ul> <li>Dr. Khan's group regarding various article</li> </ul>	
25	which you were corresponding with Mr. Upton	<sup>25</sup> projects that I've done where I've been see	
	when you were corresponding when the option	t1	8
	Dama 40		
	Page 48		Page 49
1	James P. Kababick	<sup>1</sup> James P. Kababick	Page 49
1 2	James P. Kababick		
2	James P. Kababick input or papers, reprints, things like that.	<ul> <li>asking you for help? What's the nature discussions?</li> </ul>	e of the
2 3	James P. Kababick input or papers, reprints, things like that. Q And the critique of this paper that you	<ul> <li>asking you for help? What's the nature discussions?</li> </ul>	e of the es a lot
2 3 4	James P. Kababick 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?	<ul> <li>asking you for help? What's the nature discussions?</li> <li>A Usually because their group do of publishing and research, I will inqui</li> </ul>	e of the es a lot re
2 3 4 5	James P. Kababick 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	<ul> <li>asking you for help? What's the nature discussions?</li> <li>A Usually because their group do of publishing and research, I will inqui</li> </ul>	e of the es a lot re get
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1	James P. Kababick	1	James P. Kababick
2	Q Did you speak to anybody in Dr. Khan's	2	the matter further and make a determination on
3	group about his expert report?	3	whether or not this is a dietary supplement or not
4	A No.	4	a dietary supplement. A lot of clients were on
5	Q Going back to Exhibit 2	5	the fence on what to do about this.
6	A That's this one?	6	Q And when you say "I completely support
7	Q That's the email.	7	Health Canada's position on this," what was Health
8	A Okay.	8	Canada's position?
9	Q If I could draw your attention to the	9	A I know that their evaluation of the Ping
10	second page of the email and the third paragraph	10	paper was that it was not an acceptable support of
11	down, you say, "I can only hope that FDA is	11	naturally occurring DMAA in Geranium. I don't
12	drawing back the bow string on this and not	12	remember the other information from Health Canada.
13	ignoring what I think is a blatant attempt to sell	13	Q Do you know whether, at the time of this
14	yet another pharmaceutical drug dressed up as a	14	email, Health Canada had ruled that DMAA was not
15	dietary supplement."	15	permitted to be sold as a dietary supplement?
16	Do you see that?	16	A I don't recall.
17	A Yes.	17	Q Now, you go on to say, "Despite offers
18	Q What did you mean?	18	to analyze Geranium stem and leaf for free to see
19	A I believe and this was several years	19	if it really has this compound in it, no takers
20	ago, but I believe what I was addressing here was	20	have shown up yet."
21	the use of large amounts of DMAA in products where	21	Do you see that?
22	it was claimed to be all naturally isolated from	22	A Yes.
23	Geranium.	23	Q Where did you make these offers?
24	Q And what is it you wanted FDA to do?	24	A I actually put out a call for material
25	A I was hoping that they would look into	25	to ABC and American Herbal Pharmacopeia, who are
	Page 52		Page 53
1	James P. Kababick	1	James P. Kababick
2	well connected in the industry, to see if we could	2	plant material?
3	get material, and I let it be known that I would	3	A No.
4	be interested in looking at that material in its	4	Q Was there some reason why you couldn't
5	native form.	5	get your own plant material?
6	Q And to whom did ABC or the other	6 7	A You mean as far as obtaining my own
7	company whose name I just forgot.	8	Geranium?
8	A AHP.	9	Q Mm-hmm.
9 10	Q AHP. Thank you.	10	A What I was asking for was material in
11	To whom did they send that request?	11	trade that was being used by manufacturers to extract the DMAA.
12	A I'm not sure.	12	
13	Q And so is it your testimony that as of the data of this amail no one had responded to	13	Q What do you mean "material in trade"? A The source material that manufacturers
14	the date of this email, no one had responded to your request for material?	14	claim that they were extracting the DMAA from,
15	A I don't recall at the date of this email	15	so I wanted to
16	anybody offering to provide live plant material or	16	Q What was the source material?
17	dried whole pieces.	17	A Well, they claimed Geranium stem and
18	Q Did you ask Dr. Khan or Dr. ElSohly for	18	some oil, so I wanted to get the material they
19	plant material?	19	were using before I did the extraction so I could
20	A I don't recall if I did, actually.	20	look at it.
21	Q Did you ask Dr. Li for a sample of plant	21	Q Okay, and I go back to my original
22	material?	22	question, which was: Was there some reason why
23	A I do not think I did, but I don't recall	23	you couldn't have gotten your own Geranium stem or
24	exactly.	24	oil?
25	Q Did you ask Drs. Fleming or Simone for	25	A I did not have the information on who
	- • •		

	Page 54		Page 55
1		1	
2	James P. Kababick	2	James P. Kababick
3	the manufacturers were in China that were making	3	A Well, I've analyzed essential oil
4	it. O Did you call Dr. Khan Dr. ElSahly?	4	obtained from Geranium and I've analyzed some
5	<ul><li>Q Did you ask Dr. Khan, Dr. ElSohly?</li><li>A I don't recall.</li></ul>	5	extracts, but I don't recall the details of the
6		6	specifics who it was from. I know the oil was in
7	<ul><li>Q Did you ask Dr. Li?</li><li>A I don't think I did, but I don't recall.</li></ul>	7	regard to authentication. The extract powders, I
8		8	don't recall the nature of the analysis.
9	Q Did you ask Dr. Simone and Dr. Fleming? A No.	9	<ul><li>Q And when did you do these analyses?</li><li>A I don't recall the exact date.</li></ul>
10		10	
11	<ul><li>Q Did you ask anyone?</li><li>A Yes, I believe I did.</li></ul>	11	<ul><li>Q Who were they for?</li><li>A These were for clients.</li></ul>
12		12	
13	Q Who? A I don't recall.	13	Q And I suppose you won't tell me the name of the clients.
14		14	
15	Q As we sit here today, have you run any studies on Geranium plants since the date of this	15	<ul><li>A I'm bound by confidentiality.</li><li>Q Speaking of that, we'll take it up.</li></ul>
16	email?	16	
17	A Could you be more specific?	17	And when you say you analyzed the
18	Q No, I don't think I can be.	18	Geranium plants, how did you analyze them? Actually, I take it back.
19	A What do you mean by "studies"?	19	You said oil and extracts.
20	Q Have you analyzed any Geranium plants	20	A Yes.
21	for DMAA since the date of this email?	21	Q How did you analyze the oil and
22	A I have analyzed some Geranium plant	22	extracts?
23	product, but I don't recall the specifics.	23	A Using gas chromatography and mass
24	Q What do you mean you "analyzed some	24	spectrometry, GC/MS.
25	Geranium plant product"?	25	Q And have you analyzed any Geranium
			Q And have you analyzed any octainam
	Page 56		Page 57
1	James P. Kababick	1	James P. Kababick
2	plants since the date of this email?	2	A In some cases, yes.
3	A Not whole plant material. Not that I	3	Q How many cases?
4	can recall at least.	4	A I don't recall offhand exactly how many
5	Q And how many oils did you analyze?	5	cases.
6	A Between the time of this?	6	Q Do you recall the results?
7	Q Between the time of Exhibit 2 and today.	7	A Yes. As far as I know, I don't recall
8	A I am not sure.	8	finding it in any oils that I was able to
9	Q Can you estimate?	9	authenticate as all natural.
10	A At least a dozen or two.	10	Q Where did these oils come from?
11	Q And how many extracts did you analyze?	11	A Clients submitted them from their
12	A That I don't recall at all.	12	producers or brokers, buyers.
13	Q And when you did this analysis on the	13	Q Do you know the geographic origin of the
14	dozen or so, one to two dozen oils, what	14	oils?
15	specifically were you looking for?	15	A No.
16	A I was looking at the composition for	16	Q And when you did the GC mass spec
17	various markers that are used in evaluating the	17	analysis, what were the conditions?
18	quality of the oil, as well as looking for any	18	A The GC conditions?
19 20	compounds that would be considered synthetic.	19	Q Both GC and mass spec.
20	Q And when you say you were looking at	20	First of all, what did you do to the oil
21	markers, what markers?	21 22	before you analyzed it as GC mass spec?
22	A Essential oil constituents, like		A It was diluted in a solvent and then
23 24	alcohols, terpenes, oxygenated sesquiterpenoids,	23 24	injected directly.
27	aldehydes, esters.	24	Q What solvent?
25	Q Did you look specifically for DMAA?		A We usually use ethanol for Geranium.

	Page 58		Page 59
1	James P. Kababick	1	James P. Kababick
2	Q And what were the column conditions?	2	A The extracts were the country of
3	A I don't recall the exact column	3	origin claim was China.
4	conditions, but we replicated the atom's GC/MS	4	Q Do you know what province in China?
5	essential oil conditions, and then we also ran a	5	A No.
6	second condition which used a lower starting	6	Q When you analyzed the extracts, what
7	temperature and solvent delay so that we could	7	were you looking for?
8	look at early eluting compounds.	8	A In the extracts I was looking for DMAA.
9	Q And what was the column temperature on	9	Q And what were the results?
10	the second set of conditions?	10	A There were some samples that had it and
11	A I don't recall exactly.	11	some samples that didn't.
12	Q During any of these analyses that you	12	Q How many samples had it, if you recall?
13	did on the Geranium oils, did you attempt to	13	A I don't recall, to be honest.
14	replicate the conditions in the Li or Fleming	14	Q And again, the extracts were work that
15	studies?	15	you were doing for a client?
16	A I don't recall that I did.	16	A Yes. They were commercial samples being
17	Q And same question for the extracts that	17	represented as extracts from Geranium.
18	you analyzed; what steps did you take before you	18	Q So getting back to Exhibit 2, you did
19	did the GC mass spec analysis?	19	not attempt to obtain samples yourself of Geranium
20	A Those samples were extracted in an acid	20	plants, oils or extracts to study, correct?
21	base extraction cleanup and then placed into ethyl	21	MR. O'NEAL: Object to the form.
22	acetate or chloroform and analyzed as freebase	22	THE WITNESS: Sorry. Would you
23	forms.	23	repeat the question.
24	Q And what were the geographic origins of	24	MS. WOOLSON: Can you read it back.
25	the extracts?	25	
	Page 60		Page 61
1	James P. Kababick	1	James P. Kababick
2	(Whereupon, reporter reads	2	Q And who was the vendor?
3	requested material.)	3	A I don't recall the vendor offhand.
4	THE WITNESS: Well, actually, I	4	Q And did you test this extract?
5	did. I tried to get some from industry, so I	5	A Yes.
6	put out a call for them.	6	Q And beyond that extract, did you receive
7	BY MS. WOOLSON:	7	any other material from any other vendors?
8	Q Let me rephrase the question.	8	A Not that I recall. I may have, but I
9	You did not make any attempt yourself to	9	just don't remember that far back.
10	go gather samples of Geranium plants, oils or	10	Q And this was about the 2012 time period?
11	extracts beyond this call you made to industry?	11	A I don't know exactly when it was, but I
12	A Actually, I did contact or had my	12	know it was during that time I was looking into
13	administrator contact some vendors to see if they	13	this matter.
14	would send us some material.	14	Q The last paragraph on Exhibit 2, you
15	Q Which vendors?	15	say well, you reference "peer-reviewed papers."
16	A I don't recall offhand, to tell you the	16	Do you see that, "peer-reviewed publications"?
17 18	truth.	17 18	A Where is it?
18 19	Q Did they send you materials?	18	Q The last paragraph.
20	A One company at least sent a sample of	20	A 37 years of peer-reviewed publications?
20	their DMAA material.	20	Q Yes. I'm asking you about the terms
21	Q When you say DMAA material, are you talking about a standard?	22	"peer-reviewed publications" and "peer-reviewed papers."
23	A Well, it's supposed to be a Geranium	23	Do you see where you use those terms?
24	extract, but it was a white crystalline powder,	24	A Yes.
25	nearly pure.	25	Q What do you mean by peer-reviewed papers
		I	Contract of the mean of poor fortower pupers

