

Exhibit 35

Cara R. Welch, Ph.D.

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

UNITED STATES OF AMERICA,

Plaintiff,

vs.

UNDETERMINED QUANTITIES OF
1,3-DIMETHYLAMYLAMINE
HCl (DMAA),

Defendant,

and

HI-TECH PHARMACEUTICALS,
INC., and JARED WHEAT,

Claimants.

Civil Action No.

1:13-cv-13675-

WBH-JCF

Deposition of Cara R. Welch, Ph.D.

Washington, D.C.

Tuesday, November 29, 2016

9:30 a.m.

Reported by: Laurie Donovan, RPR, CRR

Job No: 114996

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1
2 Deposition of
3 CARA R. WELCH, Ph.D.
4
5 Held at the offices of:
6 U.S. Department of Justice
7 Consumer Protection Branch
8 450 Fifth Street Northwest
9 Room 6400-South
10 Washington, DC 20001
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19 Taken pursuant to notice, before
20 Laurie Donovan, Registered Professional
21 Reporter, Certified Realtime Reporter, and
22 Notary public in and for the District of
23 Columbia.
24
25

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13 Exhibit 2 Rule 26 Expert Report of Cara
14 Welch, Ph.D. 7
15 Exhibit 3 Curriculum vitae 7
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17 Exhibit 5 Rule 26 Expert Report of
18 Dennis M. Keefe, Ph.D. 45
19 Exhibit 6 Warning Letter by FDA to Michael
20 McCandless of Smartpowders, dated
21 August 27, 2015 70
22 Exhibit 7 Amended Complaint for
23 Forfeiture 78
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25 Louis Carlacci to Dan Fabricant . 86

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1 Cara R. Welch, Ph.D.
2 A P P E A R A N C E S
3 ON BEHALF OF THE PLAINTIFF:
4 United States Food and Drug Administration
5 10903 New Hampshire Avenue
6 Silver Spring, MD 20903
7 By: Joshua Davenport, Esq.
8
9
10 ON BEHALF OF THE DEFENDANTS:
11 Epstein Becker & Green
12 One Gateway Center
13 Newark, NJ 07102
14 By: Jack Wenik, Esq.
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1 Cara R. Welch, Ph.D.
2 (Exhibits continued)
3 EXHIBIT DESCRIPTION PAGE
4 Exhibit 9 Search results by Rebecca Allen
5 and Steven Casper, Bates number
6 GOV-006883, Dec. 31, 2015 90
7 Exhibit 10 Search results by Rebecca Allen
8 and Steven Casper, Bates number
9 GOV-027778, Sept. 21, 2016 ... 93
10 Exhibit 11 Article entitled "Methylhexanamine
11 is not detectable in Pelargonium
12 or Geranium species and their
13 essential oils: A multi-center
14 investigation" 98
15 Exhibit 12 Email chain, Bates number
16 ElSohly 5891 101
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1 Cara R. Welch, Ph.D.
 2 PROCEEDINGS
 3 CARA R. WELCH, Ph.D.,
 4 having been first duly sworn, testified
 5 upon her oath as follows:
 6 EXAMINATION BY COUNSEL FOR DEFENDANT
 7 BY MR. WENIK:
 8 Q Dr. Welch, I know you've been deposed
 9 once before, but let me give you preliminary
 10 instructions which you may already have heard.
 11 As you can see, we have a court
 12 stenographer who is taking down the testimony, so
 13 when I ask you a question, we need a verbal
 14 answer. Just saying "uh-huh" or a facial
 15 expression or a nod won't work, so we need you to
 16 give an oral answer.
 17 If I ask anything, and particularly if
 18 I've mispronounced a scientific term of art or you
 19 don't understand a question, by all means, ask me
 20 to rephrase it. Otherwise, I'll assume you heard
 21 the question and understood it.
 22 Periodically your lawyer may object to a
 23 question. The way it works in this context as
 24 opposed to a court of law, we don't have a ruling
 25 on the objection. You put it on the record and

1 Cara R. Welch, Ph.D.
 2 you give an answer after the objection is
 3 interposed. Unless you are instructed not to
 4 answer a question, you should answer the question.
 5 If at any point in time you want a
 6 break, just let me know. I don't think we're
 7 going to be here the whole day. Your report is
 8 fairly narrow, so I assume we'll be out of here
 9 hopefully pretty quickly.
 10 Any questions for me before we begin?
 11 A No.
 12 (Exhibit 1 was marked for
 13 identification.)
 14 (Exhibit 2 was marked for
 15 identification.)
 16 (Exhibit 3 was marked for
 17 identification.)
 18 BY MR. WENIK:
 19 Q So with that being said, I've placed
 20 three documents in before you. Welch Exhibit 1,
 21 for the record, is the deposition notice in this
 22 case.
 23 Have you seen this before?
 24 A No.
 25 Q All right. The one question I have

1 Cara R. Welch, Ph.D.
 2 is -- lawyers formally issue these things to
 3 schedule a deposition, if you will.
 4 And looking at your Exhibit 2, which is
 5 your expert report, just take a look at that for a
 6 moment, and confirm -- I believe your signature
 7 appears on page 14 of the document.
 8 (Witness peruses document.)
 9 THE WITNESS: Yes.
 10 BY MR. WENIK:
 11 Q And the last two pages of the document
 12 are Exhibit 1, which is your reference list.
 13 Do you see that?
 14 A Yes.
 15 Q And I've actually separated out and
 16 marked as a separate exhibit your Exhibit 2 to
 17 your report, which I've marked as Deposition
 18 Exhibit 3, which is simply your CV.
 19 Do you see that?
 20 A Yes.
 21 Q All right. So getting back to the
 22 deposition notice, the Exhibit 1, the one question
 23 I have for you is -- what I've asked in there or
 24 what my firm has asked in there is that if there's
 25 anything new that you're relying on; in other

1 Cara R. Welch, Ph.D.
 2 words, any new study or treatise or textbook that
 3 you haven't cited in that exhibit list to your
 4 report, which we've marked as Welch Exhibit 2, if
 5 there's anything new, we've asked for the
 6 production of that today.
 7 Is there any new material that you wish
 8 to cite or rely on in this matter to support your
 9 opinions?
 10 A No.
 11 Q Thank you.
 12 All right. So other than any
 13 discussions with your lawyer, which I'm not
 14 interested in, could you tell me what you did to
 15 prepare for today's deposition.
 16 Did you review any documents, did you
 17 talk to any of your colleagues or peers?
 18 A I did not talk to any of my colleagues.
 19 I reviewed my expert report, Exhibit 2. I
 20 reviewed some sections of the Federal Food, Drug
 21 and Cosmetic Act.
 22 Q All right. So let me discuss a little
 23 bit about some of your prior expert witness work.
 24 So if I turn to your Exhibit 2, on page
 25 13 you have a brief section here entitled

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1 Cara R. Welch, Ph.D.
 2 "Testimony in the last four years," and you list
 3 two citations to two court cases.
 4 Do you see that?
 5 A Yes.
 6 Q So let me take the first case, so United
 7 States versus Krueger. What type of case was
 8 that? Was that a criminal case, civil case,
 9 regulatory proceeding? What kind of case was
 10 that?
 11 A This was a criminal case.
 12 Q And in what context did you testify in
 13 that case?
 14 A My testimony was speaking to a
 15 particular ingredient, that it was excluded from
 16 the definition of a dietary supplement according
 17 to Section 201(ff)(3) of the Act. It was not used
 18 as a dietary supplement or a food prior to being
 19 authorized for investigation as a new drug. The
 20 ingredient was Sibutramine.
 21 Q And in that case, the Krueger case, were
 22 you testifying as an expert witness or as a fact
 23 witness?
 24 A As an expert witness.
 25 Q And was that on behalf of the government

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1 Cara R. Welch, Ph.D.
 2 A Yes, as an expert.
 3 Q Okay, and did you prepare an expert
 4 report in that matter?
 5 A Yes, I did.
 6 Q So the good manufacturing practices that
 7 you testified about in the Cole case, did any of
 8 that have anything to do with DMAA? And I assume
 9 you understand what I'm referring to when I say
 10 "DMAA."
 11 A I do understand. It did not have
 12 anything to do with DMAA.
 13 Q Okay.
 14 I'm looking at Exhibit 3, which is the
 15 CV, your CV.
 16 A Yes.
 17 Q And I'm just looking at the professional
 18 experience blocks.
 19 So you have one block from February 2016
 20 to the present and one block from January 2015 to
 21 February 2016, and you have still another block
 22 there of January '14 to February 2016. All these
 23 of those blocks list your professional experience
 24 in one capacity or another with the Food & Drug
 25 Administration.

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1 Cara R. Welch, Ph.D.
 2 or on behalf of the defendant?
 3 A That was on behalf of the government.
 4 Q All right, and you list here that you
 5 testified at trial. Was there an expert report
 6 that was prepared in that matter as well?
 7 A Yes.
 8 Q And did you prepare that report?
 9 A Yes, I did.
 10 Q All right, and then we have another case
 11 listed here, United States versus Cole.
 12 What type of case was that, Doctor?
 13 A That was a civil case. My testimony was
 14 on current good manufacturing practices of the
 15 dietary supplement products produced by this firm.
 16 Q Actually, I should go back to the first
 17 case. When you testified in the Krueger case,
 18 were you an FDA employee at that time?
 19 A I was, yes.
 20 Q All right, and in the Cole case,
 21 similarly, were you an FDA employee at that time?
 22 A I was, yes.
 23 Q All right, and you testified as an
 24 expert in the Cole case rather than a fact
 25 witness; is that correct?

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1 Cara R. Welch, Ph.D.
 2 Do you see that?
 3 A Yes, I do.
 4 Q So just turning your attention to the
 5 earliest block on page 2, which is a January 2014
 6 to February 2016 block, one of the bullet points
 7 that you have here in your CV, you refer to having
 8 prepared expert witness testimony regarding
 9 dietary supplement labeling and GMP compliance
 10 with dietary supplement manufacturing.
 11 Does this pertain to any of the two
 12 cases we've just been talking about, or is this
 13 something else?
 14 A I -- that refers to the Cole case.
 15 Q Okay, and in the next block, I'm looking
 16 at the January '15 to February 2016 experience
 17 block, and you have a number of bullet points, and
 18 in the next to last bullet point in that block,
 19 you talk again about preparing expert witness
 20 testimony regarding dietary supplement labeling
 21 and GOP compliance.
 22 Was that also in the Cole matter, or was
 23 this a different case?
 24 A I believe that is referring to the
 25 Krueger case.

1 Cara R. Welch, Ph.D.

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

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

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

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

23 A Correct.

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

1 Cara R. Welch, Ph.D.

2 -- have anything to do with DMAA?

