

Transcript of Interview of NIH Employee 2
May 10, 2017

1 give my name to somebody, I said yes. Then that person probably sent me email,
2 whether she can visit, and she did.

3 Paul Solis: Okay, I want to walk back a little bit, and excuse me just for skipping over your
4 background a little bit. But I want to ask your title here, how long you've been
5 employed, and the nature of your work.

6 NIH Employee 2: I am an investigator at NINDS, I National Institute of
7 Neurological Disorders and Strokes. I have been at NIH total of I think more than 16
8 years. I have trained here, so I have been first eight years here as a trainee, and then
9 as a staff clinician. Then I moved away and then I was recruited back as an
10 investigator. I am here as an investigator since 2008.

11 Paul Solis: Okay, okay. So going back to that first meeting that you talked about with the chief
12 scientific officer, and now that we've been talking about it, does her name come to
13 you at all?

14 NIH Employee 2: I really don't, unfortunately I'm just, I have very bad memory for names, so.

15 Paul Solis: That's okay.

16 NIH Employee 2: Sorry.

17 Paul Solis: Is she based out of United States, or is she based-

18 NIH Employee 2: No, she lives either in Australia or New Zealand. And I'm blocking which one
19 it is, I know that.

20 Paul Solis: And what do you understand about the nature of Innate's work, or what they're
21 attempting to do?

22 NIH Employee 2: Yeah so they have a drug that is basically modulating innate immune system
23 based on the pathogen associated molecular patterns receptor called toll-like
24 receptors. And they are testing the drug in secondary progressive multiple sclerosis.

25 Paul Solis: And the types of... what that drug is attempting to do, I mean is that within your
26 expertise?

27 NIH Employee 2: Sure, sure.

28 Paul Solis: Okay. Are there other people at NIH in your department who work on those types of
29 issues, or is this something that only you do?

30 NIH Employee 2: Yeah, I mean obviously there are immunologists that work on the toll-like
31 receptors, but I work a lot in progressive multiple sclerosis. So I run clinical trials in
32 progressive multiple sclerosis, and probably from NIH I know most about
33 immunology of progressive multiple sclerosis.

34 Paul Solis: Okay, okay. So again, going back to that first meeting, and can you tell me about your
35 first interaction with Congressman Collins?

36 NIH Employee 2: Well he came for a congressional visit. This was my second congressional
37 visit I participated in. Usually the congressperson wants to know what we are doing,

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1 and we have very short presentation of what is our scientific program. And they ask
2 us questions, we answer those. Sometimes they bring constituents, sometimes they
3 don't.

4 Paul Solis: Okay, in this particular instance when he came, was he accompanied by other
5 members of congress?

6 NIH Employee 2: I believe he was alone.

7 Paul Solis: Okay. And was the meeting organized with you, did someone reach out to say he'll
8 be coming by, or how did that work?

9 NIH Employee 2: Yes, so it was organized through header.

10 Paul Solis: What is header?

11 NIH Employee 2: The person that-

12 Paul Solis: Oh okay, sorry, NIH Employee 1, yeah yeah.

13 NIH Employee 2: Heather from our institute has an office that deals with this kind of visits and
14 inquiries. So she contacted us both times when I participated in congressional visit
15 and she said, "This congressman is coming, he's really interested in multiple
16 sclerosis, would you be willing to talk about your research program, and give small
17 presentation. And answer questions." I said, "Sure." That's what happened.

18 Paul Solis: And how many times have you participated in a congressional meeting like that?

19 NIH Employee 2: Twice.

20 Paul Solis: Twice? Both times with Congressman Collins?

21 NIH Employee 2: No, only once with Congressman Collins.

22 Paul Solis: And who was the other one with?

23 NIH Employee 2: I'm really bad with names.

24 Paul Solis: I understand, the best you can recall.

25 NIH Employee 2: I think, shh, it was from New York? Shh... Republican Schuman?

26 Paul Solis: Was it a senator or a congressperson?

27 NIH Employee 2: I think it was congressperson, but I'm just so, I've really I mean whatever
28 part is supposed to remember names is just not part of my brain, I'm sorry.