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1	James P. Kababick	1	James P. Kababick
2	or publications?	2	(Exhibit 3 was marked for
3	A These were publications that are	3	identification.)
4	reviewed by scientific peers that have expertise	4	BY MS. WOOLSON:
5	in the subject matter area and are recognized as	5	Q I'm going to show you what's been marked
6	reliable scientific publications.	6	Exhibit 3. Take a look at that.
7	Q What do you mean by "reliable scientific	7	(Witness peruses document.)
8	publications"?	8	MR. O'NEAL: For the record, is
9	A That the journal has a high impact	9	this a complete version of the document?
10	rating, meaning that there's recognition by a	10	MS. WOOLSON: I believe it is.
11	larger body of scientists as to the quality of the	11	MR. O'NEAL: Okay.
12	journal and its editorial scrutiny.	12	(Witness peruses document.)
13	Q And what do you know about the	13	THE WITNESS: Yes.
14	peer-reviewed process for the publication I	14	BY MS. WOOLSON:
15	think it's called Analytical Chemistry Insights.	15	Q And do you recognize Exhibit 3?
16	A I would have to check that journal	16	A It looks like it could be the Ping
17	again. I don't remember the exact details on that	17	paper.
18	one.	18	Q Okay. What is the molecular formula for
19	Q So as you're sitting here today, you	19	DMAA, if you know?
20	don't know whether it's peer-reviewed or not?	20	A Offhand? I'd have to look it up to be
21	A No. I don't recall.	21	sure.
22	Q All right. In paragraph 15 of your	22	Q Okay. If I told you that it was
23	report you talk about the Ping paper.	23	C7H171N, does that make sense?
24	(Witness peruses document.)	24	A That could be the formula.
25	THE WITNESS: Yes.	25	Q Do you know the molecular weight?
	Page 64		Page 65
1		1	
1 2	James P. Kababick	1	James P. Kababick
	James P. Kababick A 115 is the nominal mass.		James P. Kababick A Computerized data acquisition has
2	James P. Kababick A 115 is the nominal mass. Q And you would agree with me that in the	2	James P. Kababick A Computerized data acquisition has changed, so the software has been evolving, and
2 3	James P. Kababick 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	2 3	James P. Kababick A Computerized data acquisition has changed, so the software has been evolving, and also mass spectrometry has become more mainstream
2 3 4	James P. Kababick 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?	2 3 4	James P. Kababick 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
2 3 4 5	James P. Kababick 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	2 3 4 5	James P. Kababick 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
2 3 4 5 6 7	James P. Kababick 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.	2 3 4 5 6	James P. Kababick 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
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2 3 4 5 6 7 8 9	James P. Kababick 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.	2 3 4 5 6 7 8 9	James P. Kababick 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?
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1	James P. Kababick	1	James P. Kababick
2	Let me rephrase the question.	2	you say that "Drs. Lisi, Zhang, Di Lorenzo, Austin
3	On average, what's the minimum amount of	3	and ElSohly used validated and adequately
4	mass that you need for NMR to run the sample?	4	sensitive methods."
5	A It depends on the type of NMR that	5	Do you see that?
6	you're using. If you have an advanced CryoProbe	6	A Yes.
7	NMR, you could work with microgram samples.	7	Q Are you opining that Drs. Li and Fleming
8	Q And how common are advanced CryoProbe	8	did not use adequate did not use validated and
9	NMRs?	9	adequately sensitive methods?
10	A They're pretty routine at universities	10	A No.
11	now, and several analytical labs have that service	11	Q To your knowledge, based on your review
12	as well.	12	of the publications and we'll take just the
13	Q And if you didn't have an advanced	13	ElSohly publications first for purposes of this
14	CryoProbe NMR, how much sample would you need?	14	question. How did Drs. ElSohly and Khan get their
15	A It really depends on the experiment, the	15	samples?
16	pulse rate, relaxation delay, and what you are	16	A I would have to review the paper. I
17	looking at, C-13 proton, et cetera.	17	don't recall exactly offhand.
18	Q Have you reviewed as part of your work	18	Q Do you think they went out to China and
19	in this case the studies that were performed by	19	picked Geranium plants themselves?
20	Dr. Khan and Dr. ElSohly, Dr. Lisi, Dr. Zhang and	20	A I don't know that they did that.
21	Dr. Di Lorenzo?	21	Q Do you think that they had somebody from
22	A I reviewed papers published by Li and	22	China send them plants?
23	ElSohly and Khan and others. I believe one of	23	A I don't know.
24	those was the Zhang paper as well.	24	Q And if I asked you the same questions
25	Q Okay. In paragraph 16 of your report	25	regarding Dr. Lisi, Dr. Zhang and Dr. Di Lorenzo,
	Page 68		Page 69
1	James P. Kababick	1	Page 69 James P. Kababick
1 2		1 2	
	James P. Kababick		James P. Kababick
2	James P. Kababick would your answer be the same?	2	James P. Kababick (Witness peruses documents.) THE WITNESS: Okay. BY MS. WOOLSON:
2 3	James P. Kababick would your answer be the same? A Yeah, I don't know the exact details of	2 3	James P. Kababick (Witness peruses documents.) THE WITNESS: Okay.
2 3 4 5 6	James P. Kababick 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	2 3 4	James P. Kababick (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
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<sup>17</sup> to external sources. That's all I'm asking you. <sup>17</sup> A They indicate that they obtained the	
	1
<ul> <li>A To the best of my knowledge, yes.</li> <li>Q Okay. Now, does anything in Exhibit 4</li> <li>Q And again, I'm sorry to make you flip</li> </ul>	
<sup>20</sup> tell you anything about the growing conditions, <sup>20</sup> back and forth, but with respect to Exhibit 5, t	
the soil, the water, the air, the nutrients, the soil, the water, the air, the nutrients, 21	ie
<sup>22</sup> anything? <sup>22</sup> anything? <sup>22</sup> provided to Drs. Khan and ElSohly, correct?	
<ul> <li>A No, I don't believe it does.</li> <li>A No, I don't believe it does.</li> <li>A It indicates that they were obtained by</li> </ul>	
<ul> <li>Q And so these samples in Exhibit 4 of the</li> <li>NCNPR, but that's the group which Dr. Khan</li> </ul>	anda
<sup>25</sup> plants were obtained by third parties for <sup>25</sup> so I'm not sure what his involvement was in the sure what his involvem	
so this not sure what his involvement was in u	5
Page 72 Page	73
<sup>1</sup> James P. Kababick <sup>1</sup> James P. Kababick	
<sup>2</sup> collection. <sup>2</sup> that were gathered by a third party and sent t	,
<sup>3</sup> Q Well, not all the plants came from <sup>3</sup> you for research?	
$^{4}$ NCNPR, correct? $^{4}$ A Yes.	
<sup>5</sup> A Right. <sup>5</sup> Q Now, what, if anything, did Drs. ElSe	hly
<sup>6</sup> Q Okay. So we can at least agree that the <sup>6</sup> and Khan do in Exhibit 4 and Exhibit 5 to	
<ul> <li><sup>7</sup> plants that did not come from the NCNPR were</li> <li><sup>7</sup> determine if their plant material was contam</li> </ul>	nated
<sup>8</sup> obtained by a third party, correct? <sup>8</sup> in any way?	
<sup>9</sup> A I actually don't know, because I don't <sup>9</sup> A I'm not sure that they did any testing	
<sup>10</sup> see where it says it says there were materials <sup>10</sup> for contamination.	
<sup>11</sup> from sources, but I don't know how those materials <sup>11</sup> (Exhibit 6 was marked for	
<sup>12</sup> were collected. <sup>12</sup> identification.)	
13     Q     Okay. So that information is not in     13     (Witness peruses document.)	
$^{14}$ this paper, to the best of your ability to tell? $^{14}$ THE WITNESS: Is this 2012 pape	
<sup>15</sup> A Yeah. Currently looking at it, I don't <sup>15</sup> part of this document at the back?	
<sup>16</sup> see that. <sup>16</sup> BY MS. WOOLSON:	
<sup>17</sup> Q Now, it's not unusual for samples to be <sup>17</sup> Q No. Sorry. Just a copying error.	
<sup>18</sup> obtained by a third party and sent to a lab for <sup>18</sup> That's the next exhibit you're going to get, th	
<sup>19</sup> research, is it? <sup>19</sup> Di Lorenzo paper. You should never let atto	neys
20     A You mean like in general?     20     make photocopies.	
<sup>21</sup> Q Like in general, yes, like for plants to <sup>21</sup> (Witness peruses document.)	
<sup>22</sup> be obtained by a third party and sent to a lab to <sup>22</sup> THE WITNESS: Yes.	
<sup>23</sup> be researched. <sup>24</sup> BY MS. WOOLSON:	
A Yeah, that happens. Q So you have in front of you Exhibit 6	
<sup>25</sup> Q Have you yourself ever studied plants <sup>25</sup> Do you recognize Exhibit 6?	