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

5 Q Okay.

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

12 A Yes.

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

16 A No.

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

19 A No.

20 Q On behalf of a pharmaceutical company?

21 A No.

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

1 Cara R. Welch, Ph.D.

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

5 A No.

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

11 A Yes.

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

16 A I don't recall.

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

22 A It was dietary supplement regulations.

23 Q Okay.

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

1 Cara R. Welch, Ph.D.

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

4 A Yes.

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

9 A Correct.

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

14 A I had no involvement.

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

18 A No.

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

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

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1 Cara R. Welch, Ph.D.
 2 A Correct.
 3 Q Okay. So when was it, roughly, if you
 4 can recall, that you began to serve as an expert
 5 in this case as opposed to an FDA official, if you
 6 will?
 7 A I believe I started drafting my expert
 8 report for this case in November or December of
 9 2015.
 10 Q And who made the decision that you would
 11 serve as an expert in this case?
 12 A I don't know.
 13 Q Now, as part of your preparing your
 14 expert report and your testimony today, did you
 15 consult with any of the other experts that have
 16 been -- I'll use the word "retained" -- in this
 17 matter by the government?
 18 MR. DAVENPORT: Objection to the
 19 form of the question.
 20 You may answer.
 21 THE WITNESS: No.
 22 BY MR. WENIK:
 23 Q Have you reviewed, as part of your
 24 expert analysis in this case, any of the
 25 deposition transcripts of any of the expert

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1 Cara R. Welch, Ph.D.
 2 publications or what-have-you since you prepared
 3 this one that was attached to your report?
 4 A I believe this is the most recent CV
 5 I've prepared.
 6 Q Okay, and does this CV list all of
 7 your -- I'm looking now at page -- they're not
 8 numbered, but beginning of the fourth page and
 9 going onto the fifth page, you have a section
 10 called "Scientific Publications."
 11 Does this list all the articles that
 12 you've published, this CV?
 13 A I might have a more recent publication.
 14 I haven't checked.
 15 Q Okay, and what subject matter might that
 16 more recent publication be on?
 17 A I believe we've prepared a manuscript,
 18 the dissertation topic from my grad school work,
 19 graduate school work.
 20 Q What was that topic? What was your
 21 dissertation?
 22 A It was on the chemistry and pharmacology
 23 of kinkeliba, a West African medicinal plant. We
 24 have two publications. I believe one of them has
 25 been prepared and submitted.

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1 Cara R. Welch, Ph.D.
 2 depositions of either the government's experts or
 3 the defendant/claimant's experts?
 4 A No.
 5 Q Have you reviewed any of the expert
 6 reports of either the government's experts or the
 7 defendant/claimant's experts?
 8 A I have not reviewed any of the
 9 government's expert reports. I don't believe I've
 10 reviewed expert reports of the claimants.
 11 Q Okay, and this declaration that we have
 12 in front of us, the report/declaration, Exhibit 2,
 13 does that document contain all of your opinions
 14 and conclusions in this matter?
 15 A Yes.
 16 Q Having looked at that and having
 17 prepared for this deposition, is there anything in
 18 the document, in Exhibit 2, that you wish to
 19 modify or change or amend in any fashion?
 20 A No.
 21 Q Okay. Let's move on to your CV which
 22 I've marked as Exhibit 3.
 23 Is this the most current version of your
 24 CV, or has there been a new version with perhaps
 25 different, I don't know, achievements or

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1 Cara R. Welch, Ph.D.
 2 Q Okay.
 3 Does the CV list all of your
 4 professional positions that you've had since you
 5 obtained your Ph.D.?
 6 A Yes.
 7 Q All right. When you worked at the
 8 Natural Products Association -- actually, let me
 9 back up.
 10 What's your understanding of what the
 11 Natural Products Association is?
 12 A The Natural Products Association is a
 13 trade association representing the natural
 14 products industry. They represent retailers,
 15 manufacturers, product manufacturers, and
 16 ingredient suppliers of products such as dietary
 17 supplements, cosmetics, home care products and
 18 foods.
 19 Q All right. Is it commonly known by the
 20 acronym of "NPA"?
 21 A Yes, it is.
 22 Q Are you familiar with an entity NNPA?
 23 A I'm not familiar with NNPA.
 24 Q Okay.
 25 When you were employed at the Natural

Page 22

1 Cara R. Welch, Ph.D.
 2 Products Association, did you know an individual
 3 named Dr. Daniel Fabricant?
 4 A Yes.
 5 Q And how did you come to know
 6 Dr. Fabricant?
 7 A He hired me.
 8 Q And did you report to him?
 9 A Yes, I did.
 10 Q Was Dr. Fabricant responsible for
 11 bringing you to the FDA in January of 2014?
 12 A Yes.
 13 Q And when you first began with the FDA in
 14 January 2014, did you report to Dr. Fabricant?
 15 A Yes.
 16 Q Was he your direct supervisor, or was
 17 there some intermediary between you and him?
 18 A I believe he was my direct supervisor.
 19 Q Okay.
 20 Is it true that your husband also works
 21 for the FDA? Is that correct?
 22 A Yes, it is.
 23 Q And in what capacity is he employed with
 24 the FDA?
 25 A He is a new drug reviewer for the Center

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1 Cara R. Welch, Ph.D.
 2 Exhibit 3?
 3 MR. WENIK: I may come back to it.
 4 MR. DAVENPORT: Okay. All right.
 5 Just for organizational purposes.
 6 MR. WENIK: That's all right.
 7 BY MR. WENIK:
 8 Q I'm looking at your expert declaration,
 9 paragraph 8, which is on page 5, and in paragraph
 10 8 on page 5 of Exhibit 2, your expert declaration,
 11 you talk about some of the things you did for the
 12 Natural Products Association.
 13 Do you see that?
 14 A Yes.
 15 Q And one of the things you listed as one
 16 of your responsibilities was "drafting scientific
 17 opinions, position papers, and comments in
 18 response to regulatory decisions."
 19 Do you see that?
 20 A Yes.
 21 Q All right. Did you draft, when you were
 22 at the NPA, any position papers regarding DMAA?
 23 A No, I do not believe so.
 24 Q Did you draft any scientific opinions
 25 when you were at the NPA regarding DMAA?

Page 23

1 Cara R. Welch, Ph.D.
 2 for Drug Evaluation and Research, CDER.
 3 Q All right. How long has he held that
 4 position?
 5 A I believe he was hired in -- I'm sorry.
 6 His current position?
 7 Q Yes.
 8 A Two or three years. He was hired in
 9 2010.
 10 Q By the FDA?
 11 A Yes, at FDA.
 12 Q What did he first do at the FDA?
 13 A He was a regulatory project manager, I
 14 believe is what they call it, for CDER.
 15 Q Did he ever work on the dietary
 16 supplement side of the FDA, for lack of a better
 17 word?
 18 A No.
 19 Q And does he have the same surname,
 20 Welch, or does he go by a different professional
 21 name?
 22 A He goes by Welch.
 23 Q All right. So I'm looking now at
 24 your --
 25 MR. DAVENPORT: Are you done with

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1 Cara R. Welch, Ph.D.
 2 A No, I don't believe so.
 3 Q And did you draft any comments when you
 4 were at the NPA regarding DMAA?
 5 A No, I don't believe so.
 6 Q All right. Let me drill down a little
 7 bit.
 8 So when you're referring to a scientific
 9 opinion versus a position paper, what is the
 10 difference between those two documents? What is a
 11 scientific opinion as compared to a position
 12 paper?
 13 A A scientific opinion would be a review
 14 of the scientific information at our disposal,
 15 putting forth an opinion based on purely
 16 scientific position.
 17 A position paper, how I'm referring to
 18 it here, is a position that is accepted for NPA's
 19 use, so it's a position of NPA on a topic. I
 20 think it could be broader than just scientific
 21 topic. It could be a regulatory topic or other
 22 topic.
 23 Q And when you craft or draft these sorts
 24 of documents, was there a level of review separate
 25 and apart from yourself for these position papers

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1 Cara R. Welch, Ph.D.
 2 and scientific opinions?
 3 A Yes.
 4 Q Who would conduct that review?
 5 A Depending on the nature of the position,
 6 if it were purely scientific, it would certainly
 7 be reviewed by committees from the Association.
 8 We had different committees. One committee in
 9 particular at NPA reviewed my work. It was called
 10 ComPLI, Committee on Product Labeling Integrity of
 11 regulatory decisions.
 12 If it were a broader position paper, it
 13 would certainly be reviewed by management, legal,
 14 likely, and depending on the acceptance of the
 15 position, it would be reviewed certainly by the
 16 board of directors' executive committee and
 17 possibly by the entire board of directors.
 18 Q Putting DMAA aside for the moment, did
 19 you have any role in drafting either a scientific
 20 opinion or a position paper for the NPA regarding
 21 synthetic ingredients generally as dietary
 22 supplements?
 23 A That position -- that topic was part of
 24 our comments, which is not a scientific opinion or
 25 a position paper, but the association's comments

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1 Cara R. Welch, Ph.D.
 2 So when you were drafting these
 3 scientific opinions and you're reviewing the
 4 science and you had these levels of review, before
 5 you would put your name to a document like that,
 6 if you will, what level of evidence did you need
 7 to see to issue a scientific opinion? Did it need
 8 to be uncontroverted, did it need to be a
 9 consensus, a reasonable degree of scientific
 10 certainty, some other standard that perhaps you
 11 operated under?
 12 MR. DAVENPORT: Objection to the
 13 form of the question.
 14 You can answer.
 15 THE WITNESS: Scientific opinions
 16 need to be based on peer-reviewed published
 17 information. The full methodology, if it
 18 included methodological methods, would need
 19 to be clearly laid out for our review. It
 20 didn't need to be incontrovertible, but all
 21 of the evidence would be weighed equally.
 22 BY MR. WENIK:
 23 Q And I guess I should have asked this
 24 question much earlier, but would you consider
 25 yourself a scientist? Even though you are now

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1 Cara R. Welch, Ph.D.
 2 in response to the July 2011 draft new dietary
 3 ingredient guidance from the FDA.
 4 Q And did you take the position that a
 5 synthetic could be a dietary ingredient under
 6 DSHEA?
 7 Do you understand when I say "DSHEA," I
 8 mean Dietary Supplement Health and Education Act?
 9 A I understand DSHEA, yes.
 10 The Association's position was synthetic
 11 ingredients should be considered to be dietary
 12 ingredients.
 13 Q Has your thinking on that particular
 14 topic changed since you've become a member of the
 15 FDA?
 16 MR. DAVENPORT: Objection to the
 17 form of the question.
 18 You can answer.
 19 THE WITNESS: To that particular
 20 position, not necessarily. My thinking has
 21 expanded, but ultimately I still believe
 22 synthetic ingredients can be dietary
 23 ingredients.
 24 BY MR. WENIK:
 25 Q Let me drill down a little bit more.