29 Paul Solis: It's okay, it's okay.

30 NIH Employee 2: But he came with, I know he came with constituents. So it was a large
31 delegation. And again we talked about progressive multiple sclerosis because there
32 is no treatment for progressive multiple sclerosis, and at that point NIH was really
33 running the only clinical trials for progressive MS.

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1 Paul Solis: And what you just described, that's the second meeting with this congressperson
2 from New York. When they brought constituents.

3 NIH Employee 2: Yeah, so that was the first meeting that I participated in. And Congressman
4 Collins was the second.

5 Paul Solis: Was the second meeting, okay.

6 NIH Employee 2: And I can probably get you the name, it's probably somewhere in my
7 computer, you know.

8 Paul Solis: We can cross that bridge later possibly.

9 NIH Employee 2: Okay, sorry.

10 Paul Solis: But I want to focus on the meeting you had with Congressman Collins, when he
11 came. So I asked you initially did he bring, did any other members of congress
12 accompany him, and you said no. Right? Did he bring anybody else, staff person, a
13 constituent?

14 NIH Employee 2: There may have been staff person, but I'm sure there were not constituents.

15 Paul Solis: Okay, okay. And what did the meeting entail? Did you show him some facilities,
16 some of the work you've been doing?

17 NIH Employee 2: Yes, yes.

18 Paul Solis: Can you describe that a little bit more, if you can recall what that-

19 NIH Employee 2: Well I wasn't the only person participating also Dr. Reich. Daniel Reich was
20 participating. I think it is possible, or likely, that Dr. Steven Jacobson was also
21 participating. I think I had maybe five minute PowerPoint presentation about what
22 we are doing. I think they also went down to Enrai to see facility and Dr. Reich
23 probably showed them some of the images, high resolution images.

24 Paul Solis: And when you say some of these other doctors are participating, were you all
25 together with the Congressman or did you have separate times with him?

26 NIH Employee 2: Honestly, I don't remember. But-

27 Paul Solis: When you gave your PowerPoint presentation, was it just you and the Congressman?

28 NIH Employee 2: I don't know. It was in the conference room. I think at some point I may have
29 been ... but I don't think I was ever alone with the Congressman. I think at least
30 Heather from that NIDS office was with us.

31 Paul Solis: And-

32 NIH Employee 2: But again, don't quote me. I really don't recall completely.

33 Paul Solis: Okay, and when you were discussing some of your work and conducting a
34 PowerPoint presentation, what was the topic? What were you discussing with him?

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1 NIH Employee 2: Our work. Basically the kind of rationale for research program. Why are we
2 focusing on progressive multiple sclerosis and how we are tackling progressive
3 multiple sclerosis and what kind of advances we have developed?

4 Paul Solis: So, what I wanted to do is show you a document. It's an email. I'll hand it over to you.
5 This is not from anything you produced or that's come from NIH, but it's something
6 that we've obtained. It is TAM0257 through 0259. Basically, just want to draw your
7 attention to this first page here so take a moment to read it, bearing in mind you did
8 not author this email as far as I can tell. Have you ever seen this before?

9 NIH Employee 2: No.

10 Paul Solis: Okay, take a minute to read.
11 Okay, so after reading this, do you know if this is connected to what you just told me?
12 Is this referencing the meeting that you had with Congressman Collins?

13 NIH Employee 2: Well, I'm assuming Chris means Congressman Collins, but you know, other
14 than saying that it's in a third bodex, most of what is written is complete and new to
15 me.

16 Paul Solis: Right, okay.

17 NIH Employee 2: MIS416 is the drug that was ... that is being tested in secondary progressive
18 by that company.

19 Paul Solis: And the reason, you know, I wanted to talk to you is, you'll see at the very bottom,
20 this is your name.

21 NIH Employee 2: Yeah, I can see that.

22 Paul Solis: And it says "Chris was kind enough to dig up the person's name" and it does mention
23 in this recounting of the events that there was an NIH official who Chris had further
24 talks with and, you know, so-
25 There is a connection between your name and the NIH official and after you just
26 explained to me that you had met with him, I'm just wondering if this sort of
27 recounts the story you just gave me that you met with Congressman Collins.