	Page 74		Page 75
1	James P. Kababick	1	James P. Kababick
2	A It appears to be a paper from the Drug	2	A I don't know that they took any steps.
3	Testing and Analysis Journal.	3	They don't discuss that here.
4	Q And it's by Dr. Lisi et al., correct?	4	(Exhibit 7 was marked for
5	A Yes.	5	identification.)
6	Q Have you read this paper before?	6	BY MS. WOOLSON:
7	A I think I recall reading this paper.	7	Q Let me show you what's been marked as
8	Q Okay, and this paper involved Geranium	8	Exhibit 7. Take a look at that.
9	oil and Geranium Geranium oil and supplements,	9	(Witness peruses document.)
10	correct?	10	THE WITNESS: Okay.
11	A It did involve Geranium oil, and let me	11	BY MS. WOOLSON:
12	see here. Yes, and supplements.	12	Q So showing you Exhibit 7, have you seen
13	Q And where did the Geranium oils come	13	that before?
14	from? What was their origin?	14	A I think I did see this before.
15	A They list their origins as France,	15	Q Okay. If it's helpful
16	Egypt, and then a yeah, just France and Egypt	16	A There's actually another paper attached
17	right here in the table.	17	to it, by the way.
18	Q And do you see on I just lost my	18	Q Oh, okay. There you go. Not anymore.
19	place. Oh, under "Experimental" on page 2 of the	19	A So it's just this particular paper,
20	report, these Geranium oils were purchased over	20	right?
21	the internet, correct?	21	Q It's the Di Lorenzo paper, correct?
22	A Yes.	22	A Yes.
23	Q Okay, and what steps, if any, did	23	Q If it's helpful, if you look at
24	Dr. Lisi et al. take to determine if the Geranium	24	paragraph 16 of your report, you refer to the
25	oil samples were contaminated?	25	Di Lorenzo study.
	Page 76		Page 77
1	James P. Kababick	1	James P. Kababick
2	A Yes.	2	and analysis of cannabinoids.
3	Q Where do the plant samples in the	3	
			Q And when is the last time you spoke to
4	Di Lorenzo study come from?	4	Dr. Khan or Dr. ElSohly about DMAA?
5	Di Lorenzo study come from? A They were obtained, it says, at a plant	5	Dr. Khan or Dr. ElSohly about DMAA? A I don't recall. I don't know if I've
5 6	A They were obtained, it says, at a plant nursery.	5 6	<ul><li>Dr. Khan or Dr. ElSohly about DMAA?</li><li>A I don't recall. I don't know if I've</li><li>ever spoken to Dr. ElSohly about it, and for</li></ul>
5 6 7	<ul><li>A They were obtained, it says, at a plant nursery.</li><li>Q And what information does the paper have</li></ul>	5 6 7	<ul><li>Dr. Khan or Dr. ElSohly about DMAA?</li><li>A I don't recall. I don't know if I've</li><li>ever spoken to Dr. ElSohly about it, and for</li><li>Dr. Khan it would have been a while back.</li></ul>
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	Page 78		Page 79
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1	James P. Kababick	1	James P. Kababick
2	A Not offhand, no.	2	actually found DMAA in Geranium plants when
3	Q If you look at Exhibit 5, can you tell	3	participating in this multi-centre study?
4	me where well, first of all, how many centers	4 5	MR. O'NEAL: Object to the form.
5	were involved in this multi-centre study?	-	THE WITNESS: I don't know that
6	A It indicates here that there were four	6	they did.
7	laboratories participating.	7	BY MS. WOOLSON:
8	Q Which were? Who were they?	8	Q Look at Exhibit 8 for me, and let me
9	A Based on the information up front, it	9	know, first of all, if you've ever seen this
10	would have the NCNPR University in Mississippi,	10 11	before.
11	Shanghai Institute Materia Medica School of	11	(Witness peruses document.)
12	Pharmacy in Shanghai, and I'm not sure which of		THE WITNESS: Okay. I don't know
13	the other ones is the participating laboratory.	13	that I recall this email chain, but I've read
14	Q If you look at the paper, do you see any	14	through it here.
15	published results regarding the Shanghai	15	BY MS. WOOLSON:
16	Institute?	16	Q Okay, and you would agree with me that
17	A The one named in the paper here?	17	in this email chain or would you agree with me
18	Q Yes.	18	that in this email chain, the Shanghai Institute
19	A I don't see anything that says it's	19	is reporting that it detected DMAA in some of its
20	exclusively from their institute offhand.	20	plant samples?
21	(Exhibit 8 was marked for	21	A It would appear that somebody from the
22	identification.)	22	institute believes they saw DMAA in plant samples.
23	BY MS. WOOLSON:	23	Q Before today, were you aware of that?
24	Q Before we get to questions about Exhibit	24	A I'm not sure, to tell you the truth. I
25	8, are you aware that the Shanghai Institute	25	may have heard something about it, but I don't
	Page 80		Page 81
1		1	
1 2	James P. Kababick	1 2	James P. Kababick
1 2 3	James P. Kababick recall offhand the specifics.	2	James P. Kababick A It's the Fleming paper regarding DMAA
2	James P. Kababick recall offhand the specifics. Q When you say you "may have heard," it		James P. Kababick A It's the Fleming paper regarding DMAA analysis in Geranium plants.
2 3	James P. Kababick recall offhand the specifics. Q When you say you "may have heard," it seems like you have a recollection.	2 3	James P. Kababick A It's the Fleming paper regarding DMAA analysis in Geranium plants. Q Okay. Now, do you agree that the
2 3 4	James P. Kababick 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?	2 3 4	James P. Kababick 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?
2 3 4 5	James P. Kababick 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	2 3 4 5	James P. Kababick 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
2 3 4 5 6 7	James P. Kababick 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	2 3 4 5 6	James P. Kababick 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
2 3 4 5 6	James P. Kababick 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	2 3 4 5 6 7	James P. Kababick 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.
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1	James P. Kababick	1	James P. Kababick
2	Q Have you ever followed that methodology	2	DMAA that was detected in the Fleming study is the
3	for any of the analyses that you've done in your	3	result of contamination?
4	lab?	4	A Yes.
5	A No. We use other methodologies.	5	Q And what is your factual basis for
6	Q And how do your methodologies vary from	6	saying that?
7	EPA's method, if at all?	7	A The larger body of scientific evidence
8	A I would have to review the EPA methods	8	does not report this compound in any of the
9	again to look at the specific aspects of how they	9	DMAA or any of the Geranium samples tested
10	would differ.	10	overall, and in this case they were detected.
11	Q Are you opining that use of the EPA	11	DMAA was detected at extremely low levels within a
12	method was incorrect?	12	range of what we would expect pesticide residues
13	A No, I'm not saying that.	13	and solvents to be detected in samples, or metal
14	Q In your report in paragraphs 18 and 19,	14	contaminants, and those low levels were not
15	you discuss contamination.	15	evaluated further and stand as outliers in the
16	Do you see that?	16	larger data.
17	(Witness peruses document.)	17	Subsequent to my report reviewing
18	THE WITNESS: Yes.	18	Dr. Brown's report, she also discusses the
19	BY MS. WOOLSON:	19	metabolic pathways and opines that it's not
20	Q What facts do you have to strike	20	possible for the plant to make this compound,
21	that.	21	which supports my understanding of the larger data
22	What facts are you relying upon for your	22	showing that it's not being detected.
23	opinion that the well, first of all, let me ask	23	Q So beyond the fact that there are other
24	it a different way.	24	studies that did not detect DMAA in Geranium
25	Is it your are you opining that the	25	plants, and that the concentrations were low, and
	Page 84		Page 85
	20,90 01		rage 05
1	James P. Kababick	1	James P. Kababick
1 2		1 2	
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1	James P. Kababick	1	James P. Kababick
2	regarding the multi-centre study where Shanghai	2	Q 90 percent?
3	Institute did detect DMAA in Geranium plants,	3	A I would say over 40, 50.
4	correct?	4	Q And so you have still 100 components or
5	MR. O'NEAL: Object to the form.	5	more in the oil, at least 40 to 50 percent of
6	THE WITNESS: In that email, they	6	which are compounds other than amines, correct?
7	said that they thought they found DMAA.	7	A I'm sorry. What was the question again?
8	BY MS. WOOLSON:	8	Q You have over 100 components in Geranium
9	Q Okay, and low levels of DMAA, that was	9	oil, correct?
10	your third basis.	10	A Yes.
11	Do you agree with me that plant species	11	Q And you said at least 40 to 50 percent
12	like the Geranium plant strike that.	12	of those components are chemicals other than
13	When you did your analysis on Geranium	13	amines, correct?
14	oils, how many components did you find?	14	A Yeah, at least.
15	A I don't know the exact number.	15	Q What would be the second largest
16	Q Can you give me an estimate?	16	category of compounds in the Geranium oil?
17	A Well over a hundred.	17	A It would be other volatile oil
18	Q Well over a hundred, and what was	18	constituents, sesquiterpenoids, monoterpenes,
19	largest component of the oils that you found?	19	things like that.
20	A The largest components were oxygenated	20	Q What percentage approximately of the
21	compounds, alcohols, esters, formaldehydes.	21	Geranium oil would those comprise?
22	Q And roughly, percentage-wise, what	22	A I would have to look at that. It can
23	percentage of those did they take up of the oil?	23	vary widely, depending on the distillation
24	A I'd have to look to see exactly, but	24	technique and other things. The particular
25	they were a major percentage.	25	chemotype.
	Page 88		Page 89
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1	James P. Kababick	1	James P. Kababick
1 2	James P. Kababick O And why would the concentration of those	1 2	James P. Kababick O And do you know the chemotypes of the
	Q And why would the concentration of those		Q And do you know the chemotypes of the
2	Q And why would the concentration of those compounds vary depending on the distillation	2	Q And do you know the chemotypes of the Geraniums that were studied by ElSohly and Khan?
2 3	Q And why would the concentration of those compounds vary depending on the distillation procedure?	2 3	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
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1	James P. Kababick	1	James P. Kababick
2	about distillation.	2	Allowing for that variation, can you
3	Anything else that can affect the	3	estimate for me the percentages of those compounds
4		4	in Geranium oil?
5	composition?	5	A No, I couldn't.
6	A After production and before production,	6	
7	how the material was handled can impact it.	7	Q Okay. What's the third largest category
8	Q In what way?	8	of components in Geranium oil?
9	A There's a potential for oxidative	9	A I don't know that they would be broken
10	degradation, decomposition that could result in	10	down into further categories. I'd have to look.
11	polymerization or the formation of aldehydes or	11	Q So there are a number of components in
12	amines. If it's not properly stored and it's	12	the Geranium oil or Geranium plant, correct?
13	exposed to light, you can get photooxidative	13	A Yes.
14	breakdown products.	14	Q And the largest percentage of those have
	Q And would the same be true for plants	15	nothing to do strike that.
15 16	versus oils?	16	The largest percentage of those are not
17	A For the storing of plants, do you mean?	17	amines, correct?
	Q Yes, for Geranium plant.		A For the oil, yes.
18	A Yes, to a degree it would be.	18 19	Q Not true for the plant?
19	Q Okay. So we were talking about the		A The plant, I have not seen amines
20	composition of I guess the sesquiterpenoids and	20	indicated as a major constituent.
21	monoterpenes or terpenes of the Geranium oils that	21 22	Q Now, you said that the concentrations of
22	you had studied. You said that the percentage of		DMAA that were detected were in the range of I
23	those could vary depending on these things we were	23	think you said they were pesticides or solvents or
24 25	just talking about, in terms of the handling and	24 25	trace metals?
25	processing of the oils.	25	A Yeah, trace metals.
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1	James P. Kababick	1	James P. Kababick
2	Q But DMAA is clearly not a trace metal,	2	DMAA in, and that it's possible that it could have
3	is it?	3	come from that and should be studied further, yes.
4	A No.	4	Q And what were the concentrations of the
5	Q And it's not a pesticide, is it?	5	DMAA found in the fertilizer by Dr. Simone?
6	A No.	6	A I'd have to refer back to the data to
7	Q And it's not a solvent, is it?	7	see the levels.
8	A It can be a solvent.	8	Q Why don't you look in your report,
9	Q Okay. In what circumstances could it be	9	because I think you have something in your report.
10	a solvent?	10	A I believe I do.
11	A I would have to look, but it could be	11	Yeah, these two reported at 8.4 and 8.1
12	involved in an organic synthesis.	12	nanograms per gram.
13	Q In what way?	13	Q And how does that compare with the
14	A It could be a as a freebase it's a	14	levels of DMAA that Dr. Simone and Dr. Fleming
15	liquid, mobile liquid, and it could be involved in	15	reported in the Geranium plants?
16	the furtherance of compounds or manufacture.	16	A I'd have to look back and see what their
17	Q Okay. I think the fourth thing you	17	reported levels were.
18	talked about was fertilizer, correct?	18	Q You can look at Exhibit 5 if that helps.
19	A What's that?	19	A They would fall above their detection
20	Q I think the fourth factor, the fourth	20	limit, and according to this table, they would be
21	basis for your opinion that the DMAA that was	21	below the Changzhou S11-1 and the Changzhou 1
22	detected by Fleming et al. was a contaminant was	22	samples.
23	fertilizer, correct?	23	Q You mean the concentrations of
24	A What I was saying that, that Simone	24	fertilizer?
25	discussed that there were fertilizer studies found	25	A The DMAA they reported in those two is

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1		1	
1	James P. Kababick	1	James P. Kababick
2	higher than the DMAA he reported in fertilizer.	2	Q And as you sit here today, you don't
3	Q And have you done any analysis of	3	have any facts about the growing conditions of the
4	fertilizer to determine if it has DMAA in it and,	4	plants in which Dr. Simone and Dr. Fleming
5	if so, the concentrations?	5	detected DMAA, correct?
6	A No.	6	A Only that they were transferred,
7	Q Are you aware of any efforts by the	7	according to the paper, from the soil to potted
8	United States government to analyze fertilizer to	8	plants and transferred to the institute.
9	determine if there is DMAA in it and how much the	9	Q Institute?
10	concentrations would be?	10	A In China where they were authenticated.
11	A No.	11	Q Okay, but you don't know anything about
12	Q Are you aware of any work by	12	the composition of the soil or the water that was
13	Drs. ElSohly or Khan to analyze fertilizer to	13	used or the pot that was used, anything?
14	determine if there is DMAA in there and how much	14	A No.
15	concentration there would be?	15	Q Okay. Are you aware that Dr. Simone
16	A No.	16	also detected 1,3-DMAA in a Geranium plant that
17	Q Are you aware of work by anybody other	17	was purchased in the United States?
18	than Dr. Simone to determine if there's DMAA in	18	A I don't recall that.
19	fertilizer?	19	Q In paragraph 22 of your report, you say
20	A No.	20	that Dr. Simone did not consider his 2012 study
21	Q And as you sit here today, you don't	21	"did not consider in his 2012 study or his current
22	have any knowledge of what type of fertilizer, if	22	declaration that the DMAA identified in the
23	any, was used on the plants that Dr. Simone and	23	limited number of Geranium samples could be a
24	Dr. Fleming analyzed and detected DMAA, correct?	24	contaminant."
25	A No.	25	Do you see that?
	Page 96		Page 97
1	James P. Kababick	1	James P. Kababick
1 2	James P. Kababick A And what was the question again?	1 2	James P. Kababick Q You also say in your report in paragraph
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	Page 98		Page 99
1	James P. Kababick	1	James P. Kababick
2	Q As we discussed when we were reviewing	2	Q I put in front of you what's been marked
3	the various studies that we marked as Exhibits 4,	3	as Exhibit 10. Take a look at that and tell me if
4	5, 6, 7, the vast majority of these researchers	4	you've seen it before.
5	obtained their specimens from third parties,	5	(Witness peruses document.)
6	correct?	6	THE WITNESS: Okay.
7	A In the case of the paper by Khan and	7	BY MS. WOOLSON:
8	ElSohly where they obtained them at NCNPR, I don't	8	Q So I'm showing you what's been marked as
9	know that the link of the relationship of those	9	Exhibit 10.
10	are their past experience of the samples, but	10	Have you seen that before?
11	there were materials obtained by third parties.	11	A Yes.
12	MS. WOOLSON: It's 12:25. Do you	12	Q And what is Exhibit 10?
13	want to break now?	13	
14	MR. O'NEAL: That's fine.	14	<ul><li>A This is the Li paper.</li><li>Q And did you read the Li paper at or</li></ul>
15		15	
16	(Whereupon, the lunch recess was	16	about the time it was published?
17	taken.)	17	A I believe so, yes.
18	(Exhibit 10 was marked for		Q And what, if anything, did you do after
	identification.)	18	you read the Li paper?
19	(Exhibit 11 was marked for	19	A If I'm remembering correctly, I did
20	identification.)	20	review this paper and evaluated the data and the
21	BY MS. WOOLSON:	21	validation metrics.
22	Q Are you ready to resume, Mr. Kababick?	22	Q And for what purpose did you do that?
23	A Yes.	23	A Well, it was reporting the detection of
24	Q And you're still under oath.	24	these compounds which was contrary to the larger
25	A Yes.	25	body of data, and that was a very significant
	Page 100		Page 101
1	James P. Kababick	1	James P. Kababick
2	finding, so I wanted to evaluate further the	2	industry.
3	validity of the paper as well as the steps that	3	Q And was there a consensus statement
4	were taken throughout.	4	issued?
5	Q And what did you do with that analysis	5	A I don't know that there actually was a
6	of the paper?	6	consensus statement issued, but the botanical
7	A I did, I believe, discuss that with some	7	adulterants program may have put out a guidance on
8	colleagues in email communications.	8	Geranium. I don't recall.
9	Q And why did you do that?	9	(Exhibit 11 is handed to the
10	A There was a lot of interest among many	10	witness.)
11	stakeholders in industry about DMAA in Geranium,	11	(Witness peruses document.)
12	and we were looking at the various papers that	12	THE WITNESS: Okay.
13	were out and discussing what the findings are and	13	BY MS. WOOLSON:
14	what might be going on.	14	Q Okay. Have you seen Exhibit 11 before?
15	Q Did you seek to have a consensus	15	A Yes.
16	statement issued by a particular group?	16	Q What is Exhibit 11?
17	A Yeah, I believe I talked to I'm	17	A It's an email chain discussing the Li
18	drawing a blank now. I'm sorry. Mark Blumenthal	18	paper.
19	at American Botanical Council about putting out a	19	Q And to whom well, let me strike that.
20	statement regarding the findings to date, because	20	Who is on this email chain?
21	so many stakeholders in the industry were then	21	A It looks like we have Mark Roman, Mark
22	confused about what's going on, because there's	22	Blumenthal, Joe Betz, John Cardellina, Ikhlas
23	11 d i i i i i i i i i i i i i i i i i i	23	

