

# **EXHIBIT 19**

IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
ORLANDO DIVISION

- - -

IN RE: SEROQUEL : CASE NO.  
PRODUCTS LIABILITY :  
LITIGATION : 6:06-md-01769-ACC-DAB  
:  
MDL Docket No. 1769:

- - -

May 7, 2008

- - -

C O N F I D E N T I A L

- - -

Videotape deposition of WAYNE K.  
GELLER, M.D. taken pursuant to notice,  
was held at the offices of Golkow  
Technologies, Inc., One Liberty Place,  
51st Floor, 1650 Market Street,  
Philadelphia, Pennsylvania 19103,  
commencing at 9:00 a.m., on the above  
date, before Linda Rossi Rios, RPR, CCR  
and Notary Public.

- - -

Golkow Technologies, Inc.  
One Liberty Place, 51st Floor  
1650 Market Street  
Philadelphia, Pennsylvania 19103  
877.370.3377

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1 Dorothee Wientjens..., " I'm sure I'm  
2 mispronouncing that, "...to respond to  
3 the Dutch Authorities regarding  
4 quetiapine and glucose metabolism." Did  
5 I read that correctly?  
6 A. Yes.  
7 Q. So you knew that the  
8 information you were giving to Ms.  
9 Wientjens, if I'm pronouncing that  
10 correctly, was going to be turned over to  
11 the Dutch authorities. Right?  
12 A. I was under the impression  
13 that it would be. However, I was  
14 responding to her request.  
15 Q. And you understood that her  
16 request was for information she could  
17 turn over to the Dutch authorities.  
18 Right?  
19 A. Well, again, I know that  
20 there was a request that came from  
21 Dorothee Wientjens, I believe is the way  
22 she pronounces her name, and I don't have  
23 that e-mail in front of me to answer your  
24 question with the accuracy that I would

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1 like to.  
2 Q. All right, sir. And then  
3 you said, "I sent Dorothee a copy of the  
4 recent Seroquel Safety Position Paper on  
5 DM and related disorders." True? That's  
6 what you said?  
7 A. Yes. And, again, I was  
8 referring to the document which was  
9 termed a position paper, which had -- was  
10 unofficial and, in fact, was not a  
11 position paper on this topic.  
12 MR. ALLEN: Sir, object to  
13 that as nonresponsive.  
14 BY MR. ALLEN:  
15 Q. You refer to it as a  
16 "Seroquel Safety Position Paper on DM and  
17 related disorders." Right?  
18 A. Again, to make sure that  
19 we're taking this in the right -- in the  
20 correct context, this so-called Seroquel  
21 safety position paper, as it was titled,  
22 was not, in fact, an official company  
23 document and did not reflect our view and  
24 our knowledge of diabetes at that time,

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1 sir.  
2 MR. ALLEN: Okay. Object to  
3 that as nonresponsive.  
4 BY MR. ALLEN:  
5 Q. And then you go on and you  
6 apologize. What are you apologizing for,  
7 sir?  
8 A. Well, being relatively new  
9 to the company, it occurred to me, right  
10 afterwards it was brought to my attention  
11 that Ms. Wientjens' request appropriately  
12 should have gone through the global  
13 regulatory affairs director who then  
14 should have contacted myself and others  
15 in order to respond to the Dutch  
16 regulatory agency.  
17 Q. So you made a mistake by  
18 letting the safety position paper go out  
19 to the regulatory authorities?  
20 MR. RABER: Objection to  
21 form.  
22 BY MR. ALLEN:  
23 Q. Sir?  
24 A. I made a mistake by

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1 submitting a document which was not  
2 correct, number one. And number two, I  
3 did so through an individual that was  
4 someone who I should not have given the  
5 document directly to.  
6 Q. Who -- what department did  
7 Dorothee work in?  
8 A. I don't know.  
9 Q. Who was she?  
10 A. I don't know.  
11 Q. Okay. But Exhibit 17 is a  
12 document that you believe, at least you  
13 believe this is one of the documents that  
14 the Dutch authorities received in  
15 advertently. Is that correct?  
16 A. I believe this is the  
17 document.  
18 Q. You believe it is this  
19 document. Thank you, sir.  
20 We got this from y'all's  
21 files and you authored Exhibit 17, did  
22 you not?  
23 A. Yes, I did.  
24 Q. And do you agree with the