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1 Cara R. Welch, Ph.D.
 2 perhaps wearing a regulator's hat, would you still
 3 consider yourself a scientist?
 4 A Yes.
 5 Q All right. So going back to your CV,
 6 which is Exhibit 3, I'm looking at page 2, and I'm
 7 looking at the block where you talk about when you
 8 were a vice president for Scientific and
 9 Regulatory Affairs for the Natural Products
 10 Association.
 11 A Okay.
 12 Q And in the very last bullet point there,
 13 you talk about "integrated communication
 14 department with scientific and regulatory
 15 initiatives to ensure dissemination of information
 16 to the membership, response to media inquiries,
 17 and misleading scientific articles."
 18 Do you see that?
 19 A Yes.
 20 Q What is a misleading scientific article?
 21 A The dietary supplement industry has a
 22 lot of publications that are -- has a lot of
 23 articles that are published looking at the
 24 evidence behind the efficacy of their products,
 25 and there are times when the industry believes the

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1 Cara R. Welch, Ph.D.
 2 information is misleading, giving the impression
 3 the products aren't efficacious, when, in fact,
 4 they might be, or the information is not yet
 5 settled one way or the other. Those were often
 6 the types of articles we were responding to.
 7 Q How about articles that dealt with
 8 safety; would those be in the same category of,
 9 quote-unquote, "misleading scientific articles" in
 10 addition to ones dealing with efficacy?
 11 A They could be.
 12 Q And would it be fair to say that you
 13 would review these articles with a skeptical eye?
 14 A Yes.
 15 Q Let's talk for a moment about the
 16 scientific method generally.
 17 So you mentioned earlier peer review.
 18 What is the function of peer review?
 19 A A peer review is an assurance that the
 20 information presented in an article is accepted by
 21 peers at the level peers would accept.
 22 Q All right. So when we are talking about
 23 someone that publishes a peer-reviewed article, a
 24 study of one sort or another, is it part of the
 25 scientific method that a researcher begins with a

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1 Cara R. Welch, Ph.D.
 2 from its reliability?
 3 A It's one piece of evidence.
 4 Q And evidence toward what?
 5 A One piece of evidence toward bias.
 6 Q Can a study that's funded by a
 7 commercial enterprise be a legitimate study,
 8 producing legitimate results?
 9 A Yes.
 10 Q So when an entity -- and some research
 11 sponsored by governmental entities such as the NIH
 12 or the FDA, is that common in your experience?
 13 A Yes.
 14 Q So as part of the scientific method, is
 15 it inappropriate for the sponsor, be it a
 16 government entity or a commercial entity, to
 17 comment and give feedback on the research as it's
 18 being conducted? Is that in and of itself
 19 inappropriate?
 20 MR. DAVENPORT: Objection to the
 21 form of the question.
 22 You can answer.
 23 THE WITNESS: I apologize. Can you
 24 repeat the question.
 25

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1 Cara R. Welch, Ph.D.
 2 hypothesis of some sort? Is that typically the
 3 scientific method?
 4 A Yes.
 5 Q And as a scientist, is the goal of
 6 conducting a study to provide evidence that either
 7 proves or disproves that hypothesis?
 8 A Yes.
 9 Q And is it important to you as a
 10 scientist that the researchers that are conducting
 11 the study to prove or disprove the hypothesis be
 12 as free from bias as possible?
 13 A Yes.
 14 Q And is it common in your experience --
 15 and you've worked now for a number of years both
 16 in the government and in a trade association --
 17 for peer-reviewed research to be funded by a
 18 commercial entity of one sort or another,
 19 pharmaceutical company, dietary supplement
 20 company, or what-have-you?
 21 A It is common, yes.
 22 Q Does that in and of itself, that a study
 23 or a research paper is funded by a commercial
 24 enterprise of some sort, does that in and of
 25 itself, in your opinion as a scientist, detract

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1 Cara R. Welch, Ph.D.
 2 BY MR. WENIK:
 3 Q Sure. Is it inappropriate, in your mind
 4 as a scientist -- and you are here as an expert --
 5 for the sponsor of a study, be it a government
 6 entity or a commercial entity, to comment on the
 7 research as it's being conducted by the
 8 researchers to provide them feedback?
 9 A Not necessarily.
 10 Q Is it inappropriate for the sponsor of a
 11 study, be it a government entity or a commercial
 12 entity, to provide any editing or comments to a
 13 draft of the manuscript that's submitted for
 14 publication? Is that inappropriate?
 15 MR. DAVENPORT: Objection to the
 16 form of the question.
 17 You can answer.
 18 THE WITNESS: Not necessarily.
 19 BY MR. WENIK:
 20 Q Is it inappropriate for the sponsor of a
 21 scientific study to ask the researchers to change
 22 their conclusions?
 23 MR. DAVENPORT: Objection to the
 24 form of the question.
 25 You can answer.

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1 Cara R. Welch, Ph.D.
 2 THE WITNESS: It would be
 3 inappropriate for the sponsor of a study to
 4 ask the researchers to change their
 5 conclusions.
 6 BY MR. WENIK:
 7 Q When a scientist or researcher conducts
 8 a peer-reviewed piece of research, is it the
 9 generally accepted norm in the scientific world
 10 that they report all of the data that they found,
 11 including data that goes against their hypothesis?
 12 A A well-founded study, the results of a
 13 study would provide all of the information that
 14 went into that conclusion, both positive and
 15 negative.
 16 Q Would you consider it inappropriate, as
 17 a matter of science, for a researcher to exclude
 18 from the published manuscript only that data that
 19 contradicted their hypothesis?
 20 MR. DAVENPORT: Objection to the
 21 form of the question.
 22 You can answer.
 23 THE WITNESS: It would be
 24 inappropriate to exclude information that
 25 went against the hypothesis, yes.

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1 Cara R. Welch, Ph.D.
 2 "BMPEA."
 3 Q I'm also familiar with that one. Thank
 4 you.
 5 A And possibly -- I'm looking at the
 6 dates. I would guess the ingredient picamilon.
 7 Q All right. So let me -- so I guess I
 8 first ask you, for the clarity of the record, what
 9 is CFSAN stand for?
 10 A The Center for Food Safety and Applied
 11 Nutrition.
 12 Q All right.
 13 So looking at your CV -- and let's stick
 14 with the FDA positions for a moment -- I'm looking
 15 at page 2, and it says that from September 2014 to
 16 February 2016, you were the Dietary Supplement
 17 Regulations Implementation team leader.
 18 Do you see that?
 19 A Yes.
 20 Q So that position overlapped some of
 21 these other positions; is that right?
 22 A Yes. That was the permanent position I
 23 was in.
 24 Q Okay.
 25 A I had some acting positions during that

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1 Cara R. Welch, Ph.D.
 2 BY MR. WENIK:
 3 Q Would you consider it an act of
 4 scientific dishonesty for a researcher to falsify
 5 the results that are published in a peer-reviewed
 6 paper?
 7 A Yes.
 8 Q Okay. Turning back to your CV, I'm
 9 looking at page 1, and in the second block, under
 10 the January 2015 to February 2016 block, I'm
 11 looking at the third bullet point, and you talked
 12 about "directed enforcement initiatives with
 13 CFSAN's Office of Compliance for three violative
 14 dietary ingredients, resulting in more than 20
 15 Warning Letters."
 16 Do you see that?
 17 A Yes.
 18 Q All right. So my first question to you
 19 is: What were the three violative dietary
 20 ingredients that you're referring to there?
 21 A I believe it would be an ingredient
 22 called -- an ingredient FDA refers to as "DMBA."
 23 I can spell that out if you would like.
 24 Q I'm familiar with DMBA.
 25 A Okay. An ingredient we refer to as

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1 Cara R. Welch, Ph.D.
 2 time period.
 3 Q All right. So what were your duties
 4 then as the Dietary Supplement Regulations
 5 Implementation team leader? What were you
 6 responsible for in that role?
 7 A I was officially a team leader of I
 8 believe eight FDA employees. Our work, the work
 9 of these eight employees reviewed CGMP cases,
 10 reviewed labeling cases, claims cases. They
 11 review applications for certificates of free sale.
 12 They review notifications for structure function
 13 claims.
 14 Q All right. In that role did you have an
 15 enforcement responsibility as far as issuing
 16 warning letters and seizure actions and the like?
 17 A The actions, the compliance and
 18 enforcement actions from CFSAN, Center for Food
 19 Safety and Applied Nutrition, are worked -- are
 20 spearheaded from the Office of Compliance. We are
 21 the experts, the subject matter experts, so the
 22 actions often require a support memorandum from
 23 our office, from that team in particular, for
 24 GMPs, for labeling and for claims.
 25 Q So when you assumed the role of -- I

1 Cara R. Welch, Ph.D.
2 guess I should go through these, not each one.
3 You also talk about "Regulatory Special
4 Assistant." What was that? You did it from
5 January to September of 2014.

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

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

12 A Yes.

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

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

20 Q Oh, interesting. Okay.

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

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

25 A I led the division. I supervised all

1 Cara R. Welch, Ph.D.
2 22, 23 employees. I was, I was the director for
3 both of the principal teams in the division, both
4 the Regulations Implementation Team and the New
5 Dietary Ingredient Review Team. I was in charge
6 of the medical officer, reviewing adverse event
7 reports. I -- all of that. I led the division.

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

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

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

25 MR. DAVENPORT: Objection to the

1 Cara R. Welch, Ph.D.
2 form of the question.

3 You can answer.

4 THE WITNESS: Yes.
5 BY MR. WENIK:

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

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

16 (Exhibit 4 was marked for
17 identification.)

18 BY MR. WENIK:

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

23 Have you seen this organizational chart
24 before?

25 A Yes.

1 Cara R. Welch, Ph.D.

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

4 So when you came on board in January of
5 2014 to the FDA, does this reflect, this document,
6 Welch Exhibit 4, the structure of the Food & Drug
7 Administration that existed when you came on board
8 in January 2014?

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

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

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

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

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

1 Cara R. Welch, Ph.D.
 2 of Nutrition and Food Labeling, which we are no
 3 longer a part of, and then separately the Office
 4 of Dietary Supplement Programs.
 5 Q All right, and these positions that you
 6 have -- so when you're a senior advisor, are you
 7 still in the Office of Dietary Supplement
 8 Programs, or are you in some other sub-part of the
 9 FDA?
 10 A I'm in the Office of Dietary Supplement
 11 Programs.
 12 Q All right. So as an office, does the
 13 Office of Dietary Supplement Programs now have
 14 increased staff and resources as compared to when
 15 it was just a lowly division of the Office of
 16 Nutrition and Labeling?
 17 MR. DAVENPORT: I'm going to object
 18 to the form of the question.
 19 You can answer.
 20 THE WITNESS: I don't believe we
 21 have any additional resources or employees.
 22 We are the same size as the Division of
 23 Dietary Supplement Programs. We're just a
 24 separate office now.
 25

1 Cara R. Welch, Ph.D.
 2 BY MR. WENIK:
 3 Q Has that been an issue within the FDA
 4 for a while, that the resources devoted to dietary
 5 supplements have been static or limited?
 6 MR. DAVENPORT: Objection to the
 7 form of the question.
 8 You can answer.
 9 THE WITNESS: I'm not sure it's my
 10 place to say that it is a problem. The
 11 number of employees has stayed fairly similar
 12 for the last several years.
 13 BY MR. WENIK:
 14 Q And has the industry grown in that
 15 period of time?
 16 A The dietary supplement industry is
 17 certainly touted to be a constantly growing
 18 industry, so I would assume yes, it has grown,
 19 while the office or division has retained the same
 20 number of employees.
 21 Q All right. So when you came on board,
 22 where would Dr. Fabricant have fit in on this
 23 organizational chart that I have here as Welch
 24 Exhibit 4? Would he have been replacing
 25 Mr. Spiller that's listed here or been above

1 Cara R. Welch, Ph.D.
 2 Mr. Spiller?
 3 A Dr. Fabricant was the division director
 4 in the Office of Nutrition, Labeling and Dietary
 5 Supplements, so he would not have shown up on this
 6 organizational chart.
 7 Q Okay, all right, and are you familiar
 8 with Dr. Keefe?
 9 A Yes.
 10 Q And how are you familiar with him?
 11 A He is a colleague at the Center for Food
 12 Safety and Applied Nutrition.
 13 Q All right, and I see him listed on this
 14 diagram, Exhibit 4, to the far left in the Office
 15 of Food Additive Safety; is that right?
 16 A Yes.
 17 Q Does he still work in that entity of the
 18 Food & Drug Administration?
 19 A As far as I'm aware, yes.
 20 Q All right. Does Dr. Keefe have any role
 21 in any of these enforcement initiatives regarding
 22 dietary supplements since you have been at FDA?
 23 A Dr. Keefe? Not necessarily. We do work
 24 with his office from time to time on establishing
 25 whether an ingredient is an approved food additive

1 Cara R. Welch, Ph.D.
 2 or is "GRAS," referring to "generally recognized
 3 as safe."
 4 Q Okay. Let me jump ahead for a minute
 5 then, being you're talking about that.
 6 (Exhibit 5 was marked for
 7 identification.)
 8 BY MR. WENIK:
 9 Q Dr. Welch, I've placed before you a
 10 document marked for identification as Welch
 11 Exhibit 5, which is the expert declaration of
 12 Dr. Keefe.
 13 Have you seen this document before?
 14 A I have not.
 15 Q Okay. If you will bear with me for a
 16 moment, you don't mind to turn to page 4 and look
 17 at paragraph 9 of this document, and Dr. Keefe
 18 wrote in his report that "The purpose of this
 19 Report is to provide my expert opinion that DMAA
 20 meets the definition of a 'food additive.'"
 21 Do you see that?
 22 A I do see that.
 23 Q All right. Are you making any expert
 24 opinions in this litigation as to whether or not
 25 DMAA is a food additive?