28 NIH Employee 2: Yeah.

29 Paul Solis: And you'll see the date on here that it's September 24, 2014. Is that about the time?

30 NIH Employee 2: That's possibility.

31 Paul Solis: Okay, in 2014.

32 NIH Employee 2: I'm assuming the visit may have been before 2014.

33 Paul Solis: Right, I would assume that too, probably.

34 NIH Employee 2: I can probably dig out the exact time of the visit.

35 Paul Solis: Okay, well we can-

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1 NIH Employee 2: Okay.

2 Paul Solis: Maybe we can do that-

3 NIH Employee 2: I'm sure Heather will be able to also.

4 Paul Solis: Okay. Some of these acronyms that I see in this ... again, I know you didn't author
5 this, but to the extent that you are aware of, what some of these acronyms mean-

6 NIH Employee 2: Honestly, I don't know. You know, I recognize and I ID, but ... you know, NIH
7 has two different ways of funding research, right. So ... here, where you are currently,
8 that's intramural in NIH, that's about 10% of NIH budget. We do nothing with grants.
9 So there is an extra mural in NIH and that deals with grants, so I wouldn't be able to
10 tell you anything about this form of NIH funding.

11 Paul Solis: Okay.

12 NIH Employee 2: Honestly, my involvement was strictly research involvement. Basically, the
13 person came and talked to me about a trial design and talked to me about the drug
14 and I gave her my best scientific opinion.

15 Paul Solis: Okay, and what does that entail when this person is asking your opinion? What is
16 the opinion about? What are they asking?

17 NIH Employee 2: About the trial design, right.

18 Paul Solis: Walk me through what that means.

19 NIH Employee 2: Well, so basically when you are trying to test efficiency of a drug, you know,
20 you cannot really ... so, the drug development happens in three stages. The first
21 stage is you're giving it for the first time to humans, that's called Phase 1. You're not
22 looking at efficiency at all, you're looking only on toxicity.

23 Then Phase 2 trials is usually what is ran here, we also run Phase 1, but it's basically
24 a trial when you are giving a drug to the patient that you really want to treat and
25 you are supposed to ... you're still gathering some toxicity data, you're gathering
26 data about the dose, what is the best dose, and you are gathering data that would
27 tell you whether the drug efficacious. Whether, you know, you want to invest into
28 Phase 3, which is this extremely large and expensive trial. In fact, two trials are
29 required for regulatory approval of the drug.

30 You know, the Phase 2 costs you up to 5, 6, maybe 10 million dollars. Phase 3 costs
31 you a hundred million dollars, right. You should really have a good, you know ...
32 good idea about what the drug does in Phase 3, which is extremely difficult because
33 we don't have outcomes other than clinical outcomes. So, you know, I am ... my work
34 is trying to define some other outcomes that-

35 For example, we are looking at service spinal fluid bio markers that would be able to
36 tell us in much fewer patients in much shorter time period whether the drug is
37 going to be effective or not.

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1 So, you know, I was telling them about all of these things, right. That, you know, how
2 you need to power, what are the outcomes that you need to look at, you know,
3 whether you want to look at MRI versus clinical outcomes, how long do you need to
4 treat if you want to look at clinical outcome, or all of these things.

5 Paul Solis: And were you doing this ... well, first of all, was there a request to in some way
6 conduct the trial here at NIH?

7 NIH Employee 2: No, not to me.

8 Paul Solis: Okay.

9 NIH Employee 2: Not to me.

10 Paul Solis: Okay. So why then, obviously other than your expertise, was there a plan to develop
11 the trial somewhere else other than NIH?

12 NIH Employee 2: Yeah, so it's my understanding that they were just about to initiate a trial in
13 New Zealand. So they were basically in this, they collected some data on few
14 patients, the data looked kind of semi-positive and they were going to put together
15 this phase two trial.

16 Paul Solis: Okay. When you spoke to the Chief Scientific Officer on these occasions and you're
17 sort of discussing with her the design of the trial and all that, are you doing that in
18 official capacity in your position here at NIH?

19 NIH Employee 2: So really we do that a lot. Because we are national resource, we do it a lot to
20 pretty much anybody. If an investigator would call me today and say I am designing
21 a phase two trial for progressive MS, could you help me, chances are I would help.