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<p>1 fact that based upon your review of the 2 information you had available, if you 3 look on page 11, the last page, do you 4 agree -- 5 A. I'm sorry, 11 out of -- 6 Q. Yes, sir, I see that. It's 7 the last page. Are you at the last page? 8 A. Yes. 9 Q. Do you agree with the 10 statement that you drafted, "While there 11 were no reports of positive dechallenges 12 and rechallenges, there is reasonable 13 evidence to suggest that Seroquel therapy 14 can cause impaired glucose regulation 15 including diabetes mellitus in certain 16 individuals." Do you agree with that 17 statement? 18 A. No, I disagree with that 19 statement, sir. 20 Q. Okay. Why did you write it? 21 A. That statement was an 22 artifact of an earlier discussion 23 document which was a draft discussion 24 document for the June 2000 SERM, and did</p>	<p>1 isn't it, in June of 2000 you prepared 2 this? 3 A. Exhibit 17 would have been 4 prepared sometime in the fall of 2000, I 5 believe. 6 Q. If the database that we have 7 that was given to us in the production 8 says this document was dated August the 9 10th, 2000, does that sound about right 10 to you? 11 A. No, it doesn't. 12 Q. Can you give me or the jury 13 any help by telling us why that database 14 which we were provided which said 15 August the 10th, 2000, is incorrect? 16 MR. RABER: Object to the 17 form. 18 THE WITNESS: It certainly 19 would not have coincided with the 20 request on the MEB. However, I 21 failed to consider the possibility 22 that I started to prepare a 23 position paper after the June SERM 24 that discussed the issue of</p>
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<p>1 not reflect my view of diabetes at the 2 time that I presented at SERM in June 3 of 2000. 4 Q. Well, in fact -- so you were 5 the presenter at SERM in June of 2000? 6 A. Yes, I said that previously. 7 Q. Was Dr. Brecher there? 8 A. He was on the telephone, I 9 believe. 10 Q. Did you in June of 2000 as 11 presenter specifically state that 12 Seroquel may cause impaired glucose 13 regulation in some individuals? Isn't 14 that what you did at that meeting? 15 MR. RABER: Object to the 16 form. 17 BY MR. ALLEN: 18 Q. Isn't that what you said? 19 A. I think to be absolutely 20 correct, I need to see a copy of the 21 discussion document that was circulated 22 for the June 2000 SERM. 23 Q. Now, when did you prepare 24 Exhibit 17, sir? After the SERM meeting,</p>	<p>1 diabetes mellitus and Seroquel 2 therapy. And, in fact, I recall 3 specifically using as a template a 4 draft discussion document which 5 contained the same language that 6 you just read, sir. 7 BY MR. ALLEN: 8 Q. And by the way, sir, that's 9 not a true statement, that there are no 10 reports of positive dechallenges, that's 11 just not a true statement, is it? 12 MR. RABER: Objection to 13 form. 14 BY MR. ALLEN: 15 Q. There's positive 16 dechallenges throughout the adverse 17 experience database in regard to Seroquel 18 and diabetes and hyperglycemia, aren't 19 there, sir? 20 MR. RABER: Objection to 21 form. 22 THE WITNESS: I can state 23 that when the discussion document 24 was prepared, which would have</p>

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1        been in May, roughly May of 2000,  
2        that that statement was correct  
3        and accurate.  
4        BY MR. ALLEN:  
5        Q.    You also on that same -- at  
6        or about that same time, prepared --  
7        following the June 2000 SERM meeting, you  
8        prepared Exhibit 18, the justification --  
9        MR. RABER: Hang on. You  
10       said we were going to do one more  
11       document --  
12       MR. ALLEN: Right.  
13       MR. RABER: -- and we were  
14       going break.  
15       MR. ALLEN: Yes, sir. And  
16       I'm wrong because based upon his  
17       answer, there's one more question  
18       I want to ask about Exhibit 18.  
19       MR. RABER: I just want to  
20       know when we're going to break?  
21       MR. ALLEN: And I told you  
22       my best --  
23       MR. RABER: You told me and  
24       you told me wrong.