1 Cara R. Welch, Ph.D.

2 A I am not.

3 Q Okay. So let me just ask, looking back
4 at your CV, so when you were the Dietary
5 Supplement Regulations Implementation Team leader,
6 who was your direct report? Who did you report
7 directly to within the FDA in that role?

8 A I -- when I was the regulations and
9 implementation team leader, I reported to a number
10 of acting division directors. We didn't have a
11 permanent division director at that time, so I
12 reported to -- do you want me to list the names?

13 Q Please.

14 A I reported to Charlotte Christin. I
15 then reported to -- I believe in October of 2014
16 until January 2015, I reported to Dr. Dan Levy.

17 Q And now as a senior advisor, who do you
18 report to?

19 A I report to our office director, Steven
20 Tave.

21 Q And when you first came on board to the
22 FDA, did you report to Dr. Fabricant?

23 A Yes.

24 Q All right. Were you familiar with
25 someone at the FDA known as Dr. Robert Moore?

1 Cara R. Welch, Ph.D.

2 A I am familiar with him, though I've
3 never worked with him.

4 Q Okay. How are you familiar with him?

5 A When I was at NPA, I had some
6 communications with Dr. Moore. I believe he
7 attended some meetings that we attended at FDA and
8 had some email communication with him on labeling
9 topics, I believe. I'm not sure.

10 Q What was your understanding of his area
11 of expertise?

12 A I believe his expertise is dietary
13 supplement regulations, claims, labeling. I'm not
14 sure on his expertise with GMPs, but I believe
15 it's more on claims and labeling and ingredient
16 identity.

17 Q Was he someone that had a good
18 reputation in the industry when you were at the
19 NPA?

20 A I don't know that we ever -- I don't
21 know.

22 Q Okay. All right.

23 So going back to your declaration, and
24 I'm looking at paragraph 5 on page 3.

25 A Yes.

1 Cara R. Welch, Ph.D.

2 Q Okay. So you wrote that that you have
3 "reviewed FDA enforcement actions involving
4 dietary supplements to ensure the actions were
5 supported by sound scientific principles and
6 consistent with FDA policy."

7 Do you see that?

8 A Yes.

9 Q So just so I understand what you're
10 saying there, do you look at these enforcement
11 actions before the fact, do you weigh in on them,
12 or only after the fact, because in reading your
13 CV, I got the sense that it was before the fact.

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

16 You may answer.

17 THE WITNESS: Largely probably
18 before the Act. I can foresee situations
19 where it may be after the fact.

20 BY MR. WENIK:

21 Q Okay. So you would be part of the group
22 of officials recommending proceeding in one
23 fashion or another against somebody that, in your
24 view, was violating some portion of the FDA Food,
25 Drug & Cosmetic Act?

1 Cara R. Welch, Ph.D.

2 A In my current role, yes, I would be part
3 of that conversation.

4 Q Okay, and you said that you have "served
5 as the project officer for CFSAN's Cooperative
6 Agreement with the National Center for Natural
7 Products Research at the University of
8 Mississippi, directing botanical dietary
9 supplement research priority since May of 2014.

10 Do you see that?

11 A Yes, I do.

12 Q All right. So when you wrote in your
13 CV, Exhibit 3, I'm looking at the first block and
14 the second bullet point, you talk again about the
15 National Center for Natural Products Research, and
16 you wrote that you "managed the \$2.5M budget."

17 Do you see that?

18 A I do see that.

19 Q Does "\$2.5M" stand for two and a half
20 million?

21 A Yes.

22 Q And looking at the second page of
23 Exhibit 3, in your block experience of
24 January 2014 to February 2016, in that block of
25 block of experience in your second to the last

1 Cara R. Welch, Ph.D.
2 bullet point, you talk about the National Center
3 for Natural Products Research at the University of
4 Mississippi "directing botanical dietary
5 supplement research priorities and managed the
6 \$2.5M budget."
7 Do you see that?
8 A Yes.
9 Q Does the 2.5M there stand for two and a
10 half million?
11 A Yes, it does.
12 Q All right. So when you say both in your
13 expert declaration and in your CV that you're
14 directing the research priorities, does that mean
15 that you are telling the Center what areas of
16 research the FDA would like them to look into?
17 A What do you mean by "center"?
18 Q The National Center for Natural Products
19 Research at the University of Mississippi.
20 A To an extent, yes.
21 Q Was one of the items, when you came on
22 board in January 2014, that the natural products
23 research center was looking at DMAA?
24 A I believe so. I believe the research
25 was largely finished. They were working on one

1 Cara R. Welch, Ph.D.
2 final manuscript when I started in May of 2014.
3 Q And as part of your role in approving
4 the \$2.5 million budget, do you have
5 communications with Dr. ElSohly of the University
6 of Mississippi?
7 MR. DAVENPORT: Objection to the
8 form of the question regarding approving
9 budget.
10 You can answer if you're able.
11 THE WITNESS: I don't have much
12 conversation with Dr. ElSohly. My
13 conversations are largely with Dr. Khan and
14 Dr. Chittiboyina, Amar Chittiboyina.
15 BY MR. WENIK:
16 Q All right, and do you have conversations
17 with Dr. Khan as to renewing the funding for the
18 Center at the University of Mississippi?
19 A Yes.
20 Q And is it your understanding that the
21 FDA, through this cooperative agreement, provides
22 the lion's share of the funding for the National
23 Center for Natural Products Research at the
24 University of Mississippi?
25 A I am not aware what percent of their

1 Cara R. Welch, Ph.D.
2 total funding we provide. We have provided as
3 much as \$2.5 million per year. In recent years it
4 has been less than that.
5 Q All right. Was it \$2.5 million in 2014?
6 A I believe it was, yes.
7 Q Now, you mentioned that at that time
8 there was a final manuscript being prepared
9 regarding DMAA by the University of Mississippi
10 researchers; is that right?
11 A I believe so, yes.
12 Q Did you comment on that draft manuscript
13 before it was finalized?
14 A I don't recall at this time.
15 Q Would that have been something that in
16 your role as the project officer, that they would
17 submit to you the research product that the Center
18 was producing?
19 A Dr. Khan will often send me manuscripts,
20 not necessarily for my approval but for my review.
21 Q Does Dr. Khan periodically provide you
22 updates as to the progress of the research that
23 the FDA is funding pursuant to this cooperative
24 agreement?
25 A Yes. We have quarterly, if not more

1 Cara R. Welch, Ph.D.
2 than quarterly, meetings.
3 Q Are you aware of a 2012 article
4 published by the University of Mississippi by
5 Drs. Khan and ElSohly regarding DMAA?
6 And just for ease of reference, if you
7 can look at reference 15.
8 A Yes. I'm aware of the 2012 article.
9 Q All right, and that article was the
10 result of research conducted at the National
11 Center for Natural Products Research at the
12 University of Mississippi; isn't that correct?
13 A I believe so, yes.
14 Q All right. Do you know who at the FDA
15 was the project manager for this relationship
16 prior to your assuming that role in January of
17 2014?
18 A The project officer prior to me was
19 Dr. Dan Fabricant. I am not sure when he became
20 the project officer.
21 Q Okay. So Dr. Fabricant would have been
22 the one then receiving these quarterly updates
23 from the Center?
24 A I would assume, yes.
25 Q Did you ever have any discussions with

1 Cara R. Welch, Ph.D.
2 Dr. Fabricant about the 2012 article that is cited
3 as reference 15 in your expert report?
4 A I don't believe I've ever discussed this
5 article with Dr. Fabricant.
6 Q Did you ever ask anyone at the FDA why
7 the conclusion section of the article was changed
8 after it was published?
9 MR. DAVENPORT: Objection to the
10 form of the question. Assumes facts.
11 You may answer if you are able.
12 THE WITNESS: I am actually not
13 able to answer this question.
14 BY MR. WENIK:
15 Q Were you aware that the conclusion
16 section of the research that resulted in the
17 article that you cite was changed to read "finding
18 trace amounts of DMAA" to "finding no DMAA"? Were
19 you aware of that change?
20 MR. DAVENPORT: Objection to the
21 form of the question.
22 You may answer if able.
23 THE WITNESS: I was not aware.
24 (Whereupon, a short recess was
25 taken.)

1 Cara R. Welch, Ph.D.
2 BY MR. WENIK:
3 Q Are you familiar with an entity known as
4 ElSohly Laboratories, Inc.?
5 A Yes, I am.
6 Q How are you familiar with that entity?
7 A I believe that is a firm of sorts, a
8 laboratory run by Dr. ElSohly at NCNPR. I believe
9 it's a separate entity.
10 Q Does some of the two and a half million
11 dollar annual funding block go toward work done by
12 ElSohly Laboratories, Inc.?
13 MR. DAVENPORT: Objection to the
14 form of the question.
15 You may answer.
16 THE WITNESS: I don't believe so.
17 BY MR. WENIK:
18 Q How about an entity known as
19 Phytochemical Services, Inc. or PSI? Are you
20 familiar with that entity?
21 A Not -- no, I am not familiar with it. I
22 don't believe I'm familiar with them.
23 Q Okay. How about ChromaDex; are you
24 familiar with that entity?
25 A I am familiar, yes.

1 Cara R. Welch, Ph.D.
2 Q How are you familiar with ChromaDex?
3 A ChromaDex is -- they may still be. When
4 I was at NPA, ChromaDex was a member, and their
5 principals sat on some committees that I oversaw.
6 Q Was Dr. Khan one of those principals of
7 ChromaDex?
8 A Not that I'm aware of. I don't believe
9 Dr. Khan is an employee of ChromaDex.
10 Q Do you know whether Dr. Khan is a
11 significant shareholder of ChromaDex?
12 A I have no knowledge of this.
13 Q Does ChromaDex perform any work that is
14 funded by this FDA block of funding to the
15 National Center for Natural Products Research or
16 NCNPR?
17 A No. ChromaDex isn't part of that
18 cooperative agreement.
19 Q Okay.
20 Have you had any discussions or contact
21 with any of the -- and I'm not asking you for the
22 substance of the question. I just want to know if
23 you've had contact with any of the lawyers for the
24 Federal Trade Commission that are litigating
25 currently against Hi-Tech Pharmaceuticals.