- <sup>23</sup> all these papers saying it's not there and other
- <sup>24</sup> papers saying it's present, and what's the
- <sup>25</sup> consensus of experts that are working in the
- Khan, ElSohly, Anthony Armada, myself, Armstrong,
   Frank Jaksch and Daniel W. I'm not sure who that
- <sup>25</sup> is.

	Page 102	Page 103
1	James P. Kababick	<sup>1</sup> James P. Kababick
2	Q I think that may be Daniel W. Armstrong.	<ul> <li>your comments to this wider audience?</li> </ul>
3	A Probably.	<sup>3</sup> A You mean to allow Mark to distribute it
4	Q And what is the relationship between all	<sup>4</sup> to the larger audience?
5	these people on this email?	$^{5}$ Q Yes.
6	A All scientists that have an interest in	<sup>6</sup> A He wanted to get input from various
7	the DMAA issue.	<sup>7</sup> other people on it and to see what they thought of
8	Q How is it that all of you came together	<sup>8</sup> my thoughts, so I said he could share that
9	in this email?	<sup>9</sup> information and get feedback on it.
10	A Well, many of us have co-served on	$^{10}$ Q And did you get responses to your email?
11	committees and panels or members of scientific	<sup>11</sup> A I don't recall if I got responses to the
12	societies that worked on a lot of the methodology	<sup>12</sup> email specifically.
13	in industry today and worked on a lot of the	$^{13}$ Q Okay. So let's take a look at what you
14	educational outreach, and often communicate with	14 have to say.
15	each other about various matters, and I believe	<sup>15</sup> You say you have "some serious issues
16	this one was related to seeking some input for the	$^{16}$ with the paper."
17	American Botanical Council.	$^{17}$ Do you see that?
18	Q If you look down on the bottom of the	$^{18}$ A Yes.
19	first page, it says, "Jim Kababick has given me	<sup>19</sup> Q And the first issue is that you're not
20	permission to send you his detailed comments on	<sup>20</sup> familiar with the journal that published the
21	the Li paper. He previously sent these to Ikhlas	<sup>21</sup> article?
22	Khan and to Frank Jaksch."	<sup>22</sup> A Yes.
23	Do you see that?	<sup>23</sup> Q And why was that of concern to you?
24	A Yes.	A I'm pretty familiar with the major
25	Q What was the purpose in disseminating	<sup>25</sup> journals recognized in our industry and the
	Page 104	Page 105
		1490 100
1	James P. Kababick	<sup>1</sup> James P. Kababick
1 2		
	James P. Kababick journals that typically carry the information related to discoveries of natural products and	<sup>1</sup> James P. Kababick
2	James P. Kababick journals that typically carry the information	<ul> <li>James P. Kababick</li> <li>following these papers, there was a large exposé</li> <li>on pay-to-publish journals, and many, many papers</li> <li>of credible or thought to be credible scientists</li> </ul>
2 3	James P. Kababick 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	<ul> <li>James P. Kababick</li> <li>following these papers, there was a large exposé</li> <li>on pay-to-publish journals, and many, many papers</li> <li>of credible or thought to be credible scientists</li> <li>have been discredited, and so pay-to-publish</li> </ul>
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2 3 4 5 6 7	James P. Kababick 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	<ul> <li>James P. Kababick</li> <li>following these papers, there was a large exposé</li> <li>on pay-to-publish journals, and many, many papers</li> <li>of credible or thought to be credible scientists</li> <li>have been discredited, and so pay-to-publish</li> <li>journals are under a lot of scrutiny by scientists</li> <li>and academics right now.</li> </ul>
2 3 4 5 6	James P. Kababick 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	<ul> <li>James P. Kababick</li> <li>following these papers, there was a large exposé</li> <li>on pay-to-publish journals, and many, many papers</li> <li>of credible or thought to be credible scientists</li> <li>have been discredited, and so pay-to-publish</li> <li>journals are under a lot of scrutiny by scientists</li> <li>and academics right now.</li> <li>Q As you sit here today, do you know who</li> </ul>
2 3 5 6 7 8 9	James P. Kababick 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?	1James P. Kababick2following these papers, there was a large exposé3on pay-to-publish journals, and many, many papers4of credible or thought to be credible scientists5have been discredited, and so pay-to-publish6journals are under a lot of scrutiny by scientists7and academics right now.8Q9peer-reviewed the Li article?
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1		1	
	James P. Kababick	2	James P. Kababick
2	questionable publications, would you have included	3	Do you see that?
3	that information in your expert report?		A Yes.
4	A Yeah, if I had that knowledge, I would	4	Q And why is that?
5	have included it.	5	A Because those are hypothetical states,
6	Q The second comment that you have about	6	essentially, in analytical chemistry.
7	the report is that you don't understand and I'm	7	Q And why is that?
8	paraphrasing you don't understand why the Li	8	A Because you can't be absolutely sure
9	authors made the statement that they are not aware	9	that there's not at least one molecule present or
10	of any publication that identifies 100 percent of	10	one molecule absent of something.
11	the oil content.	11	Q Okay. In comment number 3 you talk
12	Do you see that?	12	about the chromatography column that was used, and
13	A Yes.	13	you say that you would "expect resolution issues
14	Q And it seems to me you agree that no one	14	and possibly other chromatography problems from an
15	has identified 100 percent of the oils content, so	15	overload."
16	I'm not sure I understand why this comment	16	Do you see that?
17	bothered you.	17	A Yes.
18	A I would have to look at what this was	18	Q Did you make any attempt to replicate
19	speaking to specifically in the paper to see what	19	the conditions in the Li study to see if there
20	this was regarding, because I don't recall	20	were chromatography problems or resolution issues?
21	specifically.	21	A No, I did not.
22	Q Well, in the paragraph you say, "I know	22	Q In paragraph 4 you say you would have
23	of no credible scientist that would report the	23	expected some "decomposition and formation of
24	values of zero percent or 100 percent in	24	aroma chemical compounds that are amine-like in
25	analytical chemistry."	25	nature after a long travel from China."
	Page 108		Page 109
1	James P. Kababick	1	James P. Kababick
2	Do you see that?	2	A Yes. I don't know if it's the same
3	A Yes.	3	catalog number, though. I have to go back and
4	Q Why were you asking if it was unusual?	4	check.
5	A Where I say "do you see this as	5	Q Okay. In paragraph number 6 you say, "I
6	unusual"?	6	find the chromatographic separation, even for a
7	Q Yes.	7	fused core column, to be remarkable, considering I
8	A Having worked with lots of fresh	8	can't fully baseline resolve these diastereomers
9	material shipped from other countries, it is very	9	on a GC column with full baseline resolution
10	hard to get fresh material into the US without	10	(unless derivatized)."
11	•		(
± ±	delays such that usually when it comes in it is	11	As of the date that you had sent this
12	delays such that usually, when it comes in, it is compromised. Even an extra day delay can cause	11	As of the date that you had sent this email, which looks like August 9, 2012, when was
12	compromised. Even an extra day delay can cause		email, which looks like August 9, 2012, when was
	compromised. Even an extra day delay can cause issues unless it's shipped on dry ice or kept cold	12	email, which looks like August 9, 2012, when was the last time that you had attempted to resolve
12 13 14	compromised. Even an extra day delay can cause issues unless it's shipped on dry ice or kept cold another way.	12 13	email, which looks like August 9, 2012, when was the last time that you had attempted to resolve the DMAA diastereomers?
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12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>compromised. Even an extra day delay can cause issues unless it's shipped on dry ice or kept cold another way.</li> <li>Q Okay, and the decomposition that you're referring to, is that a natural process or phenomenon?</li> <li>A It can be.</li> <li>Q Okay. In the fifth paragraph you say that the standard for DMAA was purchased from Sigma.</li> <li>Do you see that?</li> <li>A Yes.</li> </ul>	12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>email, which looks like August 9, 2012, when was the last time that you had attempted to resolve the DMAA diastereomers?</li> <li>A Resolved on a GC column?</li> <li>Q Yes.</li> <li>A I don't recall.</li> <li>Q Have you, in fact, tried to resolve the DMAA diastereomers on a GC column?</li> <li>A Yes, I did work on that, and I got the diastereomers almost baseline resolved.</li> <li>Q What were you using as the source of the DMAA when you were doing this work?</li> </ul>