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1        MR. ALLEN: I was mistaken.  
2        I did not know the witness'  
3        answer. And I'm showing him  
4        Exhibit 18. I'm not trying to  
5        cause any trouble. And I'd ask  
6        him to look at Exhibit 18, which  
7        is a justification document that  
8        he also prepared concerning  
9        reasonable evidence and then we  
10       will be done.  
11       - - -  
12       (Exhibit Geller-18,  
13       Justification Document, was marked  
14       for identification.)  
15       - - -  
16       BY MR. ALLEN:  
17       Q.    Sir, I'm handing you what's  
18       been marked as Exhibit 18, which is  
19       another document from the database that  
20       you said was prepared by you on or about  
21       August the 10th, 2000. Did you prepare  
22       this justification document on Seroquel  
23       and weight gain?  
24       A.    I am listed as the author in

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1        the document. However, I wish to point  
2        out that this document, too, is a draft  
3        document.  
4        MR. ALLEN: Yes, sir.  
5        Object to that as nonresponsive.  
6        BY MR. ALLEN:  
7        Q.    Sir, did you prepare Exhibit  
8        Number 18?  
9        A.    My name is listed as the  
10       author on this document, and I recognize  
11       the fact that it is a draft that I  
12       prepared.  
13       Q.    Yes, sir. Okay. And by the  
14       way, did you review Exhibit 17 in  
15       preparation for your deposition?  
16       A.    Yes.  
17       Q.    And you've already testified  
18       you reviewed Exhibit 16 in preparation  
19       for your deposition, or not, I can't  
20       recall, to be honest with you?  
21       A.    Yes, I believe so.  
22       Q.    Did you -- have you reviewed  
23       Exhibit 18 in preparation for your  
24       deposition? The justification document

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1        on Seroquel and weight gain.  
2        A.    I don't believe I have.  
3        Q.    Okay. Now, you've already  
4        testified earlier today any documents you  
5        reviewed in preparation for your  
6        deposition in this -- these 15 or 20  
7        volumes occurred during the time you were  
8        meeting with counsel. Right?  
9        A.    Yes.  
10       Q.    You never reviewed these  
11       documents outside of the presence of  
12       counsel. Correct?  
13       A.    Correct.  
14       Q.    Okay. All right, sir. And  
15       in the justification document on Seroquel  
16       and weight gain you wrote, Exhibit 18,  
17       didn't you also state that "While there  
18       were no reports of positive dechallenges  
19       and rechallenges, there is reasonable  
20       evidence to suggest that Seroquel therapy  
21       can produce significant weight gain in  
22       select individuals. The Seroquel CDS  
23       mentioned the possibility of 'limited'  
24       weight gain associated with Seroquel

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1 safety position paper draft prepared by  
2 you, and let's -- let me stop here and  
3 it's my fault. You started working in  
4 the safety surveillance department of  
5 AstraZeneca in May of 2000. Is that  
6 correct?  
7 A. Actually in April.  
8 Q. I'm sorry, April. So in  
9 other words, your conclusions that we've  
10 seen in regard to weight gain, you were  
11 able to reach those conclusions between  
12 the time you started working in April and  
13 by the time you prepared the document.  
14 True?  
15 A. The document was prepared  
16 in -- for the June SERM, which meant that  
17 that data was looked at between my  
18 join -- in the time between my joining  
19 the company and the discussion document.  
20 Q. Thank you, sir. Now, in  
21 this Exhibit 17, safety position paper,  
22 you state, Safety data derived from  
23 clinical trials and spontaneous reports  
24 often containing limited information may

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1 represent a weak signal linking Seroquel  
2 with impaired glucose regulations --  
3 regulation, including occasional reports  
4 of new onset diabetes mellitus. None of  
5 these reports are absolutely steadfast  
6 (i.e., there are no clear index cases and  
7 there were no reports of positive  
8 dechallenges/rechallenges) and most have  
9 either incomplete information or other  
10 explainable causes. Although the number  
11 of reports is fairly sizable, it was felt  
12 that there is insufficient evidence at  
13 present to warrant an amendment to the  
14 Seroquel Core Data Sheet. Did I read  
15 that correctly?  
16 A. Yes.  
17 Q. You go on to state,  
18 "However, it was agreed that the topic  
19 will be kept under ongoing review and  
20 will be reassessed at a later time." Did  
21 I read that correctly?  
22 A. Yes.  
23 Q. Why did you say the number  
24 of reports is fairly sizable?