1 Cara R. Welch, Ph.D.
2 A I'm not aware that I've had contact with
3 these particular lawyers you're speaking of.
4 Q Okay. Amanda Basta; is that a name that
5 you are familiar with?
6 A No.
7 Q Edward Mendelson?
8 A No.
9 Q Have you reviewed any of the expert
10 reports that have been prepared in the FTC
11 litigation involving Hi-Tech Pharmaceuticals?
12 A No, I have not.
13 Q Okay.
14 So I want to talk a little bit about the
15 scope of your expert opinions that you're
16 rendering here. I want to make sure I have a very
17 clear understanding of the limits.
18 So the first question to you is: Are
19 you offering any expert opinion as to whether or
20 not DMAA is contained in geraniums?
21 A I am not offering an expert opinion on
22 that.
23 Q Are you offering any expert opinion as
24 to the composition or chemical nature of any of
25 the items that have been seized in this

1 Cara R. Welch, Ph.D.
 2 litigation?
 3 A No.
 4 Q Are you offering any opinions as to the
 5 safety of DMAA?
 6 A No.
 7 Q Are you offering any opinions as to the
 8 efficacy of DMAA, be it for weight loss or
 9 workouts or anything?
 10 A No.
 11 Q Okay.
 12 So turning back to your expert report or
 13 declaration, in paragraphs 3 and 11 you state that
 14 the purpose of your report is to "provide my
 15 expert opinion about the methods and processes
 16 available to and used by FDA to regulate dietary
 17 supplements," and you say the same exact thing at
 18 paragraph 11.
 19 Do you see that?
 20 A I do.
 21 Q So is one of the methods and processes
 22 available to the FDA to regulate dietary
 23 supplements a ban of a dietary ingredient or
 24 supplement?
 25 A I wouldn't use the word "ban," but yes,

1 Cara R. Welch, Ph.D.
 2 we can remove dietary ingredients or dietary
 3 supplements from the market.
 4 Q Is that what happened with ephedra?
 5 A We did a rulemaking for ephedrine
 6 alkaloids, stating they adulterate dietary
 7 supplements because they present a significant or
 8 unreasonable risk of illness or injury.
 9 Q So would rulemaking be one of the -- to
 10 use your phrase -- "methods and processes
 11 available to the FDA to regulate a dietary
 12 supplement"?
 13 A Yes.
 14 Q And with regard to ephedra, what exactly
 15 did that rulemaking entail? What did the FDA do?
 16 A I was not an employee of FDA at that
 17 time, but we did a rulemaking to state that
 18 ephedrine alkaloids, not all ephedra, just the
 19 ephedrine alkaloids, present a significant or
 20 unreasonable risk of illness or injury.
 21 Therefore, a dietary supplement containing
 22 ephedrine alkaloids is considered adulterated.
 23 Q Was the rulemaking published in the
 24 Federal Register?
 25 A Yes, it was.

1 Cara R. Welch, Ph.D.
 2 Q Was public comment solicited?
 3 A Yes, it was.
 4 Q Could the same process that was used
 5 with ephedrine alkaloids be employed with regard
 6 to DMAA?
 7 A No, it could not.
 8 Q Why not?
 9 A The FDA's opinion is that DMAA is not a
 10 dietary ingredient. Therefore, that provision
 11 would not apply to an ingredient that is not a
 12 dietary ingredient.
 13 Q Okay. So if it were a dietary
 14 ingredient, could it be subject to the same
 15 rulemaking that has been applied to ephedrine
 16 alkaloids?
 17 A Ephedrine alkaloids are dietary
 18 ingredients, so that method is available. Other
 19 dietary ingredients could go through that same
 20 process.
 21 Q So just to be clear, if DMAA were a
 22 dietary ingredient, then it could be subject to
 23 the same rulemaking process that was used with
 24 regard to ephedrine alkaloids; is that right?
 25 A FDA's opinion is that DMAA is not a

1 Cara R. Welch, Ph.D.
 2 dietary ingredient. If it were a dietary
 3 ingredient, rulemaking is one of many methods that
 4 could be used to regulate products containing it.
 5 Q Okay. So when we're talking about
 6 something that's not a dietary ingredient, what,
 7 in your expert opinion, are the different methods
 8 and processes available to the FDA to regulate
 9 that? What are the alternatives that you can
 10 employ?
 11 A There are -- I'm sure there are a number
 12 of methods to employ. Products that list an
 13 ingredient that is not a dietary ingredient on
 14 their label stating it is a dietary ingredient,
 15 those products would be misbranded. If this
 16 ingredient that is not a dietary ingredient is
 17 considered to be an unsafe food additive, then
 18 products containing it would be adulterated.
 19 There are other provisions of the
 20 adulteration provision that could apply, I'm
 21 certain. If a product is misbranded or
 22 adulterated, we can send warning letters. Those
 23 are public advisory actions, clarifying for the
 24 firms that it is misbranded or adulterated,
 25 whichever provision applies.

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1 Cara R. Welch, Ph.D.
 2 We could move to administrative actions.
 3 We can administratively detain adulterated or
 4 misbranded food. Or we can move to judicial
 5 actions, including injunction or seizure,
 6 injunction of the firm to produce the product, or
 7 seizure of the actual products.
 8 Q And what factors play into the
 9 decision-making process as to which of these
 10 alternatives to employ, the warning letter versus
 11 the administrative procedure versus the judicial
 12 action?
 13 A There are a number of factors that play
 14 in. FDA is a public health agency, so the safety
 15 factor of the ingredient and the products of
 16 commerce would certainly weigh in. We would
 17 evaluate what is publicly known about a product or
 18 an ingredient. If we have stated in the past that
 19 it is not a dietary ingredient and, therefore,
 20 products listing it as a dietary ingredient are
 21 misbranded and the firms continue to disregard our
 22 notice, then we may move on to either
 23 administratively detaining or seizing the
 24 products.
 25 The safety of the product weighs into

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1 Cara R. Welch, Ph.D.
 2 issue?
 3 MR. DAVENPORT: Objection to the
 4 form of the question.
 5 You can answer if you're able.
 6 THE WITNESS: I wouldn't say it is
 7 solely on the nature of the product. It is
 8 largely on the nature of the product.
 9 BY MR. WENIK:
 10 Q Does the ownership of the company that
 11 produces the product factor into your
 12 decision-making?
 13 A I would not say the ownership of the
 14 product factors in, because that implies a
 15 particular person. The firm and firm history may
 16 weigh in, but not necessarily.
 17 Q Should the ethnic composition of the
 18 workforce of the product -- let me rephrase that.
 19 Should the ethnic composition of the
 20 workforce of the company that produces the product
 21 be a factor in your decision as to whether to take
 22 action against that product?
 23 A FDA does not have statistics on the
 24 ethnic composition of firms producing a particular
 25 product, so that does not weigh into account.

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1 Cara R. Welch, Ph.D.
 2 how quickly we take action, so there are a number
 3 of factors that come into play.
 4 Q Okay. So as an expert, and you claim to
 5 be an expert in the methods and processes to
 6 regulate dietary supplements, is it an appropriate
 7 factor to consider whether you like or dislike the
 8 owner of the company that produces the product in
 9 question?
 10 A I would not say one person's opinion of
 11 another person weighs into what action FDA as an
 12 agency is taking.
 13 Q Is it your expert opinion that the
 14 factors are limited to the safety of the product?
 15 Is that what drives the decision?
 16 MR. DAVENPORT: Objection to the
 17 form of the question. Mischaracterizes her
 18 prior testimony.
 19 BY MR. WENIK:
 20 Q Do you want me to rephrase, or do you
 21 feel able to answer the question?
 22 A Can you rephrase?
 23 Q Sure.
 24 The factors that you described, are they
 25 solely focused on the nature of the product at

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1 Cara R. Welch, Ph.D.
 2 Q Would you agree with me that it would be
 3 inappropriate to take action against a product
 4 based on the fact that the majority of the
 5 management of the entity is African-American?
 6 A To repeat my answer before, FDA doesn't
 7 keep information on the ethnic composition, for
 8 lack of a better word, of firms producing a
 9 product, so it wouldn't weigh into our factor,
 10 because we don't know this information.
 11 Q Did you have any conversations with the
 12 inspectors that conducted the seizures at the
 13 Georgia facilities of Hi-Tech Pharmaceuticals?
 14 A I don't believe I had any conversations
 15 with the investigators.
 16 Q Are you aware of any comments by the
 17 investigators as to the ethnic makeup of the
 18 workforce at Hi-Tech Pharmaceuticals?
 19 A I am not aware of any comments by the
 20 investigators or any position they have on the
 21 ethnic makeup of the firm you speak of.
 22 Q Would it be appropriate, in your mind,
 23 to have it weigh in in any way, shape or form on
 24 the enforcement action, the ethnic makeup of the
 25 workforce that produces a product subject to FDA

1 Cara R. Welch, Ph.D.
 2 regulation?
 3 MR. DAVENPORT: Objection to the
 4 form of the question. It's been asked and
 5 answered.
 6 You may answer again.
 7 THE WITNESS: I would repeat my
 8 answer that FDA does not have statistics or
 9 information on the ethnic makeup of any
 10 particular firm, so it does not weigh into
 11 our decision.
 12 BY MR. WENIK:
 13 Q Okay. So I'm looking at paragraph 15 of
 14 your expert report, which is Welch Exhibit 2, and
 15 you talk about "the regular work of ODSP to
 16 regulate diet supplements includes."
 17 So I guess first, for the record, I
 18 should ask you: What does "ODSP" stand for?
 19 A It stands for the Office of Dietary
 20 Supplement Programs.
 21 Q And that was an entity that you've held
 22 positions with at the FDA; is that correct?
 23 A That is the office that I am currently a
 24 member of.
 25 Q All right, and you wrote that "the

1 Cara R. Welch, Ph.D.
 2 regular work of ODSP to regulate dietary
 3 supplements includes, but is not limited to," and
 4 you list various items here, including
 5 "investigating potentially problematic dietary
 6 supplement ingredients."
 7 So what do you mean by "potentially
 8 problematic dietary supplement ingredients"?
 9 A I'm using that phrase to cover many
 10 potential regulatory issues FDA may have with an
 11 ingredient. Our office evaluates ingredients
 12 based on whether they fit the statutory definition
 13 of a dietary ingredient, whether they are properly
 14 tested, properly manufactured, if the products --
 15 whether they are safe, whether the product,
 16 including that ingredient, the product of
 17 commerce, is safe.
 18 Q Now, in paragraph 13 of your
 19 declaration, you quote the statutory definition of
 20 what a dietary ingredient is; is that right?
 21 A Yes.
 22 Q Okay. So looking at that paragraph and
 23 compared to what we just looked at in paragraph
 24 15, is it fair to say that you can have a
 25 substance that meets the definition of a dietary