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1	James P. Kababick	1	James P. Kababick
2	obtained, and also standard from ChromaDex, and I	2	that?
3	also obtained the CPR standard from Sigma, the	3	A No. I have a method developed to do
4	uncertified one.	4	that.
5	Q And were you doing this work for a	5	Q You just don't offer it commercially?
6	client?	6	A Right.
7	A Actually, it was for a method	7	Q Okay, and when I asked you about
8	development for client services, yes.	8	resolving the diastereomers on a GC column
9	Q When you say it was "method development	9	well, I asked you about resolving the
10	for client services," do you mean it was work that	10	diastereomers on a column, and you said GC.
11	you were doing to develop a method for a specific	11	Have you done other work with regard to
12	client?	12	the DMAA diastereomers in attempting to resolve
13	A No. It was for developing methodologies	13	them?
14	to offer to clients.	14	A Yes. I've run it on liquid
15	Q And has Flora offered strike that.	15	chromatography, too.
16	Have you developed such a method and now offer it	16	Q And was the source of the material the
17	to clients?	17	same, trade material?
18	A We currently offer the analysis of	18	A Yes, the three materials that I
19	compounds or mixtures to detect the presence of	19	mentioned.
20	DMAA. We're not right now quantifying DMAA.	20	Q In paragraph 9 you talk about "the
21	Q Is there a reason why you're not	21	addition of .1 percent formic acid."
22	quantifying DMAA?	22	Do you see that?
23	A There's not enough demand right now for	23	A Yes.
24	that.	24	Q Did you do any work to determine if
25	Q So you haven't developed a method to do	25	there was any shift in the retention times caused
	Page 112		Page 113
1	Page 112 James P. Kababick	1	Page 113 James P. Kababick
1 2		1 2	
	James P. Kababick		James P. Kababick
2	James P. Kababick by the acid? A No, I did not. Q In paragraph 11 you talk about working	2	James P. Kababick HorRat equation. He had hypothesized that as
2 3	James P. Kababick by the acid? A No, I did not. Q In paragraph 11 you talk about working in the "pesticide residue chemistry area."	2 3 4 5	James P. Kababick HorRat equation. He had hypothesized that as technology advanced, that he would see precision
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	Page 114		Page 115
1	James P. Kababick	1	James P. Kababick
2	Q And how do you know they were	2	Q You say, "Considering that one of the
3	fabricated?	3	authors declares in the paper that he provided
4	A Further work and investigation yielded	4	expert witness services for the company funding
5	that information.	5	the study, I feel it is even more critical to
6	Q Okay, and as you sit here today, do you	6	emphasize why they are the only group that was
7	have any facts to suggest that the Li results were	7	able to obtain samples of oils and botanical
8	fabricated?	8	materials that had DMAA when all other researchers
9	A I do not.	9	were unable to do so."
10	Q Okay. I just want to go back to the	10	Do you see that?
11	question I was asking you about quantification of	11	A Yes.
12	DMAA. You said that that is not a service that	12	Q And in your mind, what relevance is it
13	you offer for clients.	13	that one of the authors provided expert services
14	Have you, in fact, attempted to quantify	14	to a company funding the study?
15	any DMAA in any substance?	15	A Your question was why I'm sorry.
16	A We did do some of that work in the past,	16	Q Of what significance is it to you that
17	but it rapidly dropped off with the, you know,	17	one of the authors of the study was providing
18	removal of DMAA from products. We didn't pursue	18	expert witnesses for the company who funded the
19	it.	19	study?
20	Q Do you agree with me that it is possible	20	A Well, there is a claim by USPlabs, if
21	for racemic mixtures to be created naturally?	21	I'm correct, that Geranium is a natural source of
22	A Some.	22	the compound. The only scientist who really come
23	Q Now, at the end of your analysis it's	23	out and show that in the plant were Li at this
24 25	on the page marked ElSohly 2630.	24 25	point, and he also was helping them as an expert
25	A Yes.	25	witness in that aspect. And therefore, the fact
	Page 116		Dage 117
-	Page 116		Page 117
1	James P. Kababick	1	James P. Kababick
2	James P. Kababick that his data goes against the larger body of	2	James P. Kababick USADA.
2 3	James P. Kababick that his data goes against the larger body of scientific evidence, and he's working with a group	2 3	James P. Kababick USADA. Q And to your knowledge, has Dr. ElSohly
2 3 4	James P. Kababick 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	2 3 4	James P. Kababick USADA. Q And to your knowledge, has Dr. ElSohly acted as an expert witness for USADA?
2 3 4 5	James P. Kababick 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	2 3 4 5	James P. Kababick USADA. Q And to your knowledge, has Dr. ElSohly acted as an expert witness for USADA? A I'm not sure.
2 3 4 5 6	James P. Kababick 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	2 3 4 5 6	James P. Kababick 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
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	Page 118		Page 119
1	James P. Kababick	1	James P. Kababick
2	and the synthesis of all the data, yes.	2	BY MS. WOOLSON:
3	Q And you see right above that email,	3	Q So this paper discusses next-generation
4	Joseph Betz says that he "doesn't think a	4	sequencing, correct?
5	consensus statement would be useful just yet"?	5	A Yes, of botanicals.
6	A Yes.	6	Q And it discusses the problem of
7	Q Did you have any conversations with him	7	incidental DNA in next-generation sequencing,
8	about why he didn't think that would be useful?	8	correct?
9	A I don't recall any.	9	A Yeah, the problem with incidental DNA,
10	Q Okay. Let's go back to your report,	10	meaning DNA that shows up, or fragment DNA that
11	Exhibit 1. In paragraph 19, you're discussing the	11	shows up that is linked to a certain botanical
12	possibility of foreign DNA in plant samples.	12	species.
13	Do you see that?	13	Q And the studies that were run by
14	A Yes.	14	Dr. Fleming and Dr. Li had nothing to do with
15	Q And you cite to a paper by Newmaster,	15	next-generation sequencing, did they?
16	Ragupathy and Hanner, right?	16	A No.
17	A Yes.	17	Q And they weren't detecting DNA, were
18	(Exhibit 12 was marked for	18	they?
19	identification.)	19	A Not in those studies, no.
20	BY MS. WOOLSON:	20	(Whereupon, a short recess was
21	Q So this is Exhibit 12. Take a look at	21	taken.)
22	that and let me know when you're ready to proceed.	22	BY MS. WOOLSON:
23	(Witness peruses document.)	23	Q Back to your report.
24	THE WITNESS: Okay.	24	A Yes.
25	-	25	Q In paragraph 25 you say well, are you
	Page 120		Page 121
1		1	
1	James P. Kababick	2	James P. Kababick
2	there? You say, "Dr. Simone also failed to	3	these, and then you run a formula to compare
3	utilize other available analytical techniques to	4	those.
4 5	gain additional evidence about the naturalness of	5	Q And I take it, as you sit here today,
6	DMAA in the Geranium samples studied, such as	6	you did not run isotope ratio mess spectrometry on
7	isotope ratio mass spectrometry."	7	any Geranium plant samples, did you?
8	Do you see that?	8	A No.
9	A Yes.	9	Q And would you run the isotope ratio mass
	Q First of all, what information would you	10	spectrometry on the sample itself or like on a,
10 11	expect to get from running isotope ratio mass	11	just a ground-up sample of Geranium plant, or would you process the sample somehow?
12	spectrometry?	12	• • •
13	A Isotope ratio mass spectrometry would	13	A You would prepare the sample, and depending on what analysis you were going to do by
14	give you the ratios of different carbons, carbon	14	isotope ratio, I would either prepare it by
15	12 and 13, 14. It could also give you isotope data on other elements such as hydrogen and	15	isolating and purifying the compound or setting it
16	•••	16	
17	oxygen. The goal is to determine if a compound	17	up in a volatile state where it could be separated
18	has an isotope ratio consistent with a plant source or a Petra chemical source. It's used	18	by gas chromatography. Q When you say "isolating the compound,"
19	extensively in authenticating natural products	19	what compound are you talking about? DMAA?
20	that are also available synthetically.	20	A Yeah, whatever compound I would want to
21	Q What is the difference in the ratios	21	study. The most recent one I did was on caffeine.
22	between plant and synthetic?	22	Q To your knowledge, has anyone run
23	A I'd have to look it up. It's calculated	23	isotope ratio mass spectrometry on Geranium
-			
24	against Pee Dee Belemnite and expressed in a	24	plants?

- against Pee Dee Belemnite and expressed in a
   percent-percent basis, so the data is compared to
- A Yes. I believe that there have been

25

	Page 122		Page 123
1	James P. Kababick	1	James P. Kababick
2	analyses conducted on constituents of the oil.	2	guideline or methodology that prescribes these
3	Q And by whom?	3	additional studies, or is that simply your opinion
4	A I'd have to review the literature again.	4	of what should be done?
5	Q And were any of those constituents DMAA?	5	A It's considered basic good scientific
6	A Not to my knowledge.	6	practice, if you're identifying a compound that is
7	Q In the next paragraph you say, "They	7	generally considered not to be occurring naturally
8	failed to conduct the necessary additional studies	8	in a product, to explore that further and make
9	needed to show that the compound is plant-derived	9	sure that that compound actually is coming from
10	and to rule out likely contamination sources."	10	the plant and not a byproduct of degradation,
11	Do you see that?	11	contamination or anything like that.
12	A Yes.	12	Q My question was: Is it set forth in a
13	Q Leaving aside the isotope ratio mass	13	particular methodology or procedure or guideline
14	spectrometry that we just discussed, what	14	that those are the steps that need to be taken?
15	necessary additional studies are you referring to?	15	A Not that I can recall offhand.
16	A What I would do in this case, in	16	Q And those steps that you've just
17	addition to IRMS on the compound, is to get a	17	identified for us, you didn't do any of those
18	larger population of samples to see what	18	steps, did you?
19	percentage in a larger population the material	19	A No.
20	appears, and multiple replicates of samples, so	20	Q And Dr. Brown didn't do any of those
21	from each region, additional samples. And if the	21	steps, did she?
22	material seemed to be only in certain samples, I	22	A I'm not sure if she did.
23	would further evaluate what might be the source of	23	Q You read her expert report?
24	the contamination.	24	A I did.
25	Q Okay, and is there a particular	25	Q Did you see anything like that in her
	Page 124		Dago 125
_	Page 124		Page 125
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1	James P. Kababick	1	James P. Kababick
2	Dr. Fleming, Dr. Li?	2	develop analytical methods and put those methods
3	A Only the mention that there were summer	3	or promulgate those methods out to industry.
4	and winter harvests in the one paper.	4	Originally, a long time ago, AOAC was
5	Q Beyond that, nothing?	5	part of the FDA. It was a society within the FDA
6	A Not that I recall.	6	many years ago. It was privatized and is now an
7	MR. O'NEAL: Which paper?	7	independent entity, and it includes scientists
8	THE WITNESS: The Li and Fleming	8	from all over the world.
9	paper.	9	The organization manages the official
10	BY MS. WOOLSON:	10	methods of analysis which are recognized under the
11	Q We've talked a lot about	11	C.F.R. as official test methods and are used all
12	A Yeah, the am I getting my papers	12	over the world, and when methods are needed and
13	mixed up? The Fleming and Simone paper. Let me	13	there's a call for methods, the call goes out,
14	see if I got my wires crossed here.	14	experts are assembled, and methods are evaluated
15	I believe one of the papers refers to	15	and taken to different action statuses.
16	seasonal harvest, but I need to check that, see	16	The process has changed over time
17	which one it was here.	17	because of the rapid response needed to changing
18	Yeah, "during three harvest seasons,"	18	global conditions, but they have what are called
19	yeah, so it's the Fleming/Simone paper here.	19	"official methods, first action methods," and then
20	Q Okay. We've talked at various points	20	there are methods that meet what they call
21	today about something called the AOAC.	21	"standard performance requirements" or "SPM
22	What is that?	22	methods," and these cover all kinds of things from
23	A The AOAC is a professional scientific	23	fertilizers to infant formula, vitamins, to, you
24	society that is a group of scientists and	24	know, water testing and food and supplements and
25	interested parties that collaborate, cooperate to	25	pharma. That's pretty extensive.
	Page 128		Page 129
1	Page 128	1	Page 129
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	Page 130		Page 131
1	James P. Kababick	1	James P. Kababick
2	(Exhibit 13 was marked for	2	A Oh, on the right side.
3	identification.)	3	Q "Data acquisition follows the sample
4	BY MS. WOOLSON:	4	preparation step and requires advanced analytical
5	Q You don't have to read the whole thing.	5	techniques, as the ultra-complexity of samples for
6	You can, but you don't have to. The questions	6	metabolomic analysis makes it impossible to
7	will be targeted.	7	technologically separate, quantify and identify
8	MR. O'NEAL: We'll be adjusting our	8	every metabolite within a biological sample."
9	travel schedule.	9	Do you see that?
10	THE WITNESS: Yes.	10	A Yes.
11	BY MS. WOOLSON:	11	Q Do you agree with that statement?
12	Q Have you seen Exhibit 13 before?	12	A I would say in the context of top-down
13	A Yes.	13	metabolomic pathway studies, yes, as this is
14	Q And what is it?	14	talking.
15	A This is Appendix K, which are guidelines	15	Q When you say "top-down metabolomic
16	for dietary supplement and botanical methods.	16	studies," what do you mean?
17	Q And these are guidelines issued by whom?	17	A That's the studying of metabolic plant
18	A They are issued by the AOAC.	18	pathways by looking at a variety of compounds and
19	Q Okay, and if you could turn for me to	19	data-mining those compounds using chemometric
20	page GOV-031203.	20	modeling.
21	A Yes.	21	Q And to what end I guess is the question.
22	Q At the bottom of that page, there's a	22	A Tracing the pathways by which
23	paragraph right above the table that says "Data	23	metabolites are produced in the plant.
24	Acquisition."	24	Q And if you turn to the next page,
25	Do you see that?	25	there's Table 2, and it's got listed some standard
	Page 132		Page 133
1	James P. Kababick	1	James P. Kababick
2	techniques that are used in metabolomic analysis.	2	table means regarding sensitivity and why NMR is
3	It's Table 2, not Figure 2.	3	low sensitivity versus mass spec methods?
4	A Oh, sorry. You have a question	4	A In this, related to metabolomic
5	regarding the	5	analysis, the NMR, the way it's being referenced
6	Q I do.	6	here, to my understanding, is looking at an
7	So on Table 2 there are various	7	extracted sample. You have in that sample
8	techniques that are listed for analyzing	8	multiple components as a we call Gestalt.
9	compounds, and this morning I was trying to ask	9	They're all together at once. You're getting all
10	you, in a very inarticulate fashion, questions	10	the signal from everything that responds to NMR,
11	about NMR versus mass spec, so hopefully this	11	where GC/MS and LC/MS involve some degree of
12	table will help me ask a more articulate question	12	chromatographic separation of the compound, so
13	of you.	13	you're now getting compounds separated from other
14	So looking at the table, it says for the	14	compounds.
15	technique of NMR, nuclear magnetic resonance, it's	15	Q And when you're talking about separation
16	"low sensitivity."	16	of compounds, does that mean that you are somehow
17	Do you see that?	17	performing an action on the initial product or
18	A Yes.	18	substrate in order to effect that separation?
19	Q And then for gas chromatography mass	19	A I'm not sure I understand.
20	spec, it says "high sensitivity."	20	Q Sure.
21 22	A Yes.	21 22	You're talking about separating
22	Q And for LC mass spec, it says "medium	22	compounds in LC and mass spec.
23 24	sensitivity." A Yes.	23	A Yes. And so my question was: Does that mean
25		25	Q And so my question was: Does that mean that you're operating in some way upon the
	Q What is your understanding of what this	_	that you're operating in some way upon the