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1 A. Well, it was my impression  
2 at the time that we conducted our  
3 pre-SERM activities, which would have  
4 been sometime in May 2000, that  
5 relatively speaking, that meeting,  
6 looking at a frequency table of all  
7 adverse events that had been reported in  
8 the postmarketing realm in the serious  
9 clinical trial adverse event reports,  
10 that compared to, for instance, compared  
11 to bone fractures, for instance, that the  
12 numbers seem fairly sizable. However, I  
13 have to confess that at that particular  
14 time, I had no idea how many patients had  
15 been exposed to Seroquel. So it was a  
16 statement of relative comparison, sir.  
17 Q. Of course, when the document  
18 we saw yesterday was prepared to the FDA,  
19 you did not tell the FDA, you being  
20 AstraZeneca, that you had a fairly  
21 sizable number of diabetes cases, did  
22 you?  
23 A. We presented all the data  
24 that we had from all sources, including

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1 clinical trial sources, including the  
2 literature, including the postmarketing  
3 sources that were contained in this  
4 particular document. So in answer to  
5 your question, I believe we provided them  
6 with more than what was provided here.  
7 MR. ALLEN: Objection.  
8 Nonresponsive.  
9 BY MR. ALLEN:  
10 Q. You did not tell the FDA  
11 that the number of adverse experience  
12 reports concerning diabetes mellitus, you  
13 did not use the term that they were  
14 fairly sizable, did you, sir?  
15 A. Sir, FDA requested the data.  
16 We provided them with every piece of data  
17 they requested. We provided them with  
18 our own analysis. And I have to confess  
19 that once I learned what the exposure,  
20 meaning how many patients had been  
21 exposed to Seroquel, which would have  
22 happened sometime between the preparation  
23 of the draft discussion document, from  
24 which this was based, until the SERM, it

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1 became apparent to me that the number of  
2 cases -- of reported cases of diabetes  
3 was not so sizable.  
4 Q. In fact, you not only did  
5 not tell the FDA that there was a fairly  
6 sizable number of reports, you told the  
7 FDA, you being AstraZeneca, that there  
8 were very few cases of diabetes mellitus,  
9 didn't you?  
10 A. I don't recall that  
11 specifically, sir.  
12 Q. If it's reflected in the  
13 document that you provided to the FDA,  
14 you don't recall reviewing that document  
15 in preparation for your deposition?  
16 A. I reviewed the document. I  
17 don't have photographic memory  
18 unfortunately, sir.  
19 Q. I don't expect you to. And  
20 I'm just asking you whether or not -- and  
21 no one has a -- well, some people have  
22 some photographic memory. Some people  
23 do. But do you recall in reading the  
24 document that your company submitted to

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1 the FDA in August of 2000, that your  
2 company told the FDA that there were very  
3 few cases of diabetes mellitus and  
4 hyperglycemia? Do you recall that or  
5 not?  
6 A. I don't recall that.  
7 However, I know that at the time we  
8 submitted the document to FDA, we had  
9 exposure figures to put -- to put these  
10 number of reports into context.  
11 Q. Do you recall that when your  
12 company submitted the document to the MEB  
13 in January of 2001, your company told the  
14 MEB that there was a relatively small  
15 number of postmarketing reports of  
16 glucose dysregulation? Do you recall  
17 that?  
18 A. I don't recall the specific  
19 language, sir.  
20 Q. Nevertheless, you would  
21 agree that in the documents you prepared,  
22 the safety position paper, Exhibit 17,  
23 that you prepared, you said that the  
24 number of reports is fairly sizable? Do