22 Paul Solis: You mean in this hypothetical investigator somewhere else.

23 NIH Employee 2: That's correct.

24 Paul Solis: In some other country possibly.

25 NIH Employee 2: Yeah, yeah.

26 Paul Solis: Okay.

27 NIH Employee 2: Yeah, so I'm scientist, I'm physician so we are collegial to each other, but also
28 from the NIDS leadership it has always been that we need to share our expertise
29 freely.

30 Paul Solis: So it didn't have to be in official capacity with your work here, it could just be simply
31 somebody asked you a question and because of your expertise, you share it with
32 them.

33 NIH Employee 2: Sure.

34 Paul Solis: Just sort of the spirit of collegiality?

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1 NIH Employee 2: Yeah. Definitely the other two times I have met with them at the conferences,
2 precisely. I would have answered and they did ask me follow up questions I would
3 answer those.

4 Paul Solis: Okay. That specific time where Congressman Collins was here and you met with him,
5 what did he say about Innate if anything?

6 NIH Employee 2: He basically said that he somehow associated with this Innate
7 Immunotherapeutics group and that they have just finished and they need some
8 help with the design of next Phase 2 trial and he asked me whether I would be
9 willing to help them and I said yes.

10 Paul Solis: Okay, and how did he leave it after that? The meeting ended.

11 NIH Employee 2: Yeah, the meeting ended, I think he gave me like some Congressional
12 whatever stamp or whatever that was and then I gave it to my nephew. He asked me
13 for my card, I gave him my card.

14 Paul Solis: Okay.

15 NIH Employee 2: He said that somebody will contact me and they did.

16 Paul Solis: From Innate?

17 NIH Employee 2: From Innate, yeah. So they send me email and ask me whether they can
18 come to NIH and he said that. He said that they will come to NIH to have a visit with
19 me. I said sure so then they contacted me and I don't know weeks or months later or
20 whatever and we had the visit and they came.

21 Paul Solis: Did he say, you mentioned he was somehow affiliated with Innate, did he specifically
22 say how?

23 NIH Employee 2: He may have and I don't recall it, but obviously the reason why I remember
24 his name is that it definitely felt strange to me because here you cannot be
25 associated in any capacity. I as a person cannot have any stock or anything in any
26 kind of pharmaceutical company, right, so it was surprising to me that he had this
27 relationship.

28 Paul Solis: Jeff, do you have any questions?

29 Jeff Brown: Yeah, I was just going to ask, that meeting that we were talking about after your
30 meeting with Congressman Collins, that was with the Chief Scientific Officer from
31 Innate?

32 NIH Employee 2: Yeah, that was with that lady. If I see her picture, I would immediately tell
33 you that's her. I can probably even draw the picture, I'm just bad with names.

34 Jeff Brown: Okay, thank you. How long after your meeting with Congressman Collins was the
35 meeting? Just generally.

36 NIH Employee 2: I would say weeks or months, I don't really know exactly. But I knew exactly
37 that this is related to that. Either she told me that it was from him or I definitely was
38 able to put two and two together.

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1 Paul Solis: Directing you back to this email, what is SPMS? Do you know what that stands for?
2 NIH Employee 2: Secondary Progressive Multiple Sclerosis.
3 Paul Solis: Okay. And is that what this MIS 416 is attempting to address?
4 NIH Employee 2: Yes.
5 Paul Solis: What about this CUBRC? Do you know what that is?
6 NIH Employee 2: I have no clue.
7 Paul Solis: Okay, if you look at the top here, this Tom McMahon, that name, do you know what
8 that name?
9 NIH Employee 2: No. I think Simon Wilkinson is working for Immunotherapeutics and I think
10 his name, the lady was mentioning Simon.
11 Paul Solis: Okay.
12 NIH Employee 2: Maybe there were two people who came? No, I think I was just talking to a
13 lady.
14 Paul Solis: Okay. Is Innate the only one who is developing this MIS 416?
15 NIH Employee 2: To my knowledge, yes, but I haven't really looked it up.
16 Paul Solis: When you look down here and you see Phase 2B trial, I know you just talked to me a
17 little bit about-
18 NIH Employee 2: Yeah, so I just told you, Phase 2B is basically a larger Phase Two trial that
19 really needs to give you understanding whether the drug is efficacious or not. So
20 some Phase 2B trials, like FDA would be able to consider some Phase 2B trials if
21 they were large enough as a first regulatory approval trial.
22 Paul Solis: Okay. You did touch upon this a little bit, but the paragraph discussing funding from
23 HHS and NIA [crosstalk].
24 NIH Employee 2: I really cannot help you with that. I don't do anything with the funding
25 decisions. We just don't do that.
26 Paul Solis: Given that you said that you'd met this Chief Scientific Officer even just two weeks
27 ago at a conference.
28 NIH Employee 2: I did.
29 Paul Solis: What did you talk about with her there?
30 NIH Employee 2: She was presenting [inaudible] and we talked about her work. There was
31 somebody else also with her and then, maybe this was Simon I don't know. I was
32 asking her how is it going and she said the work is going really well.
33 Paul Solis: Did she mention where they're at with their trials, the position they're in.