			-
	Page 134		Page 135
1	James P. Kababick	1	James P. Kababick
2	original substrate in order to effect that	2	Q So that other approaches may be used if
3	separation?	3	they're deemed to be appropriate?
4	A You're operating on whatever you	4	A Yes, that is the case.
5	prepared for analysis, which could be a simple	5	Q Do you agree that some compounds that
6	extraction from something like into a solvent, but	6	are characterized as drugs can still be naturally
7	even then, one must keep in mind that that's	7	occurring compounds?
8	somewhat selective. You don't put if you're	8	A When you say "categorized as drugs," do
9	working directly with plant material, not	9	you mean that they are compounds that are
10	everything is going to go into solution, so you're	10	recognized as pharmaceutical drugs by FDA?
11	always getting some kind of bias in what you're	11	Q I don't know.
12	seeing, but once you get onto the instrument,	12	(Exhibit 14 was marked for
13	whatever you have put on the instrument, the goal	13	identification.)
14	there is to get separation.	14	BY MS. WOOLSON:
15	You don't always get separation of	15	Q I'm showing you Exhibit 14, which I
16	everything. It depends on what the detector can	16	think you will recognize is an article that you
17	detect, what separates on the column and their	17	authored.
18	concentrations.	18	A Yes.
19	Q So it depends on the conditions that	19	Q Okay. So this was an article that you
20	you're employing?	20	wrote about yohimbine?
21	A Right, partly, yes.	21	A Yes.
22	Q Okay. Do you agree that the guidance	22	Q I think I said that right.
23	that the AOAC and similar organizations publish	23	A You did.
24	are simply that, they're guidance?	24 25	Q And my understanding is that it has been
25	A In general, they're guidelines, yes.	23	categorized as a scheduled prescription drug in
	Page 136		Page 137
1		1	
1 2	James P. Kababick	1 2	James P. Kababick
	James P. Kababick several parts of the country, but yet it is also		
2	James P. Kababick	2	James P. Kababick It's the email that we talked about this morning.
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	Page 138		Page 139
1	James P. Kababick	1	James P. Kababick
2	BY MS. WOOLSON:	2 Do	you recall what, if any, steps you
3	Q Okay. In the next paragraph you say,		before this email?
4	"In my continuing argument that DMAA (a/k/a		on't actually recall specifically
5	Geranium, a/k/a methylhexaneamine) is a drug with		. I don't have a good recollection of
6	dangers," and then you continue on.		ing of how this played out, because it
7	How long have you been making that	<sup>7</sup> was so lor	• • • •
8	argument?		ay. You're not a physician, correct?
9	A As far as that there could be potential	-	, I'm not a physician.
10	dangers with methylhexaneamine?		nd as you sit here today, are you
11	Q Yes.	-	bout the safety of DMAA?
12	A I don't know the specific amount of		b, I'm not opining on the safety.
13	time. When the issue started coming up, I started		ow, at the end of your email you say,
14	looking into it, but I don't have a time window,		f I turn out to be wrong about this,
15	to tell you the truth.	<sup>15</sup> and methy	Thexaneamine is actually found in
16	Q Can you estimate? Was it five years,	<sup>16</sup> Geranium	oil as per the Ping paper and confirmed
17	ten years?	<sup>17</sup> using mas	s spec and IRMS to be natural and
18	A Oh, no, I don't think anything like	<sup>18</sup> authentic,	I will be happy to be the first person
19	that.	<sup>19</sup> to publish	a correction to my position."
20	Q Okay, and what	20 I	Do you see that?
21	A This was all rapidly happening at the	<sup>21</sup> A Ye	es.
22	time.		d you publish anything to change your
23	Q Okay. So the use of the term "continued		fter the Li and Fleming papers were
24	argument" suggests that there had been preceding	<sup>24</sup> issued?	
25	argument.	25 A No	o, I did not. They did not meet the
	Page 140		Page 141
1	Page 140 James P. Kababick	1	Page 141 James P. Kababick
1 2			
	James P. Kababick	<ul> <li><sup>2</sup> Q Ag</li> <li><sup>3</sup> biosynthet</li> </ul>	James P. Kababick ain, you're not an expert in ic pathways, correct?
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	Dago 142		Dago 142
-	Page 142	-	Page 143
1	James P. Kababick	1	James P. Kababick
2	I'm not sure.	2 3	group called "ORAHQ, ORS Management at FDA."
3	MR. O'NEAL: Are you talking about	4	What group is that?
4	expert reports?	5	A That would be the Office of Regulatory
5	THE WITNESS: There was I think	6	Affairs Headquarters Management.
6	I may be thinking about his paper. There	б 7	Q And why were you communicating with
7	were these two expert reports I read, and	8	them?
8 9	then after I did my report, I was provided	9	A I don't recall why we were communicating
9 10	with Dr. Brown's and Ikhlas Khan's report and	10	regarding this.
11	read those following it, but I read	11	Q Okay, and you also sent it to the ORA lab directors?
12	Dr. Simone's and Dr. Heuer's, and I reviewed	12	
13	the other documents related to the case, the	13	A Yes.
14	papers and articles and things.	14	Q And you CC'd Daniel Fabricant, correct?
15	(Exhibit 15 was marked for	15	A Yes, it appears so here.
15	identification.)	16	Q When you look at the email, it says,
17	(Witness peruses document.)	17	"I've had a chance to review the embargoed paper and saw those two erroneous hits, and the MS data
18	THE WITNESS: Yes. BY MS. WOOLSON:	18	
19		19	did not support it, in my opinion."
20	Q You've seen Exhibit 15 before?	20	What embargoed paper are you talking about?
20	A Yeah, it looks like an email communication that I sent, and this article is	21	
22	looks like it's from Wall Street Journal,	22	A That I'm not sure. I remember looking at embargoed paper, but I do not recall whose
23	possibly.	23	paper it was. I've looked at some articles that
23		24	were embargoed, given an opportunity to review and
25	Q Okay. This email that you sent, you sent to William Martin at FDA. It looks like a	25	comment before it went to press, and also was
	sent to winnam Martin at FDA. It looks like a		comment before it went to press, and also was
	Page 144		Page 145
1		1	Page 145 James P. Kababick
1 2	James P. Kababick	1 2	James P. Kababick
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	Page 146		Page 147
1	James P. Kababick	1	James P. Kababick
2		2	A And when you say the data "doesn't fit,"
3	Q Well, that's not what my question was. My question was: Do you think omitting the data	3	is that that you determine it's not valid data?
4	from the paper is appropriate?	4	Q No, that it doesn't fit your conclusion.
5	A It depends on how it would be presented.	5	A Well, how would it not fit the
6		6	conclusion?
7	The way it was, yes, because it was making an inaccurate, unscientifically supported claim.	7	Q Well, if you're concluding that there's
8	Q How is presenting data making an	8	no DMAA in a plant, for example, and you find data
9		9	that suggests there is DMAA in a plant, that would
10	inaccurate and unscientifically supported claim? The data is the data, is it not?	10	not be consistent with the conclusion, right?
11		11	A In this hypothetical situation, just so
12	A Well, when you present it saying that it	12	I understand, are you saying that the findings are
13	identifies a compound that you're unable to	13	
14	actually empirically confirm that, then that's	14	empirically supported by the methodology or
15	misrepresenting the data.	15	that because in the cases that I recall looking
16	Q But I think you're taking my question	16	at, it was like taking noise from a radio and
17	further than my question went.	17	saying, oh, I hear the same frequencies that I
18	My question was simply: Do you think	18	hear in this Michael Jackson song, so that must be
19	omitting the data, not making any conclusion, but	19	the Michael Jackson song. You can't say that,
20	omitting the data entirely from a paper just	20	because you're in the noise.
20	because it doesn't fit, is inappropriate?	20	My concern with this was that signal was
21	A I'm not sure if you're speaking	22	in the noise, which is the level at which, as
23	specifically to this mass spec data or in general	23	scientists we say, as analytical chemists we can't
23 24	as a practice.	23	actually say what this is scientifically, and
24 25	Q Well, let's say in general as a	24	therefore we don't name this compound, because
20	practice.	25	it's not able to be named. And in the one case,
	Page 148		Page 149
1	James P. Kababick	1	James P. Kababick
2	it was missing critical ions, so it didn't even	2	looked at this Exhibit 15, it doesn't refresh your
3	look like the compound.	3	recollection about what article you were
4	So, yeah, I would say definitely in that	4	reviewing?
5	case.	5	A I don't recall with absolute certainty.
6	Q In that case, okay, but if you detect	6	Q And what would you need to look at to
7	something or you may detect something within the	7	recall with absolute certainty?
8	noise level, shouldn't you go back and do more	8	A If I had the article, that would be
9	studies to confirm whether it's there?	9	great, or the data.
10	A It depends on what you detect and what's	10	Q The end of the sentence, you say, "The
11	going on and what your scope of the application	11	lack of authentication means they could have been
12	is. So if you're looking to say whether or not	12	testing adulterated oils, and I see more
13	you're seeing something at or above a certain	13	adulterated Geranium EO than clean EO in today's
14	level and you're seeing it at that level, that's	14	market."
15	one thing. If you're seeing it below that level	15	Do you see that?
16	and you'd like to change your method and redevelop	16	A Yes.
17	it to go lower, you could opt to go back and study	17	Q Is your comment based solely on the fact
18	it further.	18	that you think that the oils were not properly
19	Q Wouldn't you want to do that if you	19	authenticated as opposed to what the results of
20	wanted to know for sure whether something was	20	the study were?
21	there or not?	21	A Yeah, the my concern is, in my
22	A It depends on what the goal of the	22	research on essential oils I have seen over the
	it depends on what the goul of the		
23	method is. It depends on what the scope is and	23	vears multiple papers discussing the chemistry of
23 24	method is. It depends on what the scope is and what levels you're trying to achieve.	23 24	years multiple papers discussing the chemistry of oils, and in some cases they were naming compounds
	<ul><li>method is. It depends on what the scope is and</li><li>what levels you're trying to achieve.</li><li>Q And again as you sit here, and having</li></ul>		years multiple papers discussing the chemistry of oils, and in some cases they were naming compounds which are known to be absolutely synthetic, and