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1 you agree with that?  
2 A. This draft so-called safety  
3 position paper does indeed contain that  
4 statement, and, again, was written  
5 without having any contextual information  
6 as far as exposure was concerned.  
7 Q. Now, at the last page of  
8 Exhibit 17, the safety position paper  
9 that was prepared by you, do you see the  
10 final paragraph?  
11 MR. RABER: Object to form.  
12 THE WITNESS: Yes.  
13 BY MR. ALLEN:  
14 Q. And you state, do you not,  
15 sir, While there were no reports of  
16 positive dechallenges and rechallenges,  
17 there is reasonable evidence to  
18 suggest -- let me start again.  
19 You state in writing, "While  
20 there were no reports of positive  
21 dechallenges and rechallenges, there is  
22 reasonable evidence to suggest that  
23 Seroquel therapy can cause impaired  
24 glucose regulation including diabetes

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1 mellitus in certain individuals.  
2 Consideration should be given to adding  
3 diabetes mellitus to the core data sheet  
4 based upon postmarketing and clinical  
5 trial safety data." That's your  
6 language, is it not, sir?  
7 A. Yes.  
8 Q. Was diabetes -- and do you  
9 agree with that statement, by the way,  
10 that you wrote?  
11 A. No, I completely disagree  
12 with that statement. As I indicated  
13 yesterday, this statement was an artifact  
14 from a draft discussion document which  
15 was not the basis for the June 2000 SERM  
16 discussion document. So this was my --  
17 this happened to be the statement which I  
18 felt was not factually correct in this  
19 document.  
20 Q. Now, did you testify that --  
21 let me come back to that in a minute.  
22 So your testimony at this  
23 juncture is that final paragraph  
24 Exhibit -- of Exhibit 17, which says that

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1 Q. That's right.  
2 A. No.  
3 Q. Did you rewrite -- strike  
4 that. Let me back up.  
5 I think you said that you  
6 used as a template for Exhibit 17 an  
7 older draft of a discussion document; is  
8 that right?  
9 MR. PIRTLE: Objection,  
10 form.  
11 THE WITNESS: Yes, I did.  
12 BY MR. RABER:  
13 Q. And is --  
14 To the best of your  
15 knowledge, is Defendant's Exhibit 202 the  
16 template that you used when preparing  
17 Exhibit 17?  
18 MR. PIRTLE: Objection to  
19 form.  
20 THE WITNESS: Yes, it is.  
21 BY MR. RABER:  
22 Q. It appears if you look at  
23 Geller Exhibit 17, the one on the right,  
24 that you rewrote that summary and

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1 conclusions paragraph; is that right?  
2 A. Yes.  
3 Q. Did you rewrite the last  
4 paragraph on Defendant's Exhibit 17 -- I  
5 mean Geller Exhibit 17?  
6 A. No. It's exactly the same  
7 as the one in Defense Exhibit 202.  
8 Q. When you say you made a  
9 mistake, is that the mistake you made, by  
10 leaving in that paragraph from this old  
11 template?  
12 A. Yes, it is.  
13 Q. Did the paragraph that got  
14 left in by mistake accurately reflect  
15 what had happened at the SERM meeting in  
16 June of 2000?  
17 MR. PIRTLE: Objection to  
18 the form.  
19 THE WITNESS: No, absolutely  
20 not.  
21 BY MR. RABER:  
22 Q. As we sit here today, do you  
23 recall whether or not you ever completed  
24 a final safety position paper after the

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1 June 2000 SERM?  
2 A. I don't recall there being a  
3 final position paper.  
4 Q. Can you explain why you  
5 don't recall one of those final documents  
6 existing?  
7 A. It is my belief, as was  
8 then, that the FDA document, which was  
9 prepared at the same time that the  
10 initial discussion document was being  
11 written, that that FDA response document  
12 really served exactly the same purpose of  
13 a position paper in that it provided all  
14 the necessary information to the reader  
15 to see that there was insufficient  
16 evidence to suggest a causal relationship  
17 between Seroquel therapy and diabetes.  
18 Q. And in the fall of 2000, did  
19 you have another SERM meeting coming up  
20 to consider this glucose and diabetes  
21 issue again?  
22 A. Yes.  
23 Q. Were you drafting documents  
24 relating to that?