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1 NIH Employee 2: No, obviously they haven't gotten the data that would show them that the
2 drug is efficacious so I think that they're still at the funding stage.

3 Paul Solis: Why do you say that's obvious? You said it's obvious that they haven't got the data
4 to show-

5 NIH Employee 2: Oh, because if you would show efficacy, she would have a platform
6 presentation. That would be the thing that she would present.

7 Paul Solis: Again, where was this last conference?

8 NIH Employee 2: In Boston.

9 Paul Solis: In Boston.

10 NIH Employee 2: It was American Academy of Neurology meeting.

11 Jeff Brown: Okay. Would NIH or you be involved if this did go to Phase three?

12 NIH Employee 2: No.

13 Jeff Brown: You wouldn't. Okay.

14 NIH Employee 2: No. In fact phase three, we are really not involved.

15 Jeff Brown: Okay, why is that?

16 NIH Employee 2: Because phase three is generally only pharma sponsored and we basically,
17 even for the drugs that we developed, so for example we have developed MS
18 treatment called [inaudible] and we have been heavily involved, basically the NIH
19 showed that the drug is effective and then once it's phase three we are hands off. It's
20 just pharma.

21 Paul Solis: By pharma you mean larger companies who are developing-

22 NIH Employee 2: Yeah, yeah. So for the [inaudible] the difference is that NIH actually has a
23 patent so I have a patent and once pharma buys those patents, then we really have
24 to be completely hands off, so it's-

25 Paul Solis: Mm-hmm (affirmative)

26 NIH Employee 2: So it's their baby and -

27 Paul Solis: Right and in an instance like this where it's a small company and this could either be
28 in the United States or somewhere else and they're going through their processes to
29 conduct trials of the drug. I mean is this something that's a common occurrence? A
30 small company or any company would reach out to you as an investigator and say
31 what do you think?

32 NIH Employee 2: Yes.

33 Paul Solis: Ask for advice, that's a common occurrence?

34 NIH Employee 2: Yeah, I mean again I think progressivism is really bad disease and we just
35 have a first approved drug so it's in my interest, interest of NIH and interest of

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1 everybody to help with development drugs for this disease, because the societal
2 need is so humongous right? So, I mean I would feel that it's part of me being a
3 federal employee to foster such ... to give that knowledge so that companies can
4 develop affective drugs.

5 Paul Solis: Okay, going back to that meeting with Congressman Collins, you had mentioned that
6 the request came through NIH Employee 1.

7 NIH Employee 2: Yes.

8 Paul Solis: Okay.

9 NIH Employee 2: And I believe she was present during the whole time because ...

10 Paul Solis: Did NIH Employee 1 ... do you recall what she said to you and I know you said you
11 might have an email or two to kind of talk about this, but do you recall what NIH
12 Employee 1 said to when she wanted you to attend this meeting with Congressman
13 Collins? What it was going to be about?

14 NIH Employee 2: No, the usual thing. This is a congressional visit, he's specified that he's
15 interested in multiple sclerosis, would you be willing to talk about your research
16 program and show him around.

17 Paul Solis: What were some of the questions and I mean the best you can remember? I realize
18 this was a few years ago, but what was some of the questions he was asking?