1 Cara R. Welch, Ph.D.
 2 ingredient, but for one reason or another it is
 3 still problematic in some fashion?
 4 A Yes. Dietary ingredients can be
 5 problematic in one fashion or another.
 6 Q And so a dietary ingredient that is
 7 problematic, you would take some sort of
 8 regulatory action against that ingredient; is that
 9 right?
 10 A It depends what level of problem is at
 11 issue.
 12 Q All right. So for something that meets
 13 the definition of a dietary ingredient yet
 14 presents a problem, in your expert opinion of the
 15 methods and processes available to take action,
 16 what are the different tools available to you to
 17 take action against a dietary ingredient that
 18 presents an issue as opposed to what you've
 19 described before as to something that may not be a
 20 dietary ingredient?
 21 A Dietary ingredients have -- a dietary
 22 ingredient, if it is a new dietary ingredient,
 23 would have to go through the -- would likely have
 24 to go through the new dietary ingredient
 25 notification process prior to being marketed in a

1 Cara R. Welch, Ph.D.
 2 dietary supplement. That is one method the
 3 industry is responsible for doing.
 4 If we find a dietary ingredient is a new
 5 dietary ingredient, and a notification should have
 6 been submitted but was not, that product is
 7 adulterated according to section 402(f) of the
 8 Act. I'm referring specifically to section
 9 413(a)(2) of the Act.
 10 That's the result of the dietary
 11 ingredient. The methods or processes which would
 12 bring it to the attention of the firm would be
 13 similar to products that contain ingredients that
 14 aren't dietary ingredients. So if the product is
 15 adulterated, if it's adulterated because it's a
 16 new dietary ingredient or if it's adulterated
 17 because it presents a significant or unreasonable
 18 risk of illness or injury, or if it is -- there's
 19 also sections 402(f)(1), (f)(1)(C) and (f)(1)(D)
 20 of the Act, referring specifically to dietary
 21 supplements containing dietary ingredients.
 22 So those adulteration provisions are at
 23 our disposal. If we decide that a product
 24 containing a dietary ingredient is adulterated, we
 25 would go through the same decision processes as

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1 Cara R. Welch, Ph.D.
 2 before, bringing it to the attention of the firms
 3 in question, either through -- likely through a
 4 warning letter, an advisory action. Depending on
 5 the result, how the firm takes that position, we
 6 could administratively detain the products or
 7 seize the products or enjoin the firm.
 8 Q All right. So let me just show you
 9 something here.
 10 (Exhibit 6 was marked for
 11 identification.)
 12 BY MR. WENIK:
 13 Q Dr. Welch, I've placed before you a
 14 document I've marked for identification as Welch
 15 Exhibit 6, which, for the record, is an FDA
 16 warning letter that I printed off of the FDA
 17 website, and it pertains to caffeine.
 18 Have you seen this document before?
 19 A I have seen the warning letter before.
 20 I have not seen this exact document before.
 21 Q All right. So were you involved with
 22 the decision-making process to sending out the
 23 warning letters regarding caffeine?
 24 A I was.
 25 Q And is caffeine a dietary ingredient as

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1 Cara R. Welch, Ph.D.
 2 use recommended or suggested in the labeling. So
 3 yes, it is a safety concern.
 4 Q Is there, in your expert opinion, a
 5 premarket approval requirement by the FDA for
 6 dietary supplements that include dietary
 7 ingredients that meet the statutory definition?
 8 A I'm sorry. Can you repeat the question?
 9 Q Sure.
 10 For a product that contains a dietary
 11 ingredient that meets the statutory definition
 12 that you set out in paragraph 13 of your report,
 13 does that product need premarket approval by the
 14 FDA before it can be marketed?
 15 A No.
 16 Q If a product contains dietary
 17 ingredients that meet the definition of dietary
 18 ingredient as you define in paragraph 13 of your
 19 report, is the burden on the FDA to show that the
 20 product presents an unreasonable risk of harm or
 21 is unsafe in some manner?
 22 A If a dietary supplement containing
 23 dietary ingredients is marketed, the burden is on
 24 FDA to demonstrate the product is adulterated.
 25 Q And does demonstrating it's adulterated

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1 Cara R. Welch, Ph.D.
 2 defined under the statute?
 3 A It is.
 4 Q All right. So in this instance, what
 5 was the thought process as to why caffeine, which
 6 is already a dietary ingredient, needs a warning
 7 letter?
 8 MR. DAVENPORT: Objection to the --
 9 correction. I'll object. You're calling for
 10 deliberative process.
 11 MR. WENIK: You're correct. Let me
 12 rephrase that.
 13 BY MR. WENIK:
 14 Q So is this warning letter an example of
 15 an instance where there is a dietary ingredient
 16 that meets the definition, yet, nevertheless, the
 17 FDA takes some action against it?
 18 A Yes.
 19 Q And in this instance, looking at the
 20 warning letter, is this a safety concern that
 21 prompted the warning letter?
 22 A This warning letter is stating that the
 23 product in question, Caffeine Anhydrous 400 Grams
 24 product, presents a significant or unreasonable
 25 risk of illness or injury under the conditions of

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1 Cara R. Welch, Ph.D.
 2 involve the safety or create any unreasonable
 3 risk?
 4 A Not always.
 5 Q So under DSHEA, it's not your opinion
 6 that the burden is on the FDA to demonstrate a
 7 product is unsafe before moving it from the
 8 marketplace if it contains only dietary
 9 ingredients that meet the statutory definition?
 10 A The definition of "dietary supplement"
 11 involves more than just containing dietary
 12 ingredients. However, if FDA is removing a
 13 product, stating a product is adulterated
 14 according to safety concerns, again, the burden is
 15 on FDA to demonstrate a product is adulterated.
 16 Q All right. So in paragraph 3 and 11,
 17 you state that it's your expert opinion that DMAA
 18 does not qualify as a dietary ingredient as
 19 defined in 21 U.S. Code 321(ff) or basically as
 20 defined in paragraph 13 of your report, and you
 21 say that again in paragraph 11.
 22 Is that opinion a scientific opinion or
 23 a regulatory opinion?
 24 MR. DAVENPORT: Objection to the
 25 form of the question. Counsel, when she

1 Cara R. Welch, Ph.D.
 2 cites to 321(ff), that's 321(ff)(1)(A),(B, (C,
 3 (D, (E).
 4 MR. WENIK: Fair enough.
 5 MR. DAVENPORT: And we agreed
 6 that's not the entire section of 321(ff), and
 7 I want to make sure that's clear.
 8 MR. WENIK: Okay.
 9 THE WITNESS: My expert report is
 10 based on a scientific evaluation of the
 11 evidence available to my review, stating or
 12 concluding that DMAA does not qualify as one
 13 of the dietary ingredients enumerated in, as
 14 Josh just stated, Section 21 U.S. Code
 15 321(ff)(1)(A) through (E). I did not weigh
 16 an opinion on (F).
 17 BY MR. WENIK:
 18 Q Okay. Do you make that opinion as a
 19 matter of science or as a matter of law, or is it
 20 a combination?
 21 A I would say largely as a matter of
 22 science, I looked at the structure of DMAA and
 23 whether it fits into vitamin, mineral, herbal or
 24 botanical amino acid or dietary substance.
 25 Q So just so we're all clear, looking at

1 Cara R. Welch, Ph.D.
 2 paragraph 13 of your report, and you actually list
 3 word for word in Section 321 -- 21 U.S. Code
 4 321(ff), all right, and your opinion only goes
 5 through subsection (A) through (E) and not (F); is
 6 that correct? Your expert opinion?
 7 A That is correct. My expert report
 8 covers 21 U.S.C. 321(ff)(1)(A) through (E).
 9 Q Okay. All right. So let me turn your
 10 attention to paragraph 17 of your report.
 11 By the way, let me ask you another
 12 couple preparatory questions.
 13 Do you have any legal training? Did you
 14 attend any law school classes of any sort or
 15 anything like that?
 16 A I have not.
 17 Q Okay. You have no degrees in law, I
 18 assume; is that right?
 19 A I have no degrees in law.
 20 Q Look at paragraph 17 of Exhibit 2, which
 21 is your report.
 22 MR. DAVENPORT: Hold on. Are we
 23 done with --
 24 MR. WENIK: Yeah, we're done with
 25 them.

1 Cara R. Welch, Ph.D.
 2 (Discussion was held off the
 3 record.)
 4 BY MR. WENIK:
 5 Q By the way, at the end we'll give all
 6 the originals to her so she can have the
 7 spellings, and you'll have an opportunity to read
 8 and sign the transcript if there's any typos or
 9 improperly transcribed.
 10 A Okay.
 11 Q In paragraph 17 you talk about DMAA not
 12 being a vitamin, and in the last line on page 8,
 13 paragraph 17, you say "DMAA is an organic
 14 substance."
 15 What do you mean by an "organic
 16 substance"?
 17 A It is composed of carbon compounds,
 18 carbon hydrogen, and oxygen and nitrogen for
 19 DMAA's purposes.
 20 Q In paragraph 18 in the middle of the
 21 paragraph, you refer to DMAA as an "organic
 22 compound."
 23 Is there a distinction between what you
 24 mean when you call something an "organic
 25 substance" versus an "organic compound," or are

1 Cara R. Welch, Ph.D.
 2 the two phrases interchangeable?
 3 A I use them interchangeably. I refer to
 4 the same thing.
 5 Q Okay, so when you say -- you're saying
 6 it's organic. Does organic compounds include
 7 plants?
 8 A A plant is not a single compound, so no.
 9 Q Does a plant include multiple organic
 10 compounds?
 11 A Yes.
 12 Q Can a constituent of a plant be a
 13 dietary ingredient?
 14 A Yes.
 15 Q Can a constituent of a botanical be a
 16 dietary ingredient?
 17 A Yes.
 18 Q Can an extract of a botanical be a
 19 dietary ingredient?
 20 A Yes, according to section 201(ff)(1)(F).
 21 Q Can an extract of a plant be a dietary
 22 ingredient?
 23 A Yes, according to that same section,
 24 (F).
 25 Q Are geraniums dietary ingredients?

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1 Cara R. Welch, Ph.D.
 2 A Geranium would be considered an herb or
 3 other botanical, so yes, it would be a dietary
 4 ingredient under Section 201(ff)(1)(C) of the Act.
 5 Q And would a constituent of a geranium be
 6 a dietary ingredient?
 7 A Yes, the constituent -- a constituent of
 8 a geranium would be considered a dietary
 9 ingredient according to Section 201(ff)(1)(F) of
 10 the Act.
 11 Q Would an extract of a geranium be a
 12 dietary ingredient?
 13 A Yes, an extract of a geranium would be a
 14 dietary ingredient according to Section
 15 201(ff)(1)(F) of the Act.
 16 Q All right. In your expert report you
 17 have a "Materials Reviewed" section on page 14,
 18 and you talk about that one of the things you have
 19 reviewed was the amended complaint, which I want
 20 to show you and ask you a couple of quick
 21 questions about.
 22 (Exhibit 7 was marked for
 23 identification.)
 24 BY MR. WENIK:
 25 Q So, Dr. Welch, I have placed before you

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1 Cara R. Welch, Ph.D.
 2 this subject matter, as to whether or not products
 3 that are labeled as having DMAA in them are
 4 misbranded because they do not, or adulterated
 5 because they do not have DMAA? Are you offering
 6 any expert opinions on this topic?
 7 A I am not offering any expert opinion on
 8 that.
 9 Q Thank you. Okay.
 10 So turning back to your expert report,
 11 I'm looking at paragraph 22, which is on page 11.
 12 You wrote that "To determine whether
 13 there is any history of DMAA's use in food which
 14 could qualify DMAA as a dietary substance for use
 15 by man to supplement the diet by increasing the
 16 total dietary intake, ODSP staff, acting under my
 17 direction, conducted a search in September 2016 of
 18 food databases and published scientific
 19 literature."
 20 Do you see that?
 21 A I do.
 22 Q Okay. So my understanding in reading
 23 that is that you did not personally conduct any
 24 database searches in this matter; is that right?
 25 A Correct.