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1 A. Yes.  
2 Q. What were you drafting in  
3 preparation for that?  
4 A. I was drafting an update --  
5 a new discussion document, but it was  
6 updated from the previous one with new  
7 data.  
8 Q. Did anybody at AstraZeneca  
9 need to have a safety position paper  
10 relating to the June SERM to take any  
11 action of any kind?  
12 MR. PIRTLE: Objection,  
13 speculation.  
14 THE WITNESS: No, not at  
15 all.  
16 BY MR. RABER:  
17 Q. If SERM is going --  
18 If there's going to be a  
19 change in the core data sheet, what kind  
20 of document gets prepared, a  
21 justification document or a safety  
22 position paper?  
23 A. A justification document,  
24 which sometimes now goes under the name

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1 of a clinical overview.  
2 Q. All right.  
3 Dr. Geller, I want to just  
4 talk about a few more things here. I  
5 want to have you keep Geller Exhibit 17  
6 in front of you, and I also want to show  
7 you Geller Exhibit 30.  
8 Now, you've testified in  
9 response to questions that you believe  
10 that Geller Exhibit 17, which is also  
11 attached to Geller Exhibit 30, is a draft  
12 of a position paper; is that right?  
13 MR. PIRTLE: Objection to  
14 the form.  
15 THE WITNESS: Yes. I  
16 already alluded to that, I  
17 believe, in my testimony.  
18 BY MR. RABER:  
19 Q. Do you recall yesterday when  
20 Mr. Pirtle leaned forward in his chair  
21 and said, I don't believe you that it's a  
22 draft. Do you remember that?  
23 A. I do, sir.  
24 MR. PIRTLE: Form.

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1 BY MR. RABER:  
2 Q. I want to talk with you a  
3 little bit about why you believe that  
4 this safety position paper that's in  
5 front of you was not a final document.  
6 Okay?  
7 A. Yes.  
8 Q. All right.  
9 Let's look at Exhibit 17,  
10 Geller Exhibit 17.  
11 If you look at the page  
12 numbering on the bottom, do you see that?  
13 A. Yes.  
14 Q. What do you see when you  
15 look at the page numbering on the bottom?  
16 A. I see in this case "Page 2  
17 of?".  
18 Q. What does the presence of a  
19 question mark in the page numbering  
20 indicate to you about whether or not that  
21 is a final document?  
22 A. It indicates that it is not  
23 a final document. It indicates that it  
24 is a draft.

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1 Q. In fact, the preliminary  
2 draft of your June discussion document, I  
3 think it's Defense Exhibit 202, can you  
4 tell us whether or not that draft has  
5 question marks in the page numbering?  
6 A. Yes. This says "Page Auto,"  
7 A-U-T-O, separate word "Page," P-A-G-E,  
8 "of?"  
9 Q. Now does --  
10 Is there any question in  
11 your mind that Defense Exhibit 202 is a  
12 draft document?  
13 A. I'm sorry. Please repeat  
14 the question.  
15 Q. Is there any question in  
16 your mind that that's a draft?  
17 A. There's no question, sir.  
18 Q. All right.  
19 Does the word "draft" appear  
20 anywhere on Defense Exhibit 202?  
21 A. No.  
22 Q. Let's go back, then, to  
23 Geller Exhibit 30, which is the e-mails  
24 with your draft position paper attached.

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1 In your e-mail, you write to Janet Spiers  
2 attaching a "position paper and  
3 justification document for diabetes, et  
4 cetera and weight gain."  
5 Do you see that?  
6 A. Yes.  
7 Q. Then you say "Vikram."  
8 Who is Vikram?  
9 A. Vikram is Vikram Dev, who  
10 was my supervisor at the time.  
11 Q. "Vikram has not reviewed  
12 either document as his father recently  
13 passed away and he is in India."  
14 Do you see that?  
15 A. I'm sorry. Can you please  
16 tell me the page number?  
17 Q. Please look at the very  
18 first page, the e-mail from you -- at the  
19 bottom from you to Janet.  
20 A. Here we go. I'm sorry.  
21 Yes.  
22 Q. "Vikram has not reviewed  
23 either document as his father recently  
24 passed away and he is in India."