19 NIH Employee 2: I think he was really interested in progressive multiple sclerosis and he was
20 asking me, he was talking about this company of his and was asking me whether I
21 am aware of their drug. I wasn't, I wasn't aware of his company and he asked me
22 what are the difficulties with setting up clinical trial for progressive MS or yeah
23 things like that.

24 Paul Solis: Did he talk about constituents in his district and SPMS? Did he talk about any ... how
25 it might relate to his representation of his constituents? That he knows people back
26 in the district who have SPMS?

27 NIH Employee 2: I don't recall him saying that. So, I think that ...

28 Paul Solis: Did he talk about ...

29 NIH Employee 2: For me being only at two congressional visits, I clearly saw the difference
30 because the first one was the congressperson did bring constituents and it was very
31 clear to me that, he was concerned about the constituents and trying to show that
32 we are doing something to address the issues that the constituents brought to him.

33 Paul Solis: Mm-hmm (affirmative) and in the second instance with Congressman Collins that
34 was not present. Did Congressman Collins talk about any legislation he was working
35 on to address some of these issues? No?

36 NIH Employee 2: Not that I can recall.

37 Paul Solis: Okay, about how long did his meeting with you last or how long was he here for?

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1 NIH Employee 2: I think he was here maybe for 30 minutes or yeah probably not much longer
2 than that. I know that they tell us that the PowerPoint presentation should be five
3 minutes so I ...

4 Jeff Brown: And was that 30 minutes just with you or was that with Doctor, I believe you said,
5 Reich and Jacobsen?

6 NIH Employee 2: Yeah I would assume that it was also with them.

7 Jeff Brown: 30 minutes between the three of you?

8 NIH Employee 2: Yeah I think, I don't remember exactly but I think that after he had
9 presentation of all three of us, he really wanted to talk to me more. So, I don't
10 remember whether ... I know I can see us sitting at the conference room and
11 discussing these things, but I don't really remember who else was there, but I know
12 that he really wanted to ask about this company and ...

13 Jeff Brown: Why would he have been more interested in talking to you as opposed to the other
14 two doctors?

15 NIH Employee 2: Because I am the person who is really running clinical trials in Progressive
16 Multiple Sclerosis. So, Dr. Jacobsen is Neurobiologist, he doesn't even really do ...
17 he's not a clinician. Dr. Reich is a clinician but he's more interested in MRI and
18 radiology and just has different research program.

19 Paul Solis: And either you know this because he said it or you got the impression that he
20 wanted to talk to you further based on your presentation or did he say he knew
21 more about your background kind of coming in to his visit.

22 NIH Employee 2: Yeah I didn't get impression that he knew anything about me before the visit.
23 I think maybe he was asking us questions when we all were there and maybe based
24 on my answers he decided to talk to me more. I don't know, but I certainly didn't
25 have impression that he knew anything about me before he came here.

26 Paul Solis: And then after you left the bigger room with the other doctors and it was the two of
27 you, was NIH Employee 1 there with you or was it just the two of you?

28 NIH Employee 2: I'm assuming Heather was with us all the time because they generally don't,
29 I mean usually she accompanies the congressperson during the entire visit so I think
30 she was with us.

31 Paul Solis: And that would have been in this office or?

32 NIH Employee 2: Oh no, this a brand new office. We were in the old place.

33 Jeff Brown: And that's NIH Employee 1's role, more generally could you tell us a little bit more
34 about NIH Employee 1's role relative to congressional visits?

35 NIH Employee 2: Yeah Heather is ... so I think somehow we have an office for congressional
36 visits and so I don't know what is her official title. Whether she's PR for NDIS, but I
37 know she's in NDIS and she always organizes this visits and each time we get any

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1 kind of inquiry, like you have, I forwarded your email to her because I know that we
2 have official channels for these things.

3 Paul Solis: You mentioned he handed you something, a stamp or something. What was ...

4 NIH Employee 2: Yeah it was this congressional, I don't know, it wasn't a stamp, it's ...

5 Paul Solis: A coin?

6 NIH Employee 2: Like a coin, yeah.

7 Paul Solis: So what did he say when he handed it to you?

8 NIH Employee 2: Thank you for spending time and gave it to me. I mean, it had some wording
9 about US congress so I gave it to my nephew and he was very happy with it.