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1 Cara R. Welch, Ph.D.
 2 a document I've marked for identification as Welch
 3 Exhibit 7, which is the government's amended
 4 complaint in this action.
 5 Is this what you were referring to, I
 6 take it, in your materials reviewed, the amended
 7 complaint?
 8 A Yes.
 9 Q So I'd just like to direct your
 10 attention to paragraphs 22, 23 and 24, and if you
 11 could take a moment just to read those to
 12 yourself, then I'm going to ask you a couple of
 13 quick questions.
 14 (Witness peruses document.)
 15 THE WITNESS: I've read 22, 23, and
 16 24.
 17 BY MR. WENIK:
 18 Q So would you agree with me that
 19 paragraphs 22, 23 and 24 discuss alleged instances
 20 where the defendant, Hi-Tech, purportedly
 21 mislabeled the product as containing DMAA when it
 22 did not?
 23 A Yes, it seems to be.
 24 Q Okay. My only question to you is: Are
 25 you offering any expert opinions in this case on

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1 Cara R. Welch, Ph.D.
 2 Q Okay. So what did you do to determine
 3 the accuracy of the database searches that were
 4 conducted to buttress your expert opinion?
 5 A I reviewed the memorandum they put
 6 together for me, ODSP staff. It included some
 7 screenshots of the databases, the database search
 8 result.
 9 Q And the staff that conducted these
 10 database searches, what were their qualifications?
 11 Were they scientists, student interns, clerks?
 12 Who were they?
 13 A The September 2016 search was conducted
 14 by a botanist and a chemist, both FDA employees.
 15 Q All right, and you list in paragraph 22
 16 the search terms that were used; is that right?
 17 A Yes.
 18 Q Who selected those search terms?
 19 A They are the same search terms that were
 20 the subject of the previous versions of these
 21 database searches in December of 2015 and sometime
 22 in 2011.
 23 Q Was any consideration given to expanding
 24 the universe of search terms for purposes of your
 25 expert report?

1 Cara R. Welch, Ph.D.

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

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

8 A No.

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

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

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

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

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

24 A I do.

25 Q Who selected those databases?

1 Cara R. Welch, Ph.D.

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

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

9 A Yes.

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

14 A Correct. I did not.

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

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

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

1 Cara R. Welch, Ph.D.

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

4 A Correct. I did not review all 51, 3 and
5 15 publications. I didn't read through all the
6 publications.

7 Q Did you read through any of them?

8 A I read through some of them.

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

12 A I selected them.

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

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

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

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

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

1 Cara R. Welch, Ph.D.

2 A Correct.

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

8 A Correct.

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

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

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

18 MR. DAVENPORT: Okay.

19 THE WITNESS: Good.

20 (Whereupon, a short recess was
21 taken.)

22 BY MR. WENIK:

23 Q Back on the record. I'm moving very,
24 very efficiently.
25

1 Cara R. Welch, Ph.D.
 2 (Exhibit 8 was marked for
 3 identification.)
 4 BY MR. WENIK:
 5 Q Okay. So, Dr. Welch, I have placed
 6 before you a document I marked for identification
 7 as Welch Exhibit 8, which, for the record, is a
 8 November 1, 2011 memorandum by Louis Carlacci to
 9 Dan Fabricant, amongst others, and you had
 10 mentioned earlier when we were talking about the
 11 database searches that there was some memorandum,
 12 and I think you referred to one from 2011, one
 13 from 2015, and one from 2016.
 14 A Yes.
 15 Q Is this the 2011 memorandum that you
 16 were referring to?
 17 A Yes, this is.
 18 Q Let me ask you a couple of questions
 19 about this.
 20 So what is your understanding of what
 21 the purpose of this document was that was prepared
 22 in November of 2011?
 23 A The purpose of this memo was a review of
 24 DMAA and whether it fits as a dietary ingredient.
 25 Q Okay, and if we look at the first page,

1 Cara R. Welch, Ph.D.
 2 we have these listed here on page 2.
 3 A Yes.
 4 Q All right. So the first item that's
 5 listed is Herbs of Commerce.
 6 Is this a publication you're familiar
 7 with?
 8 A Yes, it is.
 9 Q What is Herbs of Commerce?
 10 A Herbs of Commerce is a book published by
 11 the American Herbal Products Association, listing
 12 out herbs or botanicals used in commerce, for lack
 13 of a better term.
 14 Q Okay. It talks about a second edition
 15 that was looked at.
 16 Do you know whether that book has been
 17 revised since 2000?
 18 A I don't believe they've published a
 19 third edition, but I do think they are working on
 20 it.
 21 Q "They" meaning the American Herbal
 22 Products Association?
 23 A Yes, the American Herbal Products
 24 Association.
 25 Q Okay. Then if we go to the next

1 Cara R. Welch, Ph.D.
 2 it lists the search terms that were used for some
 3 database searches; is that right?
 4 A Yes.
 5 Q All right, and are these the same -- let
 6 me actually cross-check it. I'll take the
 7 opportunity now.
 8 Are these terms basically the same that
 9 you describe in paragraph 22 of your expert
 10 declaration?
 11 A My expert report searches more terms
 12 than are listed here. It also includes DMAA,
 13 1,3-dimethylamylamine, and dimethylamylamine.
 14 Q So for purposes of your report, you had
 15 the search terms expanded somewhat from what was
 16 done back in 2011?
 17 A Seems to be, yes.
 18 Q Okay, but again, looking back at 2011,
 19 we don't see anything here for geraniums or any
 20 synonym for geraniums, do we?
 21 A It doesn't seem to be, no.
 22 Q Okay. Let's turn to the second page.
 23 So my understanding of reading this, if
 24 you look at the very bottom of the first page, it
 25 says "databases," and that was searched, and then

1 Cara R. Welch, Ph.D.
 2 database, it says "NNFA," and it says, "NNFA List
 3 of Dietary Supplement Ingredients."
 4 Is the NNFA part of the Natural Products
 5 Association?
 6 A NPA was formerly known as the NNFA or
 7 the National Nutritional Foods Association.
 8 Q I see. All right.
 9 Then we have "CRN." What is your
 10 understanding of what "CRN" is or what it stands
 11 for?
 12 A CRN is the Council for Responsible
 13 Nutrition.
 14 Q And what is the Council for Responsible
 15 Nutrition?
 16 A CRN is a dietary supplement trade
 17 association.
 18 Q Is it, for lack of a better word, a
 19 competitor to the NPA of some sort or --
 20 A Yes, for lack of a better term.
 21 Q All right. So the first three databases
 22 here, Herbs of Commerce, NFA and CRN, look to be
 23 dietary supplement databases, correct?
 24 A Yes.
 25 Q And these other databases that follow,

1 Cara R. Welch, Ph.D.
2 AGRICOLA USDA, GRAS, PAFA, OFAS, EAFUS, these are
3 government databases?
4 A Yes, they are.
5 Q Okay.
6 (Exhibit 9 was marked for
7 identification.)
8 BY MR. WENIK:
9 Q Doctor, I have placed before you a
10 document that I've marked for identification as
11 Welch Exhibit 9, which, for the record, is a
12 memorandum dated December 31, 2015 from Rebecca
13 Allen to you.
14 My first question is: Do you recognize
15 this document?
16 A I do.
17 Q And is this the memorandum that you
18 referred to earlier when you said that there were
19 three iterations, if you will, one from 2011, one
20 from 2015, and one from 2016 of these database
21 searches? Is this the 2015 one you were talking
22 about?
23 A It is.
24 Q Okay, and so if we look at this
25 document, it lists on the first page the key words

1 Cara R. Welch, Ph.D.
2 predecessor to the NPA or to CRN, why was that?
3 Why were the dietary supplement databases not
4 searched in 2015 when you directed this update to
5 be prepared?
6 A The point of the December 2015 memo is
7 to ascertain if DMAA is a component of the diet.
8 The Herbs of Commerce, NFA list and CRN list are
9 pieces of evidence to determine whether an
10 ingredient is a dietary supplement ingredient,
11 particularly prior to 1994.
12 So it's not reasonable to search dietary
13 supplement databases to determine if an ingredient
14 is a component of the diet. We are looking for
15 components of the conventional food diet.
16 Q Did you direct that they search any
17 cookbooks or cooking websites or anything of that
18 nature?
19 A I did not direct that they look at
20 cookbooks or cooking websites. FDA needs to have
21 a standard list of databases and lists and sources
22 to determine whether an ingredient is a component
23 of the conventional food diet. Cookbooks and
24 cooking websites are not part of that --
25 Q I see.

1 Cara R. Welch, Ph.D.
2 that were used.
3 Are these all the same as what you list
4 in paragraph 22 of your declaration?
5 A Yes, it appears to be the same.
6 Q Okay. What is your understanding of
7 what the purpose -- let me back up for a minute.
8 Did you direct that this database search
9 take place in December of 2015?
10 A I did.
11 Q And what was the purpose of your having
12 this database search done in 2015?
13 A In preparation of my expert report, I
14 wanted to have an updated search of the food
15 databases, particularly to ascertain if DMAA is a
16 component of the diet, so I asked two staff
17 members, Rebecca Allen and Steven Casper, to do an
18 updated search.
19 Q So if I compare Welch Exhibit 9 to the
20 2011 document which I labeled as Welch Exhibit 8,
21 and Welch Exhibit 9 lists the databases that were
22 searched on page 1, continuing on to page 2, and
23 notably it does not list any of the dietary
24 supplement databases that were searched back in
25 2011, specifically to Herbs of Commerce or the

1 Cara R. Welch, Ph.D.
2 A -- typical search.
3 Q I see.
4 Is there any reason why in 2015 you
5 didn't search any non-governmental databases, any
6 commercial websites of any sort?
7 A No, there's no particular reason why we
8 didn't.
9 Q And would you agree with me that in
10 2015, geraniums or any synonym for geraniums were
11 not looked at either?
12 A Correct. Geranium or synonyms of
13 geranium were not searched in the 2015 memo.
14 (Exhibit 10 was marked for
15 identification.)
16 BY MR. WENIK:
17 Q Doctor, I've placed before you what's
18 been marked for identification as Welch Exhibit
19 10, which, for the record, is a September 21, 2016
20 memorandum from Steven Casper and Rebecca Allen to
21 you.
22 My first question is: Have you seen
23 this document before?
24 A Yes.
25 Q All right. What is your understanding

1 Cara R. Welch, Ph.D.
2 of what this document is?
3 A This memo is an update to the
4 December 2015 memo. As I was finalizing my expert
5 report, I wanted to ensure we had done a more
6 recent review, since nine, ten months had gone by.
7 Q And the search terms remained the same
8 as they were in December 2015?
9 A Yes, they appear to be.
10 Q And were the databases the same as well?
11 A According to the memo, the September 26
12 memo searches the dietary supplement label
13 database by NIH, whereas the December 2015 memo
14 searches the dietary supplement ingredient
15 database, which is actually separate, because they
16 are two different databases.
17 Q And were any hits derived from that
18 label database?
19 A The September 2016 memo, there are
20 results from the dietary supplement label database
21 search.
22 Q And where would those appear in the body
23 of the memo here?
24 A They don't appear to be in the body of
25 the memo.