James P. Kababick         James P. Kababick           it was with they have dimensions based on the assumption that what they have dimensions based on the assumption that what they have dimensions based sure that they are doing clinical research on antural products that are actually the natural products they think.         It may have asked you this, and the NH established expert panels, which I was involved in, to help research on antural products that are actually the natural products they think.         BY MS, WOOLSON:           image P. Kababick         It was involved in, to help research on antural products that are actually the natural something present and you don't know if the material has been tampered with, that could be a concerr.         BY MS, WOOLSON:         BY MS, WOOLSON:           image P. Kababick         It may have asked you this, and iff I did. Japologize for asking it again.         This morning you testified that you had dore some DMAA testing on extracts of Granium plants.           image P. Kababick         It is morning you testified that you had dore some DMAA testing on extracts of Granium plants.         Do you remember that testimony?           image P. Kababick         It is morning you testified that you had dore some of modifying that material.         Q           image P. Kababick         It is get it was DMAA and in one case what levels were there, so it wasn't necessary.           image P. Kababick         James P. Kababick         It have you been asked to comment on the New Zealand government; publications, identification.)           image P. Kababick         James P. Kababick         It have yo		Page 150		Page 151
2         they were making decisions based on the assumption         2         that were examined by Drs. Li and Fleming were trampered with?           3         have it.         3         Trampered with in regard to deliberately           4         A due NH established expert panels,         4         A Tampered with in regard to deliberately           5         And the NH established expert panels,         5         adulterated, no.           6         When you have in ovel on its to help research on         7         taken.)           7         some thing present and you don't know if the         3         adif I did, I apologize for asking it again.           12         because if you're going to make a conclusion about         12         Mere were materials again.           13         concorn.         14         material has been tampered with, that could be a         15           14         material ampered with that could be a         16         D you remember that testimony?           14         material ampering would be the         17         but I didn't know for sore if they were Geranium           15         athemication on material.         Tammering with samples, is it not?         16           16         q Right. So they're two different things?         A Yes.         4         Yes.           2         Q Right. So they're	1		1	
a bety what hey had was natural when they didn't       a material what they had was natural when they didn't         a have it.       And the NH established expert panels,         a material products that are actually the natural       a material products that are actually the natural         a products that are actually the natural       BY MS. WOOLSON:         a material has been tampered with, that could be a       BY MS. WOOLSON:         b cause if you're going to make a conclusion about some DMA testing on extracts of Geranium plants.       BY MS. WOOLSON:         a material has been tampering with samples, is it not?       D you remember that testimon?         a Authentication of samples is       fifterent than ampering with samples, is it not?         a Authentication owould be the process of       determining if the material appars to be an authentic material appars to be an authentic material. Tampering would be the process of         a Yes.       Q Right. So they're two different things?       A No. I didn't, because my goal in that         was just to see if it was DMAA and in one case       which you didu detect DMAA, did you do that isotope matorial appars to long gone.         a Yes.       James P. Kababick       James P. Kababick         a Gorw, My changes that by on discussed this authermoon cither?       A Yes.         a Gorw, My changes that down and the DMAA in throng the provident data with any discussed that with any dissurption of the weak of the withery outheas anathed for identification.				
4       have in due in the number of parts         5       And the NIH established expert panels,         6       which I was involved in, to help researchers make         7       sure that they are doing clinical research on         9       products they think.         10       So it's very important to have a good         11       chain of custody and authentication on materials,         12       because if you're going to make a conclusion about         13       something present and you don't know if the         14       material has been tampered with, that could be a         15       concern.         16       Q Well, authentication of samples is         17       different than tampering with samples, is it not?         18       A Authentication would be the process of         19       authentic anterial. Tampering would be the         12       Q Right. So they're two different things?         24       Q Okay, and as you sither to day, do you         25       have any facts to suggest that the Geranium plants         26       Q Sorry. My chemistry days are long gone.         27       Yeas, ddi you attermine the         28       Q Sorry. My chemistry days are long gone.         29       A Yeas.         20       S		• • •		
5       And the NIH established expert panels,       intervention         6       which I was involved in, to help researchers makes       6         7       sure that they are doing clinical research on       7         8       natural products that are actually the natural       8         9       products that are actually the natural       8         9       products that are actually the natural       8         9       products that are actually the natural       8         10       chain of custody and authentication on materials,       11         11       that material has been tampered with, that could be a       12         14       material has been tampered with, that could be a       13         15       determining if the material, appears to be an       14         16       Q       Well, authentication of samples is       15         17       A tubentication on sumples is       16         18       determining if the material.       17         19       determining if the material.       18         21       Q       Right. So they're two different things?       2         22       Q       Right. So they're two different things?       2         23       A ves.       1       Ameary facts to sugg				•
<ul> <li>which I was involved in, to help researchers make sure that they are doing clinical research on antural products that are actually the natural products that are actually the natural products that are actually the natural is something present and you don't know a good</li> <li>chain of custody and authentication on materials, the cause if you're going to make a conclusion about some that setting on extracts of Geranium plants.</li> <li>Q Well, authentication of samples is concern.</li> <li>A Authentication or samples is different than tampering with samples, is it not?</li> <li>A Authentication or ould be the process of authentic material. Thempering would be the process of modifying that material.</li> <li>Q Right. So they're two different things?</li> <li>A Yes.</li> <li>Q Kight. So they're two different things?</li> <li>A Yes.</li> <li>Q Cotay, and as you sither today, do you that was any facts to suggest that the Geranium plants.</li> <li>Page 152</li> <li>Fage 152</li> <li>Fage 152</li> <li>A Yesh, that's isotope ratio. Same thing.</li> <li>G Sorry. My chemistry days are long gone.</li> <li>G Showing you what was marked as Exhibit 1, then you discussed this in the real appears to be an authent?</li> <li>A Yesh, that's isotope ratio. Same thing.</li> <li>G Showing you what was marked as Exhibit 1, then you seen Schwas and you seen set and you seen set and you seen set and you seen set and you are none performed the DMAA in those explored to be comment's publication saying that you discussed that with any (Exhibit 16 was marked as Exhibit 1, they you seen Exhibit 16 before today?</li> <li>A Yes.</li> <li>A Yes.</li> <li>A Yes.</li> <li>A Yes.</li> <li>A Yes.</li> <li>A Yes.</li> <li>A Gon't recall for the they are and provention.</li> <li>G Kiness peruses document.)</li> <li>THE WITNESS: Okay.</li> <li>BY MS. WOOLSON:</li> <li>A Happears to be so, yes.</li> <li>A Yes, the any seen a</li></ul>			5	· ·
7     sure that they are doing clinical research on natural products that are actually the natural products they think.     7     maken.)       8     BY MS. WOOLSON:       9     Q Mr. Kababick, I may have asked you this, and if I did, I apologize for asking it again.       10     So it's very important to have a good       11     the authentication on materials.       12     because if you're going to make a conclusion about something present and you don't know if the concern.       13     concern.       14     material has been tampered with, that could be a concern.       15     concern.       16     dt Well, authentication of samples, is it not?       17     different than tampering with samples, is it not?       18     A suthentication would be the process of determining if the material appears to be an authentic material. Tampering would be the process of modifying that material.       12     Q Right. So they're two different things?       14     James P. Kababick       15     carbon 14 dating analysis that you discussed this auftermoon either?       14     James P. Kababick       15     James P. Kababick       16     that way sust need for identification.)       17     James P. Kababick       28     Q Andy tame apperiate that way discussed this authermoon either?       34     A No. I didn't.       35     Q Sorry. My chemist		* *	1	
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9     products they think.     9     Q     Mr. Kababick, I may have asked you this, and if I did, I apologize for asking it again.       10     Concern.     11     This morning you testified that you had done some DMAA testing on extracts of Geranium plants.       14     material has been tampered with, that could be a concern.     13     Do you remember that testimony?       15     concern.     16     Mr. Well, authentication of samples is different than tampering with samples, is it not?     14       18     A tuthentication of samples is different than tampering with samples, is it not?     17     Mr. Kababick, 1 may have asked you this, and if I did, I apologize for asking it again.       19     A Authentication of samples is different than tampering with samples, is it not?     16     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.       20     Right, So they're two different things?     27     A No. I didn't, because my goal in that was just to see if it was DMAA and in one case       21     James P. Kababick     2     1       22     Q Right, So they're two different things?     2       3     A Yesh, that's isotope ratio. Same thing.     2       4     A Yesh, that's isotope ratio. Same thing.     2       5     Q Showing you what was marked as Exhibit     1       6     When you determined the DMAA in those <td></td> <td></td> <td>1</td> <td>,</td>			1	,
10       So it's very important to have a good       10       and if I did, I apologize for asking it again.         11       chain of custody and authentication on materials,       11       This morning you testified that you had         13       because if you're going to make a conclusion about       12       one some DMAA testing on extracts of Geranium         14       material has been tampered with, that could be a       13       Do you remember that testimony?         15       concern.       15       A veah, there were materials sent to me         16       Q Well, authentication would be the process of       16         17       different than tampering would be the       10         18       A Authentic material.       10         19       determining if the material appears to be an       10         11       and the does one DMAA testing on extracts in       11         10       authentic material.       12         11       and the does one DMAA testing on extracts in       11         12       process of modifying that material.       12         12       Q Ray, and as you si there today, do you       14         14       Jarmes P. Kababick       21         15       Jarmes P. Kababick       21         16       When you determine the<				
11       chain of custody and authentication on materials,       11       This morning you testified that you had         12       because if you're going to make a conclusion about       12       done some DMAA testing on extracts of Geranium         14       material has been tampered with, that could be a       14       Do you remember that testimony?         15       concern.       16       Q Well, authentication of samples is       16         17       different than tampering with samples, is in ot?       17       A Yeah, there were materials sent to me         18       A Authentication would be the process of       19       plant extracts.         19       determining if the material appears to be an       19       Q With regard to these, the extracts in         22       Q Right. So they're two different things?       22       A Yes.       23         23       A Yes.       24       Q Okay, and a you sit here today, do you       24         24       Q Cay and a syou sit here today, do you       25       have any facts to suggest that the Geranium plants       25         25       have any facts to suggest that you discussed this       3       A Yes.       2         26       Garbon 14 dating analysis that you discussed this       3       A Yes.       2         2       carbon 14 dating analysis		1 · ·	1	
12       because if you're going to make a conclusion about       12       done some DMAA testing on extracts of Geranium         13       something present and you don't know if the       12       done some DMAA testing on extracts of Geranium         14       material has been tampered with, that could be a       14       Do you remember that testimony?         15       concern.       15       A Yeah, there were materials sent to me         16       Q Well, authentication of samples is       17       but I didn't know for sure if they were Geranium         16       A Authentication would be the process of       18       10       With regard to these, the extracts in         20       authentic material.       21       Q With regard to these, the extracts in       which you did detect DMAA, did you do that isotope         21       process of modifying that material.       22       A No. I didn't, because my goal in that       was just to see if it was DMAA and in one case         22       Q Okay, and as you sit here today, do you       24       A No. I didn't, because my goal in that       was just to see if it was DMAA and in one case         24       Q Okay, and as you sit here today, do you       25       Page 152       Page 153         1       James P. Kababick       2       James P. Kababick       2       plants'''.         2       A			1	
13       something present and you don't know if the       13       plants.         14       material has been tampered with, that could be a       14       Do you remember that testimony?         15       concern.       15       A Yeah, there were materials sent to me         16       Q Well, authentication of samples is       16       that were reported to be Geranium plant extracts.         19       determining if the material appears to be an       17       bit I didn't know for sure if they were Geranium         20       authentic material.       18       A Authentication would be the       20         10       getty process of modifying that material.       17       bit I didn't know for sure if they were Geranium         21       Q Right. So they're two different things?       22       A No. I didn't because my goal in that         22       Was gust to see if it was DMAA and in one case       was just to see if it was DMAA and in one case         24       Q Okay, and as you sit here today, do you       24       was just to see if it was DMAA and in one case         25       Page 152       Page 153       1       James P. Kababick       1         26       Sorry. My chemistry days are long gone.       5       New You determined the DMAA in those       DMAA - the evidence suggests that DMAA naturally         3       aft		· · · · · · · · · · · · · · · · · · ·	1	÷
14       material has been tampered with, that could be a       14       Do you remember that testimony?         15       concern.       14       Yeah, there were materials sent to me         16       Q Well, authentication of samples is       15       A Yeah, there were materials pentium plant extracts,         17       different than tampering with samples, is it not?       17       but I didn't know for sure if they were Geranium         18       authentic autoin would be the process of       18       Q       With regard to these, the extracts in         20       authentic material, Papers to be an       19       Q       With regard to these, the extracts in         21       process of modifying that material.       20       which you did cetted DMAA, did you do that isotope         22       Q Right. Sto they're two different things?       21       A No. I didn't, because my goal in that         23       A Yes.       23       was just to see if it was DMAA and in one case         24       Q Okay, and as you sit here today, do you       25       Q And I take it then you didn't do any         25       Page 152       Page 152       Page 153         1       James P. Kababick       1       James P. Kababick       1         2       extracts, did you attempt to determine the       5       New Zealand governm				-
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1	James P. Kababick	1	James P. Kababick
2	Dr. Brown's report and Ikhlas Khan's report. I	2	clandestine and drug adulteration analysis for
3	had not reviewed them prior to drafting my report.	3	detention samples.
4	Q But you did review it prior to	4	Q And when you say you were vetted by the
5	finalizing your report?	5	FDA, what does that involve?
6	A Yes, and I made no changes.	6	A The AOAC has to review candidates for
7	Q So you didn't include anything about	7	the appointments, and they compare that to what
8	Dr. Brown's biosynthetic argument, did you?	8	FDA expects of an expert to serve in those funded
9	A No, I did not.	9	committees.
10	Q And if you could go back to page 3 of	10	Q What does FDA expect of an expert in
11	your report, paragraph 4, you say, "As one of the	11	those funded committees?
12	leading experts in my field."	12	A They have to have knowledge of the
13	What is the basis for that statement?	13	chemistry of the compound's analytical techniques,
14	A I'm recognized as an expert by the Food	14	validation techniques, and experience in the
15	and Drug Administration, National Institute of	15	analysis of various components.
16	Health, AOAC International, and the United States	16	Q And is the vetting the same for NIH?
17	Pharmacopeia have appointed me to the Council of	17	A It's similar.
18	Experts.	18	Q In what way is it different?
19	Q When you say you're recognized as an	19	A Depending upon the position at NIH, you
20	expert by FDA, what do you mean?	20	may or may not need certain types of grant review
21	A It means that I satisfied the vetting	21	experience.
22	requirements to serve as an expert on FDA-funded	22	Q And do you have to meet with or
23	committees in AOAC.	23	interview with anyone from FDA or NIH in order to
24	Q FDA-funded committees in AOAC?	24	be considered an expert?
25	A And also that they recognize my work in	25	A No. I just had to fill out an
	- 156		- 155
	Page 156		Page 157
1	Page 156 James P. Kababick	1	Page 157 James P. Kababick
1 2	James P. Kababick application and submit my CV, and then that	2	James P. Kababick are grants specifically designed to expand and
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1	James P. Kababick	1	James P. Kababick
2	A No. It would be like trying to put a	2	You're not saying in your report that
3	gallon of water in this cup. It just cannot be	3	you have identified products that were spiked with
4	done. It's against the laws of physics.	4	DMAA from China, have you?
5	Q I take it you have not even attempted to	5	A In this particular report? You mean
6	do that.	6	relative to this?
7	A No.	7	Q In your report, Exhibit 1.
8	Q Have you done any work regarding	8	A No, I did not say that in this.
9	1,4-DMAA?	9	Q Have you been asked strike that.
10	A No.	10	Do you have plans to undertake in the
11	Q In paragraph 24 of your report, you're	11	future any analysis of Geranium plants for DMAA?
12	talking about "clandestine and economic	12	A I don't have any plans per se, but I'm
13	adulteration."	13	not saying that I wouldn't do that. It would
14	Do you see that?	14	depend on the situation.
15	A Yes.	15	Q But as you sit here today, you've not
16	Q And you say you've identified	16	been asked to undertake any studies in the future?
17	ingredients in products from China that were	17	A Not at this time, no.
18	"spiked with stimulants, laxatives, erectile	18	Q And beyond the things that we discussed
19	dysfunction drugs, diabetes drugs, antibiotics,	19	this morning, which were the low levels of
20	sedatives, psychiatric drugs, bath salts,	20	detection of DMAA, Dr. Brown's opinion that
21	cannabinoids" and others, correct?	21	there's no pathway, the possibility that DMAA is
22	A That were adulterated, yes.	22	in fertilizer, and the studies that did not detect
23	Q But that doesn't strike that.	23	
24	You're not let me start that over	24	DMAA, do you have any additional facts upon which
25	again.	25	you are relying for your opinion that the DMAA
	agaiii.	25	detected by Li and Fleming was not natural to the
	Page 160		Page 161
	5		Idge Ioi
1	James P. Kababick	1	James P. Kababick
1 2		1 2	
	James P. Kababick		James P. Kababick
2	James P. Kababick Geranium plant?	2	James P. Kababick (Whereupon, a short recess was
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1	James P. Kababick	1	James P. Kababick
2	feasible for a natural source.	2	Q And you omitted DMAA from that exhibit?
3	Q So then was your previous response to	3	A Well, I discuss DMAA in the rest of the
4	counsel merely that DMAA was not listed in	4	whole report. This was an addition, number 24.
5	paragraph 24?	5	These other things that I have also found showing
6	MS. WOOLSON: Objection to form.	6	that there is a history of adulteration issues and
7	THE WITNESS: Yeah, that's what I	7	in so many of these cases, their argument was made
8	thought was being asked.	8	these were naturally occurring, and in many or all
9	MR. O'NEAL: Okay. I have no	9	cases, they were ruled not to be.
10	further questions.	10	Q And yet so you left out the two examples
11	FURTHER EXAMINATION BY COUNSEL FOR DEFENDANT	11	that you claim are evidence of spiking of DMAA
12	BY MS. WOOLSON:	12	from an expert report about the presence of DMAA?
13	Q Mr. Kababick, why would you not include	13	MR. O'NEAL: Object to the form.
14	that information in your expert report if you	14	Mischaracterizes his testimony.
15	believed those samples were spiked?	15	THE WITNESS: No, I wouldn't say
16	A Because I was opining on the Li and	16	that.
17	Fleming papers and the discussion of the	17	BY MS. WOOLSON:
18	naturalness of DMAA.	18	Q And where did these two extracts come
19	Q So you would put in your report a	19	from?
20	statement that you have investigated or identified	20	A One was submitted by a client for
21	several botanical materials that were spiked with	21	testing, and the other one was provided by an
22	various substances, but you would leave out DMAA?	22	importer.
23	A Well, the body of my report was	23	Q And from where in the world did these
24	discussing DMAA. These were additional components	24	extracts purport to come?
25	that I identified in a larger picture of my work.	25	A China.
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1	James D. Kababiak	1	Jamas D. Kababiak