10 Paul Solis: Well Jeff do you have any further questions?

11 Jeff Brown: Just real quick, what's the amount of time you, can you tell us about that first
12 meeting with the Chief Scientific Officer?

13 NIH Employee 2: I would assume I spend with her at least an hour if not more. So it was quite
14 involved, she was really asking me a lot of questions and I really tried to help her
15 with the design and ...

16 Paul Solis: And that was here?

17 NIH Employee 2: That was here, yeah.

18 Paul Solis: And she had flown in from Australia?

19 NIH Employee 2: I'm assuming so yes, maybe she was attending some meeting here and did a
20 side visit here.

21 Jeff Brown: And what, I think we've talked about this a little bit, but the benefits to her is
22 tapping your expertise?

23 NIH Employee 2: That's correct.

24 Jeff Brown: How frequently do you do that?

25 NIH Employee 2: Just yesterday I had somebody calling me from Switzerland and so yeah we
26 do that. Also very often this doesn't happen ... I mean like the Switzerland was the
27 person contacted me directly, but very often basically these PR offices get these kind
28 of requests and then they hand them to us. So, yeah.

29 Paul Solis: And what if anything do you know about how New Zealand ... I mean do they have a
30 corollary NIH in New Zealand that does this type of thing?

31 NIH Employee 2: I have no clue. I have no clue.

32 Paul Solis: And I'm just wondering because phase to be trial is that universal language? That's
33 not particular to NIH?

34 NIH Employee 2: No that's universal language.

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1 Jeff Brown: I didn't want to jump ahead, I wasn't sure if you wanted to talk about this?

2 Paul Solis: Sure ask any questions. Jeff might have a question on the second page.

3 Jeff Brown: Yeah, sorry after your ...

4 Paul Solis: This is TAM 0258.

5 Jeff Brown: If you could just read the remainder of the email?

6 Paul Solis: Mm-hmm (affirmative)

7 NIH Employee 2: So maybe what I should tell you is ... so there is a way we can collaborate
8 with pharmaceutical industry in early stages of drug development.

9 Okay, very often we ... the trials that we do here are mostly what is called
10 "investigator-initiated trial." So let's say we have ... our work on cerebrospinal fluid
11 biomarkers reveal a target. All right, for something that correlates with how fast his
12 multiple sclerosis is progressing.

13 I would then go and search, is there any drug that is effecting the target? And then I
14 would go and if I find the drug, then I would go to the drug company and I would say,
15 "would you be interested in testing this drug you have for multiple sclerosis based
16 on the data that we have?"

17 And then the way it works is that there is a mechanism called "creda," collaborative
18 research agreements and it's then kind of a joint effort to develop the drug, let's say
19 for different indication.

20 I understand that some other investigators may ... in my case, it has always been like
21 that, that I have a target that I want to effect and I reach to the industry. However, I
22 understand that sometimes it's other way around. That you have a small company
23 that has a drug that believes that is interesting or good. And then they are trying to
24 partner with NIH to do the face to be trialed here to show whether the dug is
25 efficacious or not.

26 In that case, you basically have to persuade somebody that your drug is really good
27 enough. Because ... my benefit, I'm not really judged on how the company is done,
28 I'm judged based on have we ... having moved the field forward, are we closer to
29 effective treatment, are we closer to cure?

30 If I would be approached and I would be persuaded that the drug is really good, I
31 might be willing to do the trial here, with me being PI. On the other hand, if I don't
32 feel the drug is good, I have no incentive in trying to do the collaborate agreement.

33 So perhaps I don't believe he brought up the issue of running clinical trial here. I
34 don't recall it. And I certainly wasn't excited about drug enough to bring it up. And I
35 don't even recall whether the chief scientific officer brought it up or not. But if she
36 did, I was like ... I was probably ... I would probably tell her that no, I'm not
37 interested.

38 So maybe that's what it is about, I don't know.

Transcript of Interview of NIH Employee 2
May 10, 2017

1 Jeff Brown: But in short, in some instances, for lack of a better word, somebody from industry
2 could come to you [crosstalk].