1 Cara R. Welch, Ph.D.
2 So we're looking for information that
3 DMAA, the particular chemical compound, is used in
4 foods.
5 Q I see.
6 So I just want to make sure I understand
7 the scope of your opinion.
8 Are you offering an expert opinion based
9 on what we see here, that DMAA was not in the food
10 supply prior to October 15, 1994?
11 A I am offering an opinion that DMAA is
12 not a substance of the diet, referring to the
13 conventional food diet, not limited to a date of
14 October 15, 1994.
15 Q So never part of the --
16 A DMAA, according to my research, the
17 evidence for my review, DMAA has never been a
18 component of the conventional food diet.
19 Q All right, and I'm looking back at your
20 expert report, and on page 12, the very last
21 sentence, I want to make sure I understand exactly
22 what you mean in this sentence.
23 You say, "The food database searches
24 revealed no results for the compound DMAA, which
25 provides the basis for our conclusion that DMAA is

1 Cara R. Welch, Ph.D.
2 Q Okay, but I take it DMAA did not come
3 up. Is that what the people that looked at this
4 concluded?
5 A It looks like they had some hits for
6 labels containing some of the search terms. Those
7 would have been dietary supplement labels, which
8 does not weigh into whether an ingredient is a
9 component of the conventional food diet.
10 Q I see.
11 So what would you have been looking for
12 in these database searches to establish that
13 something was a component of the conventional food
14 diet? If you're not looking for a recipe, if
15 you're not looking at a cooking website, if you're
16 not looking at natural products or commercial
17 websites, what is it that you expect to find?
18 A Some of the databases, GRAS substances,
19 the PAFA, EAFUS, are databases or lists of
20 ingredients that are known to be in foods. Some
21 of them -- the AGRICOLA is looking for foods that
22 list certain ingredients. A plant database would
23 be looking to see if a plant is known to be used
24 in the food diet. The USP or the food chemicals
25 Codex is a list of chemicals found in foods.

1 Cara R. Welch, Ph.D.
2 not a food ingredient."
3 Do you see that sentence?
4 A I do.
5 Q All right. So what do you mean by "food
6 ingredient"? Is that something different than a
7 dietary ingredient?
8 A Yes. A conventional food ingredient is
9 one provision of a dietary ingredient. Paragraph
10 13, I think it was, listed out what can be a
11 dietary ingredient. "Generally a dietary
12 substance for use by man to supplement the diet by
13 increasing the total dietary intake. If an
14 ingredient is a food ingredient, it will likely
15 fit under category E of the dietary ingredient."
16 Q All right, and so basically, if I
17 understand what you're saying, it's your expert
18 opinion that DMAA does not meet subsection
19 321(ff)(1)(E)?
20 A Correct. That's my opinion.
21 Q All right, and the basis for that
22 opinion, if I understand what you're saying here,
23 are these database searches that are reflected in
24 Welch Exhibits 10, 9 and 8?
25 A Yes.

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1 Cara R. Welch, Ph.D.
 2 (Exhibit 11 was marked for
 3 identification.)
 4 BY MR. WENIK:
 5 Q Okay. So let me for a moment focus your
 6 attention back on Exhibit 9.
 7 A Yes.
 8 Q And in Exhibit 9, the memo, one of the
 9 articles that was found, if you look at the next
 10 to the last page of the document --
 11 A Oh, sorry. Next to the last.
 12 Q Yeah.
 13 A Yes.
 14 Q All right. If you look at reference
 15 number 7 here, "methylhexaneamine is not
 16 detectable in Pelargonium or geranium species and
 17 their essential oils, a multi-center
 18 investigation," and it lists a 2015 cite, and it
 19 also notes that it was e-published in 2014.
 20 Do you see that?
 21 A I do.
 22 Q And if I look at your declaration, you
 23 cited in reference -- in your Exhibit 1 to your
 24 expert declaration, reference 24, the 2015 version
 25 of the ElSohly article.

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1 Cara R. Welch, Ph.D.
 2 Do you see that up at the top?
 3 A I do.
 4 Q So my question to you is: From May 2014
 5 to when this was published, do you recall any
 6 conversations you had with any of the authors as
 7 to what conclusions they were going to publish in
 8 the article?
 9 A No, I don't recall any conversations.
 10 Q Okay. So if we look at the abstract to
 11 the article, it says in the very last line, "None
 12 of the laboratories detected MHA in any of the
 13 samples at or around the ten parts per billion
 14 detection level of the procedure used."
 15 Do you see that?
 16 A I do.
 17 Q What is your understanding what "MHA"
 18 stands for?
 19 A Methylhexaneamine.
 20 Q Is that a synonym for DMAA, if you will?
 21 A It is.
 22 Q All right. Did the authors of the study
 23 ever reveal to you in 2014, before it was
 24 published, that some of the study centers had, in
 25 fact, found DMAA in some of the plant samples that

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1 Cara R. Welch, Ph.D.
 2 A Yes.
 3 Q All right. I placed before you what
 4 I've marked for identification as Welch Exhibit
 5 11, which is the e-published version of this
 6 article that came out in 2014.
 7 My question to you is: Did you review
 8 the e-published version of the article in
 9 conjunction with preparing your expert report in
 10 this matter as opposed to the version that came
 11 out in 2015?
 12 A I don't recall at this time.
 13 Q Okay. So you came on board at the FDA
 14 in January of 2014; is that right?
 15 A Yes.
 16 Q All right, and is it fair to say that
 17 one of your responsibilities in that first year
 18 that you were with the FDA, one of your
 19 responsibilities was to be the project manager for
 20 the University of Mississippi Natural Products
 21 Research Center?
 22 A Yes. I was project officer in May of
 23 2014.
 24 Q Okay. So the e-version of this came out
 25 in August of 2014, Welch Exhibit 11.

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1 Cara R. Welch, Ph.D.
 2 were reviewed?
 3 MR. DAVENPORT: Objection to the
 4 form of the question.
 5 You can answer if able.
 6 THE WITNESS: I am not aware of any
 7 conversation discussing what you proposed.
 8 (Exhibit 12 was marked for
 9 identification.)
 10 BY MR. WENIK:
 11 Q Doctor, I've placed before you a
 12 document I've marked as Welch Exhibit 12, and I
 13 suspect you've probably not seen this before, so
 14 please take a minute or two to just thumb through
 15 it, and I want to ask you a couple of questions.
 16 (Witness peruses document.)
 17 THE WITNESS: Okay.
 18 BY MR. WENIK:
 19 Q All right. So my first question to you
 20 is: Having had an opportunity to look at what
 21 I've marked for identification as Welch Exhibit
 22 12, which, for the record, is an email chain
 23 accompanied by a series of chromatograms, have you
 24 seen this document before?
 25 A I have not.

1 Cara R. Welch, Ph.D.

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

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

8 A I don't recall at this time.

9 Q Okay.

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

12 A Okay.

13 Q All right, and there is some series of
14 chromatograms there, and it says Figure 5, and it
15 says that the "isomer of 1,3-dimethylamylamine,"
16 I'll just say DMAA, "was detected in samples
17 13040, 13041, 13047, 13048 and 13049."

18 And if I turn your attention to what I
19 marked as Welch Exhibit 11, to page 3, there's a
20 table, Table 1, that lists all the samples with
21 their identifying numbers, and if we look at the
22 list here, it lists 13040, 13041, 13047, 13048 and
23 13049 as having no DMAA detected in those samples.

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

1 Cara R. Welch, Ph.D.

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

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

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

15 BY MR. WENIK:

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

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

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

25 THE WITNESS: I'm not familiar with

1 Cara R. Welch, Ph.D.

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

6 BY MR. WENIK:

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

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

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

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

20 THE WITNESS: It's not a contract.
21 It's a cooperative agreement, which is much
22 more similar to a grant. There is a -- I
23 don't know the appropriate term. There is a
24 grant agreement of sorts.
25

1 Cara R. Welch, Ph.D.

2 BY MR. WENIK:

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

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

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

16 A I have no idea.

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

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

22 Q Yeah.

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

1 Cara R. Welch, Ph.D.

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

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

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

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

14 A Yes, I'm aware of it.

15 Q What is your understanding of what this
16 conference is?

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

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

25 A Yes, I believe so.

1 Cara R. Welch, Ph.D.

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

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

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

18 Q Let me ask you this.

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

1 Cara R. Welch, Ph.D.

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

4 A I did not attend every year.

5 Q Do you know whether you attended in
6 2013, the year before you joined FDA?

7 A I believe I did.

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

14 A No.

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

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

19 Q Have you seen the PowerPoints from that
20 2013 conference regarding his purported research
21 on DMAA?

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

1 Cara R. Welch, Ph.D.

2 University of Mississippi that was published in
3 2015, as I've shown you e-published in 2014.

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

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

10 You can answer if able.

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

17 BY MR. WENIK:

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

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

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1 Cara R. Welch, Ph.D.
 2 MR. WENIK: Okay. I think that is
 3 as good a place as any for me to conclude my
 4 questioning.
 5 MR. DAVENPORT: I have no
 6 questions. We'll read.
 7 (Signature having not been waived,
 8 the deposition of CARA R. WELCH,
 9 Ph.D. was concluded at 12:20 p.m.)
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1 NAME OF CASE:
 2 DATE OF DEPOSITION:
 3 NAME OF WITNESS:
 4 Reason Codes:
 5 1. To clarify the record.
 6 2. To conform to the facts.
 7 3. To correct transcription errors.
 8 Page _____ Line _____ Reason _____
 9 From _____ to _____
 10 Page _____ Line _____ Reason _____
 11 From _____ to _____
 12 Page _____ Line _____ Reason _____
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 14 Page _____ Line _____ Reason _____
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 23 From _____ to _____
 24 _____
 25

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1
 2
 3
 4
 5
 6 ACKNOWLEDGEMENT OF WITNESS
 7 I, Cara R. Welch, Ph.D., do hereby
 8 acknowledge that I have read and examined the
 9 foregoing testimony, and the same is a true,
 10 correct and complete transcription of the
 11 testimony given by me, and any corrections
 12 appear on the attached Errata sheet signed by
 13 me.
 14
 15
 16
 17 _____
 (DATE) (SIGNATURE)
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 19
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1 CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC
 2
 3
 4
 5
 6 I, Laurie Donovan, Registered
 7 Professional Reporter, Certified Realtime
 8 Reporter, the officer before whom the
 9 foregoing deposition was taken, do hereby
 10 certify that the foregoing transcript is a
 11 true and correct record of the testimony
 12 given; that said testimony was taken by me
 13 stenographically and thereafter reduced to
 14 typewriting under my supervision; and that I
 15 am neither counsel for, related to, nor
 16 employed by any of the parties to this case
 17 and have no interest, financial or otherwise,
 18 in its outcome.
 19 IN WITNESS WHEREOF, I have hereunto
 20 set my hand and affixed my notarial seal this
 21 2nd day of December, 2016.
 22 My commission expires: March 14th, 2021
 23
 24
 25 _____
 LAURIE DONOVAN
 NOTARY PUBLIC IN AND FOR
 THE DISTRICT OF COLUMBIA

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