1	James P. Kababick	1	James P. Kababick
2	Q And the client that submitted the	2	A Yes.
3	extract to you, was this the one that you said was	3	Q And you were told that that sample came
4	pure DMAA or the one that was 100 milligrams per	4	from China?
5	gram?	5	A Right. Yes. That's correct.
6	A 100 milligrams per gram or greater.	6	Q And the 100 milligrams per gram sample,
7	Q And the client did the client	7	that came from a client?
8	indicate to you where the sample had come from,	8	A Yes.
9	i.e., who the manufacturer was?	9	Q And you were told that came from China?
10	A No. Just that it was from China.	10	A Yes.
11	Q And that's all you know about the sample	11	Q And was this client an entity that was
12	was that it came from China?	12	interested in manufacturing or selling or using
13	A Yes.	13	this extract?
14	Q And the extract that was 100 milligrams	14	A Yes. They were interested in utilizing
15	per gram, where did that come from?	15	it in their product.
16	A That was reported to come from China.	16	Q And what was their product?
17	Q And that was sent to you by an importer?	17	A I don't know exactly what it was. They
18	A No. The extract was sent to me by the	18	said they had a formulation they were working on.
19	client. A pure compound or near pure compound was	19	Q You don't even know what kind of
20	sent to me by an importer.	20	category the product was in?
21	Q So let me start over.	21	A No, I don't. I don't remember if it was
22	The pure the product that was	22	a sports or a weight loss or what.
23	purported to be an extract but you tested and	23	Q And other than these two extracts, you
24	believed to be pure DMAA, was that sent to you by	24	have not identified any other product, natural
25	an importer?	25	products that were purportedly spiked with DMAA?
	-		~ * * * *

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1	James P. Kababick	1	James P. Kababick
2	MR. O'NEAL: Object to the form.	2	Q What was the weight loss product?
3	THE WITNESS: I'm not sure I	3	A I don't recall the exact name of the
4	understand the question.	4	weight loss product.
5	BY MS. WOOLSON:	5	Q Other than the two extracts and now this
6	Q What don't you understand about the	6	weight loss product that you didn't test for DMAA,
7	question?	7	any other products, natural products you believe
8	A Are you saying have I identified	8	that you've tested were spiked with DMAA?
9	products that were claimed to be spiked with DMAA?	9	A I'm not recalling any offhand. There
10	Is that what you asked?	10	may have been others, but due to the time that's
11	Q No. I asked you: Other than these two	11	passed and the tens of thousands of samples I've
12	extracts that you just now remembered, did you	12	analyzed, I don't recall specifically.
13	test any other natural products that you're	13	Q And I believe we talked it might have
14	claiming were spiked with DMAA?	14	been this morning, it might have been this
15	A I believe I did.	15	afternoon about your lab developing methods for
16	Q And what natural products were those?	16	detection for DMAA. These three examples that
17	A One of those was a weight loss product,	17	you've just given me, were they detected well,
18	but the goal of the analysis was not to test for	18	the two examples where you actually tested for
19	DMAA. It was related to other compounds, but it	19	DMAA, were they tested using this method that your
20	had a DMAA claim on the label. I don't know if it	20	lab developed?
21	actually had DMAA in it, because that was outside	21	A Yes, they were.
22	the scope of what I was working on.	22	Q And I believe you told me that you no
23	Q So you didn't actually test for DMAA?	23	longer are you no longer offering the DMAA
24	A Not in that one, no. It wasn't	24	detection, or is it the quantification?
25	requested.	25	A The quantification.
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1		1	
	James P. Kababick	2	James P. Kababick
2 3	Q So when is the last time you ran a DMAA	3	
4	detection test for a sample?	4	
5	A It's been several years, to my	5	
6	knowledge.	6	ACKNOWLEDGEMENT OF WITNESS
7	Q So these two examples of extracts that	7	I, JAMES P. KABABICK, do
8	you identified, how many years ago were they?	8	hereby acknowledge that I have read and
9	A I believe they were around the time of	9	examined the foregoing testimony, and the
10	this paper, 2012, right in there. I'd have to	10	same is a true, correct and complete
11	check to be sure, though. MS. WOOLSON: Subject to the	11	transcription of the testimony given by me,
12	request for information about the identities	12	and any corrections appear on the attached
13	-	13	Errata sheet signed by me.
14	of major customers of Flora Labs and the identities of the customers for whom these	14	Errata sheet signed by me.
15		15	
16	extracts tests were run, I have no further questions.	16	
17	MR. O'NEAL: Okay. We'll read and	17	(DATE) (SIGNATURE)
18	•	18	(DATE) (SIGNATURE)
19	sign. (Signature having not been	19	
20	waived, the deposition of	20	
21	JAMES P. KABABICK was	21	
	concluded at 3:27 p.m.)	22	
22	$\mathcal{O}$	1 22	
22 23	·····	23	
22 23 24	······	23 24	
23			
23 24		24	

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1     ERRATA SHEET     1     James P. K       2     Case Name:     2	<i>L</i> ababick
2 Coop Name:	
<sup>2</sup> Case Marie:	
<sup>3</sup> Deposition Date: <sup>3</sup>	
<sup>4</sup> Deponent:	
	SHORTHAND REPORTER NOTARY PUBLIC
	onovan, Registered
	orter, Certified Realtime
	eer before whom the ion was taken, do hereby
9 certify that the for	egoing transcript is a
true and correct re	cord of the testimony
<sup>11</sup> given; that said tes	stimony was taken by me
	and thereafter reduced to
	my supervision; and that I
12 amployed by any (	I for, related to, nor of the parties to this case
and have no intere	est, financial or otherwise,
16 13 in its outcome.	
	SS WHEREOF, I have hereunto
	ffixed my notarial seal this
	mber, 2016. xpires: March 14th, 2021
20 My commission et	xpires. March 14th, 2021
18	
21 19	
Signature of Deponent 20 LAURIE DONOVAN	
22     NOTARY PUBLIC I       SUBSCRIBED AND SWORN BEFORE ME     21       THE DISTRICT OF	
SUBSCRIBED AND SWORN BEFORE ME	COLUMBIA
<sup>23</sup> THIS DAY OF, 2016. 22 24 23	
24	
<sup>25</sup> (Notary Public) MY COMMISSION EXPIRES: 25	

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