3 NIH Employee 2: That's correct.

4 Jeff Brown: And try and sell you on working on ... a drug.

5 NIH Employee 2: That's correct, that's correct.

6 Paul Solis: And in reading this, is that what this could be?

7 NIH Employee 2: Uh, well, I don't know, because starting with NIH Employee 2's office, well,
8 NIH Employee 2's office is this, I mean it's not like I have an office that is giving
9 somebody some funding. I'm just a PI. I mean, I ...

10 Jeff Brown: How would that work though, if you did see a drug ... you had one of those meetings
11 and you thought that this was promising?

12 NIH Employee 2: Yeah, so ...

13 Jeff Brown: How does that work?

14 NIH Employee 2: So basically how it works is I have some assigned clinic time and some time
15 assigned ... I have my own clinical resources, right? If ... for example, generally
16 speaking, my clinical resources are 100% utilized because I make sure they are 100%
17 utilized.

18 But let's say I would be somehow lazy and I wouldn't have next trial aligned. And
19 here comes this drug that seems so incredibly good that I am really interested.

20 Well, then I would tell my office of technology transfer that I was ... that I'm
21 interested in making this collaborative agreement between the entity and NIH and
22 then ... it depends what kind of agreement you ... what you really want. Because up
23 to this point, it was always me wanting something from the company.

24 Generally speaking, my agreements are that the company provides the drug for free
25 to us and we are doing everything and we have ... we share the IP rights or things
26 like that. But it's my understanding that other investigators they may also get money
27 from the company to partially support the trial ... so pay for ...

28 Paul Solis: Okay. And are you aware of trials being conducted in other countries where NIH and
29 maybe not as you previously mentioned this division but another division giving
30 money in some way to a company developing a drug in another country. Does that
31 ever happen?

32 NIH Employee 2: The only way it could happen is through grants. I understand that there are
33 grants specifically ... NIH specifically gives grants for small businesses to advance
34 their ... so yeah ...

35 Jeff Brown: US or international?

36 NIH Employee 2: I believe it's also international, yes. I believe so. But uh, you know, you would
37 need to ask really grant people, so that's the extramural.

Transcript of Interview of NIH Employee 2
May 10, 2017

1 Paul Solis: And it does say in this email, the quote/unquote "endorsement value" of securing
2 funding from NIH. So, again we talk about whether or not there had been some
3 potential discussion to bring the trial here to NIH or whether the intention was to
4 continue the trial somewhere else but receive some sort of endorsement or money
5 potentially from NIH.

6 NIH Employee 2: So I think that my reading of this is that because you have to compete for
7 grants, if you do get grants, because the funding is so tight, if you do get grants, it's
8 kind of endorsement that people should start taking you seriously because you
9 successfully competed ... it has a scientific review and so forth.

10 Paul Solis: But this idea that says, "starting with NIH Employee 2's office," that doesn't seem to
11 make sense with the grant-making ... [crosstalk].

12 NIH Employee 2: It definitely ... I think the person Tom McMahon, whoever he is, clearly has
13 no clue who I am and what my office is ... that it is a computer and desk.

14 Paul Solis: He might mean your division as opposed to the physical office. I'm not sure.

15 NIH Employee 2: Again, I think we are just too small fries here.

16 Jeff Brown: Is there endorsement value in something less than partnering with the NIH? In other
17 words, if there's not a formal and I apologize, I'm forgetting the acronym that you
18 use, but is there something less than an official teaming agreement that could
19 provide like some goodwill to the company?

20 NIH Employee 2: No, not really. So there are several forms of this agreement, there is CREDA,
21 then there is M-CREDA, then there is a CTA Clinical Trial Agreement. So you have
22 several form of this agreement.

23 And yes, companies, if they are public companies, they always put statement that
24 they are working with us because it increase ... it gives them some kind of
25 endorsement of value ... that they should be taken seriously.

26 Paul Solis: Do you have any more questions?

27 Jeff Brown: I do not.

28 Paul Solis: Okay, well I think we are all set, and thank you for your time.

29 NIH Employee 2: Good, good. And please don't tell the other Congressman I don't remember
30 his name.

31 Paul Solis: Okay, thank you.

32